DEVELOPMENT OF FUNCTIONAL SPLINT FOR DE QUERVAIN'S DISEASE TREATMENT

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Development of Functional Splint for De Quervain's Disease Treatment

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CERTIFICATE OF ORIGINALITY

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TAM Eunice Wai-si (Name of Student)

Abstract

De Quervain's tenosynovitis (DQV) is the inflammation of the synovial sheaths of the abductor pollicis longus and extensor pollicis brevis tendons in the first dorsal compartment of the hand. This hand condition is more prevalent in women in their forties to sixties. Patients with DQV may feel pain, soreness and tenderness at the radial side of their wrist, which can cause inconvenience and difficulties in their daily life activities. To treat patients with DQV, splinting is a safe, universal and non-invasive form of therapy, especially for those with minimal symptoms. Long splints which are composed of rigid thermoplastic materials and short splints which are fabricated of soft materials, are prescribed to patients according to their severity. Problems of existing splints, such as causing feelings of excessive warmth, discomfort due to a poor fit, and bulkiness, have been shared by wearers, and these problems may lead to a reduction of wear compliance. To solve the problems, studies have proposed new splint designs. However, the efficacy of the proposed splints in the literature remains ambiguous due to the lack of wear trials. Therefore, the aim of this study is to develop a splint that can effectively treat DQV with a good fit and wear comfort. A wear trial is conducted to evaluate the performance of the proposed splint.

This study consists of five parts, including: (a) a review on the fabrication processes of clinical splints and the problems of existing splints, (b) an investigation on the ergonomic shape of the hands of healthy and DQV patient groups, (c) the design and development of a functional splint with a good fit and wear comfort to treat DQV, (d) a clinical study of the proposed functional splint for evaluation purposes, and (e) the development of a finite element model to investigate the pressure distribution on the wearer's hand from the splint.

A review of ten splinting products from the online market is conducted which shows that most of the splints are embedded with stays to support the thumb and the wrist. Two market products are purchased to undergo a range of motion (ROM) test, in order to investigate the effectiveness of the splints in controlling hand movements. The result shows that the ability of the two splints to limit wrist deviations and stabilise thumb joints is inadequate. A clinical visit is then conducted to understand more about the fabrication processes of clinical splints. Problems with the clinical splints, such as low

air permeability and bulkiness, are observed. Therefore, developing a functional splint with a good fit and wear comfort is necessary.

To develop a functional splint with a good fit, it is important to understand the shapes of the hand. Three groups of subjects: healthy young subjects, healthy mature subjects, and subjects with DQV are recruited for 3D scanning of their hands. The angles of the wrist and thumb such as the degree of wrist extension, angle between the extension of the ulna and carpals, and flexion angle of the MCP joint, have been measured. Comparisons between the measured angles of different groups and correlation testing between the angles of the patient groups have also been carried out. The measurements of the patient group is subsequently used as reference for developing the proposed splint.

To address the restrictiveness of the thermoplastic splint, the proposed splint is composed of both rigid and soft components. The thumb and ulna supporters are rigid and designed based on the measured angles in this study, so that they accommodate the shape of the hand. The supporters can stabilise and support the injured wrist. For the soft materials, spacer, powernet and satinette fabric samples have been subjected to testing to determine the most suitable fabrics for the body of the splint, and address the problems of excess warmth and bulkiness.

The performance of the proposed splint is evaluated by conducting a clinical study. Thirteen (13) female subjects with DQV are recruited to participate in a 3-month wear trial. Of the 13, 12 of the subjects underwent the entire treatment, while 1 subject terminated treatment early after the second month as her DQV is successfully treated. The study results show that the level of pain with two hand movements: thumb and finger extension and hand opposition, is significantly reduced after the intervention. The majority of the subjects indicate a reduced pain score during the extension of the thumb and fingers, while a large percentage of the subjects feel less pain during opposition of the hand. The pain scores for implementing different daily activities are also reduced. Both grip and pinch strengths are increased after the treatment. The ROM test of various splints indicates that the proposed splint can prevent the wearer's hand from excessive extension and deviation with adequate control. The splint related questionnaires that were completed by the subjects show that they are satisfied with the properties of the proposed splint, for instance, the appearance, wear comfort and

durability. The results of the *Quick*DASH questionnaire show that the *Quick*DASH Disability/Symptom scores of the subjects are significantly reduced after the splinting treatment. Furthermore, the results of the SF-12 v2 questionnaire indicate that the quality of life of the subjects is enhanced over the last session of intervention.

The design of the proposed splint aims to accommodate the hand of the patient and stabilise the affected hand effectively with wear comfort. Excessive pressure exerted onto particular areas of the hand can be detrimental. In this study, a finite element model is developed to simulate the wear process of the proposed splint. The model facilitates the simulation of splint wear numerous time instead of the tedious and time-consuming task of recruiting and conducting experiments with real subjects. The model predicted results show the pressure distribution on the hand from the splint. The results are validated by comparisons with the actual pressure measurements of the subject. Since only small steps can be successfully analysed with the developed model, the predicted stress results are much lower than the actual measurements. However, the predicted results can still act as a reference. The results show that relatively higher stress is found around the wrist area, which may be due to the location of the holding straps of the supporters. Higher stress also appears on the surface area of the splint underneath the supporters. It is interesting to find higher stress between the two types of materials in the palm region, which indicates that the seam in that area can withstand higher forces during the wear process. As for the pressure exerted onto the hand of the patient, the predicted results demonstrate an evenly distributed low level of pressure over the skin of the hand. Thus, it is believed that patients can wear the proposed splint with wear comfort and well distributed pressure.

The research results provide useful information on investigating the ergonomic shape of the human hands, utilising 3D printing technology to develop splint supporters, and designing a functional splint for treating DQV. The study results show that the proposed splint is effective enough to stabilise the affected hand of patients and reduce the level of pain caused by DQV. Furthermore, the study patients are satisfied with the proposed splint in terms of its functionality, aesthetics and wear comfort. Therefore, the proposed splint can be an alternative option for patients with DQV who are required to undergo splinting treatment. The finite element model can be used to predict the pressure distribution on the hand of the wearer from using the splint, and optimise the design of

the splint with modifications to the data. The findings of this study can also be extended to the development of other splints and orthoses, which can provide wear comfort and high effectiveness to treat DQV or other hand disorders.

Publications arising from the thesis

Journal papers:

Tam, E. W. S., Yip, J., Fang, C., Lo, C. K. Y., Yick, K. L., & Ng, S. P. (2020). De Quervain's tenosynovitis: A systematic and citation network analysis review. *Biomedical Journal of Scientific & Technical Research, 24*(5). doi:10.26717/BJSTR.2020.24.004125

Tam, W. S., Yip, J., Fang, C., Yick, K. L., & Ng, S. P. (2022). Performance of proposed functional splint to treat de Quervain's tenosynovitis. (In submission)

Tam, W. S., Yip, J., Fang, C., Yick, K. L., & Ng, S. P. (2022). An optimal de Quervain's tenosynovitis splint with ergonomic thumb supporter and evenly distributed pressure. (In submission)

Conference papers:

Tam, W. S., Yip, J., Yick, K. L., Ng, S. P., & Fang, C. (2018). *A review of new splint design for de Quervain's tenosynovitis treatment*. 11th Pan-Pacific Conference on Rehabilitation, Hong Kong. 17-18 Nov.

Tam, E. W. S., Yip, J., Yick, K. L., Ng, Z. S. P., & Fang, C. X. (2019). *Investigation of thumb curvatures for enhancement of splint for de Quervain's treatment*. College of Professional and Continuing Education Health Conference 2019, Hong Kong. 14 Jan.

Tam, E. W. S., Yip, J., Fang, C., Yick, K. L., & Ng, S. P. (2020). *The combinative thumb supporter for orthoses to treat de Quervain's tenosynovitis*. International Society for Engineering Research and Development International Conference (ISERD International conference), Zurich, Switzerland. 16-17 Feb.

Tam, E. W. S., Yip, J., Yick, K. L., Ng, S. P., & Fang, C. (2021). *Investigation of anatomical shape of thumb of de Quervain's tenosynovitis patients*. 12th International Conference on Applied Human Factors and Ergonomics (AHFE 2021), Manhattan, New York, USA. 25-29 Jul.

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List of abbreviations

A

A	Aluminium
A1	Wrist Extension Angle
A2	Angle of the MCP Joint Flexion
A3	Angle between the Extension of the Radius and Carpals
A4	Angle between the Extension of the Ulna and Carpals
ABS	Acrylonitrile Butadiene Styrene
APL	Abductor Pollicis Longus
ASTM	American Society for Testing and Materials

B

BP	Bodily Pain

C

C	Carpal
CAD	Computer Aided Design
CMC	Carpometacarpal
CNA	Citation Network Analysis
CT	Carpal Tunnel

D

DASH	Disabilities of the Arm, Shoulder and Hand
DQV	De Quervain's Disease

DQVS	Female Subjects with DQV
E	
EPB	Extensor Pollicis Brevis
F	
FDC	Fibrous and Osseous Components
FDM	Fused Deposition Modelling
FE	Finite Element
FEA	Finite Element Analysis
FEM	Finite Element Model
G	
GH	General Health
H	
HMS	Healthy Mature Female Subjects
HRQOL	Health-Related Quality of Life
HYS	Healthy Young Female Subjects
I	
IBM	International Business Machines
IP	Interphalangeal
ISO	International Organization for Standardization
K	
KES	Kawabata Evaluation System

M

MC	Metacarpal
MCL	Markov Cluster Algorithm
MCP	Metacarpophalangeal
MCS	Mental Component Summary
MH	Mental Health

N

NSAIDs	Nonsteroidal Anti-inflammatory Drugs

P

PA	Polyamide
PCS	Physical Component Summary
PF	Physical Functioning
Po	Powernet
PP	Proximal Phalangeal

Q

Q-max	Maximum Heat Flux
*Quick*DASH	*Quick* Disabilities of the Arm, Shoulder and Hand

R

R	Radius
RE	Role-Emotional
RH	Radius Head

ROM	Range of Motion
RP	Role-Physical
S	
Sa	Satinette
SD	Standard Deviation
SF	Social Functioning
SF-12	Medical Outcomes Study 12-Item Short-Form Health Survey
SF-12 v2	Medical Outcomes Study 12-Item Short-Form Health Survey version 2
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SLA	Stereolithography
SLS	Selective Laser Sintering
Sp	Spacer
Splint 1	Proposed splint with opening gap of 1 cm in width
Splint 2	Proposed splint with opening gap of 2 cm in width
SPSS	Statistical Package for the Social Sciences
SS	Stainless Steel
T	
TM	Thenar Muscles
U	
UH	Ulnar Head

UK	The United Kingdom
V	
VAS	Visual Analogue Scale
VT	Vitality
W	
WHAT	Wrist Hyperflexion and Abduction of the Thumb
WTS	Subjects who participated in the wear trial of the proposed splint in the clinical study
2D	Two-dimensional
3D	Three-dimensional

Chapter 1 Introduction

1.1 Research background

The dorsal side of the wrist of the human hand consists of six separate compartments, each of which contains tendons that control the movement of different parts of the hand, such as the thumb, fingers and wrist. De Quervain's disease or de Quervain's tenosynovitisis (DQV) is a painful hand condition that involves the inflammation of the synovial sheath of two tendons called the abductor pollicis longus and extensor pollicis brevis tendons which are located in the first dorsal compartment. The compartment is found near the radial styloid process (Patel, Tadisina, & Gonzalez, 2013). The inflammation of the synovial sheaths may cause thickening of the nearby tissues so that the abductor pollicis longus and extensor pollicis brevis tendons may also become inflamed at the same time (Goel & Abzug, 2015; Green et al., 2016), which could lead to their degeneration (Clarke, Lyall, Grant, & Matthewson, 1998). Since the two tendons control thumb movement, patients may feel pain when they perform hand movements that require thumb flexion and extension, twisting of the wrist and gripping with force.

Patients with DQV may feel pain, soreness, tenderness and swelling at the radial side of the wrist near the radial styloid process (Goubau et al., 2014; Satteson & Tannan, 2020). They may experience difficulties when performing various daily tasks that involve thumb and wrist movements, such as opening jars with a lid or carrying bags (Walker-Bone, Palmer, Reading, Coggon, & Cooper, 2004). The condition is more prevalent among women than men as it is estimated that 1.3% of women suffer from DQV while only 0.5% are male (Walker-Bone et al., 2004). Patients usually range from their forties to sixties (Júnior, Pires, Andrade, & Lima, 2016; Satteson & Tannan, 2020). The risk factors are generally the overuse of the hands, and repetitive activities that depend on thumb and wrist movements (Howell, 2012). Other possible reasons that contribute to this ailment include anatomical changes in the first dorsal compartment (Alexander, Catalano, Barron, & Glickel, 2002) and genetic factors (Stahl et al., 2015). The diagnostic test for this condition is the Finkelstein's test, in which patients are required to flex their thumb and enclose their thumb with a closed fist.

Treatment for DQV are mainly splinting, steroid injection and surgery. Surgery is recommended for patients who suffer from severe symptoms, while steroid injection is prescribed for those with moderate symptoms. Splinting is commonly recommended for patients with mild to moderate symptoms. This is a non-invasive treatment so splinting is considered to be a safe and effective way to treat such patients. Different kinds of splints are currently available in the market or from the clinic. However, splinting can be problematic. The effectiveness of splints in restricting hand movement is questionable. Patients who have used a conventional thermoplastic splint find that it is bulky and hard, and the thermoplastic places pressure on the protruding bone of the hand which leads to pain (Chow, 2009; Huang et al., 2006). Working splints, which are made of neoprene or a type of synthetic rubber, have also received complaints as they are said to cause thermal discomfort, especially during the summer. To address these problems with splinting, researchers have proposed novel designs for splints. However, these novel splints are still problematic, for example, they are hard, the durability of the splint materials is ambiguous, and there is the possibility that splinting will lead to other hand conditions due to the splint design. Furthermore, since some of the proposed splints are still in the conceptual and prototype stage, the effectiveness of splints in treating DQV is still not known yet. Therefore, the purpose of this study is to investigate the ergonomic structure of the hand, test fabrics for their mechanical and thermal properties, and select the appropriate types of fabrics and materials to develop a new functional splint with good fit properties and wear comfort. Furthermore, a finite element (FE) model is developed to predict the pressure distribution on the hand from the functional splint.

1.2 Problem statements

Splinting as a treatment is commonly adopted by patients who suffer from mild to moderate symptoms of DQV. The purpose of the splint is mainly to immobilise the thumb and wrist which would relax the tendons. Patients need to wear the splint for long hours during the day, or even at night, to allow for adequate time to heal the inflamed tissues in the first dorsal compartment. However, there are three problems associated with existing splints that may affect the outcome of splinting. They are the low compliance rate of the patients, fitting problems of the splints and limited control over hand movements.

1) Low compliance rate of patients

Chow (2009) stated that the patients in his study felt thermal discomfort from the materials used for their splint, especially during hot weather. The thermal discomfort from the splint may annoy patients and consequently, they may not fully comply with the prescribed time for splint wear. The reduction in actual splint wear results in less time for the tendons to rest and heal. Without a splint, there could be the risk of further exacerbating the symptoms of the first dorsal compartment when various activities are carried out throughout the day. To enhance the rate of compliance of patients, the perceived comfort of the splint should be enhanced. In order to do so, the fabrics used for the splint should have high air and water vapor permeabilities, high thermal conductivity and excellent moisture management ability. In this study, tests for evaluating different fabric properties are carried out, hence suitable fabrics are selected to fabricate the new functional splint.

2) Fit problems of splints

There are many splints available in the current market or from clinics for treating DQV and hand tendinitis. Most of them are tailor-made for patients. Despite the tailored fit, there is still room for improvement. Since patients have to wear the splint for long hours each day, a splint with a poor fit may lead to painful hand conditions. High levels of pressure exerted from the rigid side of the splint onto the hand for long hours may lead to irritation of the skin, or even skin ulcers. Therefore, the fit performance of splints is important. To develop a splint with a good fit, it is imperative to investigate the ergonomic shape of the hand, which includes the angles of the wrist and the curvature along the thumb.

3) Limited control over hand movements

The main purpose of splinting is to immobilise the thumb and wrist. However, the extent that the splints which are currently found in the market can restrict thumb and wrist movements is not known yet. If patients wear a splint that cannot effectively restrict the movement of the thumb and wrist, they may be prone to movement that aggravates the inflamed tendons and tissues, thus ultimately worsening their hand condition. In this study, the hand movement restriction of market samples are evaluated. Furthermore, since sufficient restriction of hand movement and restraining the hand in the resting position are important factors, a

new functional splint with good fit properties and capability to control the thumb and wrist movements is developed.

4) Uneven pressure distribution

Most of the splints designed for treating DQV have hard supporting parts to stabilise the hand. The position of the supporting parts is critical as their hardness may exert a certain amount of pressure on the hand of the user. Hard components that push against bony structures, such as the radial styloid process and thumb metacarpophalangeal joint, may exert a higher level of pressure comparatively. Chow (2009) stated that some of the DQV subjects in his study indicate that the splints are too hard and cause pain over the radial styloid process and bone of the thumb joint. Splint designers might mainly focus on the stabilising function of the splint and neglect the pressure exerted by the splint onto the hand of the wearer. Since patients need to wear the splint for long hours, adequate but not excessive pressure should be exerted onto the hand from the splint. Splint wear tightness may also affect the pressure distribution. Hence, more investigations and modelling work are needed to determine the amount of pressure exerted by the splint.

1.3 Aim of project and research objectives

The aim of the project in this thesis is to investigate the ergonomic shape of the thumb and wrist, test fabrics for wear comfort and other functional aspects so as to select the most appropriate fabrics for developing a new functional splint with a high degree of comfort and excellent fit properties. An FE model is also developed to simulate the distribution of pressure on the hand from the splint.

The specific objectives of this thesis are as follows:

1) To establish a thorough scientific basis for understanding the clinical anatomy of the hand and wrist, the epidemiology and aetiology of DQV, diagnosis and symptoms of DQV and related types of treatments, especially non-invasive splinting;

2) To review current splint products and understand the common characteristics of these products in terms of material use and design components. Then, to identify the limitations of the existing splints;

3) To understand the fabrication processes of existing splints as a means of preparing for the development of a new splint in the later stages of this study. In addition, to investigate the ergonomic shape of the hand which would contribute to the development of shape-fitting splint patterns and thumb supporters in the later stages of this study;

4) To source the most appropriate types of materials and carry out laboratory tests that identify the optimal materials for constructing a new splint with both optimal comfort and function. Then the patterns for the splint will be designed and developed which correspond to the properties of the selected fabrics to provide an excellent fit that accommodates the three-dimensional (3D) shape of the hand of patients and stabilises the hand in the rest position;

5) To conduct wear trials that evaluate whether the intended objectives of the functional splint could be achieved, and determine the functional effectiveness and comfort of the splint during practical use; and

6) To formulate a biomechanical model that simulates the pressure distribution of the splint in relation to the mechanical and stress-strain properties of the fabrication materials.

1.4 Project originality and significance

Treatments for DQV are mainly surgery, steroid injection and splinting. Among these three most common treatments for this condition, splinting is the only non-invasive type of treatment. Therefore, demand for splinting as a treatment by patients with DQV is still considerably high. However, the literature on treatment for DQV has mainly focused on steroid injection and surgery. Studies related to splinting to remedy DQV are limited, in both splint effectiveness and splint design. Therefore, more research on splinting to treat DQV is important and timely.

Patients with mild to moderate symptoms mainly choose to undergo splinting as their treatment. Since the purpose of splinting is to stabilise the hand and provide time for the inflamed synovial sheaths that surround the abductor pollicis longus and extensor pollicis brevis tendons to heal, patients are required to wear the splint for long hours each day. However, problems are found with conventional splints. Patients experience thermal discomfort, especially in hot weather. They also feel that the splint is bulky. As the most of these splints are made of thermoplastic, a poorly fitting splint may cause pain due to its hardness and pressure from the lack of a good fit. The restriction of hand movement by existing splints is also observed to be less than adequate. Therefore, a new functional splint with a high degree of wear comfort, good fit properties and effectiveness in maintaining the hand in a rest position is needed and timely.

The originality of this study is the development of a new functional splint with the aforementioned properties, based on the information from a comprehensive literature review on the splinting process of conventional splints and evaluation of the ergonomic shape of the wrist and thumb. The project addresses the research gap in the literature on splint design and splinting as a treatment for DQV. With improved fit and properties of the splint, patients might increase their compliance with the treatment. The new functional splint developed in this project could serve as a new option for patients who are required to undergo splinting to treat DQV. Furthermore, fabric tests are systematically carried out to select and evaluate the most appropriate materials for fabricating the splint. An FE biomechanical model is built to investigate the pressure distribution during splint wear. The findings may provide new insights and contribute to future research directions of DQV.

1.5 Outline of the thesis

This thesis comprises eight chapters as shown in Figure 1.1. Chapter 1 describes the background and problem statements of this thesis project. The aim and specific objectives are then identified and elaborated. The originality and significance of this thesis project are subsequently discussed.

Chapter 2 is a comprehensive literature review on DQV. A citation network analysis of studies related to DQV is presented. Knowledge gaps in this area of study are also discussed.

Chapter 3 explains the methodologies for evaluating the existing splints and determining their shortcomings. Methods for understanding the clinical examinations of patients with DQV, learning the fabrication process of splints and investigating the ergonomic shape of the wrist and thumb are then elaborated. Procedures for different fabric tests and fabrication details of the new functional splint are included. Software used to process the 3D images of the hands of the patients and the development of an FE biomechanical model for pressure simulation are also discussed.

Chapter 4 describes the evaluation and experimental results of tests done on existing splints. The observed results from clinical visits, investigation of the ergonomic shapes of the wrist and thumb, comparisons of the measured angle results between several subject groups, and the results of the fabric tests are discussed.

Chapter 5 provides an introduction on the design concept of the new functional splint. The development of the splint pattern is presented. The construction processes of the prototypes of the splint and supporting components are illustrated and explained in detail. The three-point bending test for selecting the appropriate materials for printing the supporting parts is also presented.

Chapter 6 presents the pre and post intervention results of the DQV subjects. The efficacy of the new functional splint is evaluated by comparing the wear trial results in terms of the pain level experienced by the subjects, the grip and pinch strength and the degree of satisfaction towards the splint. In addition, the pressure test and hand restriction test results of the newly designed splint are reported.

Chapter 7 provides an introduction of the steps to construct the FE model. The purpose of the model is to simulate the pressure exerted by the new functional splint onto the hand of the subject. To simulate the splint wearing process, the model includes several necessary modelled parts, for instance, the flesh of the hand, the bones of the hand, the fabric of the splint and the rigid supporting parts that are attached to the radial and ulnar sides of the splint. The tensile test for obtaining the material data for the FE model is described. The building process of the FE model and the validation of the simulated results are also discussed.

Chapter 8 offers the conclusions of this thesis project. Limitations of the study are discussed and recommendations are provided for future related studies.

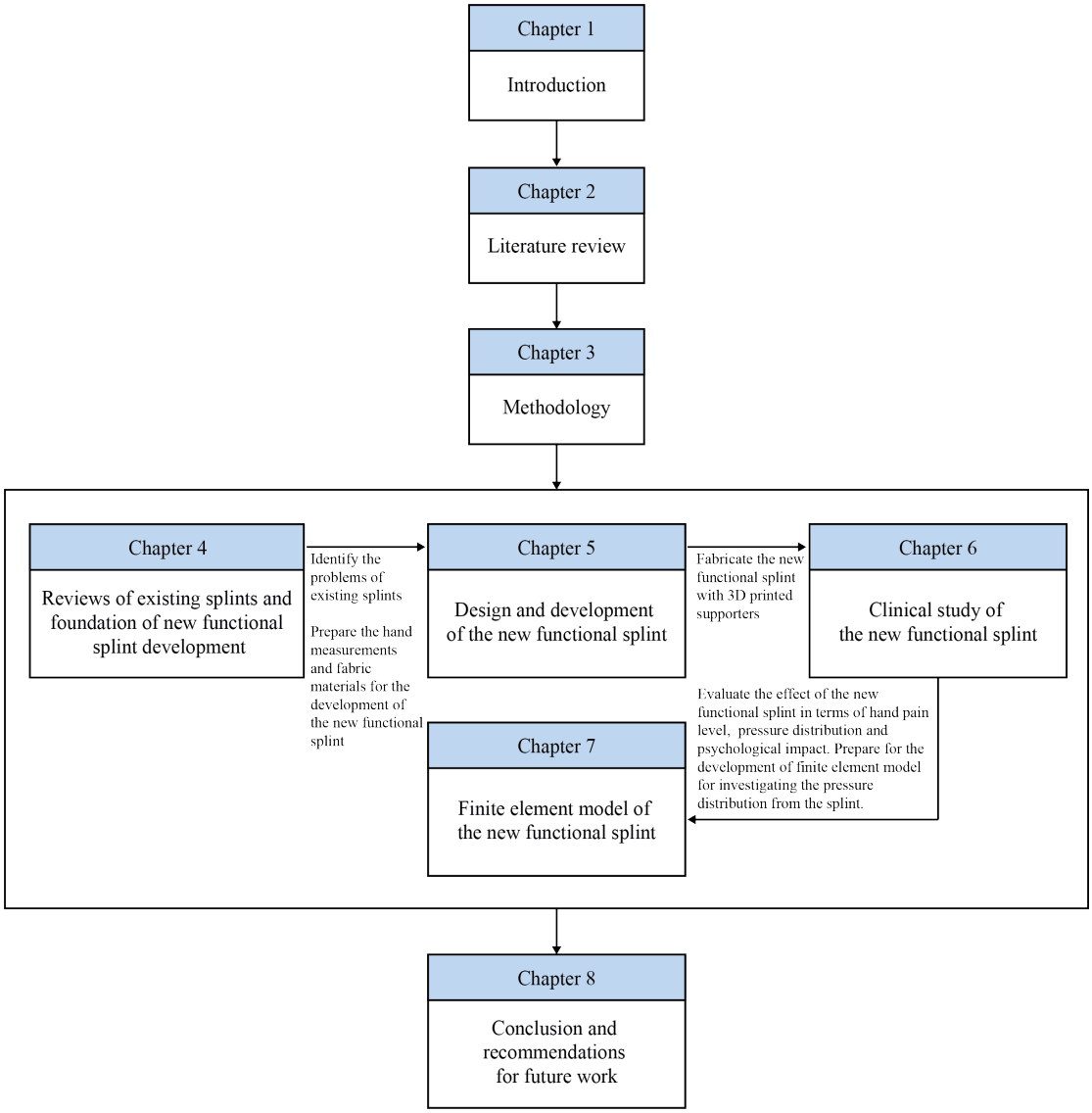


Figure 1.1 Flow chart of thesis project

Chapter 2 Literature review

2.1 Introduction

Splinting is a common and conventional means of treating DQV. In this chapter, the background information of DQV, including the clinical anatomy of the hand and wrist, epidemiology and aetiology of DQV, diagnosis methods and symptoms of this hand condition are reviewed. An overview of the different types of treatments for DQV is provided. Splinting for treating DQV and the range of movement of the thumb and wrist are discussed, followed by the specifications of splint designs. Issues around long hours of splinting and the compliance rate of patients with treatment are subsequently elaborated. A review on the splints proposed in the literature is provided, and their possible problems are discussed. There are two common types of hand gripping motions: the 'power grip' and the 'precision grip' which will be explained after the review of the splints. Finally, a citation network analysis (CNA) on articles related to DQV is presented, and the research trends and future research directions for DQV are pointed out. Studies that use the FE method (FEM) to evaluate splints for treating different hand disorders are provided in the last section of this chapter.

2.2 Background information on DQV

2.2.1 Anatomy of hand and wrist

The hand is a part of the body that carries out fine motor skills, such as grasping. The hand consists of various complex anatomical structures such as muscles, bones, tendons, joints, nerves and blood vessels. Different kinds of tasks can be performed due to the presence of a thumb and a certain degree of free movement of the hand. To mobilise the hand, the central control system and parts of the hand interact with each other (Hirt, Seyhan, & Wagner, 2017). The hand is located at the distal part of the lower arm that is connected to the forearm, which consists of two bones: the ulna and the radius, at the distal radioulnar joint. The pinch grip involves the thumb and fingers on the radial side of the hand. The power grip, which requires the cooperation between the palm and fingers, is achieved at the ulnar side of the hand (Bookman, von Schroeder, & Fam, 2010). Across the dorsal side of the wrist from the radius to the ulnar side, six separate compartments that consist of dorsal extensor tendons are identified as shown in Figure 2.1.

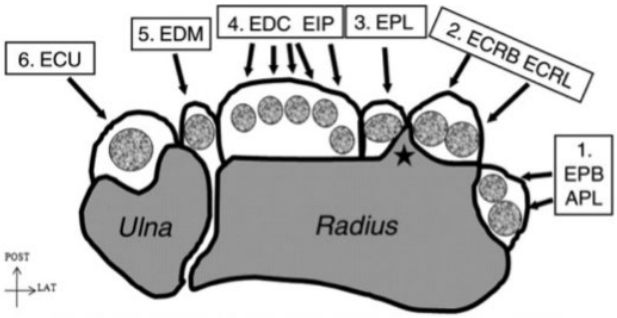


Figure 2.1 Six separate compartments across the back of the wrist
(Patel et al., 2013)

Dorsal extensor tendons are involved in hand activities that require extensions of wrist, fingers and thumb. The abductor pollicis longus (APL) and extensor pollicis brevis (EPB) are the two main tendons that control the movement of the thumb. They are found in the first dorsal compartment which can be located by using the radial styloid, the scaphoid tubercle and Lister's tubercle as the landmarks (Patel et al., 2013). These two tendons are protected by the synovial sheath. They pass through the fibro-osseous tunnel and lie beneath the extensor retinaculum (Figure 2.2a) (Bookman et al., 2010). According to the anatomy of the thumb, the APL tendon ends at the first metacarpal bones. The APL tendon is found on the lateral side of the thumb metacarpal. This tendon controls the dorsal and radial movements of the first metacarpal, and facilitates the extension and abduction of the wrist. On the other hand, the EPB tendon is inserted into the dorsal of the first proximal phalanx. The EPB tendon primarily extends the proximal phalanx of the thumb and enables the extension and abduction of the wrist (Draghi, 2014). Figure 2.2b shows the insertion locations of the APL and EPB tendons (Ilyas, Ast, Schaffer, & Thoder, 2007).

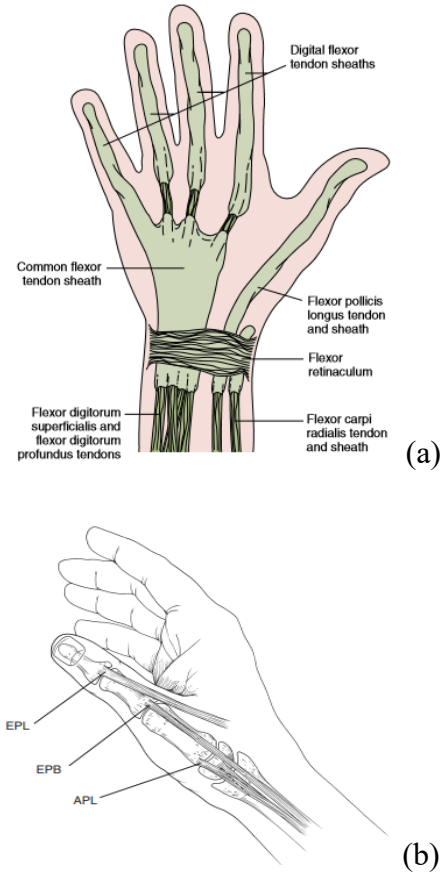


Figure 2.2 (a) Tendon, synovial sheath and the extensor retinaculum, and
(b) Insertion location of APL and EPB tendons
(Bookman et al., 2010; Ilyas et al., 2007)

2.2.2 Epidemiology, aetiology and pathology

DQV is a painful and pathological condition at the radial side of the wrist. The disease is named after Fritz de Quervain, a Swiss surgeon, who first characterised the disease in 1895 (Mallick, Jha, Majumdar, & Mahapatra, 2018; Satteson & Tannan, 2020). The condition involves tenosynovitis or inflammation of the synovial sheath at the first dorsal compartment which contains the two main tendons for thumb movement - the APL and EPB tendons, as shown in Figure 2.3 (Green et al., 2016). The inflammation of the synovial sheaths may cause thickening of the nearby tissues so that the APL and EPB tendons may also become inflamed at the same time (Goel & Abzug, 2015). The sufferer may feel pain near the radial styloid due to the friction of the APL and EPB tendons against the thickened sheaths, tendon pulleys or other neurovascular bundles (Brunelli, 2003).

DQV is one of the most common types of tenosynovitis of the hand (Graham, Hulkower, Bosworth, White, & Gauer, 2007). According to a large community-based study that was conducted in the UK, the rate of prevalence of the disease among the general population from June 1998 to August 2000 was around 1.3% among women and 0.5% among men (Walker-Bone et al., 2004). Another study carried out in Japan indicated that 3.7% in the general population have DQV (Adachi et al., 2011). In Hong Kong, the The Occupational Safety and Health Branch (2017) found that the number of cases of tenosynovitis of the hand or forearm is 63, which is approximately 19% of the most commonly found occupational diseases (N=334), or the second most common type of occupational disease in 2016 (Table 2.1). In terms of the distribution by industry of the 63 cases of tenosynovitis, the majority or 39.7% are in public administration, and social and personal services; 22.2% in accommodation and food services; 14.3% in import and export, wholesale and retail trades; and the remainder in professional and business services, information and communications, transportation, storage, postal and courier services, and construction (The Occupational Safety and Health Branch, 2017).

Table 2.1 Most common types of occupational diseases in Hong Kong in 2016
(The Occupational Safety and Health Branch, 2017)

Number of Confirmed Occupational Diseases in 2016	
Occupational Disease	**Number**
Occupational Deafness (including monaural hearing loss)	184
Tenosynovitis of the Hand or Forearm	63
Silicosis	43
Gas Poisoning	14
Occupational Dermatitis	11
Mesothelioma	7
Tuberculosis	6
Asbestosis	4
Mercury Poisoning	1
Streptococcus suis Infection	1
Total	**334**

DQV is usually prevalent among those in their forties, fifties and sixties (Júnior et al., 2016; Satteson & Tannan, 2020). The rate of prevalence is significantly higher among women than men (Wolf, Sturdivant, & Owens, 2009). However, with the rapid development of advanced technologies in the past few decades, more and more people are using their mobile phone for longer hours each day. The use of mobile phones involves a considerable amount of thumb movement. As such, young males could also be a potential group who might be afflicted with DQV (Nisa, Umer, & Hassan, 2016).

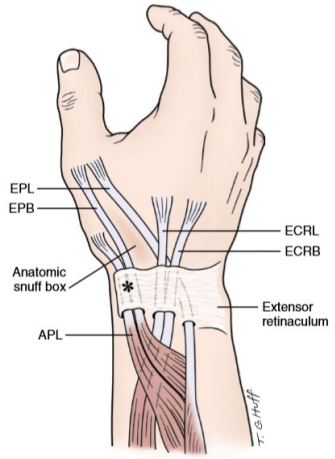


Figure 2.3 Location of tendon inflammation of DQV
(Green et al., 2016)

Table 2.2 Rate of prevalence of DQV in different age groups
(Nisa et al., 2016)

Age (in years)	Frequency	De Quervain's syndrome	
		Present	Absent
16-20	151	89 (58.94%)	62 (51.06%)
21-25	129	83 (64.34%)	46 (35.66%)
26-30	104	51 (49.04%)	53 (50.96%)

One of the causative factors of DQV is the overuse and repetitive movement of the thumb and wrist. Hand movements that involve forceful grasping with wrist ulnar deviation, thumb abduction and extension of the APL and EPB tendons at an acute angle may cause stress to them and the surrounding protective tissues. Thus, the repetitiveness of the aforementioned movements may lead to inflammation at the first dorsal compartment (Howell, 2012; Júnior et al., 2016). Occupations that involve repetitive hand movements, such as playing the piano, typing on a keyboard, using the computer mouse, sewing, cutting, putting in screws or washing clothes, may increase the risks of DQV (Nemati, Javanshir, Saeedi, Farmani, & Aghajani Fesharaki, 2017). Pregnant and lactating women are also susceptible to DQV due to changes in hormones secretions which may affect the tendons due to increase in use during infant caring

(Schned, 1986). Nisa et al. (2016) stated that the rate of prevalence of DQV among mobile users among those who are 16 to 30 years old is 58.07% of a total of 384 cases in their study, which is relatively high. Table 2.2 shows that the prevalence percentage of DQV among the recruited subjects with thumb pain is higher in the age group of 21 to 25 year-olds when compared to other age groups. The study concluded that the majority of the affected mobile users are young teen males. This may also show that with the development of advanced technologies, youths may become potential DQV patients due to the repetitive use of the thumb and wrist during smart phone usage and typing on a computer keyboard.

However, the exact reason why DQV occurs is still being debated. Júnior et al. (2016) carried out a cross-sectional study that identified the anatomical variations in the first dorsal compartment of a group of patients with DQV, and compared the result to that of a group of cadavers whose wrist did not have the determination of DQV. The study showed that there is significantly more frequent anatomical variation, with a septated first extensor compartment and supernumerary APL tendons in the DQV patients. The septated first extensor compartment could lead to isolation of the EPB tendon, which might be one of the potential causes of the disease (Alexander et al., 2002). Stahl et al. (2015) argued against heavy manual labour, trauma and anatomical variation as related risk factors for DQV, and instead, suggested that there might be suspected genes associated with DQV. On the other hand, Clarke, Lyall, Grant, and Matthewson (1998) stated that the pathogenesis of DQV might may not involve inflammation at the first extensor compartment, but is due to tissue thickening, fibrosis of the tendon sheaths with nodularities, degeneration of the tendons and deposition of *mucopolysaccharides*, which cause swelling and unsmooth movement of the tendons along the synovial tunnel which triggers pain. The degeneration of tissues might be observed at the chronic stage (Nemati et al., 2017). The causes and pathologies of DQV are still however not clear nor reached a consensus. Further research on identifying the causal factors of this disease and the pathological changes in the first dorsal compartment is timely and important for developing more accurate and precise treatment plans for patients with DQV of different levels of severity.

2.2.3 Symptoms and diagnosis

Patients with DQV feel pain across the radial styloid, which can be aggravated by activities that involve flexion of the thumb and ulnar deviation of the wrist (Goel & Abzug, 2015). Tenderness and soreness are usually found along the radial side of the wrist, swelling in the shape of a fusiform ellipse might be observed near the radial styloid (Goubau et al., 2014; Satteson & Tannan, 2020). Patients may also feel wrist crepitus (grinding sensation) during wrist movement (Antoniadou, 2018). Patients feel that it is challenging and difficult to perform daily life activities since most of the activities involve hand and thumb motions, in which the thumb is used in 45% to 60% of the time (Nemati et al., 2017). Walker-Bone et al. (2004) pointed out that daily activities are relatively impacted for patients with specific or non-specific pain at the upper limbs, such as the shoulders, elbow, wrist or hand. Table 2.3 shows that 28.3% of the patients with DQV or wrist tenosynovitis in Walker-Bone et al. (2004) reported difficulties with undoing lids on bottles or jars, and 13% of them feel that it is difficult to carry bags. Aside from daily activities, patients may also complain of upper limb pain with specific activities, for instance, lifting a child, twisting wet towels and washcloth, hammering nails or gripping sports equipment (Goel & Abzug, 2015). Therefore, more than half of these patients sought consultation from doctors or other health care professionals, such as physiotherapists, chiropractors or osteopathy practitioners.

Table 2.3 Relative impact on daily activities and health-seeking behaviour of subjects with specific and non-specific pain at different parts of upper limbs

(Walker-Bone et al., 2004)

	Shoulder		Elbow		Wrist/hand		
	Any specific disorder (n = 365)	Nonspecific pain (n = 82)	Epicondylitis (n = 70)	Nonspecific pain (n = 179)	De Quervain's or wrist tenosypovitis (n = 92)	Carpal tunnel syndrome (n = 38)	Nonspecific pain (n = 270)
Impossible to							
Sleep	2.5	0.0	2.9	1.1	2.2	0.0	1.4
Drive	2.2	0.0	2.9	1.7	3.3		1.1
Carry bags	11.5	6.1	20.0†	5.6	13.0	10.5	7.8
Dress	1.6	1.2	1.4	2.2	2.2	-	1.5
Open doors	2.2	3.7	-	-	-	-	-
Get things down from shelf	13.4†	4.9	-	-	-	-	-
Fasten clothes	9.3	3.7	-	-	-	-	-
Do heavy jobs	12.1†	3.7	-	-	-	-	-
Write	-	-	-	-	4.4	-	2.6
Undo lids on bottles/jars	-	-	-	-	28.3†	-	16.3
Fasten/unfasten zippers	-	-	-	-	-	2.6	-
Consulted							
Doctor	46.3†	34.2	42.9	35.2	47.8†	42.1	31.1
Other health care professional‡	21.6	26.8	4.3	8.4	12.0†	5.2	5.6
Had injection	9.0†	0.0	5.7	2.8	6.5†	2.6	2.2
Took							
Prescribed drugs	37.5†	23.2	37.1	26.3	44.6†	7.9†	21.1
Self-prescribed drugs	42.5	32.9	35.7	29.1	34.8	2.6†	29.6

* The figures in the body of the table represent the proportion (%) of subjects in each diagnostic group who reported the disability, consulted, or took medication because of pain at the relevant anatomic site during the post 12 months. If data is missing, the question was not asked.
† $P < 0.05$ in comparison with nonspecific pain at the same anatomic site.
‡ Physiotherapist, chiropractor, or osteopath.

A positive diagnosis of DQV can be made with the Finkelstein's test. First described by Harry Finkelstein, a U.S. surgeon, in 1930 (Venes, 2013), this test is performed to identify the stenosing tenosynovitis of the APL and EPB tendons. The patient is told to flex his/her thumb and enclose his/her thumb into the closed fist (Goel & Abzug, 2015). Then, the examiner stabilises the patient's forearm with one hand, while the other hand holds the fist with the thumb inside, and deviates it together with the wrist towards the ulnar side, as shown in Figure 2.4 (Dutton, 2005). Pain found over the APL and EPB tendons results in a positive diagnosis (Magee, 2014).

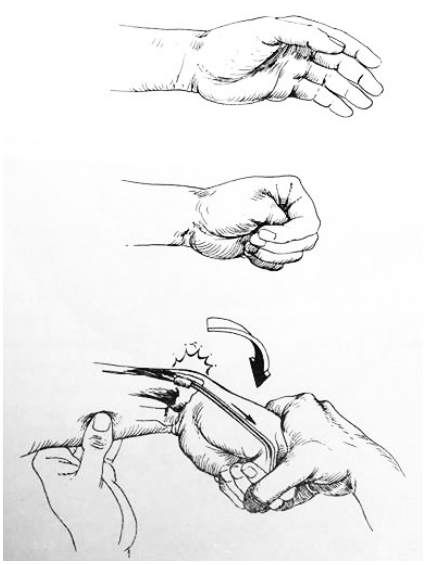


Figure 2.4 Finkelstein's test
(Dutton, 2005)

Evans (2009) stated that to more easily determine the level of severity of a hand condition, sometimes patients are requested to carry out an entire test actively. According to the posture and movement of the patient, and the level of pain indicated, the examiner can then decide whether to further perform the test passively. It is possible that the hand without DQV can still feel discomfort during the Finkelstein's test. Therefore, it is recommended that examiners ask their patient to perform the test with both the affected and normal hands, and compare the feelings and level of pain of both hands for a more accurate diagnosis (Magee, 2014). Although the majority of studies have indicated that a positive Finkelstein's test can serve as a diagnosis of DQV, some researchers also point out that the Finkelstein's test could give a false positive result. Hajder, de Jonge, van der Horst, and Obdeijn (2013) indicated that 16% of the patients recruited in their study express pain at the radial side of the wrist and a positive Finkelstein's test; however no signs of DQV are found in their first dorsal compartment through an ultrasound examination. This shows that a positive Finkelstein's test might not be due to DQV, but other hand conditions, such as arthritis. Some studies have even argued that the procedure of the Finkelstein's test with the thumb enclosed inside the palm is actually the Eichhoff's test, which was described in 1927 by E. Eichhoff (Dawson & Mudgal, 2010; Goubau et al., 2014). Eichhoff's test requires the patient to hold his/her thumb inside his/her fist while the practitioner is grasping and ulnar deviating the hand of the patient. However, the Finkelstein's test is more accurate when

done by a skilled practitioner and the testing involves four steps. First, the affected wrist is placed at the edge of the examination table with neutral positioning of the forearm, ulnar side of the wrist touching the surface of the table and hand portion hanging off the table. Then, the patient actively carries out the second step by performing a mild gravity assisted ulnar deviation of the wrist. Patients in the acute stages of the DQV may feel tenderness and pain near the radial styloid process when actively performing the ulnar deviation. Patients who feel little or no pain while carrying out the second step will then be subjected to testing by the examiner, who will hold the palm of the patient and further deviate the wrist in the ulnar direction. In the last step, the thumb of the patient is passively flexed into the palm by the examiner, as shown in Figure 2.5. A positive Finkelstein's test or diagnosis of DQV results when the patient feels pain over the radial styloid process when carrying out any of the aforementioned wrist deviation and thumb flexion movements (Dawson & Mudgal, 2010).

Figure 2.5 Thumb flexion performed by examiner
(Goubau et al., 2014)

A number of other hand movement tests have been proposed for determining DQV, for example, the Brunelli's test which requires patients to perform thumb abduction with radial deviation of the wrist so as to provoke friction and pain at the first dorsal compartment. Then there is the EPB entrapment test in which patients are asked to compare the level of pain induced by resistance to palmar abduction to that induced by resistance to thumb metacarpophalangeal (MCP) joint extension. The wrist hyperflexion and abduction of the thumb (WHAT) test requires patients to flex their wrist along with the full extension and abduction of their thumb within a tolerable level of pain while the examiner gradually applies resistance towards the thumb. However, these tests are not frequently used in clinical diagnosis practices (Alexander et al., 2002; Brunelli, 2003; Goubau et al., 2014). Although the origins of diagnostic tests are still

debatable, and there are new methods proposed in the literature, the procedure of the diagnosis of DQV is normally carried out by the patient who flexes the thumb of the affected hand into the closed fist, and then deviates the wrist in the ulnar direction in order to see if there is pain on the radial side of the hand near the radial styloid process. This procedure is commonly known as the Finkelstein's test.

Hand functions can also be assessed with the use of measuring tools. Grip strength is commonly measured for evaluating the hand function of a patient. Sealed hydraulic dynamometers, for instance, the Jamar dynamometer, are usually used in clinics for measuring grip strength. It has been shown that the Jamar dynamometer can measure the grip strength accurately and provide valid and reliable results (Mathiowetz, Weber, Volland, & Kashman, 1984). The Jamar dynamometer has five settings for the grip handle which can be adjusted according to the requirements of different strength tests; for example, the five-position grip strength test, rapid exchange and simultaneous grip test and rapid repeat test (Dutton, 2005). In a clinical grip strength test, the patient is asked to hold the Jamar dynamometer in his/her hand with the arm positioned right beside the body with an approximately 90-degree elbow flexion, as shown in Figure 2.6.

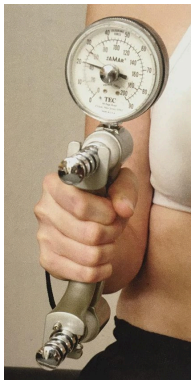


Figure 2.6 Holding position of Jamar dynamometer
(Magee, 2014)

The handle width is set according to the size of the hand of the patient as the dynamometer should be held between the first metacarpal and the middle of the other four fingers. The patient squeezes the dynamometer with maximum force for few seconds, and the result will be recorded. Both hands will perform the test alternately, and three trials will be carried out. The results of each hand will then be recorded. The

mean value of the trials of both hands is calculated and compared. The normal values of the combined grip strength of both hands of different age groups and gender are shown in Table 2.4 (Magee, 2014).

Table 2.4 Normal values of combined right and left hand grip strength (kg) of different age groups and gender

(Magee, 2014)

Normal Values by Age Group (Years) and Gender for Combined Right and Left Hand Grip Strength (kg)

	AGES 15 TO 19		AGES 20 TO 29		AGES 30 TO 39		AGES 40 TO 49		AGES 50 TO 59		AGES 60 TO 69	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Excellent	≥113	≥71	≥124	≥71	≥123	≥73	≥119	≥73	≥110	≥65	≥102	≥60
Above average	103–112	64–70	113–123	65–70	113–122	66–72	110–118	65–72	102–109	59–64	93–101	54–59
Average	95–102	59–63	106–112	61–64	105–112	61–65	102–109	59–64	96–101	55–58	86–92	51–53
Below average	84–94	54–58	97–105	55–60	97–104	56–60	94–101	55–58	87–95	51–54	79–85	48–50
Poor	≤83	≤53	≤96	≤54	≤96	≤55	≤93	≤54	≤86	≤50	≤78	≤47

Pinch strength can also be measured to assess the hand function. A pinch meter, as shown in Figure 2.7, is used to measure the pinch strength (Magee, 2014). Three trials are carried out and their mean values are calculated and recorded. Table 2.5 shows the average strength of pulp-to-pulp pinch of the thumb with the other digits of 100 subjects in (Dutton, 2005). The force exerted by the injured hand for both the hand grip and pinch strength tests is always smaller than that exerted by the healthy hand.

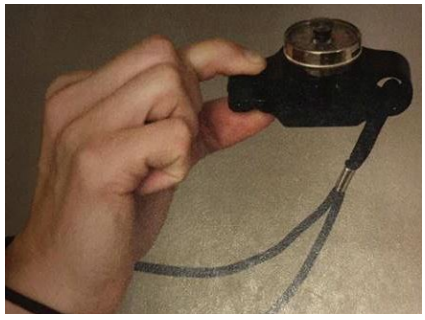


Figure 2.7 Pinch meter for pinch strength measurement

(Magee, 2014)

Table 2.5 Average pulp-to-pulp pinch strength of thumb with other digits (100 subjects) (Dutton, 2005)

	Pulp-to-Pulp Pinch (kg)			
	Male Hand		Female Hand	
Digit	Major	Minor	Major	Minor
II	5.3	4.8	3.6	3.3
III	5.6	5.7	3.8	3.4
IV	3.8	3.6	2.5	2.4
V	2.3	2.2	1.7	1.6

Aside from measurements, questionnaires are sometimes used for assessing the functional ability of the hand, level of pain at the wrist and satisfaction with splinting treatment of patients (Nemati et al., 2017). The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire is designed to evaluate the health status of patients in the previous week. This questionnaire is a reliable indicator for assessing the function of the hand and severity of any issues by asking questions related to the difficulties of hand function and impacts during daily life activities and experienced symptoms. It is also able to monitor the changes of the hand condition over time (Williams, 2014). The pain visual analogue scale (VAS) is another standard scale used to assess attitude or feelings, such as the intensity of symptoms, with a score that ranges from 0, which represents no pain to 100, which is extreme pain. The VAS can also be used to assess splinting, in which 0 denotes very dissatisfied while 100 denotes very satisfied (Nemati et al., 2017).

In summary, there are a variety of diagnostic tasks, measurement tools and questionnaires for evaluating the health conditions of patients with DQV, however, each of these methods can only assess a single or specific aspect of the situation; for example, the functional ability of the hand, physical symptoms of the patient such as level of pain and tenderness of wrist, and psychological aspects, such as satisfaction and feelings towards the splinting and quality of life. Therefore, it is necessary to implement a combination of different assessments so as to involve all of the different aspects to understand the hand condition. With a full understanding of the situation of the patient, doctors or other professionals can prescribe the best treatment plan for them.

After reviewing the studies in the literature, a thorough understanding of the fundamentals of the background information of DQV has been obtained. The key reviewed points of DQV are summarised in Table 2.6. This background knowledge provides the important foundations of this study.

Table 2.6 Key reviewed points of DQV

Anatomical location	• The first dorsal compartment at the radial side of the wrist near radial styloid process
At-risk individuals	• More prevalent in women • Common age range from forties to sixties • People in occupations that require repetitive thumb and wrist movement • Pregnant and postpartum women due to changes in hormone secretion that may affect the tendons and increased infant caring tasks • Possible rise in rate of prevalence of younger populations due to use of mobile phone and typing on computer
Possible Causes	• Overuse of thumb and wrist due to repetitive activities • Anatomical variations at the first dorsal compartment • Suspected genes
Controversial pathologies	• Inflammation of the synovial sheaths that surround the APL and EPB tendons in the first dorsal compartment • Degeneration of tendons, fibrosis of tendon sheaths and thickening of nearby tissues
Possible symptoms	• Pain, soreness, tenderness and swelling over the radial styloid region • Difficulties in performing activities that require movement of thumb and wrist, such as gripping and opening a jar

Acknowledged diagnostic tests	• Finkelstein's test: flexion of the thumb in the closed fist, and then deviate the wrist in ulnar direction ○ Pain over the first dorsal compartment which is a positive diagnosis.
Other tests or scales for assessing hand functions and level of pain	• Grip strength measured by dynamometer • Pinch strength measured by pinch meter • DASH questionnaire • VAS

2.3 Treatment for DQV

There are various kinds of treatment and combinations of them for patients with DQV, which are offered by doctors, occupational therapists or physiotherapists. Patients with the disease in the early stages usually seek conservative treatment, which include splinting, heat and cold compression, friction massage, therapeutic exercise and modalities, medications such as nonsteroidal anti-inflammatory drugs (NSAIDs), activity adjustment and rest (Goel & Abzug, 2015; Howell, 2012). A combination of conservative methods may also be advised. However, many studies show that splinting is the most effective for patients in the early stages of DQV. In the study of Lane, Boretz, and Stuchin (2001), patients received a combined treatment of splintage with a nonsteroidal anti-inflammatory drug - naproxen and steroid injection for two to four weeks. The patients included those with minimal symptoms, some with more pain at the radial side of the wrist with mild symptoms, and a third group who experienced moderate or severe interference in daily activities due to the disease. They found that splintage and naproxen work for 15 of the 17 patients in their study group with minimal symptoms which is approximately an 88% efficacy rate, while steroid injection works better for those with moderate or severe symptoms,. In the study of Mallick et al. (2018), the outcome of steroid injection treatment and conservative treatment was compared. One group of patients underwent conservative treatment and wore a thumb splica splint during the day with rest, and received local ice or hot compression and a topical NSAIDs gel thrice a day. The other group received corticosteroid injections on their wrist. They concluded the splinting is a viable option to injection for those with mild symptoms. Nemati et al. (2017) conducted a study that compared the effectiveness of traditional and dynamic splints, and concluded that there is in improvement in the

palmar and lateral pinch strengths of the thumb in both groups of patients after splinting. However, patients who were treated with dynamic splint indicated a higher satisfaction level. Figure 2.8 shows a sample of a thermoplastic splint for treating DQV. Overall, the effectiveness of splinting might be relatively lower in patients with moderate or severe symptoms. Moreover, inappropriate use of materials or poor fit of splints may cause skin reactions or discomfort during splinting treatment.

Figure 2.8 Thermoplastic splint for treating DQV
(Goel & Abzug, 2015)

Patients who are unable to find pain relief or improvement to their condition after a few weeks or months of the above discussed conservative type of treatments may find that their doctor will prescribe steroid injections, which is also a conservative but somewhat more invasive treatment, as shown in Figure 2.9. Steroid is injected into the first dorsal compartment, and into the sheath between the APL and EPB tendons (Graham et al., 2007).

Figure 2.9 Injection into first dorsal compartment sheath
(Bookman et al., 2010)

The accuracy of the injected site is critical and important for relieving the symptoms (Zingas, Failla, & Van Holsbeeck, 1998). To enhance the accuracy of the steroid injection, Hajder et al. (2013) proposed the use of ultrasound to determine the synovial condition of the first compartment and guide the injection with the correct needle position (Figure 2.10). They showed that ultrasound-guided injections with triamcinolone could treat DQV effectively. Like conservative treatment which can entail a combination of different treatments such as splinting and NSAIDs, injection can also be combined with other therapies. Cavaleri, Schabrun, Te, and Chipchase (2016) systemically reviewed and compared the effectiveness of treatments with orthosis alone, injection alone and combination of orthosis use and corticosteroid injection. The study showed that combined treatment of splinting and injection is more effective in treating the disease. However, Richie and Briner (2003), who conducted an evaluation and pooled quantitative studies, indicated that the efficacy of injection alone is 83%, which is higher than that of combined treatment of injection and splinting, splinting alone and use of NSAIDs. Earp, Han, Floyd, Rozental, and Blazar (2015) examined the success rate of a single corticosteroid injection for the short and long terms, and found that 82% of the symptoms are resolved in patients at a 6 week follow up. However, close to 50% of the patients experience recurrence of DQV at an average of about 3 months after injection. Similarly, McDermott, Ilyas, Nazarian, and Leinberry (2012) carried out a study to examine the effectiveness of ultrasound-guided injection, which showed that the symptoms are at least partially resolved in 36 of 37 patients at the 6 week follow up. However, 14% of the patients showed recurrence of symptoms. McDermott et al. (2012) also observed that all of the patients with recurrence of symptoms had subcompartmentalisation within the first dorsal compartment, which may indicate that anatomical variation is one of the risk factors of DQV. Complications of the hand after corticosteroid injection are also possible. Jirarattanaphochai et al. (2004) provided adverse events of patients after receiving triamcinolone injection which include subcutaneous nodules, ecchymosis and skin hypopigmentation. Occurrence of atrophy of subcutaneous fat tissues may also be observed after the injection (Sawaizumi, Nanno, & Ito, 2007). Baack and Brown (1991) pointed out an atypical complication after steroid injection for DQV, which is a mycobacterium skin and soft-tissue infection at the dorsal radial zone of the wrist.

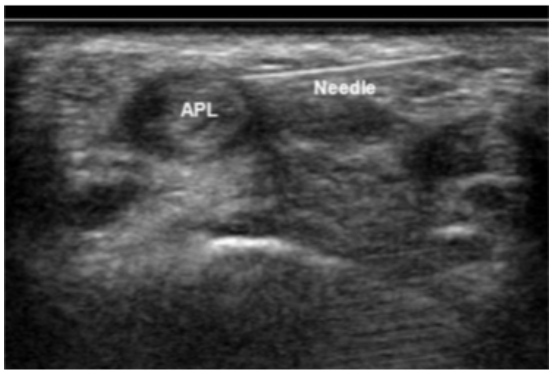


Figure 2.10 Location of APL tendon and needle position prior to injection
(Hajder et al., 2013)

When there is no relief of symptoms or even worsening of the DQV after adopting the conservative methods for 3 months or longer, and patients continue to experience difficulties in performing some of the daily activities due to pain or tenderness, the last resort is surgery (Astifidis, 2016). The purpose of surgery is to free the tendons from the thickened sheath. During the procedure, an oblique incision is made at the centre of the first dorsal compartment, then the tendon sheath is opened for tendon release (Saghieh, Weinstein, & Hoballah, 2013). Surgical treatment is an effective method to treat DQV with a high efficacy of 91% and no post-surgery complications as found in the study of Ta, Eidelman, and Thomson (1999). However, since this is an invasive treatment, the cost of the operation might be higher than other types of treatments. Furthermore, the risks of surgical complications, such as wound infection, nerve injury, partial displacement of the tendons and incomplete release of the tendons which leads to continuous pain, may still be possible (Saghieh et al., 2013).

Table 2.7 Treatments for DQV

	Splinting	Injection	Surgery
Level of severity of symptoms	Minimal to moderate	Moderate to serious	Serious
Treatment characteristics	• Non-invasive • Requires commitment of 2 weeks or more	• Minimal invasive • One-off with post-injection healing period	• Invasive • One-off with post-surgery healing period
Variation of treatment	Large variation of splint designs	Minimal variation of injection approaches	Low variation of surgical methods
Efficacy and symptom improvement	• Minimal symptoms of DQV can be completely eliminated after splinting and NSAID, of 88% efficacy • Relatively low efficacy for patients with moderate to severe symptoms (Lane et al., 2001)	• Majority of symptoms resolved in patients at 6 week follow up. However, half show recurrence of DQV at about 3 months after injection (Earp et al., 2015)	• High efficacy of 91% without post-surgery complications (Ta et al., 1999)
Cost	Low	Moderate	High
Side effects	Possible discomfort due to improper splint design	Wound pain	Wound pain
Complications	• Skin allergies	• Subcutaneous nodules • Ecchymosis • Skin hypopigmentation Atrophy of subcutaneous fat tissues • Mycobacterium skin and soft-tissue infection at the dorsal radial zone of wrist	• Wound infection • Nerve injury • Partial displacement of tendons • Incomplete release of tendons

According to Table 2.7, the effectiveness of both steroid injection and surgery is higher than that of splinting, however, since these two approaches are both invasive which may lead to relatively higher risks of complications, and the cost of these two treatments may also be higher due to the need for skilled physicians, patients with DQV, especially pregnant or postpartum women and those in the early stages of the disease, may prefer to undergo splinting. According to Jongprasitkul, Suputtitada, Kitisomprayoonkul, and Pintawiruj (2011), splinting is a safe and effective approach for treating the disease, particularly in mild cases, by immobilising and resting the APL and EPB tendons, and reducing the occurrence of friction in the first dorsal compartment. As such, the demand for splinting is high and such demands means that research on improving the effectiveness of splinting is necessary.

Knowledge gap 1: There is high demand for splinting to treat DQV due to its non-invasiveness and lower risks, however, there is still room for improvement in the effectiveness of splinting, which may be associated with the splint design and impacts the compliance rate of patients.

2.4 Splinting for treating DQV

2.4.1 Principles of splinting

Splinting is one of the conservative treatments for DQV, especially for patients who are in the early stages of DQV. The main purpose of the application of a thumb spica splint is to immobilise the thumb and wrist. Hand movement, such as flexion of the thumb at the MCP joint or ulnar deviation of the wrist, can be restricted (Goel & Abzug, 2015). The use of a splint can help the injured wrist to rest and reduce the inflammation at the first dorsal compartment by reducing the use of the related muscles. In doing so, this limits the gliding and pulling of the tendons (Nemati et al., 2017). On the other hand, the splint does not have to immobilise the interphalangeal (IP) joint of the thumb as the movement of this joint is not related to the two inflamed tendons (Chen, 2018).

According to Shurr and Cook (2002), there are six steps for fabricating an orthosis, as shown in Table 2.8. The first step is to evaluate the situation of the patient. The occupational therapist has to understand the needs of the patient, plan the treatment schedule and decide on the type of orthosis that is suitable for the patient's condition.

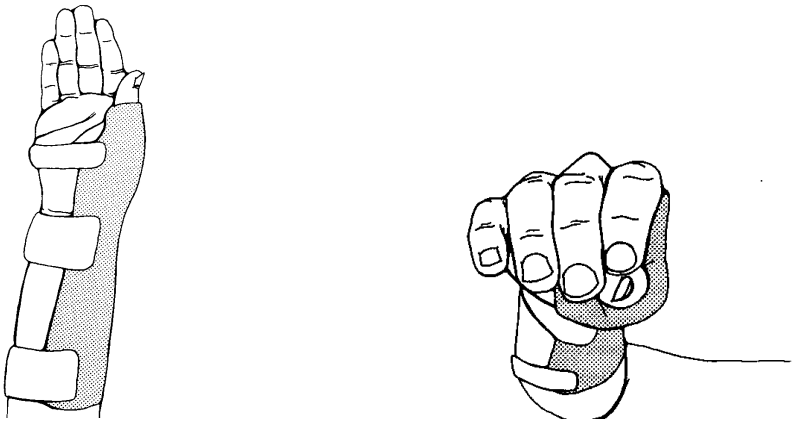
Then, the occupational therapist has to measure the body part and identify the body landmarks, and select the proper size of the material for fabricating the orthosis. The third step is to fabricate the orthosis according to the shape and size of the injured part with appropriate materials and fabrication equipment. After fabrication of the orthosis, the patient will don the orthosis to evaluate the fit and comfort of the device. The occupational therapist will then fine-tune and adjust the device according to the patient's feedback. Lastly, follow-up of the orthosis wear will be carried out in subsequent clinical check-ups.

Table 2.8 Process of orthosis fabrication
(Shurr & Cook, 2002)

Step 1	Evaluation/ prescription
Step 2	Measurement/ impression taking (casting)
Step 3	Fabrication/ bench alignment
Step 4	Fitting/ static alignment
Step 5	Modification/ dynamic alignment
Step 6	Re-evaluation/ follow up

The splint for treating DQV has to be able to immobilise the thumb, but at the same time, it is important to allow easy opposition of the thumb and other fingers. The wrong positioning of the thumb and wrist during splint wear may lead to unnatural movement of the hand when the patient attempts to grip or hold objects. As a result, other hand disorders or pain may result after wearing the splint for a period of time. Therefore, when moulding the thermoplastic in accordance with the shape of the patient's hand, the thumb and wrist should be positioned properly in the resting position. When performing the resting position, the distal phalanx of the thumb touches the middle phalanx of the index finger. The resting position in the static and neutral state is shown in Figure 2.11 (Lin, Kuo, Liu, Wu, & Su, 2010). Figure 2.12 shows the proper hand positioning in the splint which allows for easy opposition of the index finger and other fingers for performing different tasks during the day (McKee & Morgan, 1998).

Figure 2.11 Resting position
(Lin et al., 2010)



(a) (b)

Figure 2.12 Proper hand positioning in splint (a) Palmar view;
(b) Fingertip view – opposition of thumb and fingers
(McKee & Morgan, 1998)

The majority of the DQV splints cover the hand to part of the forearm in order to stabilise both the thumb and the wrist. The splint should hold the wrist in a neutral resting position, with the thumb at 30 degrees of both flexion and abduction (Ilyas et al., 2007). Nemati et al. (2017) stated that during the shaping process of an orthosis, the wrist of the patient should be held in a position that is a 10 to 20 degree of extension and the thumb can be maintained in a radial abduction without discomfort. Wilton (2014) also indicated that the immobilised position of the hand controlled by the orthosis is to maintain the normal and natural anatomical relationships. Wilton (2014) agreed with Nemati et al. (2017) that, when fabricating a splint, the wrist should be held between a 10 to 20 degree of extension with a slight ulnar deviation, and the thumb with a slight carpometacarpal (CMC) joint abduction and slight flexion of the MCP and

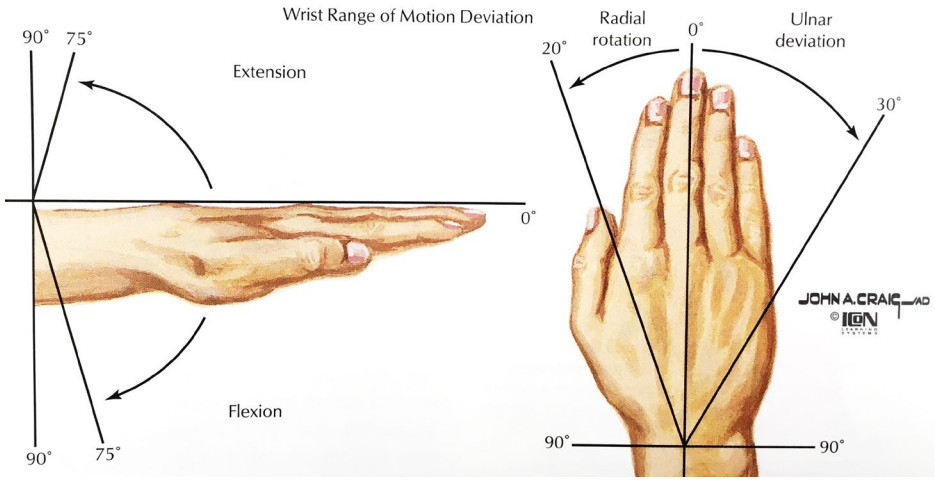
IP joints. Hart, Kleinert, and Lyons (2005) also stated that splints designed for the thumb MCP joint can stabilise the MCP joint with slight opposition and flexion at around 15 to 20 degrees. They proposed a modified thumb spica splint that can be used by DQV patients after steroid injection, which fixes the wrist at around a 10 to 20 degree of extension, maintain slight palmar abduction of the CMC joint and approximately 30 degree flexion of the MCP joint and neutral placement of the IP joint. As mentioned in Wilton (2014), the EPB and APL tendons and the surrounding synovial tissues may be stretched when performing thumb flexion and wrist ulnar deviation, and these two hand movements are performed in the Finkelstein's test to determine a positive diagnosis when pain is felt at the radial side of the wrist. Therefore, the thumb spica splint should be able to immobilise the hand as much as possible to avoid these two motions, especially thumb flexion.

It is important to ensure that the splint provided to the patient can fit the three dimensions of the hand properly, and maintain the wrist and thumb in the appropriate angles and resting position. Moulding the thermoplastic shape correctly during the fabrication process of the splint is critical. A poorly fitting splint may lead to wrong positioning of the hand and the patient may perform daily activities in an unnatural way, which results in development of pain and problems in other parts of the hand. Therefore, the fit and shape of the splint are critical factors that affect the efficacy of the treatment. Furthermore, the splint should be able to protect the wrist, restrict the range of motion of the thumb and wrist which may exacerbate the symptoms, but should not over-control the hand movements that do not affect the injured condition of the first dorsal compartment, such as the IP joint of the thumb and opposition of the fingers.

2.4.2 Range of motion of hand

As mentioned in the previous section, it is important to restrict the hand of the patient in the resting position with the thumb and wrist placed at a certain angle during the fabrication of a splint so as to avoid improper positioning which will impact daily activities thus triggering or applying extra stress to the two inflamed tendons in the first dorsal compartment. Therefore, it is worthwhile to study the details of hand movements that are associated with the APL and EPB tendons and elaborating on the ways to measure the angles that are in the range of motion (ROM) of basic hand movements.

DQV is associated with the APL and EPB tendons in the first dorsal compartment. These two tendons are connected to the abductor pollicis longus muscle and extensor pollicis brevis muscle respectively. These two muscles are mainly involved in the movement of the wrist and thumb. The basic movements of the wrist joints include flexion, extension, radial deviation and ulnar deviation. As shown in Figure 2.13, wrist flexion is a downward action in the sagittal plane with the palm of the hand moving towards the anterior surface of the forearm. On the other hand, wrist extension is the opposite movement of flexion in that the palm of the hand is moving upward with the dorsal side approaching the posterior surface of the forearm (Hamilton, Weimar, & Luttgens, 2012). The ROMs of wrist flexion and extension are measured starting from the zero position, which is defined as the forearm in the pronation position and the carpal bones are aligned with the plane of the forearm as marked in Figure 2.13(a) as 0°. An alternative method of measuring the flexion and extension angle of the wrist is to place a goniometer on the triquetral bone as vertex and measure the angle from the lateral midline of the ulna to the lateral midline of fifth metacarpal (Norkin & White, 2016). Wrist radial and ulnar deviation occur in the coronal plane (Figure 2.13(b)). Radial deviation is the movement of hand towards the thumb side away from the body, whereas ulnar deviation is moving the hand towards the side of the little finger. Radial deviation of the wrist is performed by using the flexor carpi radialis and extensor carpi radialis longus muscles, and may involve the APL and EPB muscles that are linked to the APL and EPB tendons at the first dorsal compartment (Hamilton et al., 2012). The ROM of wrist deviation is the angle between the midline along the third metacarpal bone at the zero starting position and the deviated position. For carrying out measurements of wrist flexion and extension, and ROM of wrist deviation, it is suggested that the examinee should be sitting next to a supporting surface and his/her forearm should be placed on the surface with a 90-degree abduction of the shoulders and a 90-degree elbow flexion (Norkin & White, 2016).



(a) (b)

Figure 2.13 ROM of wrist: (a) zero position, and
(b) radial and ulnar deviation in the coronal plane
(Palastanga, Soames, & Palastanga, 2008)

For the thumb, the basic ROMs of the different joints include thumb abduction and adduction, CMC joint flexion and extension, MCP flexion and extension, IP joint flexion and extension, and opposition. Thumb adduction and CMC flexion may sometimes be interpreted as thumb hyperadduction and CMC hyperflexion correspondingly when adduction and flexion are defined as the return movements of abduction and extension (Figure 2.14). The four main muscles that are involved in thumb abduction include the APL and EPB muscles, which are linked to the tendons along the first dorsal compartment of the hand (Hamilton et al., 2012).

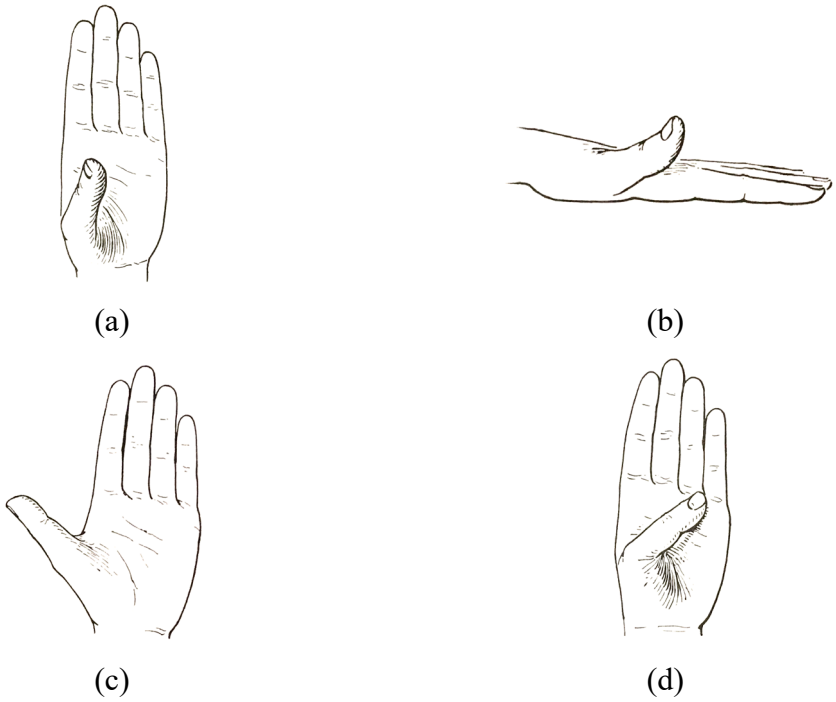


Figure 2.14 (a) Thumb abduction; (b) Thumb adduction (hyperadduction);
(c) CMC joint extension; (d) CMC joint flexion (hyperflexion)
(Hamilton et al., 2012)

To measure the angle of the thumb abduction, the forearm and hand are placed on a supporting surface with the ulnar side of the forearm touching the surface. Measurements start with the wrist and thumb joints all in a 0 degree of motion (Norkin & White, 2016). Thumb abduction is the forward movement of the thumb away from the palm in a perpendicular direction (Hamilton et al., 2012). The ROM of thumb abduction is measured by using a goniometer that is placed between the dorsal midline of the first metacarpal bone and the lateral midline of the second metacarpal bone with the vertex on the lateral side of the scaphoid, as shown in Figure 2.15. However, thumb adduction is not often measured as it is mainly defined as the return action of thumb abduction (Norkin & White, 2016).

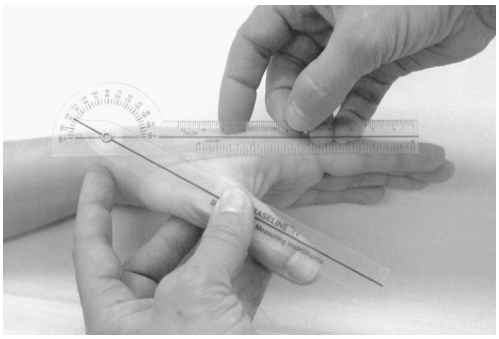
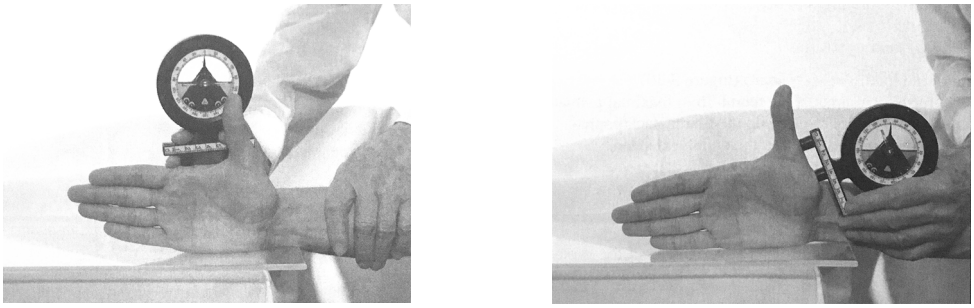


Figure 2.15 Measuring ROM of thumb abduction
(Norkin & White, 2016)

CMC joint flexion and extension are the radial movements of the thumb towards the center of the palm and away from the palm respectively. Thumb extension is mainly performed by the APL muscle with possible help from the EPB muscle, which are linked to the APL and EPB tendons that cause DQV (Hamilton et al., 2012). The angle of the CMC joint flexion and extension is measured from the starting natural position of the hand with palm facing upwards on a supporting surface. The initial angle between the palmar midline of the radius with the palmar midline of the thumb metacarpal bone in the natural position is recorded. Then, CMC joint flexion or extension is carried out and the angles are measured. The ROMs of CMC joint flexion and extension are the differences between the measured and the initial angles (Norkin & White, 2016). An alternative method of measurement of thumb extension is done by using the inclinometer, which measures the angle between the second metacarpal bone and the first metacarpal bone, as show in Figure 2.16. During the measurement, the ulnar side of the forearm is placed on a supporting surface and the thumb is pointing upwards (Gerhardt, Cocchiarella, & Lea, 2002).



(a) (b)

Figure 2.16 (a) Starting position at the second metacarpal bone;
(b) Thumb abduction angle measured at the first metacarpal bone
(Gerhardt et al., 2002)

The MCP joint flexion angle is measured by using a goniometer that is placed between the dorsal midline of first metacarpal bone and the proximal phalanx, with the vertex on the MCP joint. Note that MCP joint extension is usually considered as 0 degree because it is always defined as the starting position of flexion. The ROM of the IP joint in terms of its flexion and extension is measured by using a goniometer that is placed between the dorsal midline of the proximal phalanx and distal phalanx of the thumb, with the vertex on the IP joint (Norkin & White, 2016). Some publications related to orthopaedics, human movement and kinesiology have provided the normal active ROM of the wrist and thumb, see Table 2.9 (Dutton, 2005; Greene & Netter, 2006; Magee, 2014; Norkin & White, 2016; Palastanga et al., 2008).

Table 2.9 Normal active ROM of Wrist and Thumb

Publication	(Dutton, 2005)	(Magee, 2014)	(Norkin & White, 2016)	(Greene & Netter, 2006)	(Palastanga et al., 2008)
Wrist					
Flexion	80° to 90°	80° to 90°	60° to 80°	75°	85°
Extension	70° to 90°	70° to 90°	60° to 75°	75°	85°
Radial deviation	15°	15°	20° to 25°	20°	15°
Ulnar deviation	30° to 45°	30° to 45°	30° to 40°	35°	45°
Thumb					
Abduction	60° to 70°	60° to 70°	40° to 50°	/	Total range: 80°
Adduction	30°	30°	/	/	
CMC joint flexion	45° to 50°	45° to 50°	15° to 25°	/	Total range: 40° to 50°
CMC joint extension	/	/	15° to 35°	/	
MCP joint flexion	50° to 55°	50° to 55°	50° to 60°	50° to 60°	45°
MCP joint extension	0°	0°	0°	Not typically observed	0°
IP joint flexion	85° to 90°	85° to 90°	Around 80°	55° to 75°	Exceeds 90°
IP joint extension	0° to 5°	0° to 5°	20° to 30°	5° to 10°	No more than 10°
Notes: CMC: carpometacarpal, MCP: metacarpophalangeal, and IP: interphalangeal					

The table shows that the ROM of the wrist in terms of flexion and extension is similar, which ranges from 60° to 90°. Comparatively speaking, the radial and ulnar deviations of the wrist are more limited with an angle less than 45°. The ROM of the thumb in terms of its abduction is relatively larger than that its flexion at the CMC joint. The flexion angle of the MCP and IP joints is much larger than their extension angle with a difference of approximately 50° or more.

Apart from thumb and wrist movements, the opposition of the thumb and fingers also needs to be considered, as the splint should not restrict opposition. The opposition movement of the thumb can be measured by using the total opposition scale in Kapandji (1986). A score of 1 to 10 is given based on the degree of thumb opposition, which is the furthest that the tip of the thumb can reach. For example, a score of 1 is given when the tip of the thumb can touch the lateral side of the middle phalanx of the index finger, while a score of 10 is given when the tip of the thumb can reach the distal palmar crease of the hand. Figure 2.17 shows the regions for scoring the degree of thumb opposition (Barakat, Field, & Taylor, 2013). It is important that the individual should complete the opposition tasks in sequence in accordance with the scoring system (Norkin & White, 2016).

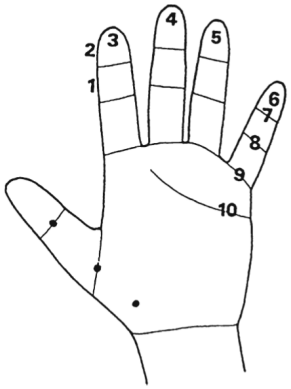


Figure 2.17 Total Opposition Scale
(Barakat et al., 2013)

2.4.3 Patient-splint interaction and design specifications

When prescribed splinting as a treatment, DQV patients are required to wear the splint for long hours each day during both daily activities and rest. As such, the user and device interact. According to Desmet and Hekkert (2007), there are different types of human-product interactions, which include instrumental, non-instrumental or non-physical interaction. Instrumental interaction is related to the usage and operation of the products. For a patient with DQV, instrumental interaction is how the patient manages and uses the splint. Non-instrumental interaction is defined as interaction with the elements that are not directly related to the function of the product. For example, the feelings towards the hand feel and appearance of the splint. Non-physical interaction is defined as the anticipated and imagined consequences after using the product, for instance, the patient may expect to find pain relief after wearing the splint for a period of time. While interacting with the splint, patients will become experienced with its use. As such, Desmet and Hekkert (2007) indicated that there are three types of product experiences, which are aesthetic experience, experience of meaning and emotional experience (Figure 2.18). Aesthetic experience is related to how the product elicits sensory enjoyment. Experience of meaning is when user creates meaning and understands the significance of the product. For instance, a patient may give a value to the splint as the splint is an important device that can help ease the symptoms. Emotional experience is the pleasure or displeasure of the user with the product during use, that is, the emotions of the patient while wearing the splint.

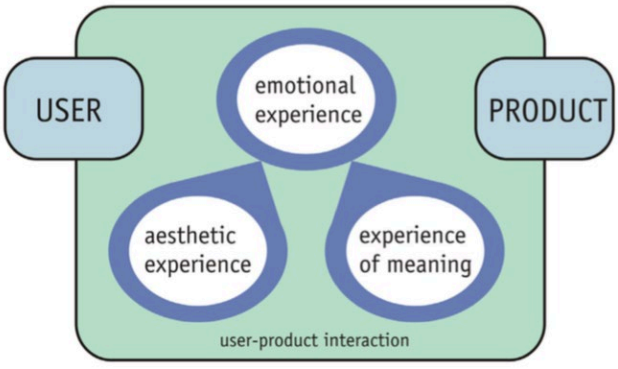


Figure 2.18 Three types of product experiences
(Desmet & Hekkert, 2007)

The interactions and experiences with the splint are closely related to satisfaction towards the splint. Furthermore, such evaluations are mainly affected by the quality, usability and design elements of the splint. According to ISO standard 9000, the satisfaction of users is determined by the quality of the products and services offered by an organisation. The quality of a product includes its functional performance and benefits to the user. Mital (2008) stated that a good quality product can meet or even exceed user expectations. The value of the usage of the product is also essential because it can change user experience. Figure 2.19 shows the demand elements that can reflect the usability of a product (Kimmel, 2015). Therefore, a splint for treating DQV should have high usability and quality, which give patients a positive product experience and satisfaction.

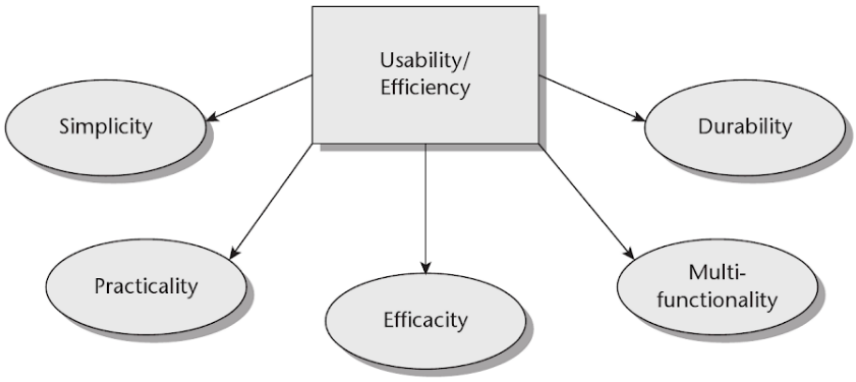


Figure 2.19 Elements of usability demand for products
(Kimmel, 2015)

To fabricate the 'ideal' orthosis, Shurr and Cook (2002) listed five major design specifications: 'Function', 'Comfort', 'Cosmesis', 'Fabrication' and 'Economics'. A good splint should be able to perform its function precisely and meet the needs of the patient. Functionally, the splint should also be simple in design so that patients can learn how to use the splint quickly and easily. The splint should function well on a continuous basis with minimal repair. 'Comfort' is one of the most important aspects in splint design. A comfortable splint for treating DQV should offer a good fit to the hand of the patient without exerting excess pressure on the skin of the hand and causing skin irritation. A lightweight splint with an appropriate degree of perforation for air-ventilation is preferred for enhancing comfort during splint wear (Lusardi, Jorge, & Nielsen, 2012). 'Cosmesis' refers to the appearance, sound and smell of the splint (Shurr & Cook, 2002). Offering options in colour for materials used in the device allows

patient involvement in the process of constructing a splint which could result in higher acceptance and wear compliance (Lusardi et al., 2012). As the splint has to be worn and kept close in contact to the body for long hours, the splint should be stain-resistant for ease of handling and cleaning. For the 'Fabrication' aspect, the materials of the splint should be prepared in advance and the fabrication time for custom-made parts, such as moulding of thermoplastic sheets into thermoplastic components, and splint adjustment, should be kept within a short period of time so that the amount of time for each clinical check-up can be controlled and delays of next appointment can be prevented. From an economics perspective, the production cost of the splint should be affordable and the cost on par with treatment outcome (Shurr & Cook, 2002).

The usability, quality and design specifications of splints are critical factors that will influence patient acceptance of the splinting treatment. A well-designed splint with high usability and good quality might offer a more favourable splint wear experience and hence, enhance the compliance rate.

2.4.4 Concerns: splinting length and compliance rate of splinting

Patients need to wear a splint for long hours each day in order to rest their wrist and provide enough time for the tendons and synovial sheath to heal. Since patients have to do so for a long period of time, the 'comfort' of the splint is very important. As mentioned in Section 2.4.3, 'comfort' is one of the major design factors that contributes to an 'ideal' splint. However, if patients feel that the splint causes discomfort, they may reject the splint, which results in a low compliance rate. Satteson and Tannan (2020) pointed out that the compliance rate with the thumb spica brace is low, which may lead to treatment results such as partial and temporary relief of symptoms and higher chance of symptom recurrence. The reason for the low compliance rate could be due to the poor design of the splint. Chow (2009) indicated that some rigid thermoplastic splints cause pain at the protruding bony structures of the wrist and thumb like the radial styloid process and MCP joint. The material could also be an issue as it causes thermal discomfort after the splint is worn for long hours. Skin reactions also ensued in some of the patients in Chow (2009). In addition, Huang et al. (2006) stated that traditional orthoses are bulky and heavy which cause thermal discomfort during splinting. Therefore, to increase the compliance rate of patients during splinting, a better splint

design that would enhance the wear comfort in terms of thermal conductivity, air permeability, hand feel and fit, is needed.

Knowledge gap 2: The compliance rate of patients with splinting for long hours is low due to thermal discomfort, and weight and bulkiness of the splint. It is important to determine how to increase the compliance rate. A new splint design that is lighter in weight with modified properties that enhance wear comfort is the proposed solution.

2.4.5 Types of splints and proposed designs

Two kinds of splints are usually prescribed to patients with DQV according to the severity of their condition or kind of activities that are done during the day. The first type of splint is a rigid thumb spica orthosis, as shown in Figure 2.20a. This rigid splint is mainly made of thermoplastic sheets with the thickness of 2 mm or 2.5 mm (Chow, 2009). Thermoplastic sheets become flexible after heated up at 60°C to 70°C, and return to a rigid state after cooling down. As the splint is rigid and fits the shape of the hand, the splint can restrict hand movement and maintain the thumb in a slight abduction and the wrist with an appropriate degree of extension. The rigid splint is used in the early stages of the disease, and aims to relieve pain and other acute symptoms, such as inflammation and swelling at the radial side of the wrist (Astifidis, 2016). As patients may encounter difficulties in performing daily activities with the use of a rigid splint, a rigid splint is usually prescribed as a resting splint, which is worn during the night while sleeping (Chow, 2009). The second type of splint is a soft splint made of more flexible materials, such as neoprene (Figure 2.20b). Small pieces of plastic may be inserted into the splint for better support. The soft splint is usually recommended for patients with less severe symptoms or after alleviation of severe symptoms (Astifidis, 2016). Since the soft splint is more flexible and convenient, it is always offered to patients as a working splint, and recommended to be worn during the day (Chow, 2009).

(a) (b)

Figure 2.20 (a) Thermoplastic rigid splint, and (b) Neoprene soft splint
(Astifidis, 2016)

Since the early 2000s, studies have been carried out to understand the limitations of current splints for treating DQV. Some researchers have proposed new splint designs accordingly. For example, Hart et al. (2005) proposed a splint composed of a strip of plaster and stockinet, as shown in Figure 2.21. The splint is applied to the hand by a single turn of the materials. Elastic bandage is added for extra support. The material cost is low and the splint is light in weight. The splint can be removed easily, however, as it has no opening with a fastening system, long term repeated use might not be possible. Furthermore, the main purpose of this splint is for emergency hand pain or as a post-injection splint to protect the hand for a few days. Therefore, this splint design might not be appropriate for patients who require splinting for weeks or months.

Figure 2.21 Proposed splint composed of a strip of plaster and stockinet
(Hart et al., 2005)

Huang et al. (2006) developed a splint by using an FE model to optimise the shape of the splint so that it would be light in weight in comparison to a traditional splint. They also tried to remove excess covering materials for better air ventilation, but at the same

time, maintain the ability of the splint to immobilise the thumb and wrist. The optimal thickness of the splint was calculated to be 3.2 mm. The splint developed by using an FE model is shown in Figure 2.22. Although the thermoplastic component is minimised, the entire splint is composed of rigid plastic. Patients may therefore feel the hardness of the splint and its inconvenience while carrying out daily tasks due to the restriction of even slight movements of the thumb and wrist.

Figure 2.22 FE modelled splint
(Huang et al., 2006)

Chow (2009) pointed out the problems of the resting and working splints that are currently used in Hong Kong, and proposed a new pattern design for splint fabrication. The splint features sandwiching the hand between two big panels of thermoplastic sheets linked at the web space between the thumb and index finger, and leaving the radial and ulna side of the wrist exposed, as shown in Figure 2.23. If the radial side of the wrist is exposed, then the pressure in the areas with protruding bones and joints could be minimised. This design could then reduce the use of thermoplastic compared to a traditional splint. The splint in Chow (2009) has a universal pattern that can accommodate all hand sizes and the splint could be adjusted easily with Velcro tape. Although the splint was designed to allow the radial styloid process and MCP joint to be free from pressure, the sandwiching feature of the splint with thermoplastic at the palmar and dorsal sides of the hand may exert pressure onto other important anatomical structures of the hand, so that the compression of the median nerve along the palmar side of wrist may lead to carpal tunnel syndrome. Applying excess pressure along the palmar and dorsal sides of the wrist may lead to other complications of the hand.

Figure 2.23 Splint with new pattern design
(Chow, 2009)

Nemati et al. (2017) modified a traditional splint into a dynamic hand orthosis, and compared its effectiveness. They found that the motions of the flexor and extensor muscles do not involve deviations of the wrist which would not trigger inflammation of the tendon sheath at the first dorsal compartment. Therefore, they developed a dynamic splint that was characterised by the addition of a hinged joint (Figure 2.24). This splint thus allows wrist flexion and extension of the hand, but at the same time, limits the lateral deviations of the wrist. Although their dynamic splint was well received with a high satisfaction rate from patients, the splint is entirely fabricated with rigid thermoplastic material. It is still possible for some patients to feel discomfort due to the hardness of the splint and the pressure exerted onto the joint and other parts of the forearm. Furthermore, with the thick and wide Velcro tapes that wrap around three regions from the hand to forearm, the splint is still bulky in appearance.

Figure 2.24 Dynamic splint
(Nemati et al., 2017)

To address the weight of the splint, and lack of air permeability and aesthetics of traditional splints, Fernandez-Vicente, Escario Chust, and Conejero (2017) explored a

new design workflow and constructed a splint with an open lattice structure (Figure 2.25) by using advanced 3D scanning technology, computer aided design (CAD) software and desktop 3D printing. The open lattice structure contributes to a lighter weight, air ventilation and pleasing appearance. A fastening strap is used to facilitate ease of wear. Although a number of advantages are realised with the new design constructed by using advanced technology, there are still some problems with the splint. First, there is the durability issue which depends on the materials used for 3D printing. Secondly, the cost of using scanning and a CAD system and the 3D printing machine might be relatively more expensive. Lastly, the operations of using a scanning device, CAD system and 3D printing machine might require skilled workers.

Figure 2.25 Splint constructed by using advanced technologies
(Fernandez-Vicente et al., 2017)

Table 2.10 summarises the features and issues of the proposed splint designs in the literature. The development of new splints has been beneficial to both patients and clinicians. The primary goals of the proposed splints include enhancing the wear comfort by reducing the weight of the splint, increasing the air ventilation and enhancing convenience to increase the satisfaction of the user. Some new splint designs may also benefit clinicians due to a simpler and quicker fabrication procedures. Although improvements in the splint designs are observed from the proposed splints, there are still problems found in each design. Furthermore, the effectiveness of some of the proposed splints is ambiguous with no wear trials done. Research on the development of splint design for treating DQV is also limited. A new splint design composed of both rigid and soft materials might be the solution to remedy some of the problems found in current or proposed splints. More wear trials of the different splint designs to demonstrate their effectiveness should be conducted in the future.

Table 2.10 Proposed splint designs in literature

	Hart, Kleinert and Lyons, 2005	Huang et al., 2006	Chow, 2009	Netami et al., 2017	Fernandez-Vicente, Escario Chust & Conejero, 2017
Splint image					
Materials	• A stripe of plaster and stockinet	• Thermoplastic: AQUcast	• Thermoplastic	• 2-mm thick orfit sheet	• 3-mm black ABS copolymer thermoplastic filament
Improvements	• Light weight • Easy to fabricate	• Reduce material use • Reduce weight • Increase air ventilation	• Reduce material use • Reduce weight • Increase air ventilation	• Dynamic • Allow acceptable movement of wrist	• Reduce weight • Increase air ventilation
Problems	• No opening • Not appropriate for treatment over weeks	• Rigid and hard • Air permeability at the regions covered by thermoplastic may be low	• Inappropriate pressure applies along the wrist to palm may lead to other hand conditions	• Bulkiness • Rigid and hard • Air ventilation may be low	• May have durability issue • Require skilled operator for 3D printing

Knowledge gap 3: Problems are found in current and proposed splints in the literature. The effectiveness of some of the proposed splints is ambiguous due to lack of wear trials. Therefore, it is timely for the development of a new splint design to address the existing problems. Wear trial studies that evaluate the effectiveness of a new splint are also needed.

2.5 Gripping for Daily Life Activities

Gripping or hand prehension is a complex action which is more frequently used in daily life in comparison to other types of motion (Hamilton et al., 2012). Gripping actions can be fine hand motions, such as unlocking a door by twisting a key and holding a fork during a meal, or gross hand motions, such as playing basketball or grasping a tennis racquet during a game. The process of gripping an object is divided into 4 steps. First, the hand opens up for space between the digits and the palm. Then, the fingers and thumb position and close to grasp the object according to its shape and size. Thirdly, force is exerted depending on the characteristics of the object, such as the texture of the surface of the object, its weight and fragility. Lastly, the hand opens up again for the release of the object. All of the above steps involves several different muscles, for instance, the intrinsic, extrinsic, opposing and extensor muscles (Magee, 2014).

As mentioned earlier, there are two types of gripping: the ‘power grip’ and the ‘precision grip’. The former is usually used when force and strength are considered. The ulnar side of the hand works together with the radial side of the hand for high stability and control. The wrist is slightly ulnar deviated and extended. During the grip, the object is hold by the digits against the palm, while the thumb may or may not be involved (Magee, 2014). As strength is the main concern of the power grip, the related actions involve the use of the long flexor and extensor muscles of the forearm (Palastanga et al., 2008). The five main types of power grips include cylindrical, fist, hook, spherical and span grips. Cylindrical grip is a type of palmar prehension, which is the most powerful grasp. Cylindrical objects, such as cups or bottles, are wrapped by the entire hand and fingers, with the thumb as support. Fist grip is similar to the cylindrical grip, in which the fingers and thumb wrap around a narrow object, such as the handle of a badminton racquet. The strength of holding a narrow object is strong as the exerted power can be greater when the distal part of the index finger is able to touch

the thumb. Spherical grip involves all of the digits and palm when moving around a ball with a larger degree of opposition. Hook grip does not require the use of the thumb. This grip can be possible with only the index and middle fingers or all of the fingers in a flexed position. Hook grip is utilised when holding the handle of a bag or a bucket. Span grip is placing the distal pulps of the flexed fingers and the abducted thumb, together with the palm around and on top of a circular object with a relatively larger diameter, such as jar lids. Figure 2.26 shows the different types of power grips. (Magee, 2014; Palastanga et al., 2008)

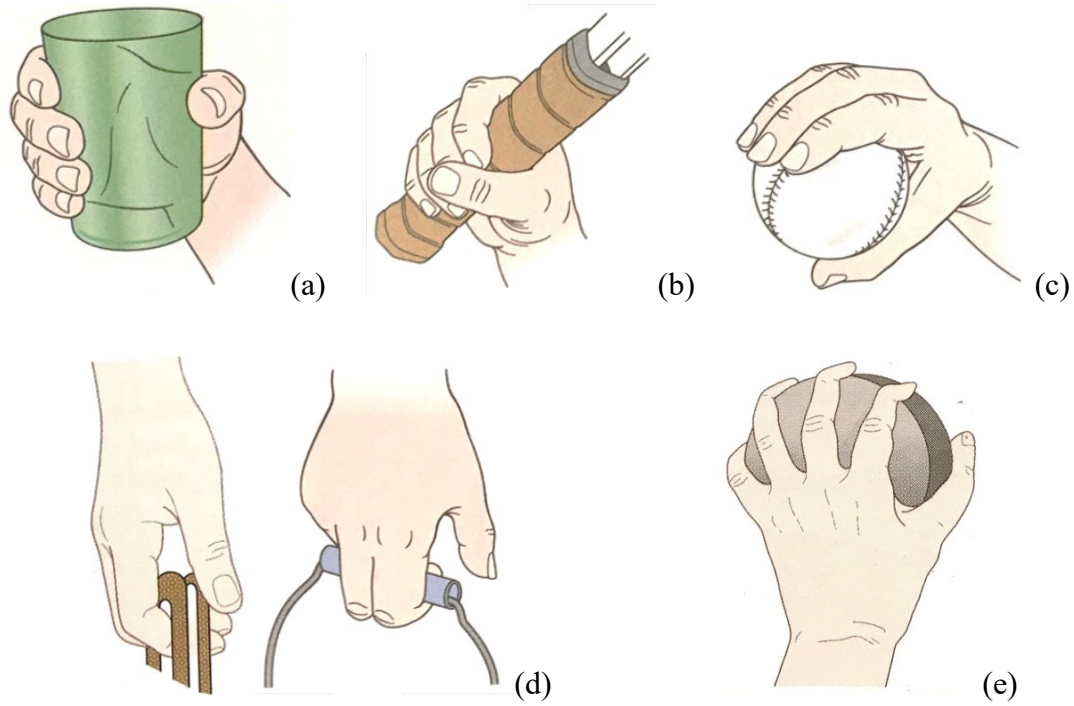


Figure 2.26 Different types of power grips
(a) Cylindrical grip; (b) Fist grip; (c) Spherical grip; (d) Hook grip; and (e) Span grip
(Magee, 2014; Palastanga et al., 2008)

Precision grips are fine hand motions that mainly involve the MCP joints and phalanx parts at the radial side of the hand (Magee, 2014). The intrinsic muscles are always functioning during precision prehension. Types of precision grips include pulp-to-pulp, three-point, five-fingered, lateral prehension and tip pinches. Pulp-to-pulp pinch is the most common precision grip used in the daily life. It is the opposition of the hand between the pulp of the thumb and pulp of one or more digits. Similarly, three-point pinch is a kind of pulp-to-pulp pinch that requires opposition between the palmar surfaces of the thumb, and index and middle fingers, for example, holding a pen. Five-

fingered pinch involves the distal pads of all of the fingers to hold or grip an object with a larger surface area, such as a towel. Lateral prehension is the pressing of the thumb pulp against the lateral side of the index fingers, or sometime other fingers. It is less fine but a strong precision grip. Tip pinch is the most precise pinch which uses the tips of the thumb and fingers (Dutton, 2005; Magee, 2014; Palastanga et al., 2008). The different precision grips are shown in Figure 2.27.

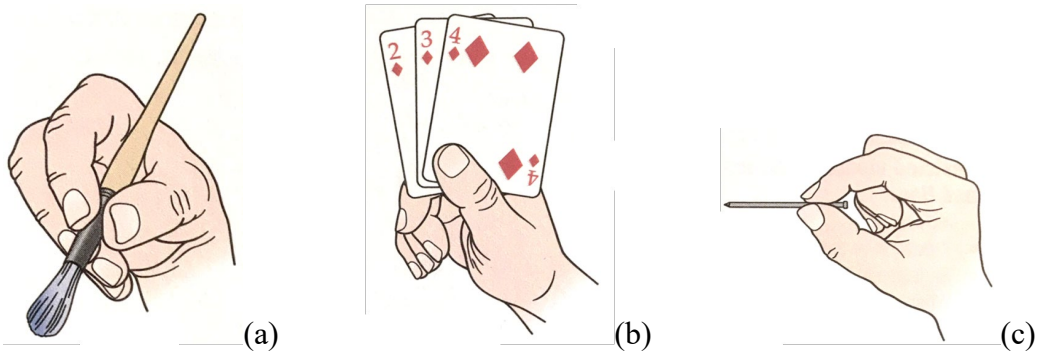


Figure 2.27 Different types of precision grips
(a) Three-point pinch; (b) Lateral prehension; and (c) Tip pinch
(Magee, 2014)

Power and precision grips are frequently used for completing different tasks in daily life. The percentage of grips used for daily life activities is estimated and shown in Table 2.11 (Dutton, 2005). The table shows that the pulp-to-pulp and lateral pinches are the most frequently used types of gripping. The usage of three and five-finger pinches, and fist and cylindrical grip is high, while spherical and hook grips are not as frequently performed.

Table 2.11 Estimated use of different types of grips (percentage)
(Dutton, 2005)

Type of Grip	Estimated Use (%)
Pulp-to-pulp pinch	20
Lateral pinch	20
Five-finger pinch	15
Fist grip	15
Cylinder grip	14
Three-fingered pinch	10
Spherical grip	4
Hook grip	2

Since DQV is associated with the overuse of the hand, patients should pay attention to the gripping actions that might trigger the pulling of the APL and EPB tendons against the synovial sheath. Since thumb extension is mainly performed by the APL muscle possibly along with the EPB muscle, and the four main muscles that are involved in thumb abduction include the APL and EPB muscles (Hamilton et al., 2012), patients need to be aware of the gripping motions that involve thumb extension and thumb abduction, as those require a certain level of force, such as opening of jar lids (span grip), twisting a wet towel (fist grip) and donning a pair of pants (lateral grip at pant waistline).

2.6 Citation Network Analysis

A CNA is an objective method for analysing the interconnections between articles based on their citations and references, and then visualising the connections with a network structure (Colicchia, Creazza, & Strozzi, 2018). In a citation network, studies are divided into different clusters based on their citation relationships, as researchers in similar fields tend to cite each other. On the other hand, some articles that are not as strongly associated with other studies may not be grouped into a specific cluster and thus are isolated from the network (Dorsch, Vierimaa, & Plucinik, 2019). Nodes found in the network represent articles and the linkage between two nodes represents the citation connections between two articles. In a CNA with directional networks, the relationships of ‘cite’ and ‘cited’ between two articles are shown by a directional arrow (Colicchia et al., 2018; Hummon & Dereian, 1989).

In this study, a CNA is conducted to review the articles related to DQV. The major objectives of this analysis are: 1) to identify the research trends and main research domains of DQV and 2) to determine research opportunities for future studies in this field. To conduct a CNA, the first step is to collect relevant studies related to DQV. A literature search was therefore carried out by using the *Web of Science* database. Two sets of keywords were inserted into the search base. The first set of keywords included derivations of 'DQV', and the second set included other names of the disease, which are commonly used in the general public. Table 2.12 shows the search formulae of the two sets of search keywords. Studies that include the first set of keywords or the second set of keywords are counted in the review collection. The collection includes studies related to DQV that were published from 1970 to Feb 2019, and written in English. The exclusion criteria included: 1) document types other than articles, for instance, letters, news items, biographical items, proceeding papers and reviews, and 2) studies that are not related to DQV of the hand, such as de Quervain's thyroiditis and other similar hand diseases like brachial artery thrombosis and osteoid osteoma of the radial styloid process.

Table 2.12 Formulae of keywords to search studies related to DQV

Root term	De Quervain's tenosynovitis
Formula of first set of search keywords	(Quervain OR "Quervain's" OR "de Quervain" OR "de Quervain's" OR deQuervain OR "deQuervain's") AND (tenosynovitis OR synovitis OR tenovaginitis OR tendovaginitis OR tendinitis OR tendonitis OR tendinosis OR tendinopathy OR peritendinitis OR paratenonitis OR syndrome OR disease)
Formula of second set of search keywords	"Blackberry thumb" OR "Gamer's thumb" OR "Washerwoman thumb" OR "Mother's thumb" OR "Mummy thumb"

The research result from the *Web of Science* database is 410 studies related to DQV. After excluding the studies that fell into the exclusion criteria, the final number of studies included in this study for the CNA is 197. Figure 2.28 shows the selection process of the studies.

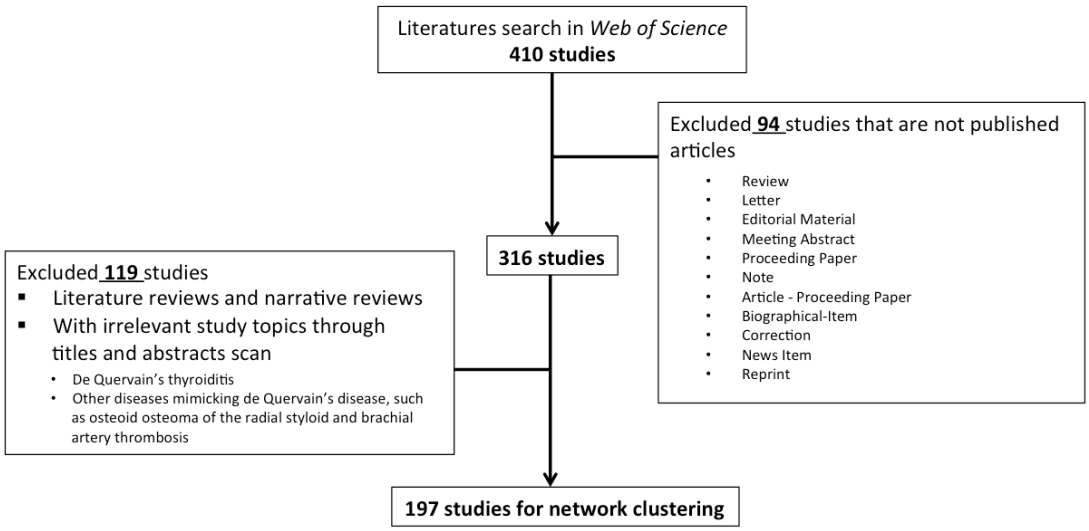


Figure 2.28 Selection process of studies

The 197 articles were distributed according to the year of publication (Figure 2.29). In the past three decades, more and more researchers have been focusing on DQV. A gradual increase in publications can be observed in Figure 2.29. The number of publications in the past six years is 89 studies, which accounted for about 45% of the total number of articles published since the 1990s. One study was published at the beginning of 2019 in February.

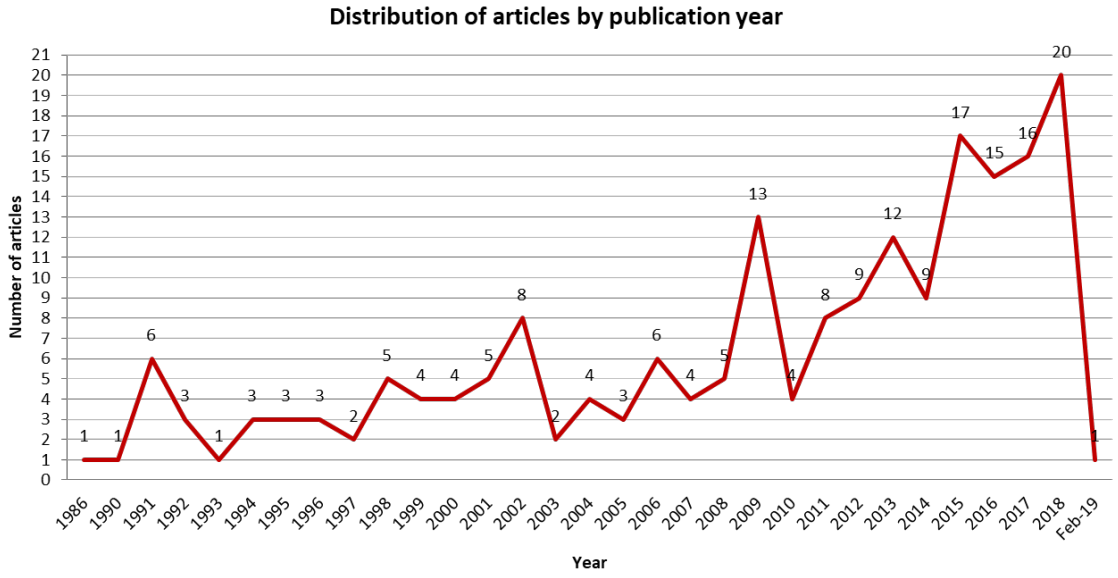


Figure 2.29 Distribution of articles by publication year

While there is evidently a growing trend of research on DQV, however, the main research areas of DQV are still not known. To investigate the main research domain of DQV, a CNA was developed by using a Markov Cluster Algorithm (MCL). The MCL is used to carry out random walks from node to node, and moves the nodes with stronger linkages together to form clusters. A connected and more linked cluster means that there is a low probability that the nodes cross the boundaries of another cluster, in which the resulting clustering based on the existing network structure node tends to stay within the strong bonded cluster (Cherven, 2015). The citation network of the articles related to DQV was generated and the numbering of clusters based on the colour of the nodes is shown in Figure 2.30. The modularity value of this citation network, which measures the strength of the network structure (Khokhar, 2015), is 0.415. The modularity value of 0.415 is within the normal range of 0.3 to 0.7 (Newman & Girvan, 2004). The resulting number of clusters is 67, with 56 clusters determined as scattered groups as they contain less than 5 articles. The remaining 11 clusters are the main groups that point to the main research areas of studies related to DQV. The cluster themes were labelled in accordance with the research area of the dominant articles in each cluster. Table 2.13 shows the research themes that correspond to the numbering of the clusters. The number of articles in each cluster is shown in Figure 2.31.

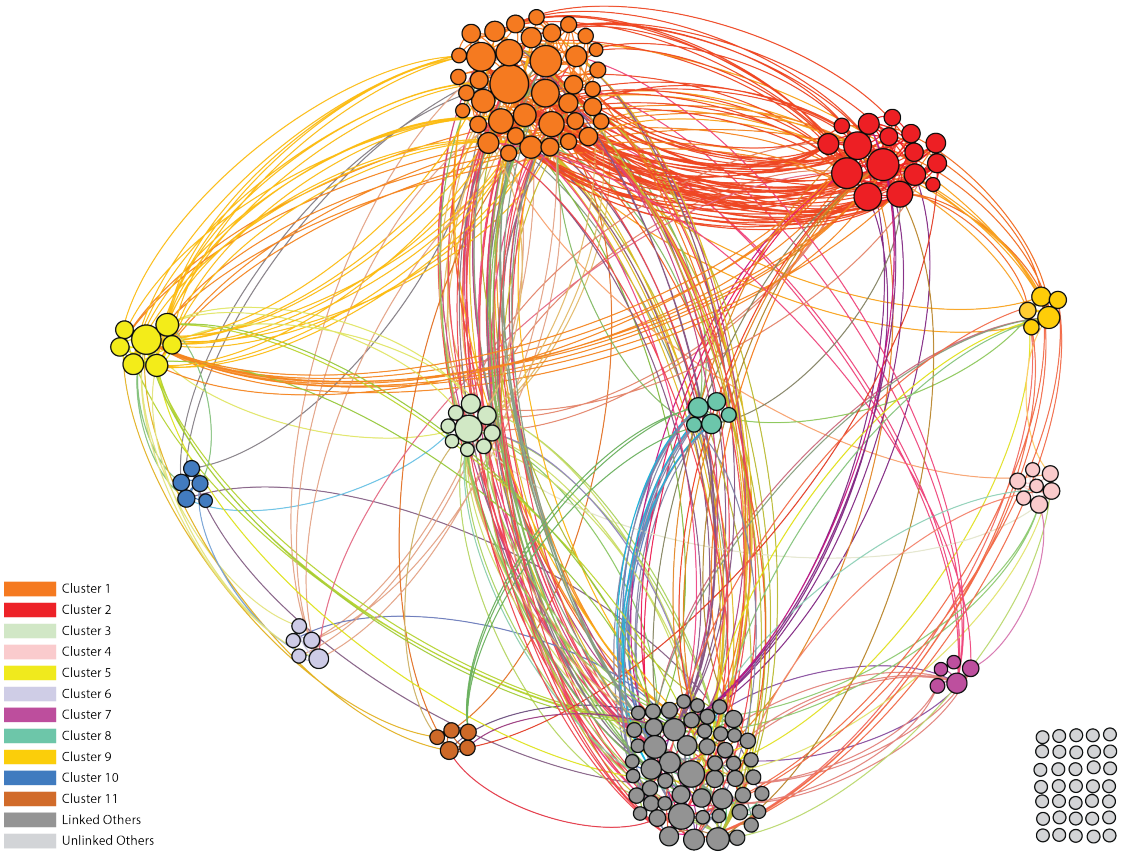


Figure 2.30 Citation network of articles related to DQV

Table 2.13 Cluster themes corresponding to numbering of clusters

Cluster 1	Effectiveness and Comparisons of Treatments and Combined Therapies
Cluster 2	Ultrasound-guided Injection and Injection Accuracy
Cluster 3	DQV in Relatively Younger Age Population
Cluster 4	Work-related Musculoskeletal Disorders of Upper Limbs - DQV
Cluster 5	Anatomical Structures and Characteristics in FDC - Fibrous and Osseous Components
Cluster 6	Anatomical Variations of the Tendons in the FDC and Corresponding Muscles
Cluster 7	Pregnant and Postpartum Females who Suffer from DQV
Cluster 8	Alternative Approaches to Surgery for Prevention of Tendon Subluxation

Cluster 9	Concerns around Superficial Radial Nerve and Related Complications
Cluster 10	Radiographic Evaluation of DQV
Cluster 11	Underlying Mechanisms and Effectiveness of Tests and Treatments in Relation to Tendons in first dorsal compartment

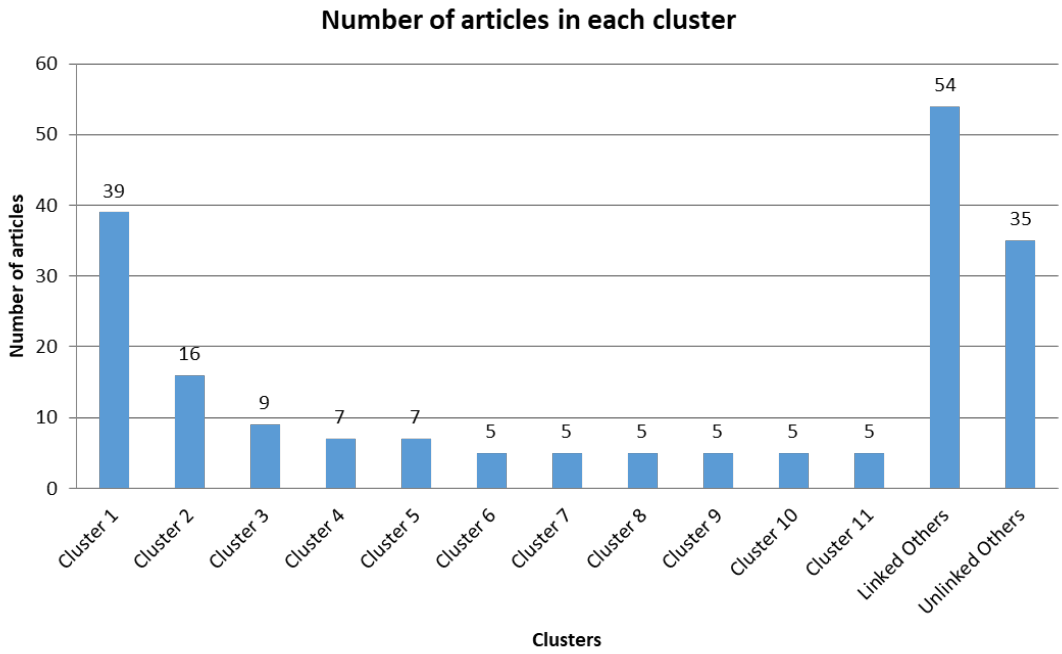


Figure 2.31 Number of articles in each cluster

The most popular research area in DQV (Cluster 1: orange nodes) is determining the effectiveness of treatments and combined therapies and comparing them. After reviewing the articles in Cluster 1, it was noted that they mainly focus on injection. Studies in Cluster 1 compared the effectiveness among treatments that involve injection, for example, injection versus injection plus splint (Mardani-Kivi et al., 2014), splint versus injection plus splint (Mehdinasab & Alemohammad, 2010) and two-point injection versus four-point injection (Pagonis, Ditsios, Toli, Givissis, & Christodoulou, 2011). The second largest group (Cluster 2: red nodes) of studies on DQV also revolves around injection, but mainly focusing on ultrasound-guided injection and injection accuracy. Apart from injection, a smaller cluster focuses on surgery treatment of DQV, and proposes alternative surgical approaches for reducing the occurrence of post-surgical complications. A cluster specifically related to non-invasive treatments, such as splinting treatment and physiotherapy, is not identified in this citation network. This may point to two phenomena. First, studies on non-invasive treatments are not strongly

connected to each other in terms of citation. Second, there are few studies on non-invasive treatments. Investigating the articles in details, it was found that only two articles are related to new splint designs to treat DQV. One study compared the effectiveness between two splints with different designs and a few studies covered non-invasive treatments, such as low level, ultrasonic and mechanical therapies. It is found that studies on non-invasive treatments for DQV are limited, therefore, doing research in this area is necessary.

DQV is usually found in those who are in their forties, fifties or sixties (Júnior et al., 2016; Satteson & Tannan, 2020). However, with the development of advanced technologies, the occurrence of DQV in relatively younger populations is likely to increase due to repetitive hand movements during use of mobile phones and typing on a keyboard. It is interesting to find a small specific cluster of studies that have researched relatively younger age groups. For example, (Rossi, Cellocco, Margaritondo, Bizzarri, & Costanzo, 2005) examined DQV in volleyball players with a mean age of 24 years old. Turkay, Inci, Aydeniz, and Vural (2017) evaluated the APL and EPB tendons of DQV and non-DQV groups by using shear wave elastography. The median age of the two groups is 34 and 37.5 years old respectively. This small cluster shows that there are few studies related to DQV in the younger population, however, some researchers are interested in this group of patients. This shows that DQV in the younger population could be a research area in the future.

DQV is also known as ‘Mother’s thumb’, which means that pregnant and postpartum women are at high risk of DQV. For pregnant women, the changes in their hormone secretion may affect the tendons, which could be related to the occurrence of DQV. For postpartum women, the increase in repetitive wrist and thumb movements when they are caring for their baby may increase their risk of DQV (Schned, 1986). Although pregnant and postpartum women could be suffering from DQV, only a small cluster of studies in the citation network mainly focus on this specific group of patients. While this shows that some researchers are interested, the number of corresponding studies is low. Therefore, research studies on DQV in pregnant and postpartum women can be one of the future research directions of this hand condition.

Knowledge gap 4: Studies related to non-invasive treatments for DQV, including splinting treatment, are scarce. In addition, research on the relatively younger population, and pregnant and postpartum women who suffer from DQV is limited. Therefore, more studies on these three areas are needed to be carried out in the future so as to enrich the research knowledge in this field.

2.7 Finite element modelling

The FEM, also known as FE analysis (FEA), is a method for simulating different field problems and providing numerical solutions accordingly. FEM can simulate the spatial distribution of the determined dependent variables, for instance, the distribution of stresses, displacements and temperature over an object (Cook, Malkus, Plesha, & Witt, 2002). To evaluate the stress from the splint on the hand when patients are performing various wrist or thumb movements, or to investigate the heat transfer from the skin of the hand to the outside environment through the splint material, FE modelling is an appropriate method to conduct the stimulation and predict the desired results by changing the data inputs, without repeated production of prototypes and implementation of wear trials.

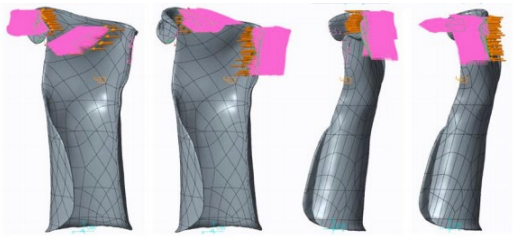
The implementation of the FEM requires the researcher to divide the 3D modelling structure into smaller parts, or FEs. After selecting the appropriate types of elements, computer software can automatically divide the 3D model into parts; this procedure is called ‘meshing’. During meshing, the FEs should not be overly distorted in order to minimise the presence of internal anomalies and simulation errors (Rugarli, 2010). A 2D plane model can be built up with 2D solid elements, such as triangular, rectangular and quadrilateral shaped elements. These elements can be composed with straight and curved edges depending on the shape functions. The first developed element for 2D solids was the linear triangular element. The element that is more accurate than the triangular element is the rectangular element. However, the quadrilateral element, which has unparalleled edges, is more practical and useful (Liu & Quek, 2013). In the industry and research fields, the majority of the problems are in the form of 3D structures with x, y, and z coordinates. Therefore, 3D solid elements are more commonly used in solving field problems. Three dimensional solid elements are formed by a number of faces that are bounded by edges. All of the edges are defined by nodes.

In a 3D solid element, each face shares an edge with another face, in which the edge can be defined by two or more nodes (Rugarli, 2010). Tetrahedrons and hexahedrons are the two most common shapes of 3D solid elements. Similar to 2D elements, 3D solid elements can be composed of flat or curved surfaces according to the shape function (Liu & Quek, 2013).

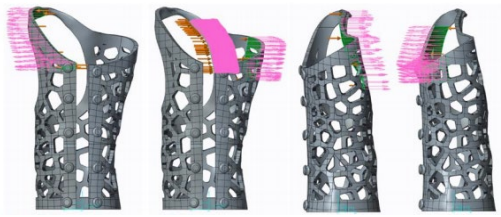
An FEA involves three main steps, which are 'preprocessing', 'numerical analysis' and 'postprocessing'. 'Preprocessing' means inputting the necessary data, for example, material properties, boundary conditions and load, into the model software. Appropriate types of elements, element size, and mesh density should also be selected for the programme to create the mesh of the 3D structure. After preparing the background data, the researcher can proceed to the next step of conducting a 'numerical analysis'. In this step, the researcher can order the software to start the calculation. The software can automatically calculate the matrix of each element one by one, and lastly combine the matrices into a large matrix to describe the overall behaviour and changes of the 3D solid model. Afterwards, the solution and simulation results can be listed or graphically displayed. This is the 'postprocessing' step. The researcher can select the most suitable presentation form of the results. For models that are used to analyse and simulate the distribution of stress, the results can be displayed in an animated form, and potentially finishing with a deformed model (Cook et al., 2002).

Nowadays, FE modelling is commonly used in the engineering sciences. This method can help to solve equations and describe the behaviours of physical systems, such as thermodynamics and mechanics of fluids and solids (Dhatt, Touzot, & Lefrançois, 2012). Since some experiments are costly, for example, research on structures of ships, aircrafts and buildings, FE modelling is an effective method to create stimulations of these large facilities in a virtual space without producing solid waste due to repeated trials and waste of time and money (Bergman, 2018). Apart from the engineering sciences, more and more researchers in the medical field are using FE modelling to conduct simulations. Jabran, Peach, Zou, and Ren (2019) developed an FE model to simulate the treatment of the two-part fracture of the proximal humerus with a spatial subchondral support plate. Bui, Tomar, and Bordas (2019) presented real-time simulation of needle insertion into soft tissue by using the corotational cut FE method. Focusing on FE model related to splint treatments for hand disorders, Cazon, Kelly,

Paterson, Bibb, and Campbell (2017) built two FE models to compare the stresses and displacements between a splint constructed by additive manufacturing and a traditional splint made of low temperature thermoplastic in the radial, ulnar, flexion and extension directions. Figure 2.32 shows the load applied onto the two splints for four major wrist motions. Hua, Wang, Lu, Ma, and Yin (2018) developed FE models to evaluate the stress distribution in soft tissues with three different fixed splints for distal radius fracture treatment, including the willow, anatomical and paper-based splints. Figure 2.33 shows the three types of splints and Figure 2.34 illustrates the stress distribution in the soft tissues by the willow splint. Huang et al. (2006) utilised the FEM to calculate the redundant materials of a splint for treating DQV, hence to reduce the weight and improve the air ventilation of the splint. Figure 2.35 shows the coverage comparison between a traditional and the optimised splints with a reduction of the abundant materials.

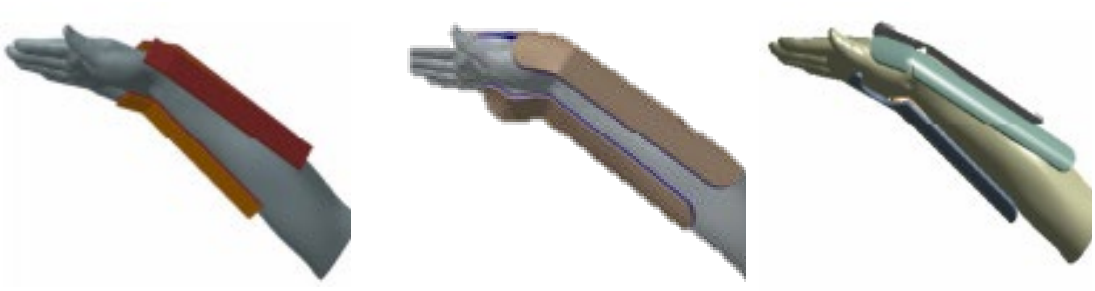


(a)



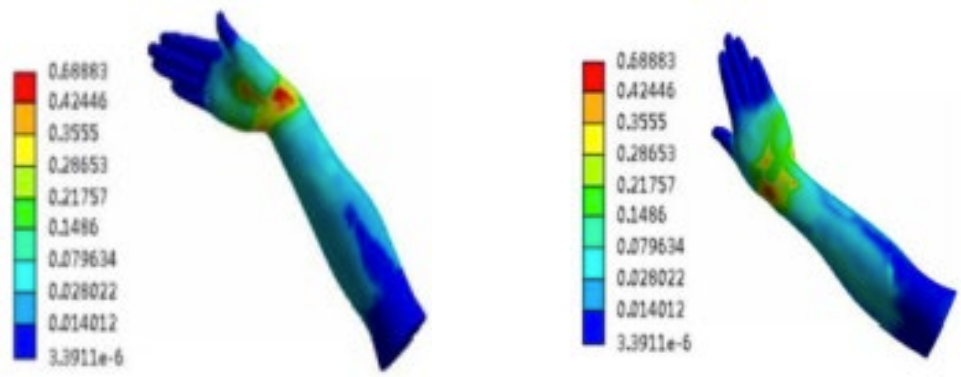
(b)

Figure 2.32 Load applied on two splints for four major wrist motions:
(a) Additive manufactured splint and (b) Traditional low temperature thermoplastic splint (Cazon et al., 2017)



(a) (b) (c)

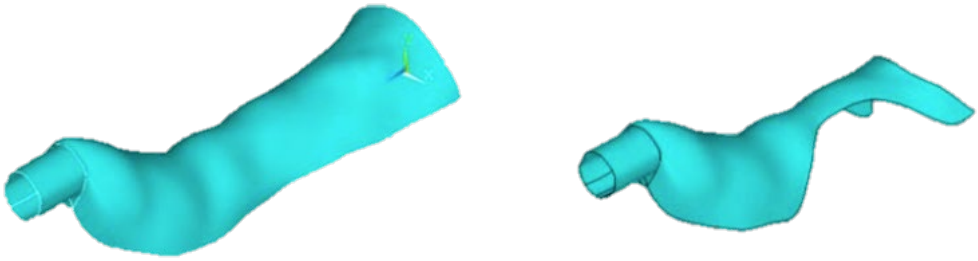
Figure 2.33 (a) Willow splint; (b) Anatomical splint; (c) Paper-based splint
(Hua et al., 2018)



Value unit: MPa Value unit: MPa

(a) (b)

Figure 2.34 Stress distribution in soft tissues by willow splint:
(a) Palmar view, and (b) Dorsal view
(Hua et al., 2018)



(a) (b)

Figure 2.35 Coverage comparison between (a) traditional splint and (b) optimised splint (Huang et al., 2006)

Knowledge gap 5: Finite element models that simulate the effects of splinting on hands with different hand disorders are found in the literature. However, studies that evaluate the properties and performance of the splints, especially those for treating DQV, are scarce. Furthermore, the splints evaluated by using the FEM are mainly rigid splints. Therefore, more research on the effects of splints, particularly those composed of both hard and soft materials, is needed to be done in the future.

2.8 Chapter summary

DQV is a painful condition found at the radial side of the wrist, near the radial styloid process. It is commonly known as the inflammation of the synovial sheaths of the APL and EPB tendons in the first dorsal compartment. DQV is diagnosed through the Finkelstein's test, during which patients flex their thumb and enclose the thumb into a closed fist, then deviate the wrist to the ulnar side. A positive diagnosis is given if the patient experiences pain over the first dorsal compartment when performing the movements. The causes of this hand condition are still ambiguous, but could include overuse and repetitive movement of the wrist and thumb, anatomical variations at the first dorsal compartment and suspected genes. Occurrence of this hand disorder in females is more prevalent than in males. Pregnant and postpartum women are potential sufferers of this disease due to changes in hormone secretion and increased hand movements when caring for their baby. The three main treatments for DQV are splinting, steroid injection and surgery.

Splinting is a common practice in clinics nowadays. In fact, patients may prefer splinting before undergoing other treatments due to its non-invasiveness. During splinting, patients are required to wear the splint for long hours. However, thermal discomfort and inconvenience due to the bulkiness of traditional splints have been reported. The discomfort may lead to low compliance with treatment. To address the problems found with the use of traditional splints, some researchers have proposed novel splint designs. However, problems such as hardness and material durability, are still found in the proposed novel splints. Therefore, a new functional splint needs to be developed to resolve the existing problems with splints.

A CNA related to DQV has been developed and conducted in this study. The results show that studies related to non-invasive treatment for DQV, including splinting, are limited. Therefore, more research on splint design and effectiveness of splinting is needed. The results of the CNA also show that research on relatively younger populations and pregnant and postpartum women with DQV is relatively scarce and can serve as the future research directions of this disease.

More and more researchers in the medical field are using FEM to simulate medical related issues. Simulations of stress from different types of splints for different hand disorders are found in the literature, however the number of such studies is still relatively low. Therefore, it is necessary to conduct more FE model related studies on splint performance. Since most related studies are mainly on rigid splints, more studies on splints composed of both rigid and soft materials should be carried out. Pressure distribution of the splint on the hand in static positions or during hand movements can be further investigated on the basis of FE modelling.

Chapter 3 Methodology

3.1 Introduction

To design the proposed functional splint with appropriate types of materials and good fit properties with the ability to immobilise the affected hand of patients, it is important to explore the different splint designs available in the current market for DQV, the materials used and the problems of current splints. An understanding of the fundamentals of splint production and ergonomic shape of the hand for splint design is also imperative. Here, fabric tests are carried out to evaluate the properties of the materials, in terms of their stretch and recovery, thermal conductivity, moisture management and air permeability, and thus provide the best options for the different components of the proposed splint. This chapter comprises eight sections. Section 1 is the introduction. Section 2 is the research plan and Section 3 is the evaluation of current splints. Sections 4 and 5 discuss the development and fabrication of the proposed functional splint respectively. Section 6 presents the details on the preliminary wear trial, while Section 7 discusses the formation of an FE model to determine the pressure distribution on the hand from the proposed splint. Section 8 is a summary of the chapter.

3.2 Research plan

The flow chart diagram of this study is illustrated in Figure 3.1. Issues with existing splints for treating DQV are identified at the beginning of the study. To consolidate the basic knowledge around splint development, background information is collected; for example, current splint products are reviewed, clinical observations are made and the shape of the hand is investigated. After gathering the background information, the design concepts of the proposed functional splint are developed. Suitable materials are tested and selected to fabricate the splint. The splint components, such as the thumb and ulna supporters, are also designed and then produced. A wear trial is subsequently carried out to evaluate the performance of the proposed functional splint. Moreover, an FE model is built to simulate the splint wearing process and evaluate how the pressure from the splint is distributed on the hand.

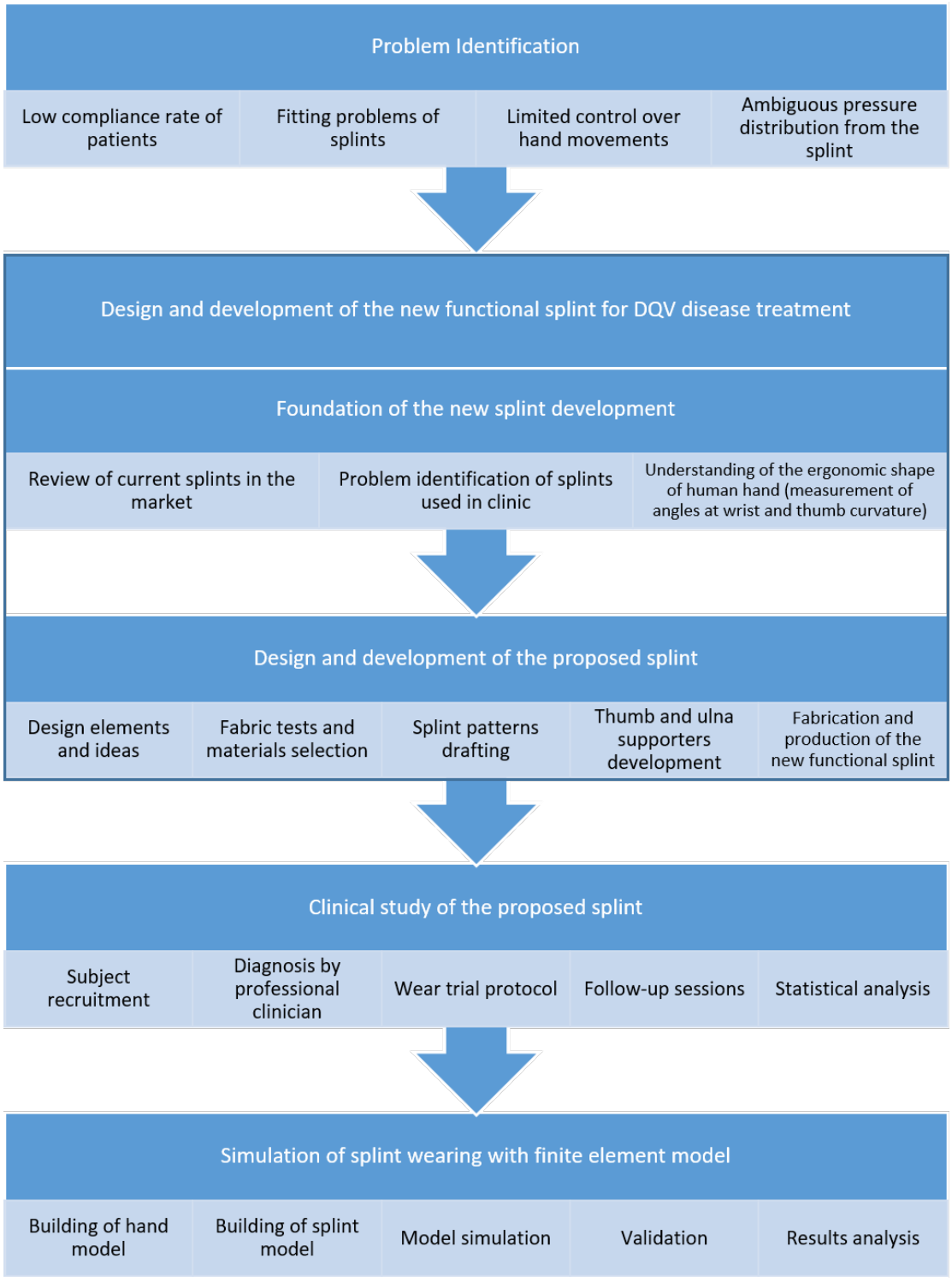


Figure 3.1 Research plan

3.3 Evaluation of current splints

3.3.1 Online search for splints in current market

Since DQV is a common hand condition among the general population, a number of textile companies have targeted patients with DQV and developed splints especially for managing DQV or hand pain. Splints with different kinds of designs and fabrics are available in the current market, or both physical and online stores. In this study, an online search of 10 splint designs for managing hand pain or DQV is carried out. Characteristics of the splints were identified and described in terms of the type of fabric used, properties and functions. Comparisons between splint products available in current online stores were also conducted.

3.3.2 Measurements of hand restriction of splint samples

Splints for DQV comprise a rigid component that aims to immobilise the thumb during abduction and wrist movement (Huang et al., 2006). To immobilise the wrist in a comfortable position, the shape and structure of the splint should maintain the hands in the resting position. According to several studies in the literature, the resting position of hand is a 10 to 20 degree extension of the wrist, slight radial abduction at the CMC joint, slight flexion of the MCP joint of approximately 30 degrees and neutral position of the IP joint (Hart et al., 2005; Ilyas et al., 2007; Nemati et al., 2017); (Wilton, 2014).

An experiment was carried out to investigate the ability of the splint samples purchased in the current market to maintain the optimal hand position. Two splints were purchased from two different brands: the Medex and Futuro splints. Both splints indicate that they specifically target thumb related hand conditions, such as thumb joint pain associated with repetitive motions like those during gaming, or specific hand disorders like DQV and trigger thumb. Table 3.1 lists information on the two splints including but not limited to their material composition, treatment target and size.

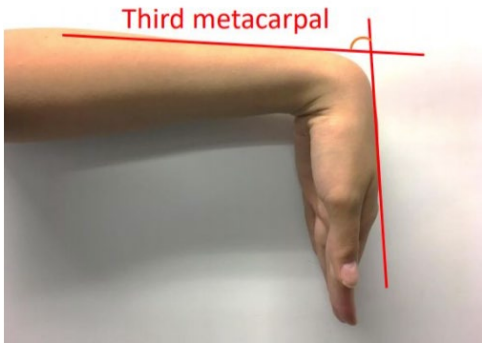
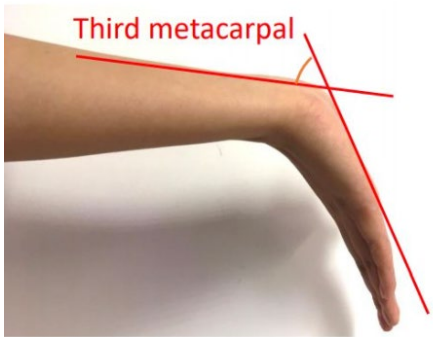
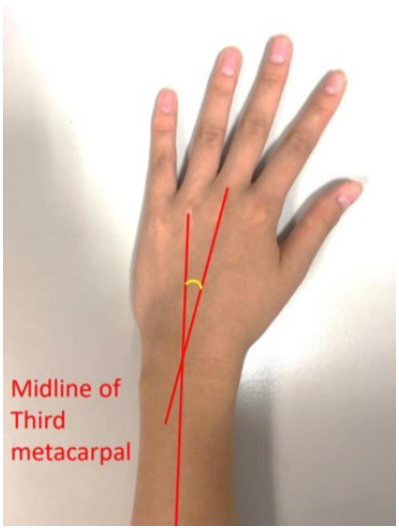
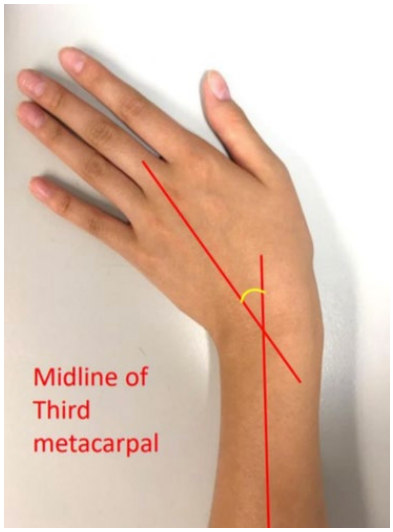
Table 3.1 Two splint samples

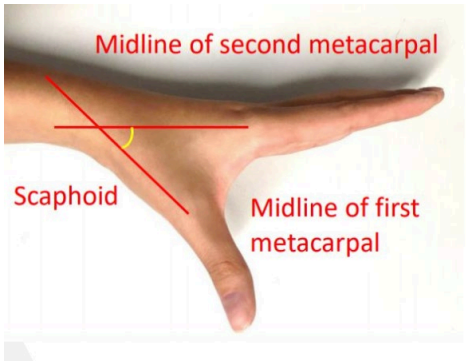
Splint appearance:		
Name:	DQV Thumb Splint	Deluxe Thumb Stabiliser
Brand:	Medex	Furuto
Material composition:	Velcro-plush fabric Contour plastic stay	Nylon Polyester Polyurethane foam Rayon Elastane
Treatment target:	DQV Sprained thumb Fractured thumb (stabiliser) Trigger thumb	Helps to relieve thumb joint pain associated with arthritis Helps to relieve thumb joint pain associated with texting and gaming
Side of hand:	Right-hand	Right-hand
Size:	Universal	Small to medium

Six healthy female subjects between 20 and 30 years old were recruited for the experiment. All of the subjects were instructed to undergo three sessions to measure the ROM of their wrist and thumb in different conditions. In the first session, the subjects performed a set of ROM tests of the wrist and thumb without wearing a splint.

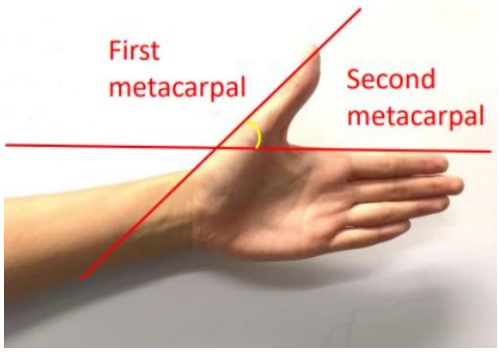
The angle of each condition was measured and recorded. The same ROM tests and angle measuring process were repeated in the second and third sessions with the subjects but wearing the two splints. The ROMs measured in this experiment were based on the joint motion measurement assessments in Gerhardt et al. (2002) and Norkin and White (2016).Table 3.2 lists the measured ROMs of the wrist and thumb in the experiment with images that show the position of the corresponding angles. Explanations are also provided for ROMs that are not measured in this experiment.

Table 3.2 Measured ROMs of wrist and thumb

<table>
<tr><td colspan="2">Four measured ROMs of wrist</td></tr>
<tr><td>Flexion
 
</td><td>Extension
 
</td></tr>
<tr><td>Radial deviation
 
</td><td>Ulnar deviation
 
</td></tr>
</table>

<table>
<tr><td colspan="2">Eight measured ROMs of thumb</td></tr>
<tr><td>Abduction
 
</td><td>Adduction

Did not measure because thumb adduction is normally treated as the starting point of thumb abduction (Norkin & White, 2016).</td></tr>
<tr><td>Carpometacarpal joint flexion

Did not measure because it is difficult to measure the CMC joint flexion precisely when patients are wearing the splints. The splints may hold the thumb in a slightly abducted position so that it is difficult to flex the thumb medially and close to the palm.</td><td>Carpometacarpal joint extension
 
</td></tr>
<tr><td>Metacarpophalangeal joint flexion
  </td><td>Metacarpophalangeal joint extension

Did not measure because MCP joint extension is normally treated as the starting position of MCP joint flexion. MCP joint extension is commonly noted as 0 degree (Norkin & White, 2016).</td></tr>
</table>

Interphalangeal joint flexion	Interphalangeal joint extension
	

All of the subjects participated in the 3 sessions and their ROMs with and without a splint were recorded. The angles were compared so as to determine the effectiveness of the splint samples on restricting hand movement.

3.4 Development of proposed functional splint

3.4.1 Splint construction process investigation – clinical visit

To develop the proposed functional splint for treating DQV, it is important as the first step, to understand the basics of the construction process of traditional splints. It is also important to understand the entire medical check-up flow of a patient. With this information, the design and fabrication steps of the proposed splint can be considered based on real clinical settings and conditions, and thus the use of the proposed splint would be more feasible.

Clinical visits were arranged from October 2017 to June 2018 at the David Trench Rehabilitation Centre in Sai Ying Pun, Hong Kong (see Figure 3.2(a)). Since the aim of this clinical visit was to gain a better understanding of the medical check-up flow of patients with DQV, the clinical visit was arranged as part of the DQV group session at the Occupational Therapy Department (Figure 3.2(b)) which took place twice per month, on Thursdays every other week from 3:30 p.m. to 5:30 p.m. Throughout the sessions, the check-up flow was observed and recorded. Details of the steps of the splint fabrication process were also observed and noted, and used for reference in the development of the proposed functional splint.

(a) (b)

Figure 3.2 (a) David Trench Rehabilitation Centre, and
(b) The Occupational Therapy Department

3.4.2 Measurements of angles of wrist and thumb

The splints for treating DQV aim to maintain the affected hand in the correct position. Patients might be advised to wear the splint for long periods of time every day; for example at least 6 hours each day for 2 weeks (Jongprasitkul et al., 2011), so as to provide sufficient time for the wrist and thumb to rest and allow the tendons and nearby parts to heal. Since the patient has to wear the splint for a long period of time, the shape of the splint should be well fitted to the patient's hand. If the patient wore a splint that does not fit his or her hand, the patient may feel uncomfortable, and take off the brace, which results in low compliance with treatment. A poorly fitting splint may also exert inappropriate levels of pressure to certain parts of the hand or force the patient's hand into an unnatural position. If these situations persist for long periods of time, problems such as hand pain, soreness and pressure ulcers may emerge.

A well-fitting splint is important for patients undergoing treatment. As such, an experiment was designed to investigate the 3D shape of the hand, so that the angle measurement results of the hand could be used as a reference for the development of the proposed splint pattern design in the later stages of the study. This experiment

involves two stages. The first stage is to obtain the 3D shape of the right or left hand from the recruited subjects. With the 3D images obtained in stage one, the second stage involves measurements of the angles at the wrist and MCP joint, and the curvature of the thumb by using different software.

3.4.2.1 Subject recruitment

In the first stage, three groups of patients of different age groups were recruited for a comparison of their hand shape. The first group included 10 healthy young female subjects (HYS) who are 20 to 29 years old. The second group included 16 healthy mature female subjects (HMS) who are 40 years old or above. Finally, the third group included 16 female subjects with DQV (DQVS) who are 18 years old or older, of which 11 of the DQV patients are 46 years old or older. The inclusion criteria for the recruitment of the DQV patients are: 1) female subjects who are18 years old or older and 2) have DQV with a positive Finkelstein's test diagnosed by a professional clinician. On the other hand, the exclusion criteria include subjects who have received steroid injections for DQV in the past three months or have a history of hand surgery. All of the participants signed a consent form to demonstrate that they fully understood the experiment details and agreed to participate in the study.

3.4.2.2 Scanning and measuring hand angles

After the subjects were recruited, each underwent the activity in Stage 1; that is, their hands were three-dimensionally scanned. Figure 3.3 is the flow chart of the experiment, in which Stage 1 is the participation process of the subjects and provides the scanning details, and Stage 2 involves the use of software for image processing and data collection.

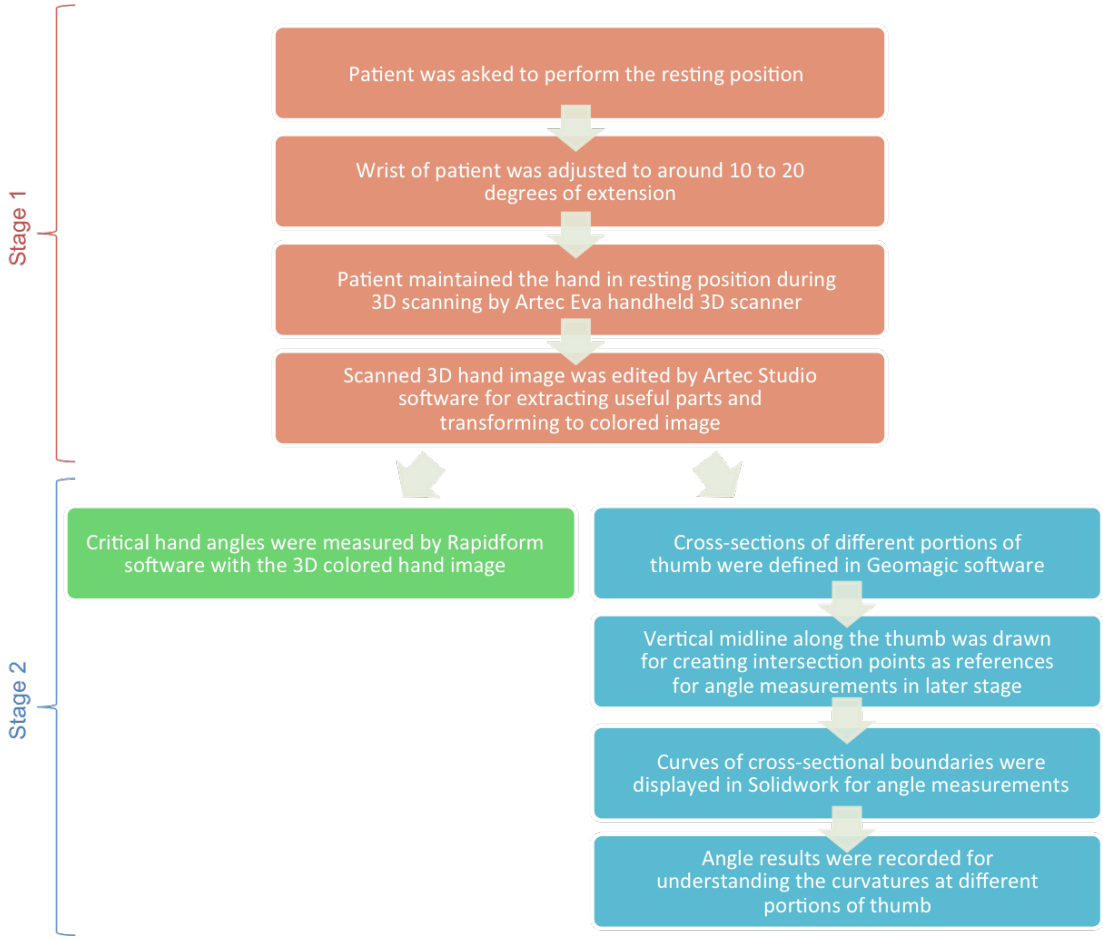


Figure 3.3 Flow chart of the experiment

The Artec Eva handheld scanner (Figure 3.4) was used to scan the hands of the subjects. This scanner can scan objects with high accuracy and detect small changes in volume (Koban et al., 2019). Since the splint should maintain the hand in the resting position, the subjects were instructed to place their hand in the resting position (Figure 3.5) during the scanning process. To do so, they were asked to maintain a 10 to 20 degree wrist extension during scanning as suggested in the literature. For instance, Hart et al. (2005); Wilton (2014) recommended that the splint hold and rest the affected hand in a 10 to 20 degree wrist extension. The scanned images were obtained and edited by using Artec Studio to extract the useful forearm and hand information, and transform the images into colour format for better illustration purposes.

Figure 3.4 Artec Eva handheld scanner

(Artec 3D, 2022)

Figure 3.5 Resting position

In the second stage, the 3D images of the hand were imported with different software to measure the angles of the wrist and curvature of the thumb. Three critical angles were measured: 1) between the extension of the radius or ulna and carpal portion at both sides of the wrist, and the angle of the MCP joint flexion. The three critical angles are clearly illustrated in Figure 3.6. The 3D hand images in coloured format were imported into Rapidform software (Figure 3.7) to measure the critical angles. These angles of the right or left hands were measured and recorded to enhance understanding of the shape of the hands.

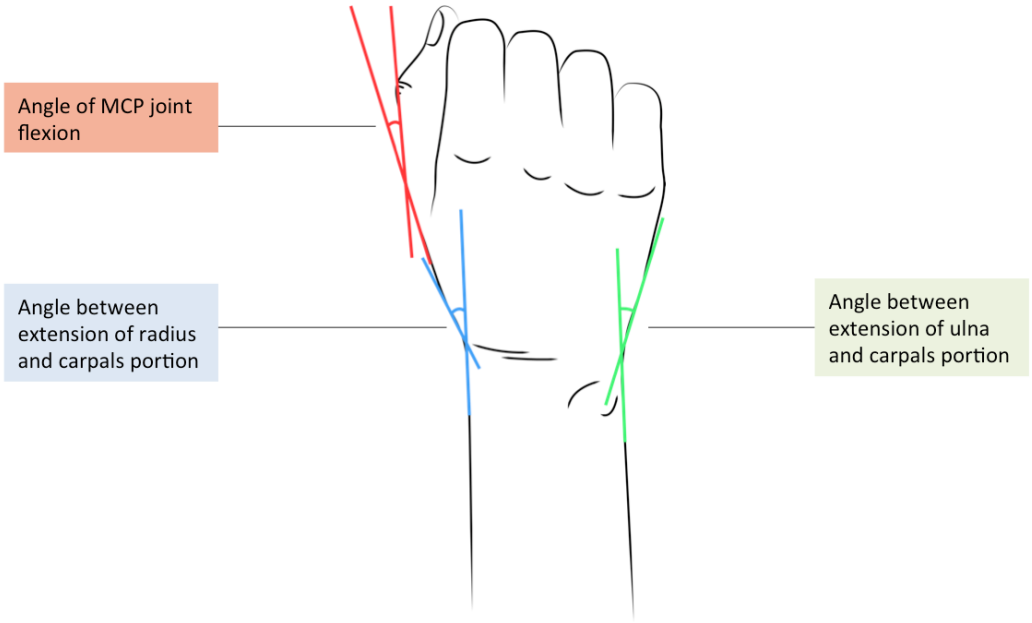
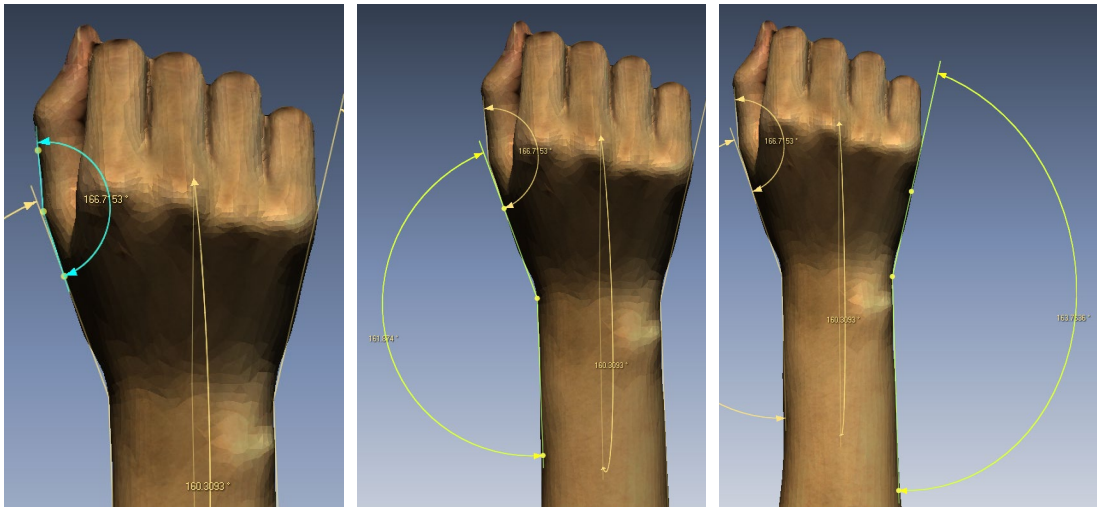


Figure 3.6 The three critical angles



(a) (b) (c)

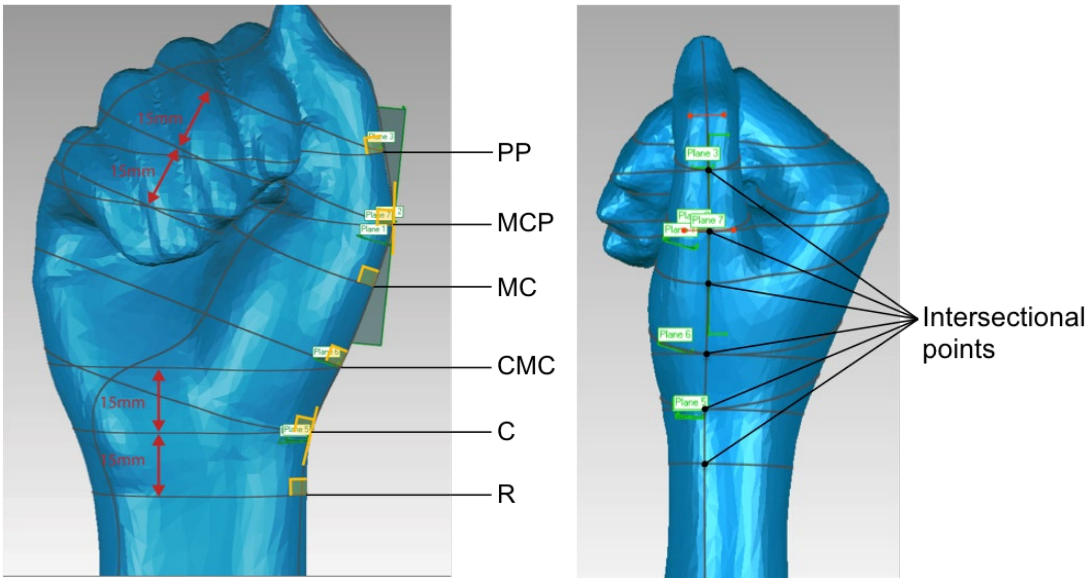
Figure 3.7 Angle measurements

(a) Angle of MCP joint flexion

(b) Angle between extension of radius and carpal portion

(c) Angle between extension of ulna and carpal portion

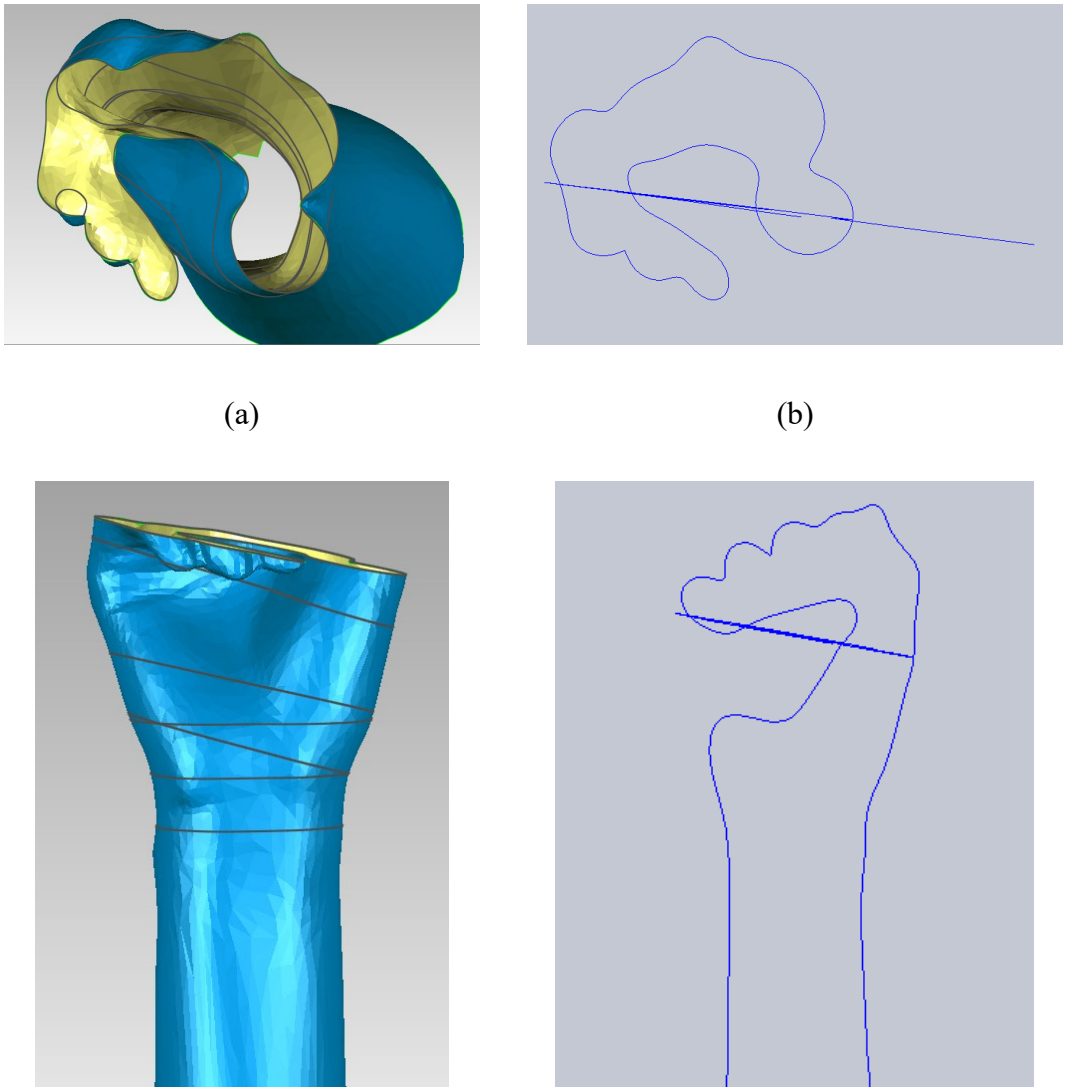
The thumb supporter is one of the key components of the splints in supporting the affected tendons along the thumb. To design a thumb supporter that accommodates the thumb of the patients, an investigation on the curvature along the thumb is necessary. Three-dimensional images of the right hands were imported into Geomagic software to cross section the hands at different regions. Two reference levels were initially set: at the MCP joint (level at the MCP) and the most concave region near the scaphoid bone (level at C representing level at carpal). Two cross-sectional planes were then cut perpendicular to the tangents of the MCP and C points in the palmar view. Four additional parallel lines were added spaced 15 mm apart from the two reference levels superiorly and inferiorly, thus forming four reference points at the outline of the radial side of the hand. The four reference points were named in accordance with the anatomy of hand (from the top to the bottom): the proximal phalangeal (PP), metacarpal (MC), and carpometacarpal (CMC) bones and radius (R). Cross-sectional planes were cut at the four points perpendicular to the radial outline at specific regions of the hand. Figure 3.8(a) illustrates the aforementioned steps. A vertical midline at the thumb was created to provide the intersectional points (Figure 3.8(b)) as reference for the angle measurements in the next step.



(a) (b)

Figure 3.8 (a) Cross-sections forming step at different levels of thumb, and
(b) Vertical midline that form steps along the thumb to provide intersectional points

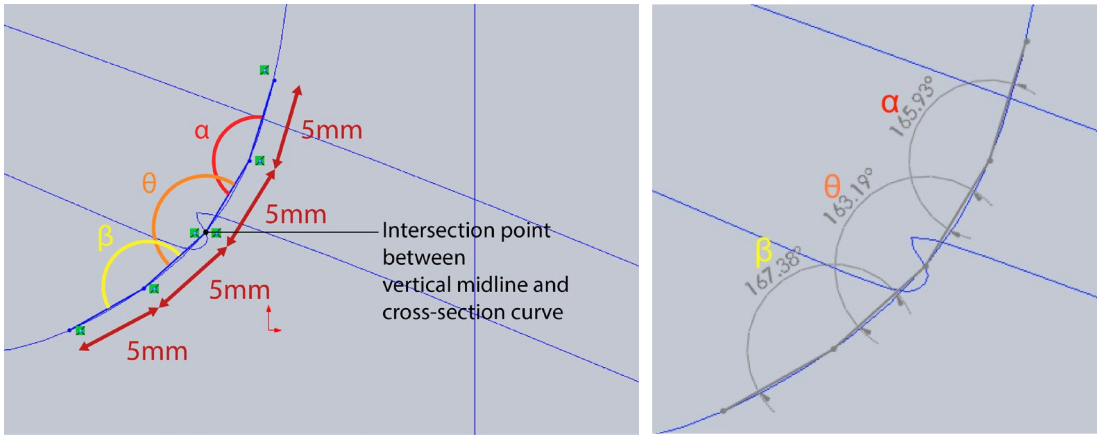
After saving the images from Geomagic software, files of the cross-sections of the hands were imported into Solidworks for angle measurements at different levels of the thumb. Figure 3.9 shows the curves of the cross-sectional boundaries shown in Solidworks that correspond to the cross-sectional planes of the hand made by Geomagic software. In each cross-section, the curvature line of the thumb is magnified to show the intersection point, which is the point determined between the cross-section curve and the vertical midline. Using the intersectional point as reference, four points are marked along the thumb curvature line with spacing of 5 mm between the points. Four straight lines are formed by connecting the points and three angles labelled α, β and θ are obtained as shown in Figure 3.10. The measured angles were also recorded to understand the curvatures at different parts of the thumbs and provide reference for designing the thumb supporter of the proposed splint in this study.



(a) (b)

(c) (d)

Figure 3.9 (a) Top view of cross-section of 3D hand model in Geomagic;
(b) Top view of curve of cross-sectional boundary in Solidworks corresponding to (a);
(c) Palmar view of 3D hand model in Geomagic; and
(d) Palmar view of curve of thumb's vertical midline cross-sectional boundaries in Solidworks corresponding to (c)



(a) (b)

Figure 3.10 (a) Formation of α, β and θ along curvature of thumb, and (b) Measurement of α, β and θ

3.4.2.3 Statistical analysis of angles

After scanning and collecting the measured angles of hands from the HYS, HMS and DQVS groups respectively, a non-parametric Mann-Whitney test was conducted to compare the differences between the measured angles in the two sets of data. The first compared set of data is between HYS and HMS, in which both groups involved healthy subjects with only difference in age. On the other hand, the second compared set of data is between HMS and DQVS, in which both groups included a majority of mature adults who are 40 years old or more. The difference between the HMS and DQVS groups is the absence and presence of DQV. Apart from carrying out independent tests, the Spearman's rank order correlation test was implemented to investigate the correlations between the angles of the injured hands of the DQVS group. The confidential interval values of the tests were defined at 95% ($p < 0.05$). The IBM Statistical Package for Social Science (SPSS) version 26 was used.

3.4.2.4 Questionnaire

The *Quick* Disabilities of the Arm, Shoulder and Hand (*Quick*DASH) questionnaire, which is the short form of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire was given to the patients to understand their hand conditions. Validation of *Quick*DASH was conducted by Gummesson, Ward, and Atroshi (2006), who showed that the *Quick*DASH questionnaire has a similar precision for upper limbs disorder to full length DASH. The DASH questionnaire was designed to assess the health status of

patients in the past few weeks by asking questions related to the level of difficulties in performing activities due to problems with upper limbs, symptoms and pain level of the hand disorder and impacts of the problems on personal and social lives (Williams, 2014). Apart from understanding the hand conditions of the subjects, another questionnaire that focuses on the importance of different properties and characteristics of the splint, for instance, appearance, functionality, ease of donning and doffing, durability, air permeability etc., was given to the patients for their completion. The comments of the subjects on the importance of various splint properties were used as reference for the score weighting of fabric selection.

3.4.3 Selection of fabrics

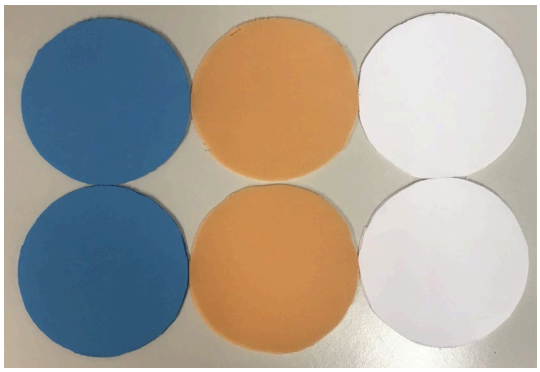
3.4.3.1 Fabric weight and thickness

Patients who are undergoing splinting treatment for DQV are required to wear a splint for long hours each day. As the splint is worn while performing daily activities, the splint should be adequately light in weight to facilitate daily tasks to be done conveniently. Furthermore, a lighter weight splint can minimise the weight bearing of the tendons and muscles at the wrist and forearm. Less force and stress exerted to the tendons, especially the APL and EPB tendons, are preferred to facilitate healing of the inflamed components in the first dorsal compartment. Thickness of the splint fabric is also considered in accordance to their applications in the different regions of the hand. Thicker fabric may be considered for areas near the affected compartment so as to serve as a protective layer. For the other regions of the hand, thinner fabrics can be used to minimise the overall weight of the splint.

To measure the weight of the fabric specimens for standard areas, ASTM D3776 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric were carried out. The procedures of the fabric weight measurement test are described as follows.

1. The fabrics were conditioned in a room with a standard atmosphere of 21 ± 1°C and relative humidity of 65 ± 2%.
2. A circular die cutter was used to cut the sample fabrics into circular pieces with an area of 100 cm^2. Figure 3.11 shows the circular die cutter and the circular fabric specimens.

(a)



(b)

Figure 3.11 (a) Circular die cutter, and (b) Circular fabric specimens

3. The fabric specimens were placed onto a *Mettler PE 360 DeltaRange®* digital scale balance to determine the mass (grams), as shown in Figure 3.12.

Figure 3.12 Mettler PE 360 DeltaRange® digital scale balance

4. The weight of the fabric, which is the mass per unit area, was then calculated. The following formula in ASTM D3776 was used to calculate the weight of the fabric:

$$\text{Weight of fabric } (\text{g/m}^2) = \frac{10^3 M}{LW}$$

where M is the mass of the fabric (kg), L is the length (m) of the fabric and W is the width (m) of the fabric.

In this study, the mass of the fabric specimens was measured (grams) and the area of the fabric pieces was cut into 100 cm^2, which gives the following formula,

$$\text{Weight of fabric } (g/cm^2) = \frac{fabric\ mass}{fabric\ area}$$

$$= \frac{fabric\ mass}{100}$$

5. Three fabric specimens were cut from each type of tested fabric for weight measurements. The mean weight was calculated for comparison purposes of the fabrics.

Fabric thickness was measured in accordance with ASTM D1777 Standard Test Method for Thickness of Textile Materials. The *HAN BAER AG CH-ZURICH telex 57767* fabric thickness tester was used to measure thin fabrics like powernet and satinette. On the other hand, the *PEACOCK* thickness gauge was used to measure thicker fabrics like spacer fabric. Figure 3.13 shows the two fabric thickness gauges.

(a) (b)

Figure 3.13 (a) *HAN BAER AG CH-ZURICH telex 57767* fabric thickness tester; (b) *PEACOCK* thickness gauge

The fabric thickness was measured according to the following steps.

1. A fabric thickness measurement test was carried in a room with a standard atmosphere of 21 ± 1°C and relative humidity of 65 ± 2%.
2. The pressure foot of the thickness tester was lifted up to insert the thin fabrics (powernet and satinette) between the pressure foot and metal platform. The pressure foot was then lowered gradually to apply pressure on the fabric surface (Figure 3.14). The pressure applied was set to 6 g/cm^2. The thickness of the spacer fabric was measured by clipping the fabric between the two pressure foots of the *PEACOCK* thickness gauge.
3. The thickness of each fabric specimen was measured five times and recorded in millimetres. The mean thickness was calculated for fabric comparison purposes.

Figure 3.14 Measurement of fabric thickness

3.4.3.2 Air Permeability

Air permeability is a measure of how easily air flow passes through a given area of a garment. This property influences the level of ventilation of the garment and may also affect the heat release rate across the fabric from the body to the external environment (Coldea & Vlad, 2011). A splint that is very air permeable would allow sufficient air exchange between the internal space of the splint close to wearer's skin and the external environment. Heat could be transferred out and prevent overheating where the splint is worn, and thus reduces any discomfort due to splint wear. To select appropriate fabrics with higher air permeability for fabricating a splint, their air permeability was measured by using a *KES-F8-AP1* air permeability tester.

The air permeability test followed the ASTM D737-18 Standard Test Method for Textile Fabrics which aims to measure the airflow penetration rate across a fabric perpendicularly within a standard area during a fixed period of time. The penetration rate is determined by the pressure difference between both sides of the fabric. The standard settings of the tester are as follows:

Speed of piston = 2 cm/s

Cross sectional area = 4 π cm^2

Air flow rate = 4 π × 2 = 8 π cm^3/s

As the area of the small hole is 0.2 π cm^2, the corresponding air flow rate per unit area

= 8 π / 0.2 π / 100 = 0.4 m/s.

As the area of the medium hole is 2 π cm^2, the corresponding air flow rate per unit area

= 8 π / 2 π / 100 = 0.04 m/s.

Therefore, the air flow rate per unit area of the small hole is 10 times greater than that of the medium hole.

The air permeability of the fabric samples was measured by following the steps below:

1. The air permeability test was carried out at a temperature of 21 ± 1°C and relative humidity of 65 ± 2%.

2. The metal plate of the tester was lifted up and the fabric sample was gently placed on the platform, which covered the airflow hole, through which air enters the sample.

3. The fabric was fixed between the metal plate and platform with two clamps at two sides, with the fabric surface in contact with wearer's skin facing downward, as shown in Figure 3.15. For fabric that is less air permeable, metal plate with a medium size hole for air movement was used. While, metal plate with a small size hole was used to test fabric with higher air permeability.

4. The rate was reset to zero before each test. The 'Start' button was then pressed to allow air to pass through the hole and the fabric, consequently measuring the air flow rate of the fabric.

5. The resulting air flow rates of the fabric samples were recorded and calculated as KPa · s/m to show the degree of air permeability of the fabrics.

6. Each fabric was measured five times and the mean value was calculated for comparison.

Figure 3.15 Air permeability tester KES-F8-AP1

3.4.3.3 Thermal conductivity

The temperature of the human body is normally maintained at 37°C for the core region and approximately 28°C at the hand region, as shown in Figure 3.16 (White, Bosio, Duplantis, & Nano, 2011). Skin temperature is an important physiological indicator of a person's thermal comfort (Liu, Wang, Di, Liu, & Zhou, 2013). To maintain the skin of the hand which is covered by the splint within a normal range of temperature, the splint materials need to have good thermal conductivity so that extra heat from the body can be transferred to the external environment. In the end, the patients would have a good wear experience.

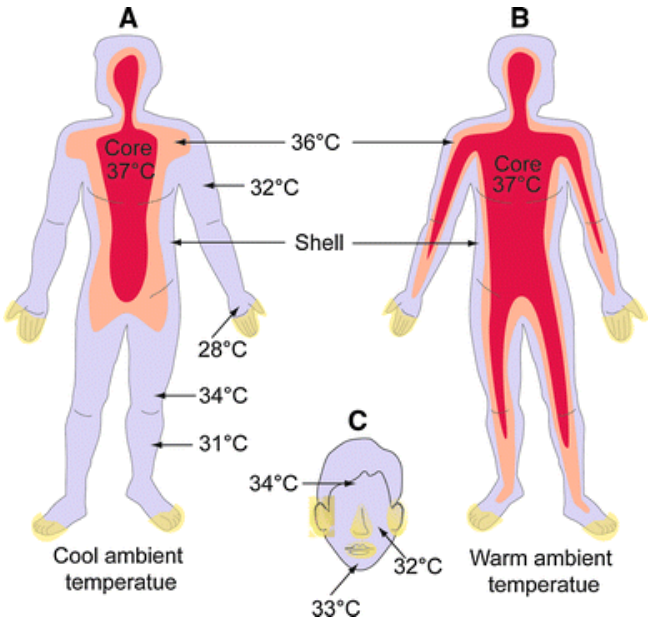


Figure 3.16 Temperatures at different regions of the human body

(White et al., 2011)

To select materials with good thermal conductivity for constructing the proposed splint, the thermal conductivity of the fabric samples was measured by using the Thermal Property-Measuring Instrument KES-F7 THERMO LABO II; see Figure 3.17. Thermal conductivity is defined as the transfer of heat between two bodies through a medium. In this test, heat is transferred from the B.T. box to the water box, and the medium is the sample fabric. Figure 3.18 shows the B.T box and the water box.

Figure 3.17 Thermal Property-Measuring Instrument KES-F7 THERMO LABO II

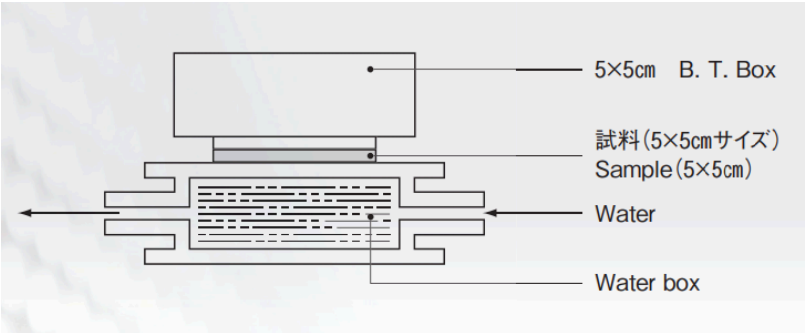


Figure 3.18 B.T. box and water box

(KATO TECH CO. LTD., 2007)

The thermal conductivity test was carried out according to the following procedures,

1. The heat plate placed at the bottom of the B.T. box was set to approximately 30°C, which is the same as the temperature of the surface of the human body. The water box was set at room temperature or lower, or approximately 20°C.

2. The fabric specimen was placed between the heat plate of the B.T. box and the water box. The pressure given by the B.T. box is 6 g/cm^2.

3. When the reading of the heat transfer from the B.T. box to water box reached a constant value, the heat flow loss of the heat plate of the B.T. box was recorded in watts (W).

4. The thermal conductivity of the fabric was calculated by using:

$$K = \frac{WD}{A\,(\Delta T)}$$

where W is the heat flow loss of the B.T. box, K is the thermal conductivity, A is the area of the heat plate placed on the B.T. box (25 cm^2), ΔT is the temperance difference between the B.T. box and water box (10°C) and D is the sample thickness measured under a pressure of 6 g/cm^2.

5. Steps 2 to 4 were repeated 5 times for each type of fabric and the calculated results are marked in W/cm °C for comparison purposes.

3.4.3.4 Stretch and Recovery

A splint with a good fit can be maintained in an appropriate position, which may enhance convenience when patients are performing daily activities while wearing the splint. The stretchability of the fabric used may help to enhance the fit. In addition, the stretchability of the fabric across the girth of the hand may allow ease of splint wear and an adequate degree of motion for patients to carry out activities while wearing the splint. Therefore, fabric with good stretchability is important for the proposed splint development. Besides, since patients have to wear the splint while doing various tasks, and don and doff the splint every day to shower, the materials should have excellent recovery to avoid deformation of the splint, and ensure that the splint fits the hand well even if worn for certain period of time.

ASTM D6614 – 07 Standard Test Method for Stretch Properties of Textile Fabrics – CRE Method was used to measure the stretch and recovery properties of the fabrics. In the testing, a specific load was applied to the fabric sample by extending the fabric with the extension tensile machine at a constant speed. The length of the fabric sample was measured when the load reached a specific value and held for a prescribed period of time. Then, the load was removed and the fabric sample was allowed to relax for a fixed period of time. A small amount of force was applied to extend the fabric slightly to prevent folds, and the length of the fabric sample was measured and recorded. After calculation, the stretch and recovery ability values of the fabric were obtained. The following describes the procedural steps of this test:

1. The sample fabrics were conditioned at a temperature of 21 ± 1°C and relative humidity of 65 ± 2%.

2. The sample fabrics were cut into dimensions of 35 cm (length) × 5 cm (width). Two fabric samples along the wale direction and two along the course direction were prepared.

3. A fabric sample was then clamped by the upper and lower jaws of the *Instron 4411* tensile tester which had a distance of 25 cm between them (Figure 3.19).

4. The tensile tester extended the fabric sample until 1814 ± 1.0 g and held the sample for approximately 5 minutes. The length of the fabric sample was recorded by using computer.

5. After holding for approximately 5 minutes, the jaws returned to the start position and the fabric was relaxed.

6. The fabric sample was slightly extended to prevent folds, and the fabric length was measured.

7. The fabric stretch and fabric growth were calculated by using:

$$Fabric\ stretch\ (\%) = [(B - A)\ A]\ \times\ 100$$

$$Fabric\ growth\ (\%) =\ [(C - A)\ A]\ \times\ 100$$

   where A represents the initial distance between the jaws (25 cm), B is the distance between the jaws in Step 4 and C is the distance between the jaws in Step 5.

8. The mean fabric stretch and fabric growth in percentage were calculated and compared.

Figure 3.19 Instron 4411 tensile tester

3.4.3.5 Water Vapor Transmission

When the affected hand of the patients was covered and protected by the splint for a long period of time, moisture from the respiration of skin cells might be trapped within the space between the splint material and the skin. A high level of humidity in the inner space of the splint may lead to discomfort. Therefore, to maintain a suitable humidity level for the internal environment of the splint, the fabrics used should have good water vapor transmission. ASTM E96 Standard Test Methods for Water Vapor Transmission of Materials Test was implemented to test water vapour transmission. During the testing, the opening of the small cups that were filled with distilled water were sealed with the fabric specimens with the same dimensions as the opening. The weight of the cup of distilled water covered with the fabric was measured before and after a fixed period of time. The weight difference indicates the water vapor transmission rate through the fabric. The experimental procedures are as follows:

1. The experiment was carried out under standard conditions of 21 ± 1°C and relative humidity of 65 ± 2%.
2. For each type of tested fabric, two fabric specimens were cut into dimensions that matched the opening of the small cup.
3. Distilled water was poured into the cups. The opening was then sealed with the fabric specimens, as shown in Figure 3.20. For the spacer fabrics, the edges of the fabrics were sealed with tape so as to prevent the loss of the water vapour through the middle layer of the spacer fabrics instead of passing across the fabrics.
4. The cups together with the distilled water and fabric cover were weighed individually.
5. After the measurements were carried out, the cups were placed in standard conditions for 24 hours.
6. After 24 hours, each cup along with the distilled water and fabric cover was weighed again.
7. The differences in the weight of the cups before and after 24 hours were calculated and recorded to calculate the water vapor transmission (WVT) rate of each specimen.
8. The WVT rate was calculated by using:

$$WVT = \frac{G}{tA}$$

where G represents the weight difference, t is the duration (time), which is 24 hours, and A refers to the area of the opening of the cup.

9. The results of the WVT test were recorded in g/h · m^2 for comparison purposes.

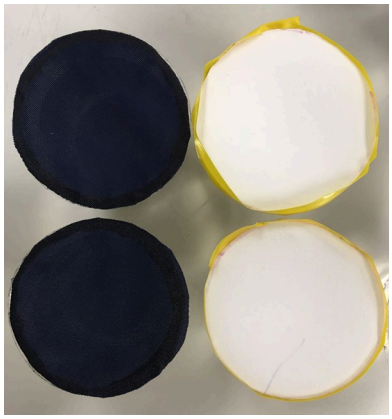


Figure 3.20 Opening of cups sealed with fabric specimens

3.4.3.6 Moisture management test

Patients with DQV need to wear a splint for long periods of time each day. During the summer or in hot weather, patients may sweat easily, which may cause discomfort while wearing the splint. However, they should not reduce their compliance with the treatment. To reduce their discomfort due to sweating while wearing the splint, the splint material should have good sweat wicking and moisture management properties. Since powernet fabrics have an obvious net structure with pores that are large enough for sweat droplets to escape from the inner side of the fabrics to the outside environment, only satinette and spacer fabrics, which have a higher fabric density than that of powernet fabrics, are tested with the AATCC 195 Liquid Moisture Management Properties of Textile Fabrics standard. In the test, the fabric specimen was placed between a top and a bottom sensor plate. A special solution with a standardised percentage of sodium, which replicates the sweat produced by the human body, was dripped onto the centre of the fabric piece. The spreading of the solution at the fabric surface and the penetration of the fluid to the bottom of the fabric sample were detected by the two sensor plates. The fibre composition, knit structure and finishing of the fabric may affect the solution spread. The testing procedures are described as follows:

1. Three square fabric specimens with dimensions of 8 cm (length) × 8 cm (width) was prepared from each test fabric.

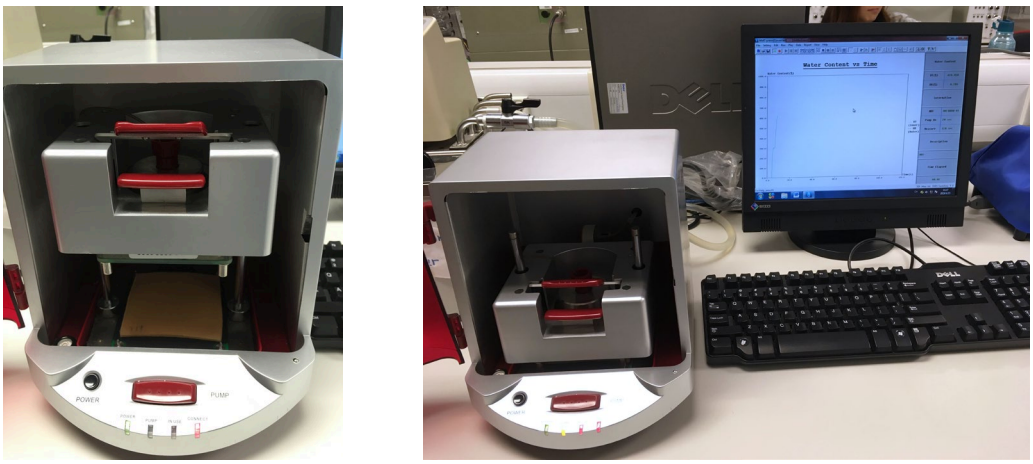
2. The fabric specimen was placed on the bottom sensor plate as shown in Figure 3.21(a).

3. The top sensor plate was gently lowered to secure the specimen between the two sensor plates (Figure 3.21(b)).

4. Computer software then triggered the commencement of the dripping of the solution. The 'Pump-On Time' was 20 seconds and the 'Measure Time' was 120 seconds.

5. Data related to the degree of solution spread and water penetration were measured and recorded.

6. Steps 2 to 5 were repeated to evaluate three specimens for each test fabric. It was ensured that the bottom sensor plate was dry before testing the next fabric specimen.



(a) (b)

Figure 3.21 (a) Fabric specimen placed on bottom sensor plate and
(b) Fixing specimen between top and bottom sensor plates

3.5 Fabrication of proposed functional splint

After conducting the fabric tests above, the most suitable fabrics were selected for constructing the proposed splint. For the areas along the thumb near the inflamed first dorsal compartment, which is where the thumb supporter is placed, a suitable spacer fabric was selected to protect and relieve the pressure from the rigid supporter. Satinette and powernet fabrics were used for the main part of the splint to control the shape. The materials of the main part of the splint have high air permeability and stretchability which can enhance the wear comfort and fit.

3.5.1 Splint pattern development

The development of splint patterns greatly depends on the shape and size of the hand. The Association of Hong Kong Gloves Traders Limited indicates that the hand circumference is measured with a measuring tape across the palm. The measurement starts at 20 mm from the crotch between the thumb and the index finger to the ulnar side of the distal palmar crease, as shown in Figure 3.22. The measurements of the hand circumference are then used to determine the hand size (Association of Hong Kong Gloves Traders Ltd, 2002).

Nominal sizes of Japanese gloves — Dimensions in millimeters

Hand size	6	6½	7	7½	8	8½	9	9½	10
Circumference	152	165	178	191	203	216	229	241	254

Figure 3.22 Measurement method of hand circumference and corresponding hand size

(Association of Hong Kong Gloves Traders Ltd, 2002)

The glove pattern of a ladies size 6.5 developed by Emlyn-Jones (1974) was adopted as the reference for the development of the proposed functional splint pattern. The pattern pieces in Emlyn-Jones (1974) include the main body and thumb pieces, fourchette and quirk for ease, and cuff pieces for decoration (Figure 3.23). For the proposed functional splint, the fourchettes and the finger parts of the main body pieces can be eliminated since the inflamed part is found along the radial side of the wrist which only involves the thumb. Furthermore, the distal part of the thumb piece could be adjusted as it is not necessary to cover the thumb tip with the splint. A splint with an opening at the thumb distal phalanx could allow better contact and sensation when performing pinch grip motions. Patients who wear the functional splint with the thumb opening may find it more comfortable with better air ventilation across the splint.

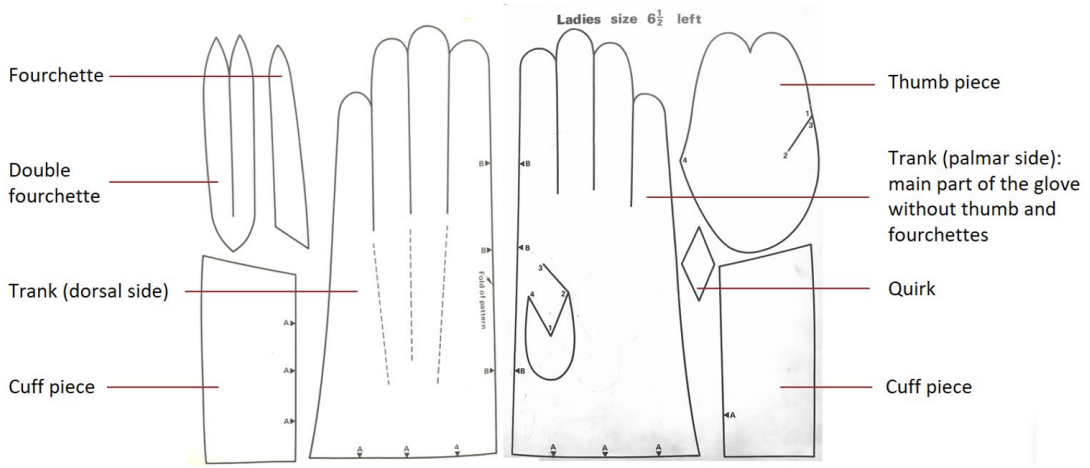
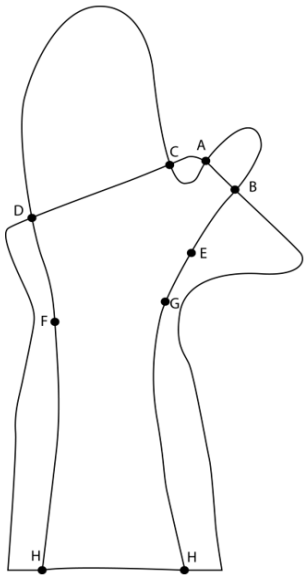


Figure 3.23 Basic glove pattern
(Emlyn-Jones, 1974)

Patterns for a thumb spica orthosis (Mahle & Ward, 2018) and a radial gutter thumb immobilisation orthosis (Coppard & Lohman, 2014) were reviewed (Figures 3.24 and 3.25). The material of both orthoses is a thermoplastic sheet. Both orthoses aim to immobilise the thumb and wrist motions, but at the same time, protect the injured hand from accidental shocks. This concept matches the idea for the immobilisation element of the functional splint for treating DQV. The pattern of both orthoses focus on the location of the radial and ulnar styloid of the wrist, radial and ulnar sides of the distal palmar crease, and the CMC joint. Both patterns show the boundaries of the thumb piece at the IP joint. Both orthoses cover around three quarters of the total forearm length for better support of the hand and wider distribution of pressure from the splint to the skin. The top edges of the splint edges at the line are created between the second and the fifth metacarpal heads, near the distal palmar crease, which allow the wearer to have higher range of finger movement and folding of the palm.

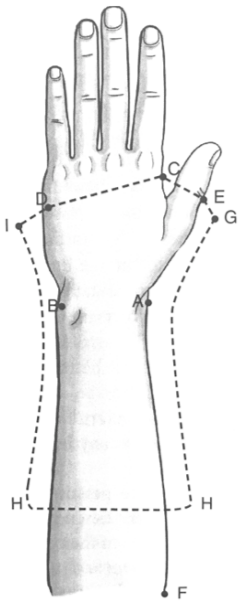


Pattern for thumb spica orthosis

- A, B: IP joint
- C: Radial side of the distal palmar crease
- D: Ulnar side of the distal palmar crease
- E: CMC joint of the thumb
- F: Ulnar styloid of the wrist
- G: Radial styloid of the wrist
- H: ¾ length of forearm

Figure 3.24 Pattern for thumb spica orthosis

(Mahle & Ward, 2018)



Pattern for a radial gutter thumb immobilization orthosis

- A: Radial styloid
- B: Ulnar styloid
- C: The second metacarpal heads
- D: The fifth metacarpal heads
- E: IP joint
- F: Olecranon process of the elbow
- G: Point extended from line CE (1-1.5 inches)
- H: Points along 2/3 length of the forearm (1-1.5 inches)
- I: Point extended from line CD (1-1.5 inches)

Figure 3.25 Pattern for a radial gutter thumb immobilisation orthosis

(Coppard & Lohman, 2014)

3.5.2 Splint fabric assembling

Single-needle lockstitch, also known as ISO #301 lockstitch (Cassidy & Goswami, 2018), is formed by interlacing a needle thread with a bobbin thread (Figure 3.26). This lockstitch is secure as a single stitch breakage in the middle of the seam would not lead to the complete unravelling of the seam. Since the single-needle lockstitch is a secure stitch, it can be applied to the proposed functional splint for the different combinations of fabrics, attach the fastening and Velcro tapes, and binding of fabric edges. The seams formed with single-needle lockstitches are strong enough to maintain and control the shape of the splint.

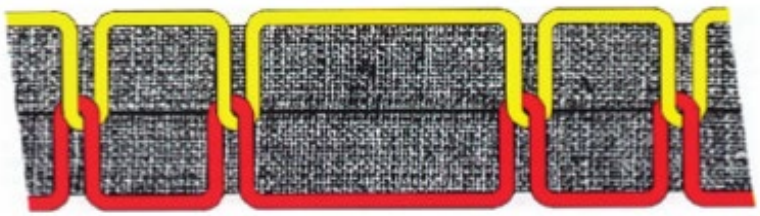


Figure 3.26 Single-needle lockstitch
(Cassidy & Goswami, 2018)

3.5.3 Development of hard components

3.5.3.1 Thumb and ulna supporter development

The thumb and ulna supporters are the two hard components attached to the splint body at the two sides of the hand. They are important components for limiting wrist and hand movements, and protecting the injured hand. After measuring the wrist and thumb curvature angles of the DQVS group, the mean results of angles α, β and θ at different cross-sectional curves were obtained. Using the measured angle results as reference, 3D models of the thumb and ulna supporters were created with Solidworks software. Figures 3.27 and 3.28 show the drawing process of the thumb and ulna supporters based on the measured angles.

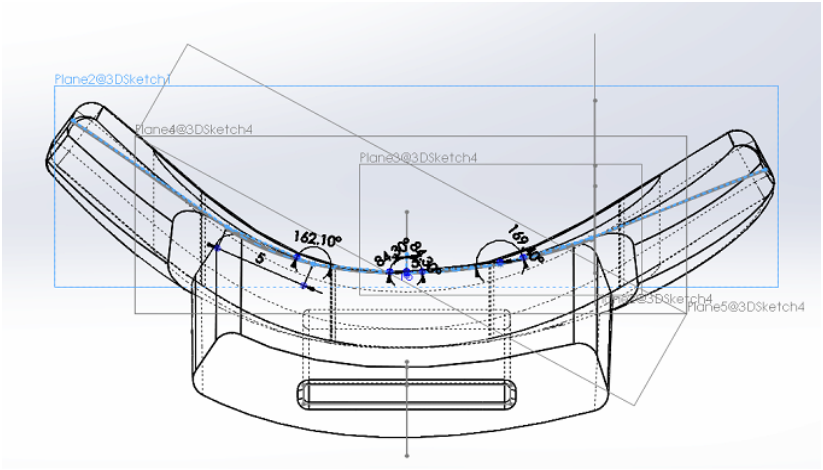


Figure 3.27 Drawing process of the thumb supporter

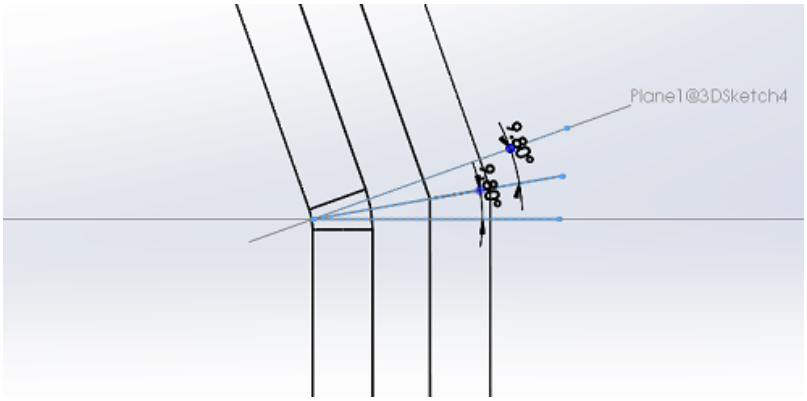


Figure 3.28 Drawing process of the ulna supporter

After developing the models of the two supporters, the models were exported as .stl files for 3D printing. Three types of 3D printing methods or additive manufacturing can be used to create the supporter prototypes for comparison purposes. Additive manufacturing is also known as 3D printing which creates model pieces by building and adding the materials layer by layer, from nothing to the final model product (Information Resources Management Association USA, 2017). The three 3D printing methods used were fused deposition modelling (FDM), stereolithography (SLA) and selective laser sintering (SLS). FDM builds 3D models by melting and extruding thermoplastic filaments from a heated printer nozzle onto the printing plate layer by layer. SLA forms a solid inside a liquid resin bath by solidifying the liquid resin layer by layer with exposure to high intensity light, such as a laser (France & Ebrary, 2014). SLS builds a solid by melting and fusing the particles with a high power laser beam (Marketsandmarkets, 2013). The plastic powder mainly used in this method is nylon.

To print the supporter prototypes, FDM was used on the Fortus 450mc machine, with acrylonitrile butadiene styrene (ABS). On the other hand, SLA was implemented with the Formlabs Form 2 printer, with grey resin. SLS was conducted with the EOS Formiga P 110 3D printer, with nylon plastic (PA12) powder.

3.5.3.2 Three-point bending and recovery test

In the design of the proposed functional splint, a metal piece was decided to be inserted inside the 3D printed pieces for linkage and reinforcement. 18 sets of metal pieces were prepared with specific dimensions for undergoing the three-point bending and recovery test. The goal was to select the most suitable metal piece for the thumb supporter. The selection was based on the recovery percentage results and the load results at the maximum flexural extension. Figure 3.29 shows the 18 sets of metal pieces and Table 3.3 shows the details of the materials and dimensions.

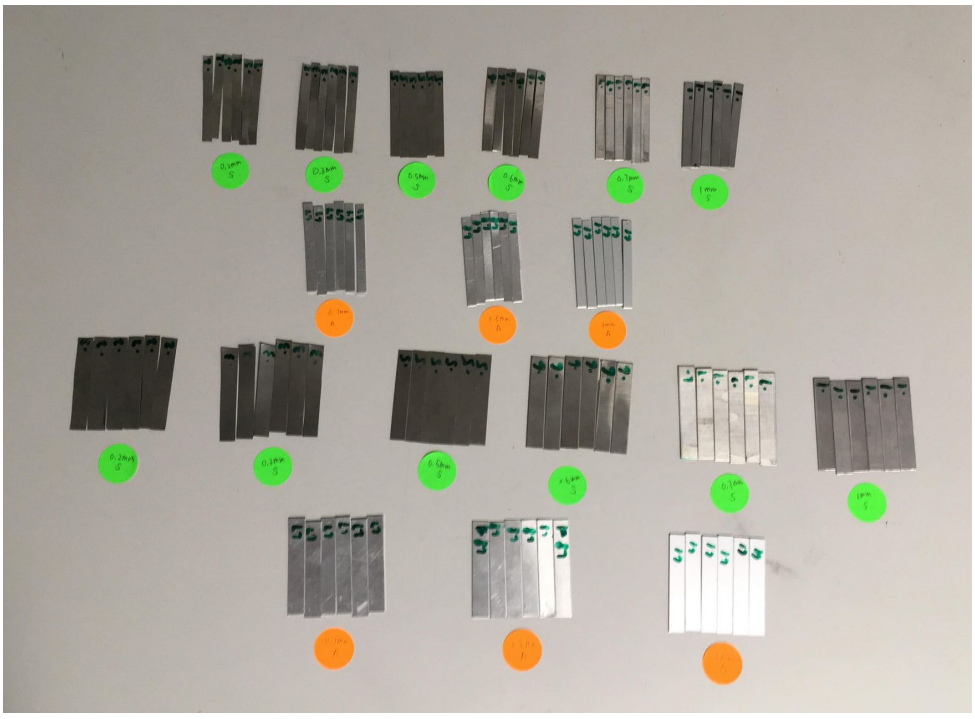


Figure 3.29 Sets of metal pieces

Table 3.3 Materials and dimensions of the metal pieces

Set number	Material	Thickness (mm)	Width (mm)	Testing distance between anvils (mm)
1	Stainless steel	0.2	6	35
2	Stainless steel	0.3	6	35
3	Stainless steel	0.5	6	35
4	Stainless steel	0.6	6	35
5	Stainless steel	0.7	6	35
6	Stainless steel	1	6	35
7	Aluminium	0.7	6	35
8	Aluminium	0.8	6	35
9	Aluminium	1	6	35
10	Stainless steel	0.2	10	35
11	Stainless steel	0.3	10	35
12	Stainless steel	0.5	10	35
13	Stainless steel	0.6	10	35
14	Stainless steel	0.7	10	35
15	Stainless steel	1	10	35
16	Aluminium	0.7	10	35
17	Aluminium	0.8	10	35
18	Aluminium	1	10	35

When carrying out the three-point bending and recovery test, a piece of metal was placed on the flexure fixture, with a gap distance of 35 mm between the two anvils. The top anvil, which was attached to the load cell, was placed onto the middle of the metal pieces. After setting the positions of the testing piece and the load cell, the top anvil was lowered for 5 mm, exerting pressure at the mid-point of the metal piece (Figure 3.30). The top anvil was then lifted up and returned back to the start position. During the bending test, the load exerted onto the metal piece at the lowest position of the top anvil was measured. In addition, the recovery ability of the metal piece after mid-point bending was obtained. The metal piece with higher strength and recovery ability was selected for composing the thumb supporter.

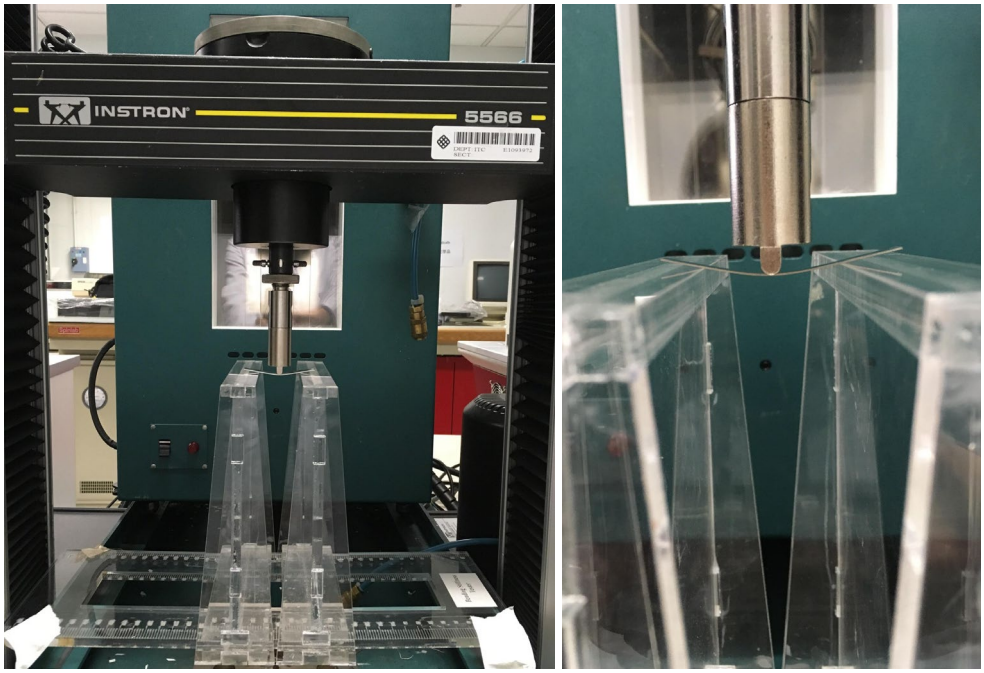


Figure 3.30 Three-point bending and recovery test of a metal piece

As with the test settings mentioned earlier, the three-point bending and recovery tests were also carried out on the printed prototypes for comparison purposes. After bending the specimens, the most appropriate type of material was chosen to be printed as the thumb and ulna supporters for the proposed design. Table 3.4 shows the materials information and tested dimensions of the specimens. Figure 3.31 shows the bending test of the specimen printed with ABS.

Table 3.4 Materials and dimensions of 3D printed prototypes

Material	Thickness (mm)	Width (mm)	Testing distance between anvils (mm)
ABS	3	15	35
Resin	3	15	35
Nylon	3	15	35

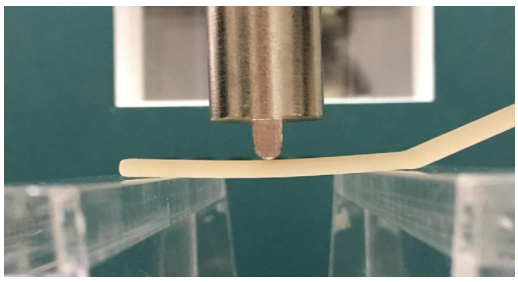


Figure 3.31 Three-point bending and recovery test of the ABS specimen

3.6 Preliminary Wear Trial

3.6.1 Inclusion criteria for subject recruitment

Women who are 18 years old or older, with DQV diagnosed by a professional clinician based on a positive result of the Finkelstein's test were recruited for the wear trial.

3.6.2 Exclusion criteria for subject recruitment

Those who received steroid injections for DQV in the past three months or have a history of hand surgery were excluded.

3.6.3 Study design and method

The study design of the wear trial is a single group pre-and post-test design. The purpose of the wear trial was to evaluate the effectiveness of the proposed functional splint. The intervention period was approximately three months, with interval follow-up sessions every month. Thirteen (13) subjects were recruited (WTS) who are all diagnosed with DQV by an orthopaedic physician. After the clinical session, a pre-test assessment was arranged for each subject to evaluate her hand condition and measure

her hand to prepare a splint with a thumb supporter that has the appropriate length. At the beginning of the pre-test, the diagnosis Finkelstein's test was performed by the patient to further ensure their symptom of DQV. Then, a form with a visual analogue scale (VAS) to assess pain level when conducting thumb and fingers extension and opposition and other daily activities was completed. The grip and pinch strengths were measured as the baseline data before the intervention. A ROM measurement test was carried out to investigate the degree of hand movement restrictions from the proposed functional splint. Pressure sensors were attached onto the hand to determine the pressure distribution exerted by the splint when the subject was performing different tasks. The 3D shape of the hand with and without the splint donned was scanned to understand the hand morphology and build an FE model in the later stages of the study. The *Quick*DASH questionnaire was completed to provide a better understanding of the patient's situation before the intervention took place. The subjects were instructed to take the splint home and start to wear the device, and wear the splint as much as possible, for at least 8 hours each day for protecting and stabilising the hand. On the second week, a short questionnaire was delivered to them via a social communication app to understand their splint wear and other concerns. Face-to-face follow up sessions were then arranged in the first, second and third months. During each follow up session, diagnosis testing was carried out, questionnaires were given to the participant, and grip and pinch strength measurements were performed to collect data to compare the hand conditions before and after the intervention. Figure 3.32 illustrates the flow of the wear trial.

Figure 3.32 Wear trial flow

3.6.3.1 Questionnaire for hand condition evaluation

The primary outcome of this study are the changes in pain level of the injured hand of the patients. To understand these changes, the *Quick*DASH questionnaire was completed by the patients before and after the splint wear trial. This questionnaire is a proper tool to evaluate health status in the past week, difficulties of the patients when carrying out daily tasks, the symptoms and pain level of their affected hand, and the impacts on their personal and social aspects due to the hand condition.

3.6.3.2 Grip and pinch strengths

Nemati et al. (2017) carried out a study to compare effectiveness of traditional and dynamic splints, in which they measured the pre and post-test palmar and lateral pinch strengths of patients to evaluate the effectiveness of the two types of splints. Therefore, to evaluate the effectiveness of the proposed functional splint, the grip and pinch strengths before and after the intervention will be measured and compared in the wear trial in this study. The grip and pinch strengths are the secondary outcomes of this study. They will be measured by using a dynamometer and pinch gauge respectively, as shown in Figure 3.33(a) and 3.33(b).

(a) (b)

Figure 3.33 Hand strength measuring tools: (a) Dynamometer, and (b) Pinch meter

3.6.3.3 Pressure test

Since the patients were instructed to wear the proposed functional splint, which is composed of both hard and soft elements, for at least 8 hours per day, it is worth investigating the pressure distribution of the splint on the patient's skin. It is important to control the pressure exerted by the splint as applying high levels of pressure on the skin for long periods of time may lead to skin irritation and pressure ulcers. To investigate the pressure distribution from the splint, the Pliance®-xf-16 system (Figure 3.34) was utilised, which measures the contact pressure by using 6 distal sensors between two contact surfaces. The sensing area of each distal sensor is 78 mm^2. The measured range of pressure is 0 kPa to 60 kPa. Each sensor was assigned and attached at different locations of the patient's hand so as to measure the pressure given from different parts of the splint, especially parts that have rigid supporters. The locations of the 6 sensor heads are shown in Figure 3.35. Measurements were done at two static positions for 30 seconds: holding up of hand in resting position and with fingers extended.

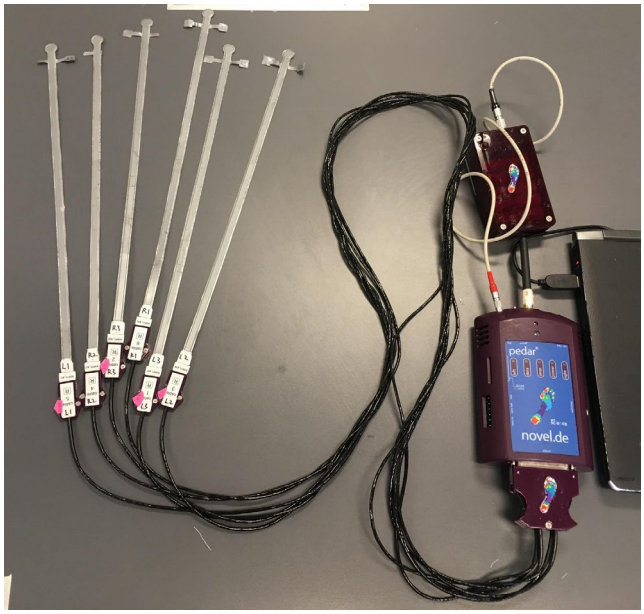


Figure 3.34 The Pliance®-xf-16 system

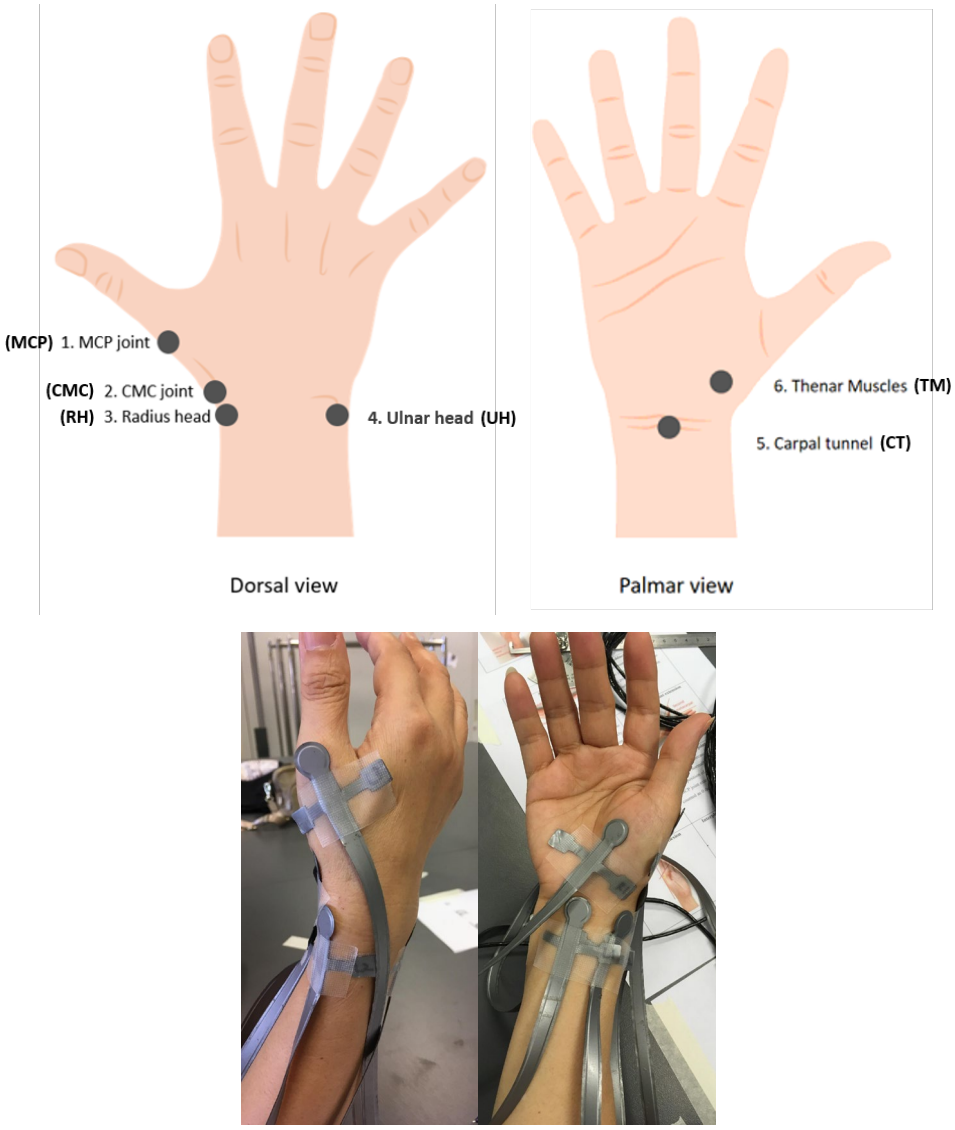


Figure 3.35 Locations of the 6 pressure sensor heads

After measurements were conducted in the two static positions, the subject was instructed to perform two sets of movements. The pressure at the 6 assigned locations was measured and recorded during hand movement. The first set of movements was to grip and move a bottle filled with 250 ml of liquid between two points with a fixed distance. Bottle gripping is one of the common types of 'power grips', during which the object is held by the digits against the palm with the help of the thumb, and involves the use of certain levels of force and strength. Figure 3.36 shows the setting of the experiment. The patients were asked to hold up and move the bottle between Points A and B for 3 times. Between each move, the subject's hand rested at Point C for 10 seconds.

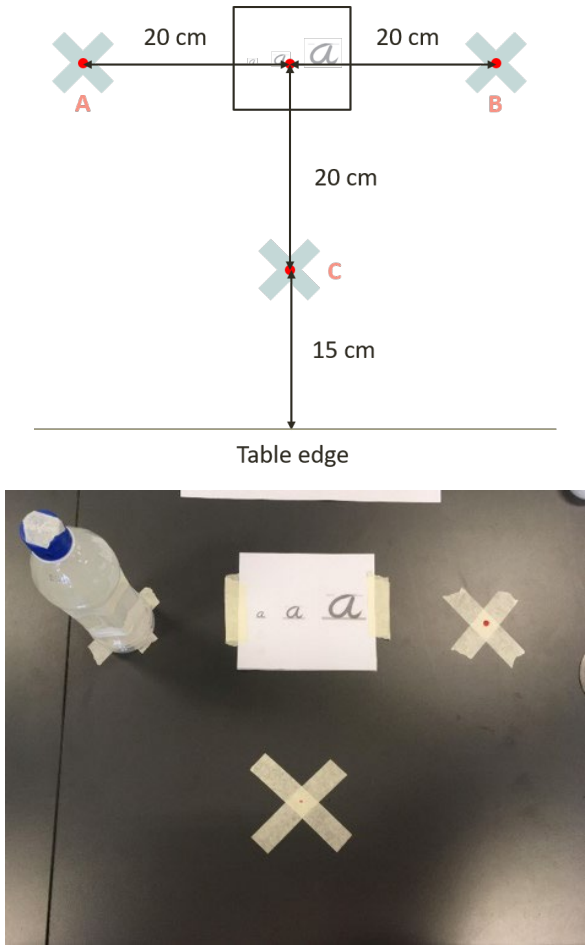


Figure 3.36 Experimental setting of bottle gripping test

The second set of movements was to write three different sizes of the letter ‘a’, in order of ascending size. Between the writing of each letter, the hand of the subject rested at Point C for 10 seconds. Writing is one of the most common movements that involve ‘precision grips’. ‘Precision grips’ are fine hand motions that are performed mainly by using the MCP joints and phalanges. Figure 3.37 shows the experimental setting and writing process of the letter ‘a’ with a donned splint.

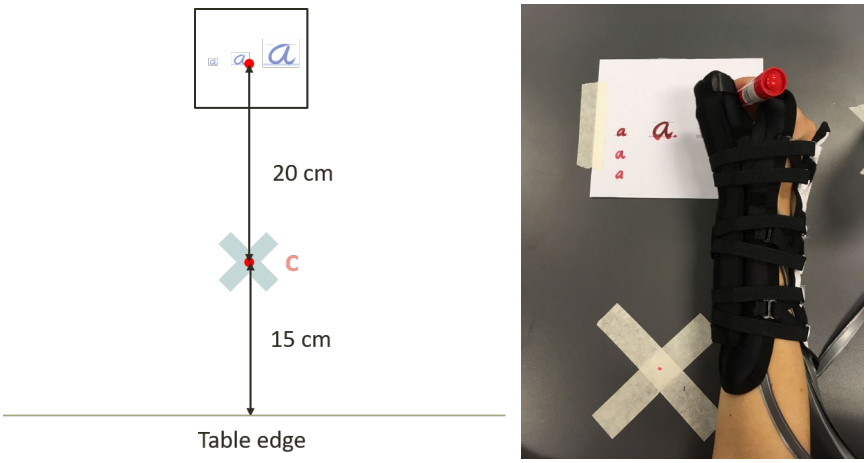


Figure 3.37 Experimental setting of letter writing test

3.6.3.4 Hand restriction test with proposed functional splint

The main purpose of splinting is to control the injured hand in the resting position and restrict hand movement. To evaluate the degree of restriction controlled by the proposed functional splint, the subjects were requested to perform various hand positions with and without the splint. The hand positions include wrist flexion, wrist extension, radial deviation, ulnar deviation, thumb abduction, CMC joint extension and MCP joint flexion. The ROM of each hand position was measured by using goniometer and recorded for comparison purposes.

3.6.3.5 Splint evaluation questionnaire

The functional ability of the proposed splint can be reflected by the pain level experienced by the wearers, who were instructed to complete the *Quick*DASH questionnaire at the pre-test and post-test stages. Their satisfaction with the proposed splint is also important since the results may affect their compliance with the treatment. To measure the degree of satisfaction with the splint, a questionnaire that contains questions related to fit, breathability and comfort of the splint, and VAS to determine the level of satisfaction, were given to the subjects to complete after intervention.

It is also worthwhile to gain a better understanding of the quality of life of the patients when they were wearing the splint on a daily basis. Therefore, the Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12) was used to measure the physical and mental conditions of the patients. The patients were asked to fill in the SF-12 at their second and third follow up sessions. The SF-12 is a shortened version of the

Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), which can produce the physical component summary (PCS) and the mental component summary (MCS) scales (Lam, Lam, Fong, & Huang, 2013). The SF-12 is a reliable alternative based on the SF-36 with multiple R squares of 0.918 and 0.911 in the predictions of the SF-36 mental and physical component summary scores respectively (Ware, Kosinski, & Keller, 1996). Compared to the completion time for SF-36, less time is needed for the SF-12, which can increase the efficiency of each follow-up session. The SF-12 v2 is an edited version of SF-12. Compare to the SF-12, some of the terms have been changed and more answer options are added to some of the questions in the SF-12 v2 (Soh et al., 2021). The standard SF-12 was first validated by Lam, Tse, and Gandek (2005) who indicated that it is valid for the Chinese population. Afterwards, the SF-12 v2 was again validated and proved to be reliable and sensitive to the Chinese population by Lam et al. (2013).

The survey rates health and overall body functions in the past week. The assessment of health status includes two scores, the PCS and the MCS. The PCS is derived from four scales: 'Physical Functioning (PF)', 'Role-Physical (RP)', 'Bodily Pain (BP)' and 'General Health (GH)'. On the other hand, the MCS is derived from four other scales: 'Vitality (VT)', 'Social Functioning (SF)', 'Role-Emotional (RE)' and 'Mental Health (MH)' (Ware, Kosinski, & Keller, 1995). The score of each scale is calculated from specific questions, as shown in Figure 3.38.

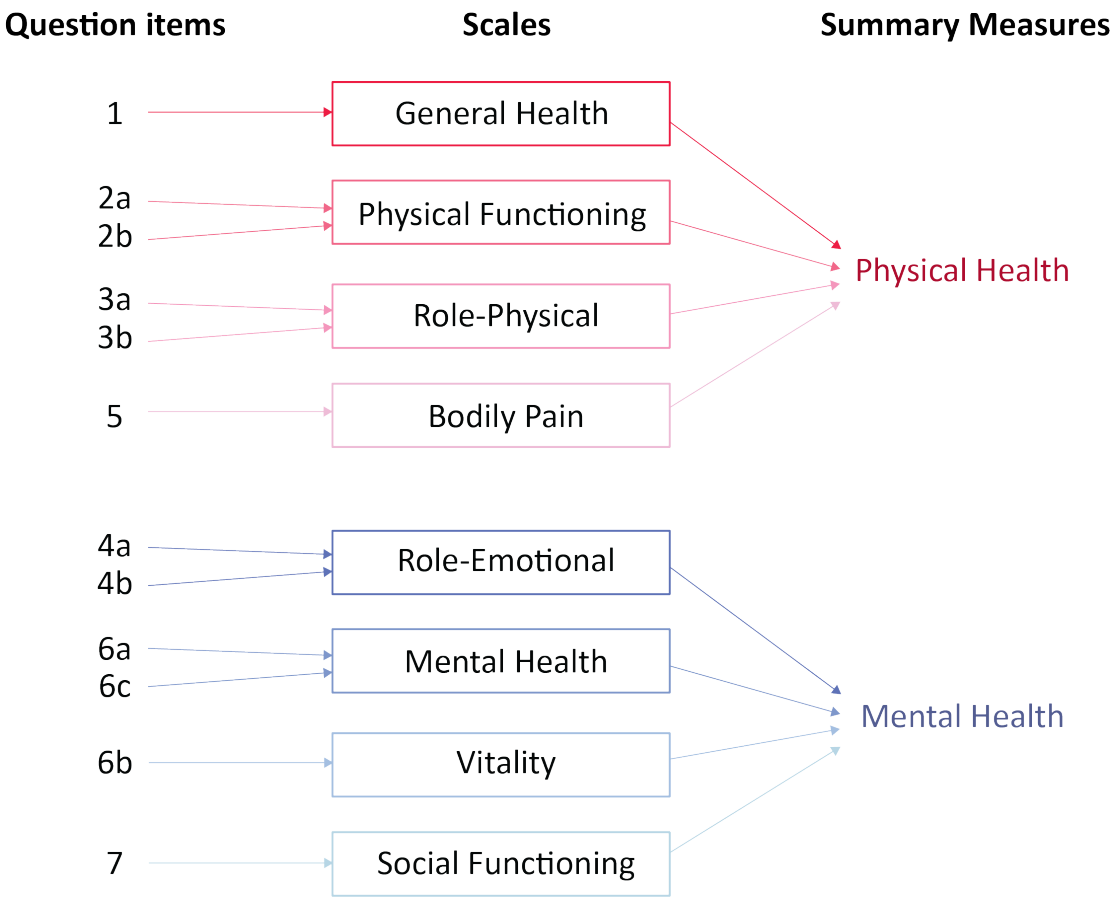


Figure 3.38 Scoring system of SF-12 v2

3.6.3.6 Statistical analysis

The IBM SPSS version 26 was used to analyse the responses to the questionnaires. Referring to the results of the normality tests of the data, a non-parametric Friedman test was carried out to compare the pain level of specific hand positions, while, a repeated measures ANOVA was conducted to compare the hand grip and pinch strength between the pre-test and post-tests. The ROM results of patients with the wearing of proposed splint and bare hand were compared with the Wilcoxon signed ranks test. The *Quick*DASH and further ROM study results were analysed by using the Friedman test. A Spearman's rank correlation test was carried out to investigate the correlations between the VAS and the *Quick*DASH scores.

3.7 Finite element model of proposed functional splint

Patients who undergo splinting for DQV need to wear the splint for long hours but according to Chow (2009), some feel that the thermoplastic splint is too hard and cause pain at the protruding bony structures of the wrist and thumb, like the radial styloid process and the MCP joint. Due to the discomfort, compliance might be reduced which ultimately may affect the degree of relief of symptoms during and after treatment. To understand more about the pressure exerted by different parts of the splint onto the hand, an FE model was developed to simulate splint wear and predict the pressure distribution from the splint. The simulation was carried out by using FE modelling software ABAQUS/CAE (Dassault Systémes SA, France). The simulation of the pressure distribution from the splint primarily requires two items: first, the hand, and second, the splint, which includes the fabric and supporters. The steps for building the simulation model are: 1) constructing the hand model, 2) constructing the splint model, 3) selecting the type of element, 4) importing data of material properties, 5) mesh development of the models, 6) determining the initial and boundary conditions, 7) determining the component displacements, 8) simulating the defined model, 9) evaluating the simulated pressure distribution results, and 10) validating the results.

3.7.1 Constructing hand model

A hand model was constructed for the simulation of the pressure exerted from the proposed functional splint to the subject's hand. A subject with DQV was recruited and participated in the development of the FE model. Since the simulation only concerns the pressure distribution on the surface of the hand, cross sections of the hand are not necessary. To obtain the surface of the injured hand, the 3D shape of the hand was scanned by using the Artec Eva handheld scanner. The 3D image of the hand was adequate enough to build the flesh body of the hand model.

The details of the hand model include the bone and ligament models. The bone model was derived from a set of 3D human bone model (Figure 3.39). The 27 hand bones were selected and extracted from the set of human bones. Each of the hand bones was scaled and re-oriented by using Solidworks (Figure 3.40), so as to match the contours of the flesh model (Figure 3.41).

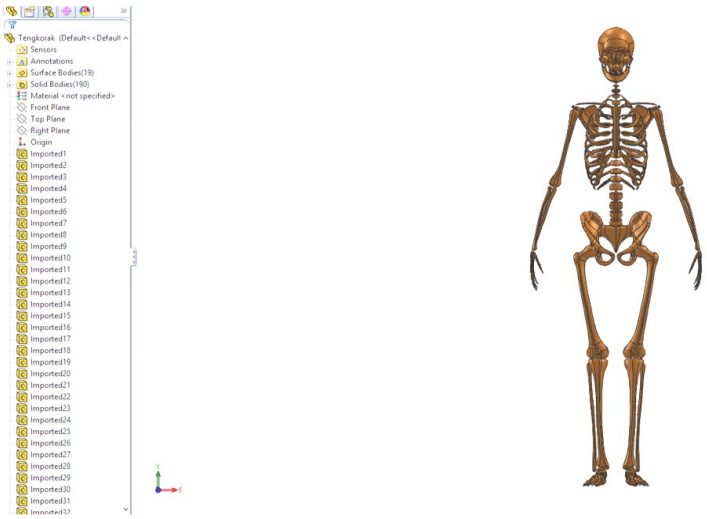


Figure 3.39 Set of human bones model

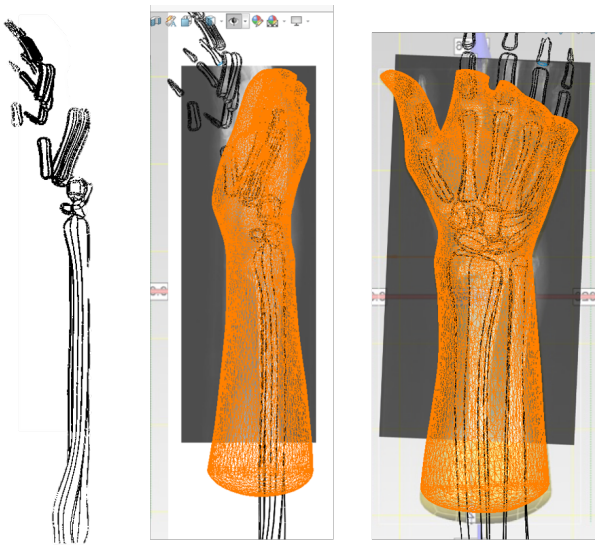


Figure 3.40 Scaling and re-orientation of 27 hand bones

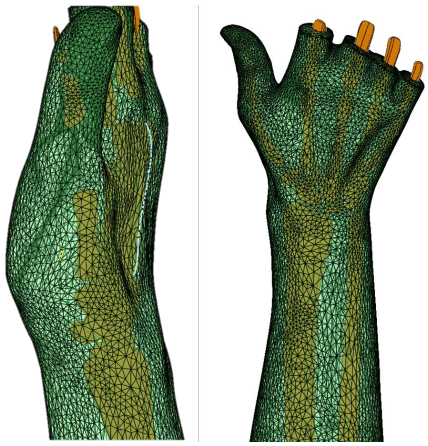


Figure 3.41 Matching with the contours of the flesh model

With reference to the anatomical structure of the hand ligaments (Figure 3.42) (Drake, 2015; Joseph, 2006), a simplified version of the ligament model was developed to act as the linkages between the bones (Figure 3.43).

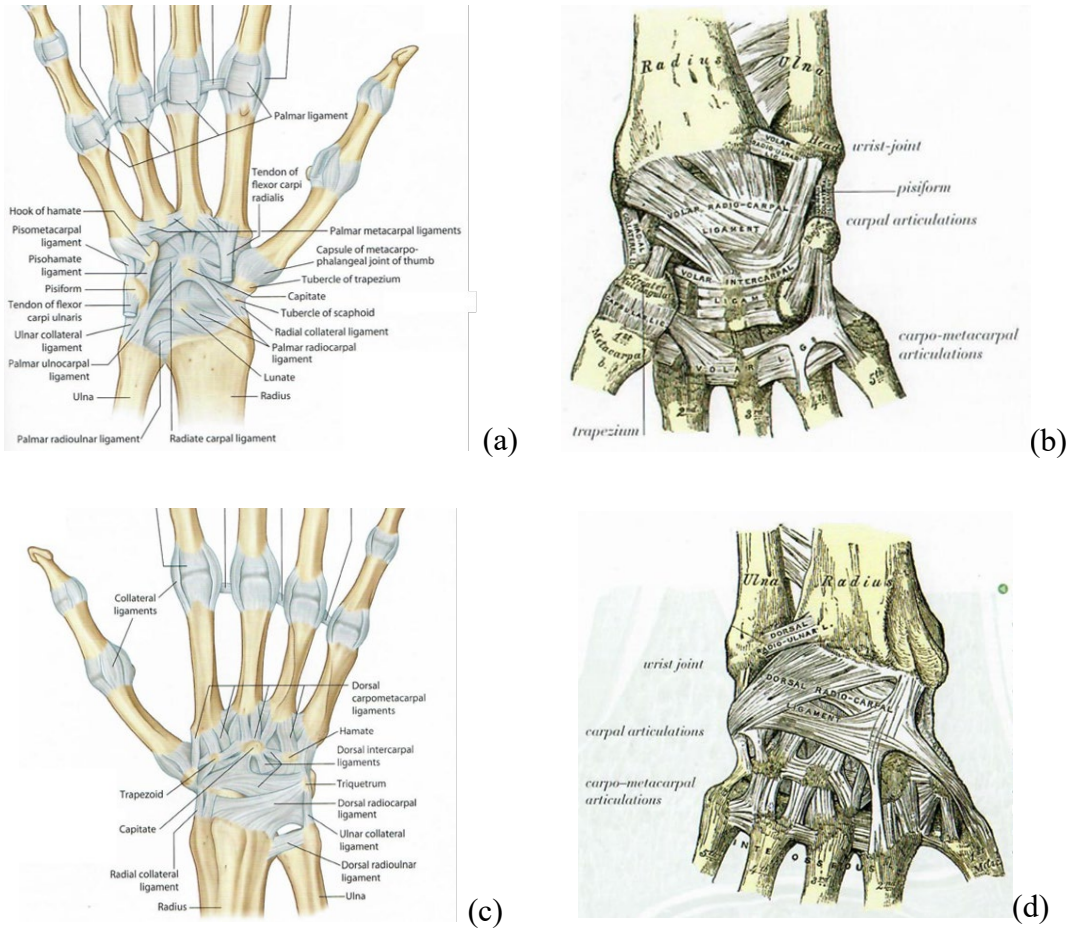


Figure 3.42 Anatomical structure of the hand ligaments:
(a) and (b) palmar views of right hand; and (c) and (d) dorsal views of right hand
(Drake, 2015; Joseph, 2006)

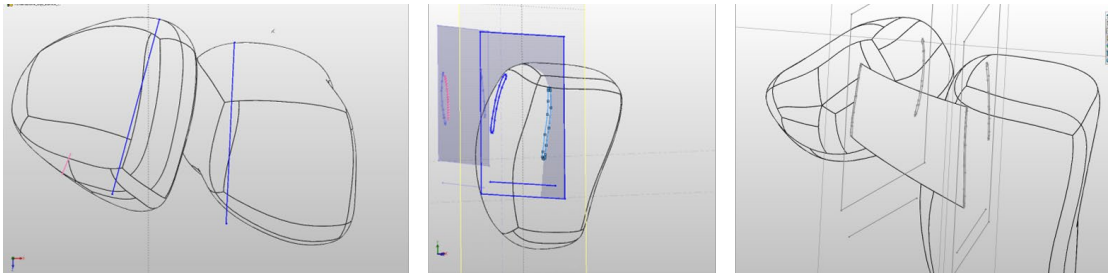


Figure 3.43 Development of ligament piece between two bones

3.7.2 Constructing splint model

The splint model includes two main parts, the fabric and the supporters. The splint model was developed based on the hand model and the splint design. Since the splint fits well on the subject's hand, the contours of the fabric model were extracted from the hand model in Geomagic software. The fabric at the radial portion of the hand represents the spacer fabric with a thickness of 2 mm. The fabric at the ulnar portion of the hand represents the combination of satinette and powernet fabrics with a thickness of 1 mm. The thumb and ulna supporter models were created with SolidWorks 2018 in accordance with the hand joint angles and thumb curvature results measured from the DQVS group.

3.7.3 Selecting type of element

Tetrahedron and hexahedron elements are commonly used in 3D solid models. The elements were particularly arranged so that the mesh of the solid was formed. The entire mesh is represented by the algebraic equations in the system (Cook et al., 2002). During the analysis process, the system will calculate the equations of each element step by step and ultimately complete the simulation work. Tetrahedron elements were used to build up all the parts of the model. The mesh size of the flesh model is 10. On the other hand, the mesh size of the splint at the thumb and ulnar sides are 8 and 3.2 respectively.

3.7.4 Determining the boundary conditions

The FE model in this study simulates the wear process of the splint, so as to observe the changes in pressure distribution from the splint to the hand. To simulate the wear movement of the splint, setting static and displacement boundary conditions was necessary. The static boundaries were set at the bottom of the hand and the vertical seams between the fabrics along the palm to the wrist. The displacement boundaries were set along the two edges of the fabrics at the dorsal area of the hand. The two fabric edges were set to move towards each other, so as to simulate the closing of the splint opening. The splint fastenings are neglected for simplification purposes. Interaction between the splint and surface of the hand was determined as 'surface-to-surface contact'.

3.7.5 Importing data on material properties

The different values of the fabric properties are imported into the modelling system, which were obtained from the real fabric test results. The properties of the supporters, such as the Young's modulus and Poisson's ratio, were tested for data insertion. The equations for calculating the Young's modulus and Poisson's ratio are shown as follows,

$$E = \frac{\sigma}{\varepsilon}$$

where

E: Young's modulus

σ: stress

ε: strain

$$\nu = \frac{\varepsilon_1}{\varepsilon_2}$$

where

v: Poisson's ratio

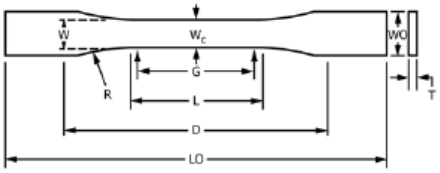
ε_1: lateral strain (strain that occurs perpendicular to the direction of the load)

ε_2: axial strain (strain that occurs along the same direction of the load)

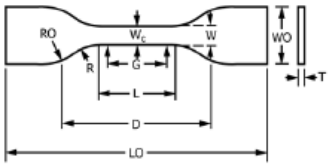
According to ASTM D883 Standard Terminology Relating to Plastics, plastics with a Young's modulus higher than 700 MPa are defined as rigid plastics. Plastics with a Young's modulus between 70 to 700 MPa and less than 70 MPa are classified as semi-rigid and non-rigid plastics, respectively. Since the Young's modulus of the selected ABS materials used to construct the supporters of the splint is less than 70 MPa, the ABS material here is defined as a non-rigid plastic. To obtain the Young's modulus and Poisson's ratio of the selected ABS material, the ABS specimens were tested with the Instron 5982 tensile machine (Figure 3.44).

Figure 3.44 Instron 5982 tensile test machine

According to the ASTM D638 Standard Test Method for Tensile Properties of Plastics, non-rigid and semi-rigid plastics should be tested in the form of Type IV specimens when direct comparisons between the materials in various rigidity cases are required. Therefore, the test specimens of the selected ABS material for the splint supporters are referenced to the dimensions of Type IV specimens, as shown in Figure 3.45. However, in order for the clamps of the Instron 5982 tensile tester to accommodate the specimens and provide sufficient areas for detection at the middle of the specimens to obtain the Poisson's ratio with marked points, all of the standard measurements of Type IV specimens were scaled up to two times that of the original dimensions.



TYPES I, II, III & V



TYPE IV

Specimen Dimensions for Thickness, *T*, mm (in.)[A]

Dimensions (see drawings)	7 (0.28) or under		Over 7 to 14 (0.28 to 0.55), incl	4 (0.16) or under		Tolerances
	Type I	Type II	Type III	Type IV[B]	Type V[C,D]	
W—Width of narrow section[E,F]	13 (0.50)	6 (0.25)	19 (0.75)	6 (0.25)	3.18 (0.125)	±0.5 (±0.02)[B,C]
L—Length of narrow section	57 (2.25)	57 (2.25)	57 (2.25)	33 (1.30)	9.53 (0.375)	±0.5 (±0.02)[C]
WO—Width overall, min[G]	19 (0.75)	19 (0.75)	29 (1.13)	19 (0.75)	...	+ 6.4 (+ 0.25)
WO—Width overall, min[G]	...	...	...	...	9.53 (0.375)	+ 3.18 (+ 0.125)
LO—Length overall, min[H]	165 (6.5)	183 (7.2)	246 (9.7)	115 (4.5)	63.5 (2.5)	no max (no max)
G—Gage length[I]	50 (2.00)	50 (2.00)	50 (2.00)	...	7.62 (0.300)	±0.25 (±0.010)[C]
G—Gage length[I]	...	...	...	25 (1.00)	...	±0.13 (±0.005)
D—Distance between grips	115 (4.5)	135 (5.3)	115 (4.5)	65 (2.5)[J]	25.4 (1.0)	±5 (±0.2)
R—Radius of fillet	76 (3.00)	76 (3.00)	76 (3.00)	14 (0.56)	12.7 (0.5)	±1 (±0.04)[C]
RO—Outer radius (Type IV)	...	...	...	25 (1.00)	...	±1 (±0.04)

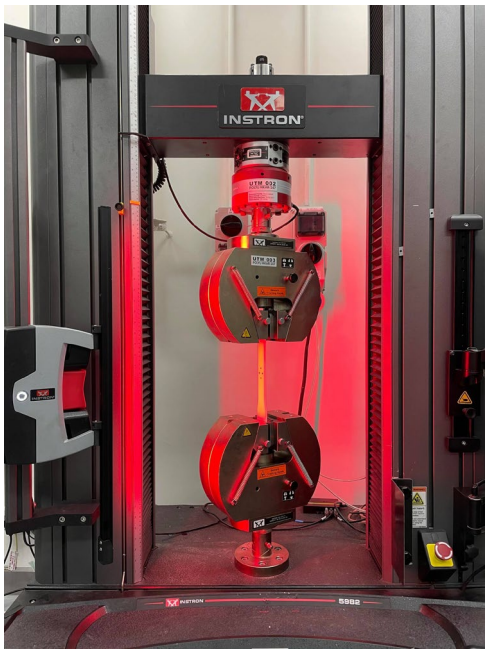
Figure 3.45 Specimen dimensions from ASTM D638 standard test

The Young's modulus of the fabrics used in different parts of the splint was also tested and measured by using the Instron 5982 tensile tester. Spacer fabric was used for the radial part of the splint while the ulnar part of the splint was composed with combined layers of satinette and powernet fabrics. The dimensions of the specimens are 25 mm (length) x 5 mm (width). The length of the fabric specimen was placed at the same direction of the stress applied. Five specimens of the printed ABS, spacer fabric and satinette and powernet fabrics were prepared and tested (Figure 3.46). The mean values were calculated and inputted into the FE model database. Figure 3.47 shows the testing processes of the 3D printed ABS and fabric specimens.

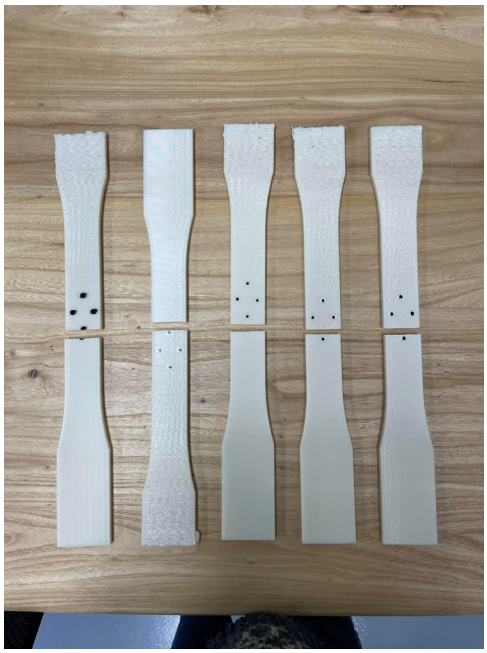
Figure 3.46 Test specimens for the ASTM D638 standard test

(a)

(b)



(c)



(d)

Figure 3.47 (a) Testing processes of the specimens, (b) spacer fabric;
(c) combined sample of satinette and powernet fabrics; and
(d) 3D printed ABS

The FE model can simulate the stress given by different parts of the splint according to their properties and predict the pressure distribution on patient's hand while wearing the splint. To investigate the effect of different fabrics used in the splint on the resultant pressure exerted at different regions of the hand, the properties of the fabrics in the splint model can be modified. Validation of the model was carried out by comparing the produced results from the model to the real measured results in the wear trial.

3.8 Chapter summary

This chapter describes the methodologies used to investigate the designs and fabric used in splints available in the current market. Two splint samples are purchased for conducting an experiment that aims to evaluate the effectiveness of the two splints in restricting hand movement. The ROM of the wrist and thumb is discussed and the subjects in the experiment conducted different hand movements.

After gaining a better understanding of the characteristics and performance of the two currently available splints and identifying their limitations, a functional splint is proposed. To develop this proposed splint, the first step is to investigate the condition of patients with DQV, basic clinical check-up process and the clinic procedures of fabricating splints. Afterwards, investigations on the ergonomic shape of the hand and curvature of the thumb are carried out. The results of the measured angle of the hand serve as reference for developing the proposed splint with a good fit. Different devices and software are used for hand scanning and angle measurements.

Fabric tests are then carried out for selecting the most suitable fabrics to construct different parts of the splint. The selected spacer fabric is used to protect the affected areas of the hand, and fabrics with higher air permeability, such as satinette and powernet, are used for the other unaffected parts of the hand. The hard components, which are the thumb and ulnar supporters, are developed by using Solidworks software with reference to the measured angle results.

After constructing the proposed functional splint, a pre and post-test wear trial study is carried out to evaluate the effectiveness of the proposed splint in terms of grip and pinch strengths, the scores of *Quick*DASH score and degree of satisfaction towards the proposed splint. The post-test stage includes 3 follow up sessions, which are carried out on a monthly basis.

The last part is the formation of the FE model to predict the pressure distribution on the hand from the splint. The FE model includes the hand and splint models which are composed of soft fabric parts and hard supporting components. The FE model simulates the closing motion of the splint fasteners and investigates the stress exerted from the splint to the surface of the hand during and after the wear process. Validation of the FE model is conducted by comparing the predicted results with real data collected from the wear trial.

Chapter 4 Review of available splints and development of proposed functional splint

4.1 Introduction

In this chapter, an evaluation of splinting products available in the current market is conducted. The experimental results after evaluating the effectiveness of two splints that limit hand movement purchased in the market are presented. After evaluating the commercially available splints, the observed results from a visit related to the clinical check-up of patients with DQV and fabrication procedures of the two splints offered by the clinic are presented. Possible issues with the two clinical splints are discussed. To develop a splint with an excellent fit, an investigation on the ergonomic shape of the wrist and thumb is implemented. The different angles of the wrist and curvatures of the thumb are measured. Comparisons between the results of the measured angles between the subject groups are done. Explanations are also provided on the fabric test results so as to choose the most appropriate fabrics to construct a splint with wear comfort.

4.2 Evaluation of current splints

4.2.1 Review of splinting products in current market

BraceAbility Thumb & Wrist Tendonitis Splint for DQV Treatment

The BraceAbility wrist splint (Figure 4.1) is used to treat various kinds of wrist injuries, including DQV, rheumatoid arthritis, rhizarthrosis, tendonitis, and sprains and strains of the wrist or thumb. A removable aluminium stay is inserted in the splint along the thumb so as to provide support and immobilise the MCP joint and CMC saddle joint. The rigid thumb stay might be moulded to the shape of the hand of the user. The splint is composed of durable and breathable materials with a padded lycra lining for comfort enhancement. The palmar stay is used to stabilise the wrist. The splint is contoured at the palmar area, fifth MCP joint and thumb supporting region to allow a reasonable degree of hand movement, such as clenching and grasping. Three hook and loop closures are used from the wrist to the forearm to ensure the fixed position of the splint. Hook and loop closures also make it easy to don and doff the splint. Black colour is used so that stains and dirt will not show. Four sizes from XS to L are available.

Figure 4.1 BraceAbility Thumb & Wrist Tendonitis Splint for treating DQV
(BraceAbility, 2022)

BRACOO TP31 Thumb & Wrist Brace

The *BRACOO* thumb and wrist brace (Figure 4.2) claims to treat DQV, carpal tunnel syndrome and arthritic symptoms. The brace comprises breathable fabrics that are soft and skin-friendly. The material compositions include 35% polyester, 25% nylon, 25% cotton and 15% rubber. A contoured metal insert is embedded in the splint along the thumb region to restrict the lower thumb joints, so as to allow the inflamed tendons to rest and heal. Velcro straps are used as the fastening system of the splint for users to adjust the tightness based on the size of their hand. The splint is donned by wrapping the fabric with Velcro straps around the hand from the thumb to the wrist, thus securing the attachments. The tip of the thumb is not covered and restricted, so that users can perform simple daily tasks with minor thumb tip movements.

Figure 4.2 BRACOO TP31 Thumb & Wrist Brace
(BRACOO, 2022)

PROCARE® Quick-fit™ W.T.O.

The *PROCARE®* splint (Figure 4.3) is worn to address different pain conditions of the hand, such as scaphoid injuries, sprains and strains of the hand, gamekeeper's thumb and DQV. The splint is composed of nylon foam which contributes to the light weight of the splint. A contoured rigid palmar and thumb supporting component made of aluminium is embedded to hold the hand in the proper position. Elastic straps with D-ring closures, together with a piece of dorsal fabric attached beneath the straps allow free size adjustment. Universal size is available for both the left and right hands.

Figure 4.3 PROCARE® Quick-fit™ W.T.O.
(DJO Global, 2022)

Mars Wellness New 8" Universal Wrist and Thumb Splint

The *MARS Wellness* wrist and thumb splint (Figure 4.4) provides support to the wrist and thumb and is suitable for patients with DQV or strains and sprains of the MCP joint or basal joint arthritis or other hand disorders. The splint provides an adjustable thumb supporter for thumb immobilisation and a malleable palmar stay for wrist support. The fastening combination of hook straps and D-ring closures offers universal sizing of the splint.

Figure 4.4 Mars Wellness New 8” Universal Wrist and Thumb Splint
(Mars Med Supply, 2022)

Velpeau Wrist Brace with Thumb Spica Splint Support

The *Velpeau* wrist brace (Figure 4.5) provides support to the wrist and thumb. The brace claims to relieve pain of the hands of patients with DQV, scaphoid fracture, carpal tunnel syndrome or other painful hand conditions. The splint is also suitable for athletes who injure their hand during sports events. The splint is constructed with comfortable and lightweight materials. Joint stabilisation is enabled by protecting the joints with breathable compression fabric. A soft sponge pad is placed in the palm region for wear comfort. The Velpeau splint exerts a small amount of pressure across the wrist at the CMC joint to support and stabilise the wrist. The wrist and thumb are also supported with a flexible plastic thumb supporter, two flexible supporting strips at the dorsal side of the hand and two removable aluminium contoured stays at the palm. The brace can also absorb sweat. Velcro straps are available to adjust the tightness of the brace. Users can select from regular or shorter versions of the device.

Figure 4.5 Velpeau Wrist Brace with Thumb Spica Splint Support
(Amazon, 2022)

Copper Compression Recovery Thumb Brace

The purpose of the *Copper Compression* recovery thumb brace (Figure 4.6) is to treat hand pain, tendinitis, arthritis, trigger thumb and other hand problems. The splint is designed to stabilise and support the thumb comfortably with a specific type of fabric that contains of 88% copper nylon. This special kind of fabric can withstand washing and maintain the functional performance of the splints. Velcro tape is used to adjust the size, thus this universal size meets the need of both male and female users.

Figure 4.6 Copper Compression Recovery Thumb Brace
(Copper Compression, 2022)

Össur Formfit® Thumb Spica Splint

The *Össur* thumb spica splint as shown in Figure 4.7 is suggested for those who suffer from tendonitis like DQV or other soft tissue injuries like gamekeeper's thumb, sprains and strains. The spica splint is designed to fit the contours of the hand from the wrist to the thumb, ultimately to restrict the movement of the wrist and thumb. It is composed of breathable and lightweight materials. Customisation of the rigid insertions can be done. Contact closure straps are used to fasten and fix the splint into the right position. The splint is available in a range of sizes from XS to XL based on wrist circumferences. A gel pad for hot or cold therapy, which is the same size as the thumb spica, can be ordered as an option.

Figure 4.7 Össur Formfit® Thumb
(Össur, 2022)

Mueller Adjust-To-Fit® Thumb Stabilizer

The *Mueller* thumb stabiliser (Figure 4.8) aims to relieve pain caused by ligament strain, degenerative joint pain, osteoarthritis, and other thumb joint pain associated with repetitive thumb movement, such as gaming and texting. The thumb stabiliser is designed to support and restrict movement of the thumb, especially the MCP joint. The amount of compression exerted by the stabiliser can be easily adjusted by using the three attached straps. The adjustable straps also facilitates donning and doffing of the device with ease. The materials used are said to be odour resistant and antimicrobial, and the splint does not use latex, neoprene or natural rubber, as these materials might trigger skin allergies.

Figure 4.8 Mueller Adjust-To-Fit® Thumb Stabilizer
(Mueller, 2022)

FUTURO™ Thumb Deluxe Stabilizer

The *FUTURO* thumb stabilizer (Figure 4.9) provides moderate support to the thumb and stabilisation of the lower thumb joints. This device supports those who often conduct repetitive thumb movements, like texting, gaming and gardening. The splint also helps to relieve thumb pain and soreness due to repeated stress injuries, strains, sprains and arthritis. The *FUTURO* stabilizer is designed in accordance to the ergonomic shape of the hand and constructed with breathable and soft materials. The splint comprises two plastic stays to support the thumb and enhance stabilisation of the thumb. Other fingers are permitted to move with a large range of motion. Wearers can adjust the size of the stabiliser easily and conveniently with the durable lacing system. Sizes from S to XL are offered but only black colour is available.

Figure 4.9 FUTURO™ Thumb Deluxe Stabilizer
(3M, 2022)

Medex® De Quervain's Thumb Splint (W05)

The ailments that can be remedied by the *Medex®* De Quervain's thumb splint (Figure 4.10) include DQV, trigger thumb, and thumb fractures and sprains. The splint is mainly composed of Velcro-plush fabric to more strongly secure the fabric attachments. The thumb is immobilised in an extended position with a moulded strip so as to accelerate the healing process of the injured regions. The remaining fingers are allowed to move freely. Velcro tape and pressure bands are adjustable to stabilise the splint. The splint is universal in size and offered in black.

Figure 4.10 Medex® De Quervain's Thumb Splint (W05)
(Medex®, 2022)

After reviewing the ten splinting products from current online stores, their features are summarised in terms of fabrication, support of thumb and wrist, fastening system, colour and size, as shown in Table 4.1.

Table 4.1 Summary of ten splinting products

Brands	Indications	Fabrications	Thumb Support	Wrist Support	Fastening system	Color	Size
BraceAbility	**De Quervain's disease,** rheumatoid arthritis, rhizarthrosis, tendonitis, sprains and strains of wrist or thumb	Durable and breathable fabrics with padded lycra lining	Moldable aluminum stay	Palmar stay	Three hook and loop closures	Black	XS, S, M and L
BRACOO	**De Quervain's tenosynovitis,** carpal tunnel syndrome and arthritic symptoms	Breathable, soft and skin friendly fabrics 35% polyester 25% nylon 25% cotton 15% rubber	Contoured metal stay	/	Velcro straps	Nude	Universal size
PROCARE	Scaphoid injuries, sprains and strains of hand, gamekeeper's thumb and **de Quervain's disease**	Lightweight nylon foam	Contoured aluminum stay	Contoured aluminum palmar stay	Elastic straps and D-ring closures	Black	Universal size
Mars Wellness	**de Quervain's disease,** strains and sprains of MCP joint, basal joint arthritis and other hand disorders	/	Adjustable thumb supporter	Malleable palmar stay	Hook straps and D-ring closures	Black	Universal size
Velpeau	**de Quervain's disease,** scaphoid fracture, carpal tunnel syndrome and other hand painful situations	Comfortable, lightweight materials and breathable compression fabrics Soft sponge pad at palm area Materials with sweat absorption ability	Flexible plastic thumb stay	Two flexible supporting strips at dorsal. Two removable aluminum contoured stay at palm.	Velcro straps	Mainly black with blue outlines	Short version and regular version

Copper Compression	Hand pain, tendinitis, arthritis, trigger thumb and other hand problems	Comfortable fabrics comprised of 88% copper nylon Fabrics that can withstand washing and maintain functions overtime	/	/	Velcro tapes	Black	Universal size
Össur	Tendonitis like de **Quervain's disease** and other soft tissue injuries like Gamekeeper's thumb, sprains and strains	Breathable and lightweight materials Optional gel pad	Customizable stay	Customizable stay	Contact closure straps	Black	XS, S, M, L, XL
Mueller	Repetitive thumb motions like texting, gaming and gardening Thumb pain and soreness due to repetitive stress injuries, strains, sprains and arthritis	Breath and soft materials	Two plastic stays	/	Lacing system	Black	S, M, L, XL
Medex®	**De Quervain's disease**, trigger thumb, thumb fracture and sprain	Velcro-plush fabric	Molded strip	/	Velcro tapes and pressure bands	Black	Universal size

'/' represents information that is not mentioned in the products' descriptions

The table shows the common design features, materials characteristics and basic components of the ten splints available in the current market. It can be observed that some of the splints specifically treat DQV. While some indicate that they are used for treating tendinitis or thumb pain due to repetitive hand movement, these symptoms are also associated with DQV. All of the investigated splints are suitable for multiple hand conditions. Apart from DQV, these splints can alleviate trigger thumb, arthritis, Gamekeeper's thumb, scaphoid fracture, sprains and strains. To do so, the splints are purposely designed to stabilise the thumb and wrist, especially the thumb. Most of the reviewed splints incorporate a thumb supporter. The supporters are mainly constructed with aluminium or plastic due to their mouldability and reasonable flexibility. Half of the reviewed splints contain a wrist-supporting stay. The wrist supporter controls the wrist movements, which may help to reduce the chances of triggering the tendons or other tissues associated with the thumb. It can be observed that the thumb supporter is an essential component in the splint for treating conditions that cause pain, including DQV. On the other hand, the wrist supporter appears to be more an option, however, the supporter could be an important component for enhancing the stabilisation of the affected hand. Although most of the thumb stays are supposedly pre-contoured, it is questionable whether the stays fit the flexion angle and curvature of the thumb. Furthermore, the wrist stays in some of the splint designs aim to restrict wrist movement; however, whether the wrist stays can stabilise the hand in the rest position effectively is still contentious. Therefore, an investigation on the effectiveness of the currently available splints in restricting wrist and thumb movements is needed. Measurements of the angles of the wrist and investigation of the curvatures along the thumb with the hand in the rest position are worth carrying out to develop the proposed splint with an excellent fit.

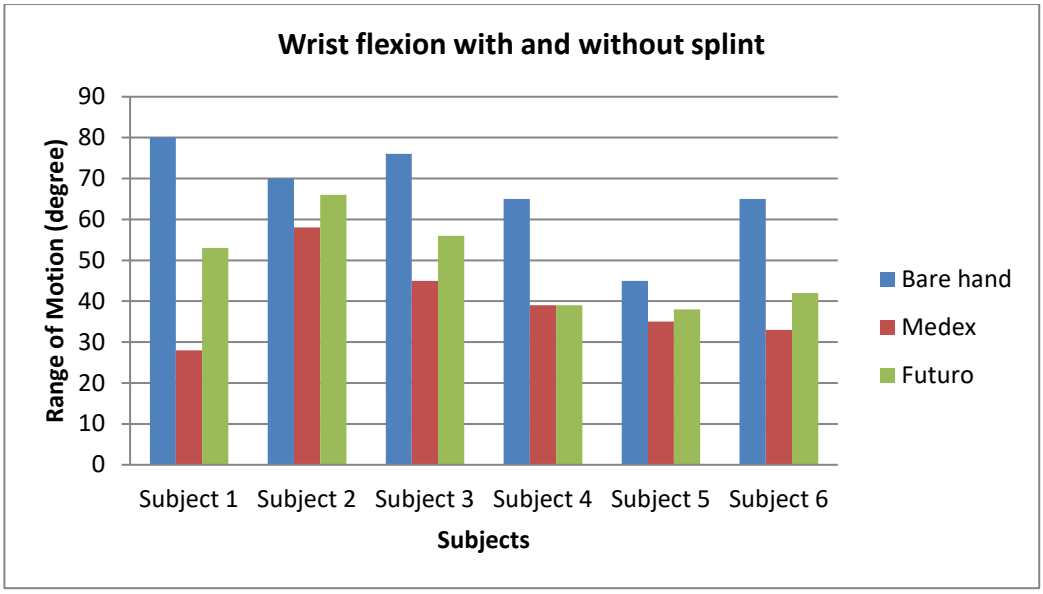
It can be observed from the products that the common properties of the fabrics used in the splints include breathability, light in weight and soft hand feel. To enhance the comfort of splints, soft padding may be added. Velcro tapes and straps with D-ring closures are the two most common types of fastening systems used in hand splints. In considering that the patient has only one hand to use because the other is affected by the disease, both fastening systems can be easily donned and doffed with a single hand. The colour of the splints is mainly black, which might be that this colour is well received by both genders, and grime would hardly show on black. Splints with an

adjustable fastening system are marketed as having a universal size. However, some companies may offer sizes that range from extra small to extra large, with a flexible fastening system for fine adjustments. After reviewing the fabric contents, fastening system, colours and size of the splints, it was noted that wear experience is an important factor that should be considered during the splint design process. Therefore, two major areas that splint designers should consider are the effectiveness of the splint in immobilising the thumb and wrist, and the concerns of users, such as whether the splint can be easily donned, the degree of perceived wear comfort during splinting and the appearance of the splint.

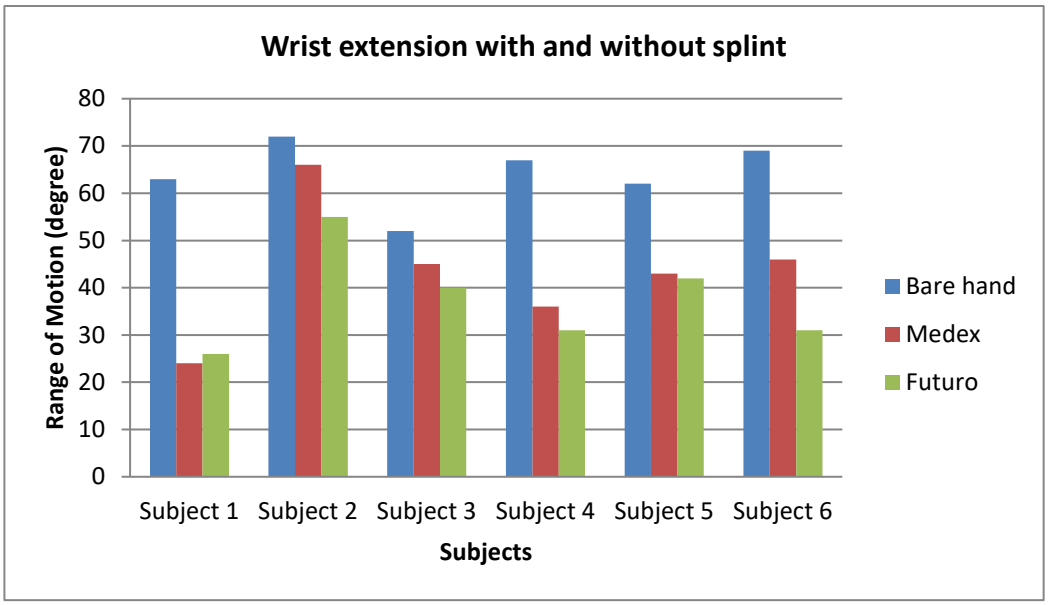
4.2.2 Effectiveness of splint samples in limiting hand movement

Two splint samples were purchased in the current market to investigate their effectiveness in controlling the movement of the wrist and thumb. The two splints are the Medex and the Futuro splints. Six healthy female subjects between 20 and 30 years old were recruited for the experiment. The patients were instructed to perform four ROMs of the wrist and five ROMs of the thumb in three conditions: the bare hand, wearing the Medex splint and wearing the Furuto splint. The following is a discussion on the measured ROM results.

The measured angles of wrist flexion and extension are shown in Figure 4.11. It can be observed that splints can somewhat limit wrist flexion and extension from a few degrees to approximately 30 degrees. In terms of limiting the wrist flexion, the Medex splint has a better performance whereas in terms of limiting the wrist extension, the Furuto splint has a better performance. Although both splints can limit wrist flexion and extension to a certain degree, the subjects could still flex and extend their wrist for more than 20 degrees. Since the rest position maintained by the splint is recommended to be 10 to 20 degrees (Nemati et al., 2017; Wilton, 2014), it was found that the limitation of the wrist flexion and extension by both splints might not be adequate.



(a)

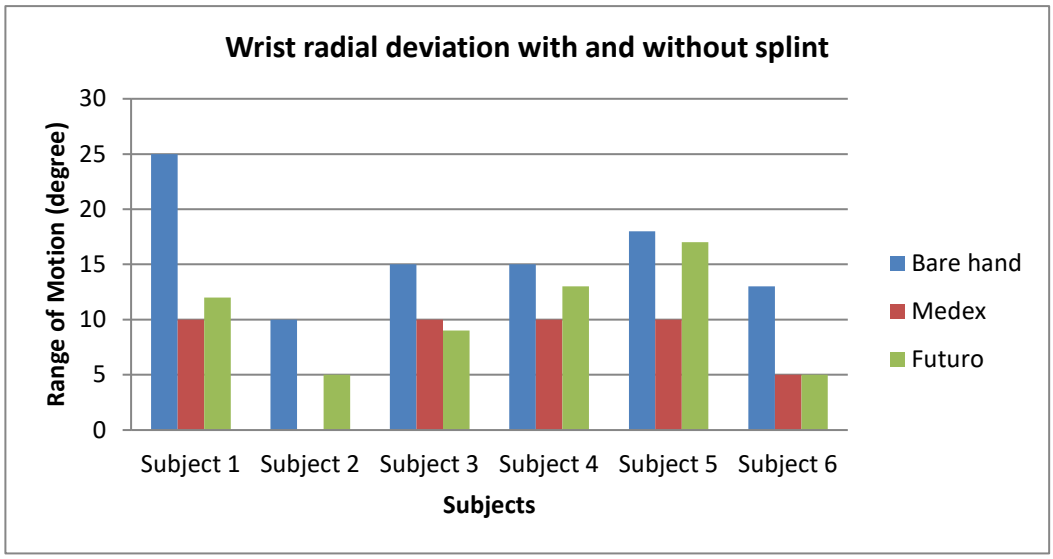


(b)

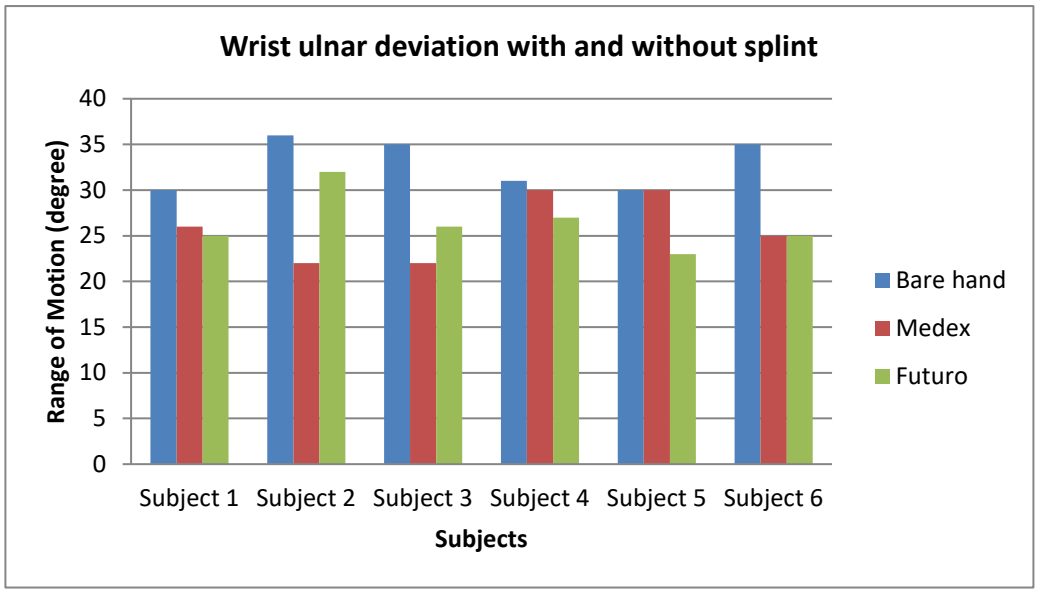
Figure 4.11 Angle measurements of (a) wrist flexion with and without splints; (b) wrist extension with and without splints

The subjects were instructed to perform wrist deviations and the measurements were recorded and shown in Figure 4.12. The bar chart shows that the Medex splint can restrict the wrist from radial deviation to a larger extent than the Futuro splint. Both splints can somewhat restrict the wrist from ulnar deviation from a few degrees to around 15 degrees. Wilton (2014) recommended that the wrist could be held in minimal ulnar deviation in the splint. However, in the diagnosis test, the patients are requested

to perform ulnar deviations that may trigger pain at the radial side of the hand. Therefore, only minimal wrist ulnar deviation is preferred. Figure 4.12(b) shows that after wearing the splints, the subjects could still deviate their wrist in the ulnar direction for more than 20 degrees. This may indicate that limiting wrist ulnar deviation by using one of these two splints are not enough.



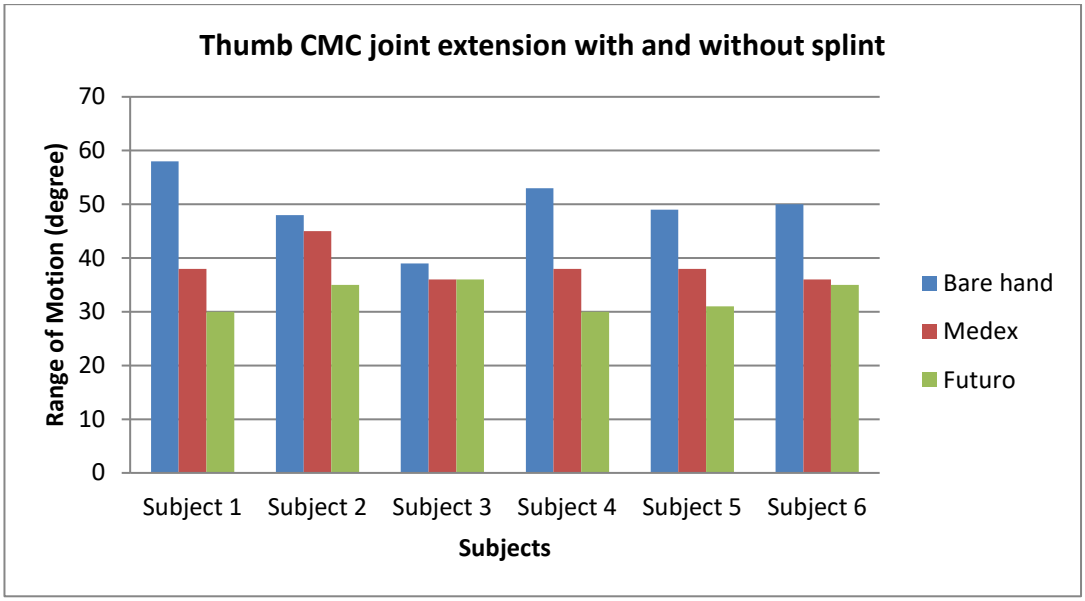
(a)



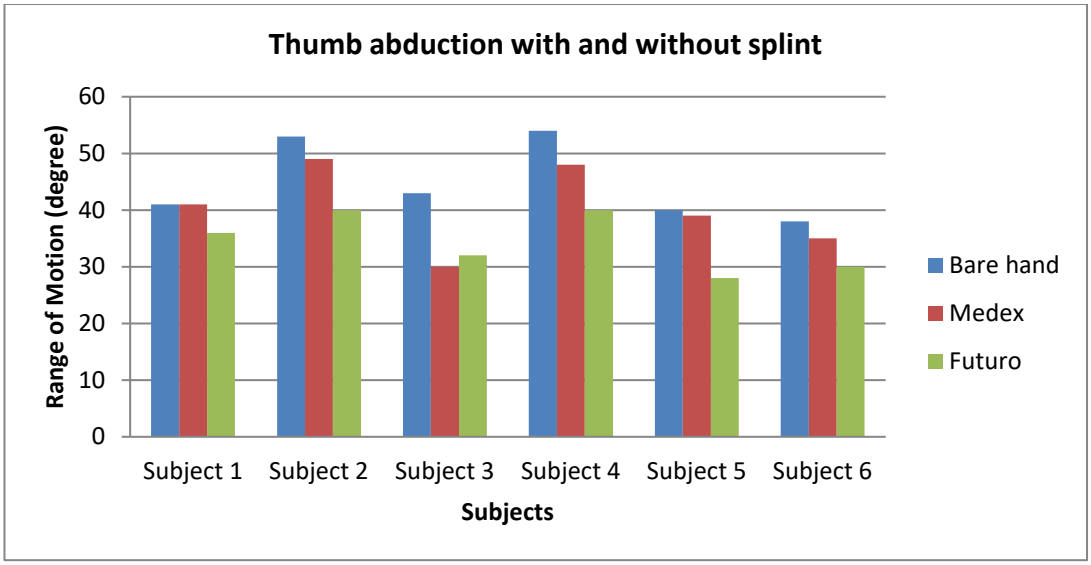
(b)

Figure 4.12 Angle measurements of (a) wrist radial deviation with and without splint; (b) wrist ulnar deviation with and without splint

The Futuro splint performed better than Medex splint in restricting both the thumb abduction and CMC joint extension. According to Hamilton et al. (2012), four muscles are require to control thumb abduction, which involve the APL and EPB muscles. Thumb extension is mainly performed by the APL muscle with possible help from the EPB muscle. Therefore, limiting these two movements can be realised. Some limitations on thumb extension can be observed in Figure 4.13(a). For thumb abduction, Ilyas et al. (2007) suggested that the rest position of the thumb to include approximately 30 degrees of abduction. From the results shown in Figure 4.13(b), it can be observed that the limitation of thumb abduction by these two splints is inadequate as most of the subjects can abduct their thumb for more than 30 degrees.



(a)



(b)

Figure 4.13 Angle measurements of (a) CMC joint extension with and without splint; (b) wrist abduction with and without splint

According the Wilton (2014), the thumb MCP joint should be kept in a slightly flexed position. However, Figure 4.14 shows that half of the subjects can flex their MCP joint while wearing the Futuro splint while none can flex their MCP joint while wearing the Medex splint. The reason for the over-restriction of MCP joint flexion could be the hardness of the thumb supporter with a poor fit. Therefore, a thumb supporter with appropriate hardness and excellent fit which allows the MCP joint to be flexed slightly needs to be developed, so as to allow patients to rest their thumb in the correct position.

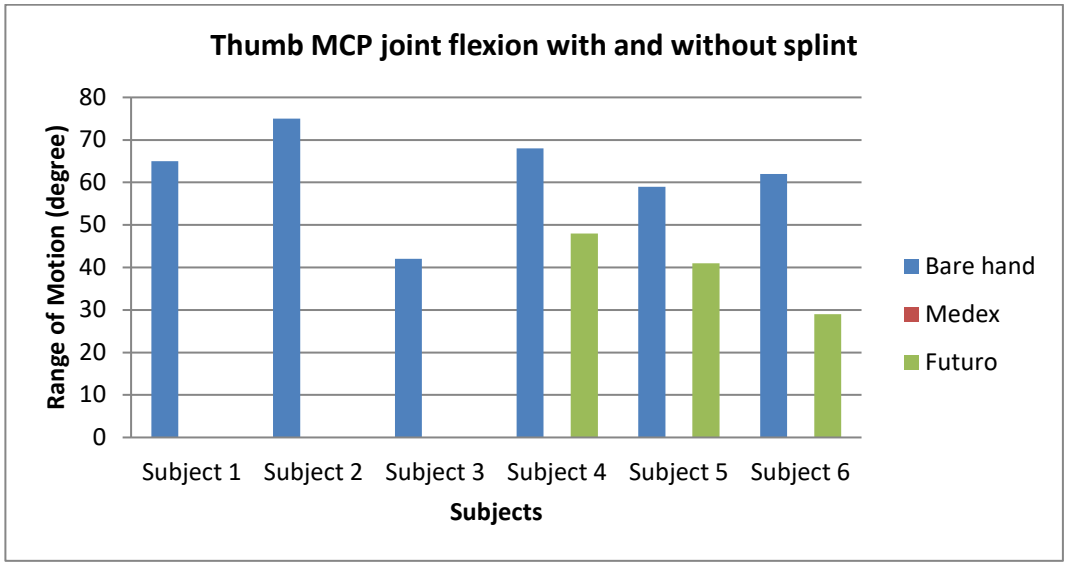
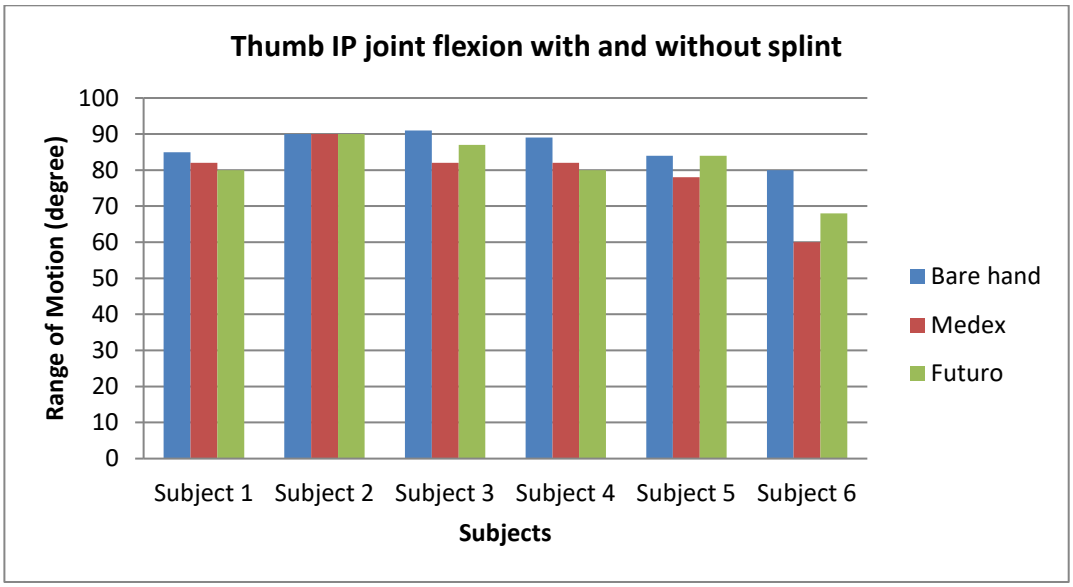
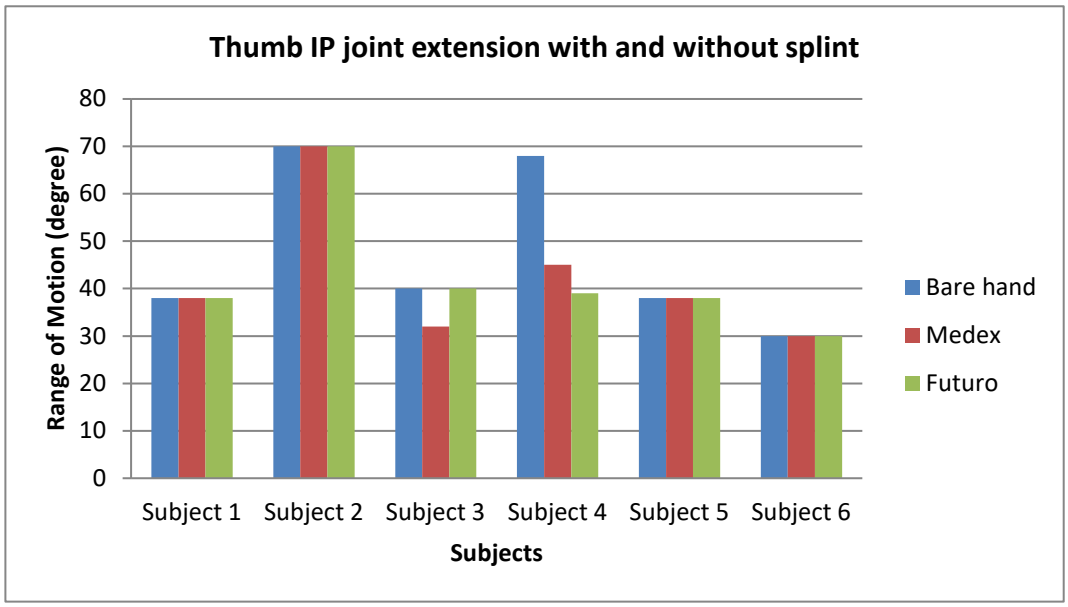


Figure 4.14 Angle measurements of MCP joint flexion with and without splint

The movement of IP joints is not related to control from the APL and EPB tendons (Chen, 2018). Figure 4.15 shows that the majority of patients can move their thumb distal phalanx freely with the splint donned. The reason for the obvious restriction of the IP joint extension of Subject 4 is that the thumb part of the splint is too long compared to the thumb of Subject 4, so the IP joint may be covered by the fabric, thus inhibiting IP joint motion.



(a)



(b)

Figure 4.15 Angle measurements of (a) IP joint flexion with and without splint; (b) IP joint extension with and without splint

To conclude, although the two splints allow a large degree of IP joint movement, their effectiveness in restricting wrist flexion, extension and ulnar deviation is low. Their restriction of thumb abduction is also not enough. On the other hand, over restriction of the MCP joint flexion is observed, especially with the Medex splint, and this could be due to the poor fit of the thumb supporter. Therefore, the development of a proposed functional splint is necessary to improve the restriction of wrist and thumb movements appropriately, maintain the hand of the patients in the proper rest position and enhance the fit performance of the splint.

4.3 Development of proposed functional splint

4.3.1 Clinical practice and splint construction process

Patients with DQV are the end-users of the splint. Before developing the proposed functional splint that can help patients and provide them with wear satisfaction, it is important to first understand more about the situation of the patients and the basic fabrication process of traditional splints. A clinical visit could help to inform on the procedures of a normal clinical check-up of patients. During the check-up, diagnostic tests and prescription of splint could be clearly observed. The process of customising the fabrication process of splints for patients could also be learnt. A clinical visit to the Occupational Therapy Department of the David Trench Rehabilitation Center, Sai Ying Pun from Oct 2017 to June 2018 was done. The observed results from the clinical visit included two parts: 1) flow of clinical check-up of patients with DQV and 2) the fabrication procedures of customised splints.

4.3.1.1 Flow of clinical check-up of patients with DQV

In a normal clinical check-up for patients with DQV, they are first asked to point out which hand is affected. Then, they are instructed to perform two hand movements and rate the level of pain from 0 to 10 at the radial side of the hand near the radial styloid process, with 0 representing minimal pain and 10 is severe pain. The first movement is the abduction of the fingers together with the extension of the thumb. The second movement is the opposition of the hand by sliding the tip of the thumb from the distal phalanx to the CMC joint of the small fingers. The purpose for performing these two movements is to confirm that the location of pain is over the first dorsal compartment and preliminarily understand the level of pain. Then, the occupational therapist will

survey the patients on the main challenges in daily life due to the pain at the wrist. Possible answers could include twisting towels, holding utensils while cooking, washing dishes, donning pants and holding a pen to write. All of these tasks involve twisting of the wrist or movement of the thumb which may exert stress onto the APL and EPB tendons. After listing their main challenges, patients are asked to rate the pain level of each movement that causes difficulty. Then, the occupational therapist will measure the grip and pinch strength of both hands with a dynamometer and pinch meter respectively, in order to evaluate the level of weakness of the affected hand in comparison to the unafflicted hand based on international standards. After measuring the strength of the hands, the occupational therapist will confirm once again the hand condition of patients was DQV by carrying out the Finkelstein's test even though the patients might have already received a referral to the occupational therapist from the hospital. The Finkelstein's test requires the patient to flex his/her thumb and enclose the thumb into the closed fist. Then, patient is instructed to deviate the wrist with the closed fist to the ulnar direction and point out the location of the pain on the hand. A positive sign is given when the patient experiences pain over the first dorsal compartment. The pain level at the radial side of the hand is rated while performing the diagnostic test. After verifying the hand condition, an appropriate splint is prescribed based on the pain level rated by the patients and the strength of the hand according to the patient. A short splint is usually prescribed for patients with minimal symptoms and low levels of pain. On the other hand, a long splint is prescribed for patients with moderate symptoms and higher level of pain. Splint fabrication is implemented during the check up as the splint is customised according to the patient's hand. After constructing the splint, the patients are asked to don the splint for a while outside the check-up room and gauge whether there is any discomfort due to the splint. If there is discomfort, further adjustment of the splint is done at a later session. Cleaning instructions for the splint are then provided by the clinical assistant. Lastly, patients can attend a short talk about DQV to find out more about the hand conditions and kinds of activities to heed to avoid exacerbation of the symptoms. Figure 4.16 illustrates the flow of the clinical check-up process for patients with DQV.

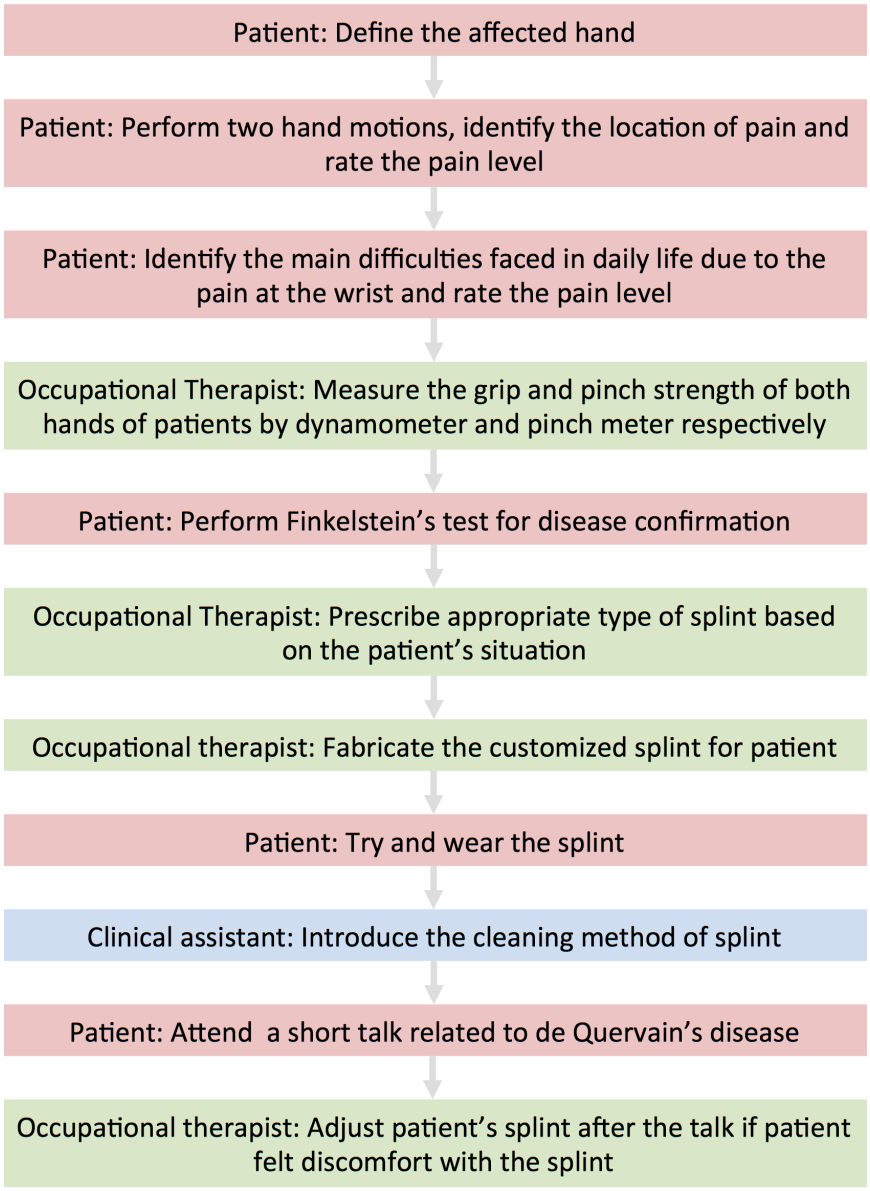


Figure 4.16 Flow of the clinical check-up for patients with DQV

4.3.1.2 Fabrication procedures of customised splints

As stated earlier, two types of splints are usually constructed by clinics - a short or a long splint. The former is constructed of soft and thick fabric, like neoprene, with a thumb supporter inserted into the pocket made with thin fabric along the thumb. Velcro tape is sewn onto the distal part of the thumb and around the wrist. The latter is composed of two layers of satinette fabric. A thumb supporter and a wrist stay are moulded and inserted between the two layers. Three pieces of Velcro tape are sewn into the dorsal part of the splint, along the wrist to the distal forearm. Figure 4.17 shows the two types of splints constructed by the clinic in this study.

(a)

(b)

Figure 4.17 Radial view, palmar view and dorsal view of: (a) short splint (left to right); (b) long splint (left to right)

The fabrication of short and long splint were shown in Figure 4.18. For short splint, neoprene fabric in the shape of splint pattern and thermoplastic thumb stay were prepared before meeting the patient. By knowing the side of affected hand of patient, the corresponding side of splint fabric was selected. Patient was requested to place the ulnar side of the hand on a flat surface with a towel supporting the wrist slightly and perform the resting position. The thermoplastic thumb stay was then put into a water bath with around 60 to 70 degrees. Once the thermoplastic stay was soften, the stay was taken out from the water bath and placed along the patient's thumb gently from right below the IP joint to the distal radius for molding. The thumb stay was waited to be cooled down and harden. The hardened thumb stay was then inserted into the fabric pocket. The splint fabrics with the thumb supporter wrapped around the patient's hand and the positions of Velcro tape were marked based on the girth of the thumb and wrist. These marks allowed the clinical assistant to sew the Velcro tapes onto the splint fabric.

For the long splint, satinette fabric was cut in accordance with the splint pattern. Two layers of satinette fabric and Velcro tape were sewn together to form the splint before meeting the patient. The thermoplastic of the thumb and wrist stays was cut into specific shapes and prepared for moulding. The splint of the correct side of the hand was selected after asking the patient to indicate the side of the affected hand. The patient was then instructed to place the hand onto a towel on the table with the palm facing up. The thermoplastic wrist stay was placed into a hot water bath. After softening of the thermoplastic, it was placed at the ulnar side of the hand for moulding. The wrist stay covered from the ulnar side to the palmar side of the wrist. The top of the stay was placed right below the distal transverse crease and extended to the distal ulna. The coverage of the wrist stay can restrict wrist movements but would not affect the opposition of the thumb and fingers. After the wrist stay cooled down and inserted between the two layers of fabrics, the patient was instructed to don the splint. Then, the patient was instructed to place the hand in the rest position with the forearm upright to the right and the elbow on the table. The occupational therapist took the thumb stay and placed it along the thumb, marking the position of the MCP joint and concave region at the carpals. The occupational therapist then softened the plastic stay at the marks with a hot gun and bent the shape of the stay in accordance with the contours of the hand. The contoured stay was inserted between the fabric layers. Customised positioning of the thumb stay and wrist supporter was done, and the clinical assistant stitched the stay and supporter into place. This completed the construction of the long splint. Figures 4.18 and 4.19 show the fabrication process of the short and long splints respectively.

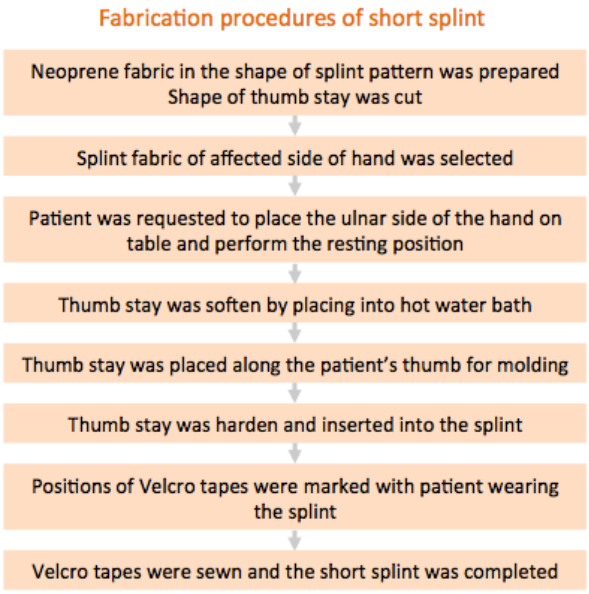


Figure 4.18 Fabrication process of short splint

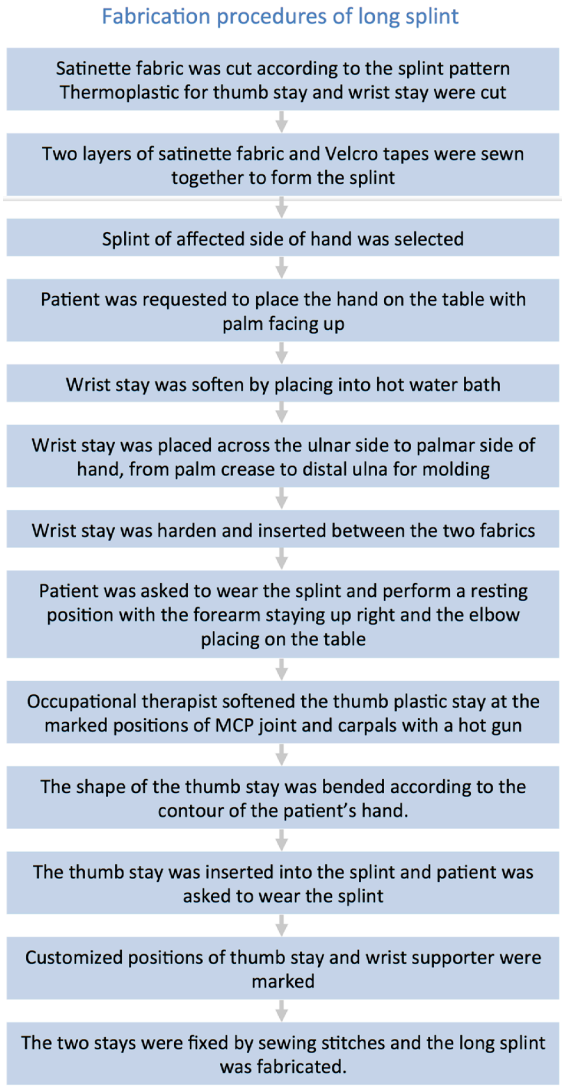


Figure 4.19 Fabrication process of long splint

4.3.1.3 Possible problems of splints provided by clinic

Since the short splint is composed of neoprene fabric, its air permeability and moisture management are relatively low in comparison to other stronger or more protective fabrics, such as satinette and spacer fabrics. As such, patients may feel warm hands when sweat is trapped in the splint after wearing for a long period of time, especially during the summer. In addition, as the neoprene fabric is only wrapped around the distal radius and ulna, the wrist may twist or deviate freely and easily. A large degree of wrist ulnar deviation may exacerbate stress on the two tendons at the first dorsal compartment. For long splints, fabric folds and creases are observed from the dorsal view (see Figure 4.17 (b)). The fabric fold shows that there is extra fabric at the dorsal region of the hand and this problem might be resolved by adjusting the splint pattern. Furthermore, the three large pieces of Velcro tape at the ulnar side of the hand may increase the bulkiness of the splint. Possible problems of the two splints provided by the clinic were found which could resolved by selecting more suitable fabric with higher air permeability and moisture management performance. Thus the pattern of the splints needs to be modified and a better fastening system needs to be designed. All of these issues were taken into consideration when developing the proposed functional splint.

4.3.2 Design foundations - Angles of wrist and thumb curvature

The human hand consists of complex 3D contours and shapes. It is therefore worthwhile to conduct a comprehensive investigation on the angle variations at different parts of the human hand, which contributes as fundamental knowledge on the shape of hand and the development of the proposed splint. For a splint to treat DQV, the wrist angles are critical for designing a splint that accommodates the hands well. The critical angles of the wrist include the angle between the extension of the radius and carpals, and the angle between the extension of the ulna and carpals. These two angles at the wrist should be considered when drawing the patterns of the splint for optimising the fit of the shape. To develop a well-fitting thumb supporter, the angles of the MCP joint flexion and between the extension of the radius and carpals need to be studied. The curvature of the thumb at different areas of the hand should also be studied in detail.

4.3.2.1 Subject recruitment

In the first stage, three groups of patients of different age groups were recruited for a comparison of their hand shape. The first group included 10 healthy young female subjects (HYS) who are 20 to 29 years old. The second group included 16 healthy mature female subjects (HMS) who are 40 years old or older. Finally, the third group included 16 female subjects with DQV (DQVS) who are 18 years old or older, of which 11 of the DQV patients are 46 years old or older. Table 4.2 provides the demographics of the recruited subjects.

Table 4.2 Demographic information of the HYS, HMS and DQVS groups

Subject code	Gender	Age group	Injured hand	Primary hand	Injection	Surgery	Other hand disease	Period of pain
HYS001	F	20-29	/	R	N	N	N	/
HYS002	F	20-29	/	R	N	N	N	/
HYS003	F	20-29	/	R	N	N	N	/
HYS004	F	20-29	/	R	N	N	N	/
HYS005	F	20-29	/	R	N	N	N	/
HYS006	F	20-29	/	R	N	N	N	/
HYS007	F	20-29	/	R	N	N	N	/
HYS008	F	20-29	/	R	N	N	N	/
HYS009	F	20-29	/	R	N	N	N	/
HYS010	F	20-29	/	R	N	N	N	/
HMS001	F	56-65	/	R	N	N	N	/
HMS002	F	56-65	/	R	N	N	N	/
HMS005	F	46-55	/	R	N	N	N	/
HMS006	F	46-55	/	R	N	N	N	/
HMS007	F	46-55	/	R	N	N	N	/
HMS008	F	56-65	/	R	N	N	N	/
HMS009	F	46-55	/	R	N	N	N	/
HMS010	F	46-55	/	R	N	N	N	/
HMS011	F	46-55	/	R	N	N	N	/
HMS012	F	46-55	/	R	N	N	N	/
HMS013	F	46-55	/	R	N	N	N	/

HMS014	F	46-55	/	R	N	N	N	/
HMS015	F	46-55	/	R	N	N	N	/
HMS016	F	46-55	/	R	N	N	N	/
HMS017	F	46-55	/	R	N	N	N	/
HMS018	F	56-65	/	R	N	N	N	/
DQVS003	F	65 or older	R&L	R	N	N	N	3 months
DQVS004	F	65 or older	R	R	N	N	N	6 months
DQVS005	F	26-35	R&L	R	N	N	N	6 months
DQVS007	F	46-55	R	R	N	N	Carpal tunnel syn-drome	5 years or longer
DQVS008	F	56-65	R	R	N	N	N	4 months
DQVS009	F	36-45	R&L	R	N	N	N	/
DQVS010	F	56-65	R	R	N	N	Arthritis	6 months or longer
DQVS011	F	56-65	R	R	N	N	N	6 months
DQVS012	F	56-65	R	R	N	N	N	8 months
DQVS013	F	18-25	R	R	N	N	N	3 months
DQVS015	F	56-65	R	R	Y	Y (carpal tunnel)	Carpal tunnel	1 year and 8 months
DQVS016	F	65 or older	R&L	R	N	N	N	3 months
DQVS018	F	26-35	R	R	N	N	N	9 months
DQVS019	F	46-55	R	R	N	N	N	1 year or longer
DQVS020	F	36-45	R	R	N	N	N	6 months
DQVS022	F	46-55	R	R	N	N	N	8 months

4.3.2.2 Angle measurement results of HYS group

The angle measurement results are important references in developing the pattern of the splint and designing the shape of the thumb supporter. In the experiments, both of the hands of those in the HYS group were scanned. During scanning, the subjects were requested to maintain their hand in the rest position. As mentioned in Nemati et al. (2017), the wrist should be held in a 10° to 20° wrist extension. The angle of the wrist extension can be measured along the midline of the palm to that of the forearm. Figure 4.20 shows the wrist extension angles of the subjects during scanning.

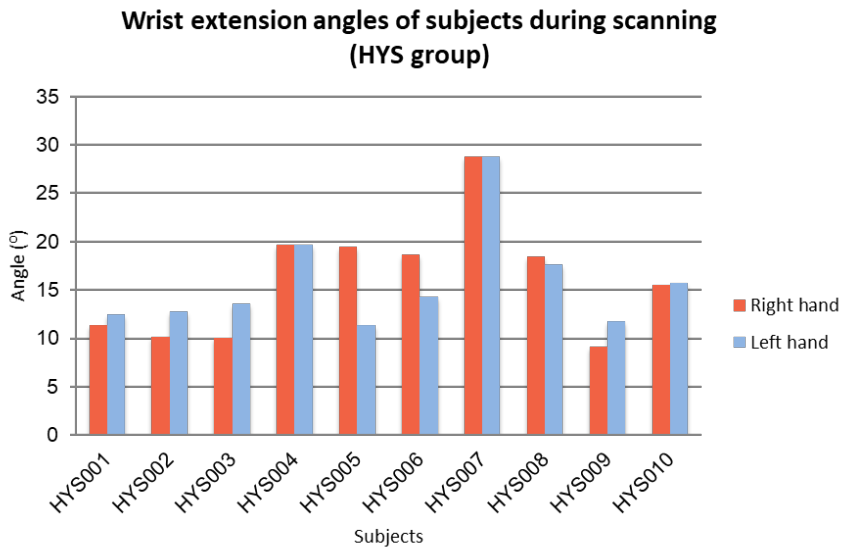


Figure 4.20 Wrist extension angles of subjects during scanning (HYS group)

Figure 4.20 shows that the majority of the patients can maintain wrist extension at 10° to 20° and maintain their hand in the rest position during scanning. The mean of the wrist extension of the right hand is 16.13° (S.D.= 6.14) and left hand is 15.83° (S.D.= 5.26). The critical angles at the wrist and thumb, and the curvature of the thumb were measured by using different software and the results are presented in the following figures. The mean of the angle of the MCP joint flexion of the right hand as shown in Figure 4.21, is 26.34° (S.D.= 12.63) and that of the left hand is 21.60° (S.D.= 7.91). The mean of the angles between the extension of the radius and carpals of the right and left hands is 26.55° (S.D.= 10.73) and 24.86° (S.D.= 7.07) respectively, as shown in Figure 4.22. On the other hand, the mean of the angles between the extension of the ulna and carpals of the right and left hands is 19.87° (S.D.= 7.09) and 19.38° (S.D.= 6.62) respectively (Figure 4.23). Figure 4.24 summarises the angle measurements

results with red angles representing angles of MCP joint flexion, blue angles representing the angles between the extension of the radius and carpals, and green angles representing the angles between the extension of the ulna and carpals. Figure 4.25 illustrates a simplified splint pattern and thumb supporter and shows the locations of the reference angles.

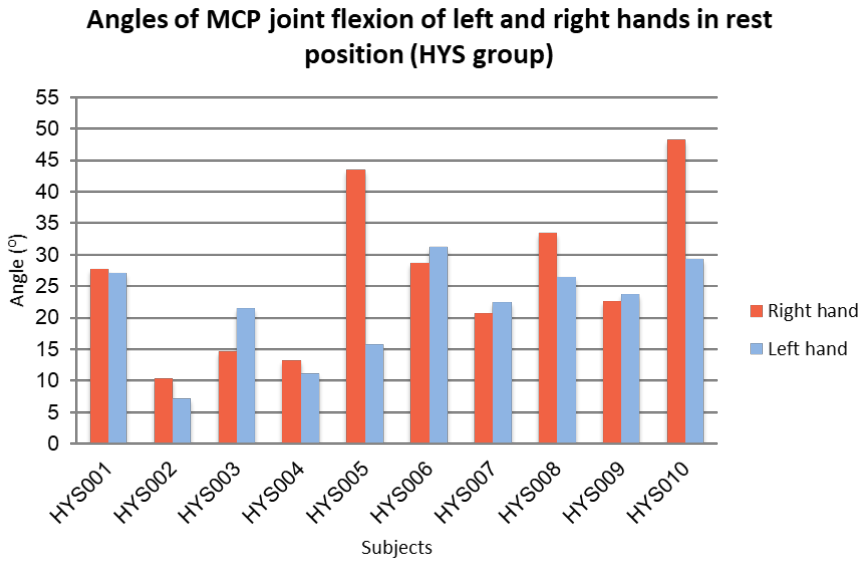


Figure 4.21 Angles of MCP joint flexion of left and right hands in rest position (HYS group)

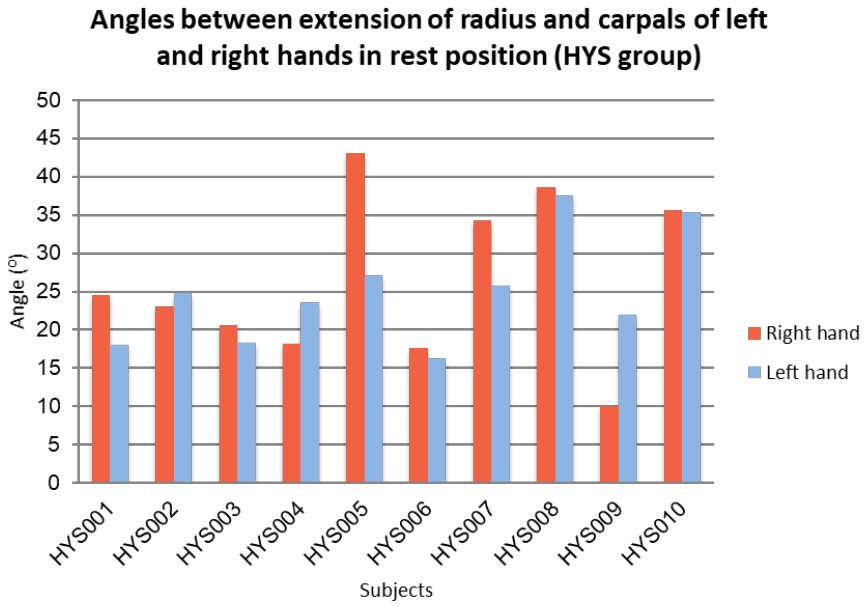


Figure 4.22 Angles between extension of radius and carpals of left and right hands in rest position (HYS group)

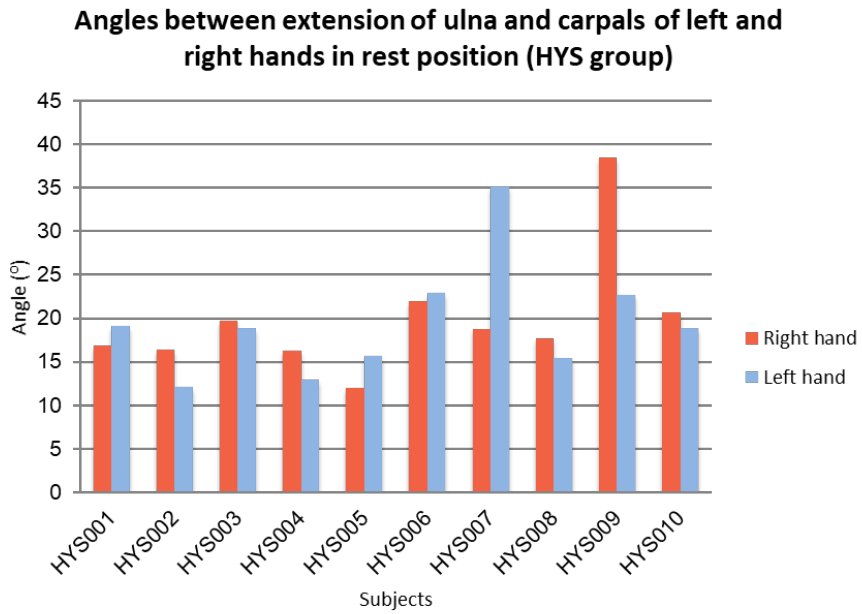


Figure 4.23 Angles between extension of ulna and carpals of left and right hands in rest position (HYS group)

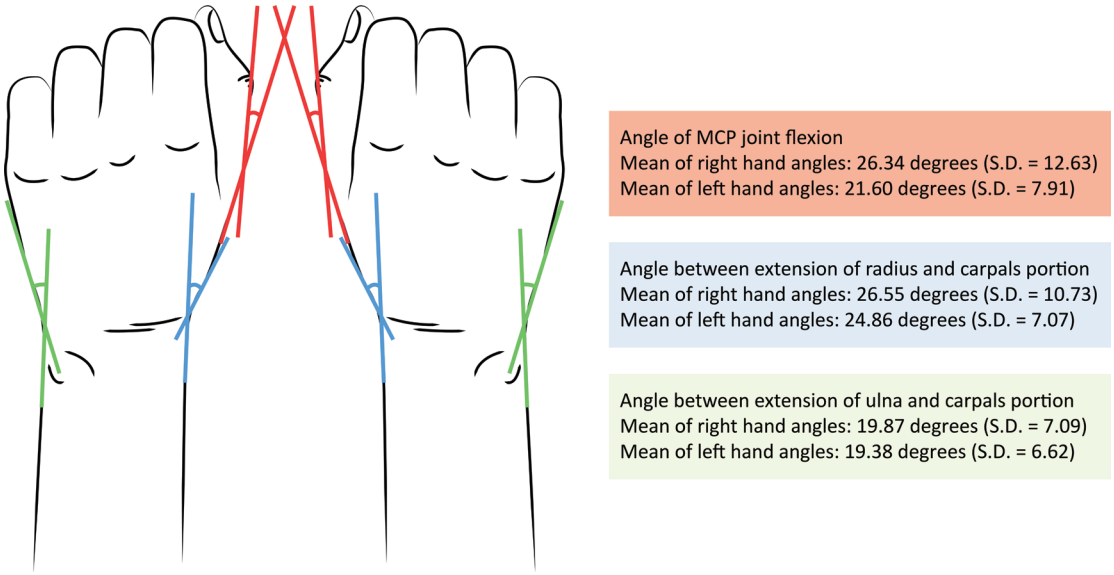


Figure 4.24 Summary of angle results at the MCP joint and the two sides of wrist (HYS group)

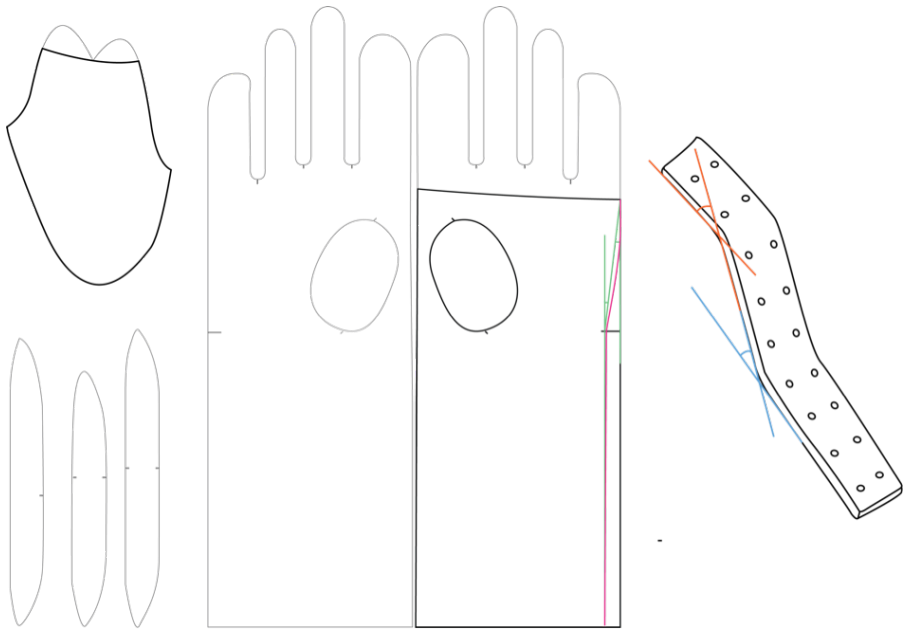


Figure 4.25 Location of the reference angles in a simplified version of splint pattern and thumb supporter

The curvatures along the thumbs are critical for the fit of the thumb supporter. The right thumb of the HYS group was sectioned into several segments. The cross-sectional levels were named according to the anatomical structure of the thumb, which include the proximal phalanx (PP), metacarpophalangeal joint (MCP), metacarpal (MC), carpometacarpal joint (CMC), carpals (C) and radius (R). The curvature lines of the thumb at each level were obtained, and angles α, θ and β were measured to understand the curvatures along the thumb. Angles α, β and θ located along the curvature of the thumb in the cross sectional view are shown in Figure 4.26. The angle results obtained could facilitate a better understanding of the curvatures along the thumb in a numerical sense instead of visual subjective assessment.

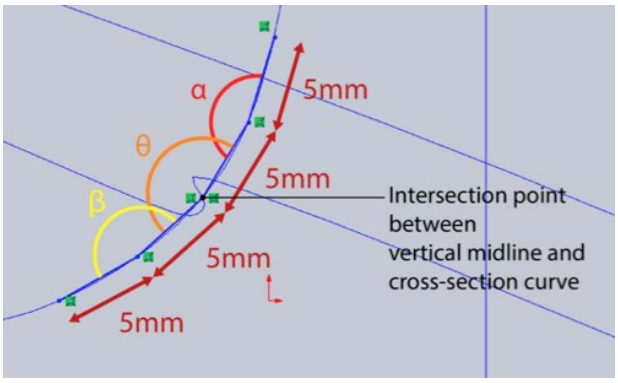


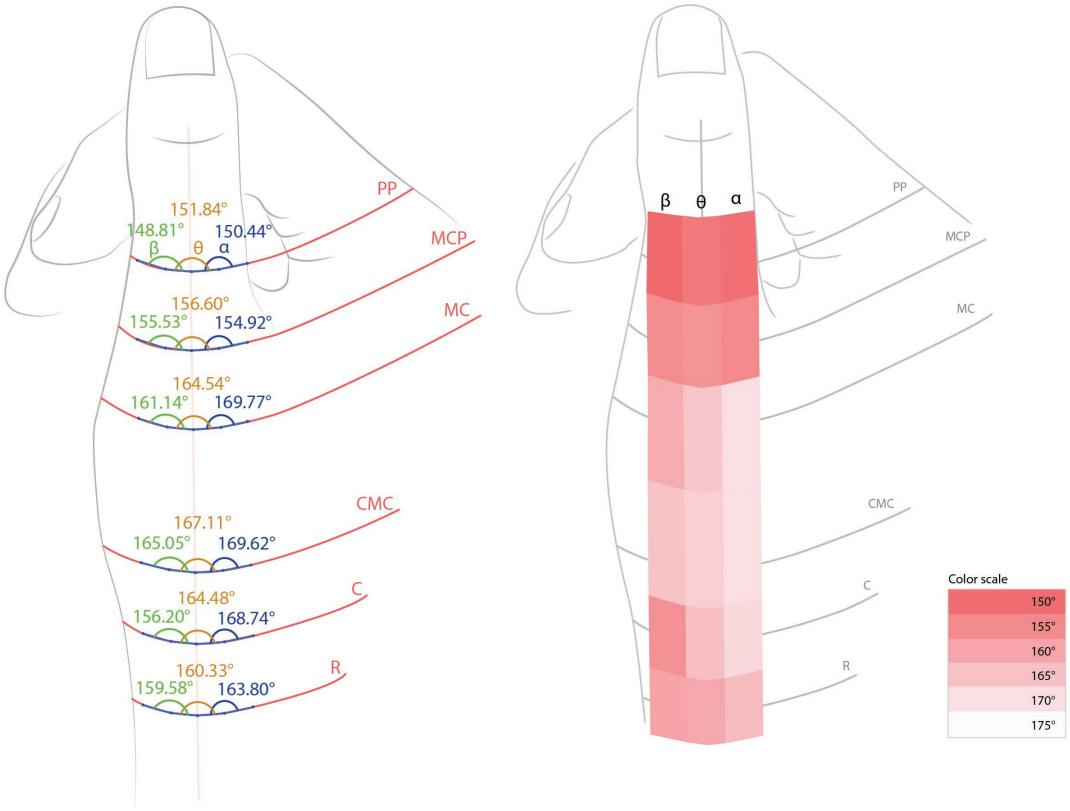
Figure 4.26 Location of angles α, β and θ along the curvature of thumb in cross sectional view

The angle measurement results at different areas of the right hand are listed in Table 4.3. The angles measured along the radial side of the hand of the HYS group approximately range from 140° to 180°. The smallest angle, which means the highest curvature, is located in the β area along the PP. On the other hand, the largest angle, which has the flattest surface, is located in the α area along the MC.

Table 4.3 Mean, S.D. and range of α, θ and β at different cross section levels along the thumb (HYS group)

Position	Angle	Mean	S.D.	Range
PP	α	150.44°	4.46	144.87°-158.63°
	θ	151.84°	5.26	146.31°-160.18°
	β	148.81°	5.61	141.12°-160.35°
MCP	α	154.92°	3.67	147.95°-160.20°
	θ	156.60°	3.72	150.11°-160.48°
	β	155.53°	2.31	152.05°-160.07°
MC	α	169.77°	2.48	166.64°-173.42°
	θ	164.54°	2.96	161.07°-169.35°
	β	161.14°	2.33	156.89°-163.67°
CMC	α	169.62°	4.08	164.71°-176.85°
	θ	167.11°	3.82	163.19°-175.89°
	β	165.05°	2.96	157.68°-167.76°
C	α	168.74°	3.77	163.27°-174.86°
	θ	164.48°	6.51	156.07°-172.41°
	β	156.20°	3.97	149.04°-162.51°
R	α	163.80°	4.88	157.05°-173.91°
	θ	160.33°	3.42	156.71°-165.47°
	β	159.58°	5.09	150.98°-165.80°

The mean of α, θ and β at different cross section levels along the thumb is summarised in Figure 4.27(a). By drawing a thumb supporter along the thumb based on a gradient map, the curvature at different parts and levels can be clearly visualised (Figure 4.27(b)). A redder hue in the area means that the curvature is larger. This experiment investigates the curvature of the thumb by measuring the angles at several cross-sectional levels along the thumb. The numeric form of indicating the curvature of the thumb can be realised. This data could help to develop a thumb supporter with a higher fit accuracy by using the data of the angles as reference when constructing the stay.



(a) (b)

Figure 4.27 (HYS group)

(a) Summary of mean of α, θ and β at different cross section levels along the thumb;

(b) Gradient map of angle results

4.3.2.3 Angle measurement results of the HMS group

The subjects in the HMS group were requested to hold up their right hand in the standardised rest position at a 10° to 20° wrist extension. With reference to Figure 4.28, most of the subjects can perform wrist extension within the angle range during the scanning process. The mean of the angle of the wrist extension of the right hand is 16.31° (S.D.= 5.94).

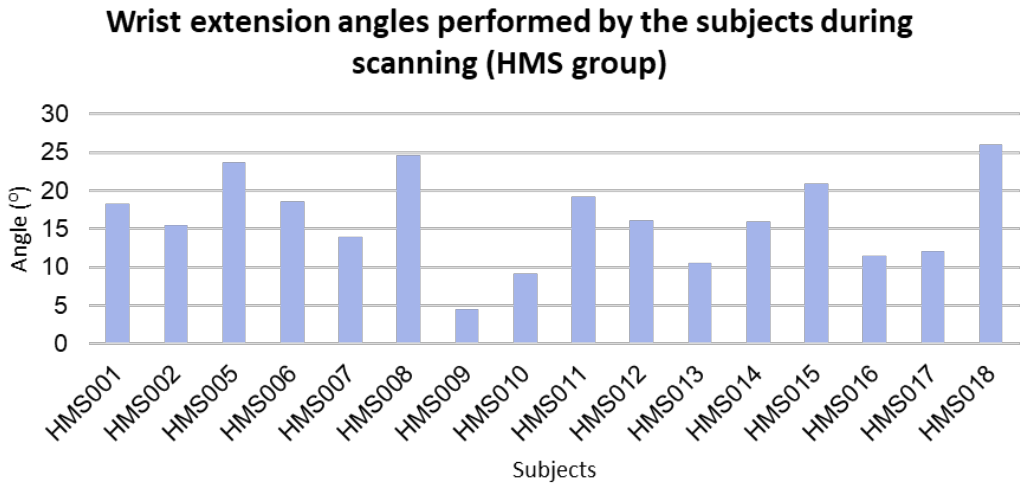


Figure 4.28 Wrist extension angles performed by the subjects during scanning (HMS group)

The measured angles at the MCP joint of the thumb and two sides of the wrist are shown in Figures 4.29, 4.30 and 4.31. The mean of the angle of the MCP joint flexion of the right hand of the subjects is 27.85° (S.D.= 9.13). The mean of the angle between the extension of the radius and carpals is 29.12° (S.D.= 9.17). On the other hand, the mean of the angle between the extension of the ulna and carpals is 16.76° (S.D.= 4.37). Figure 4.32 shows the mean and S.D. results which correspond to the measured location of the specific angles.

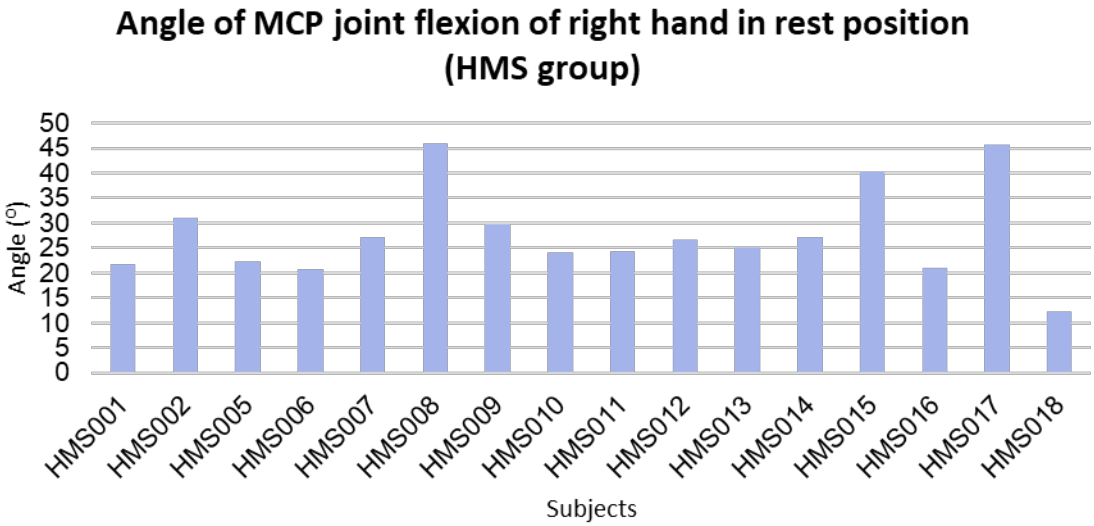


Figure 4.29 Angle of MCP joint flexion of right hand in rest position (HMS group)

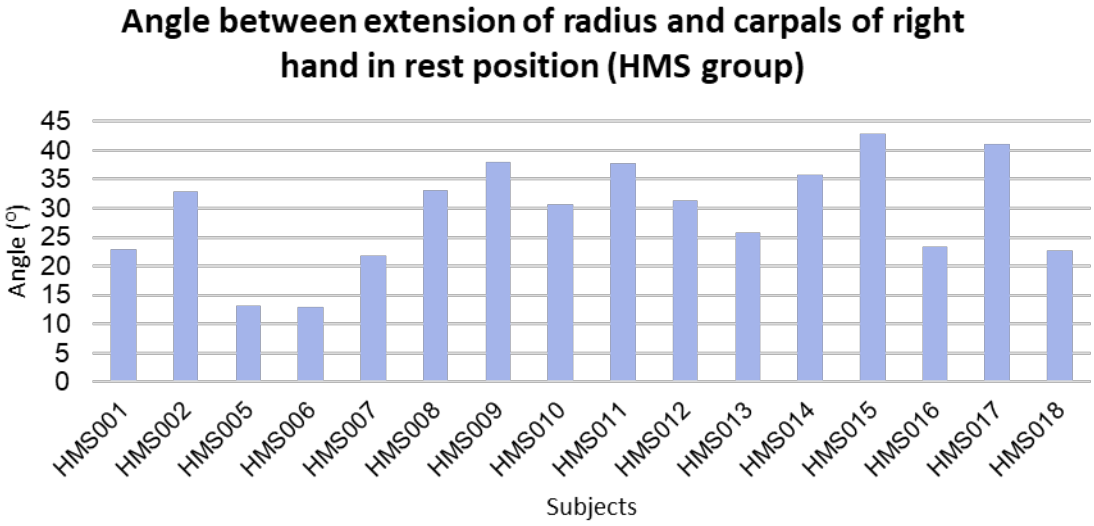


Figure 4.30 Angle between extension of radius and carpals of right hand in rest position (HMS group)

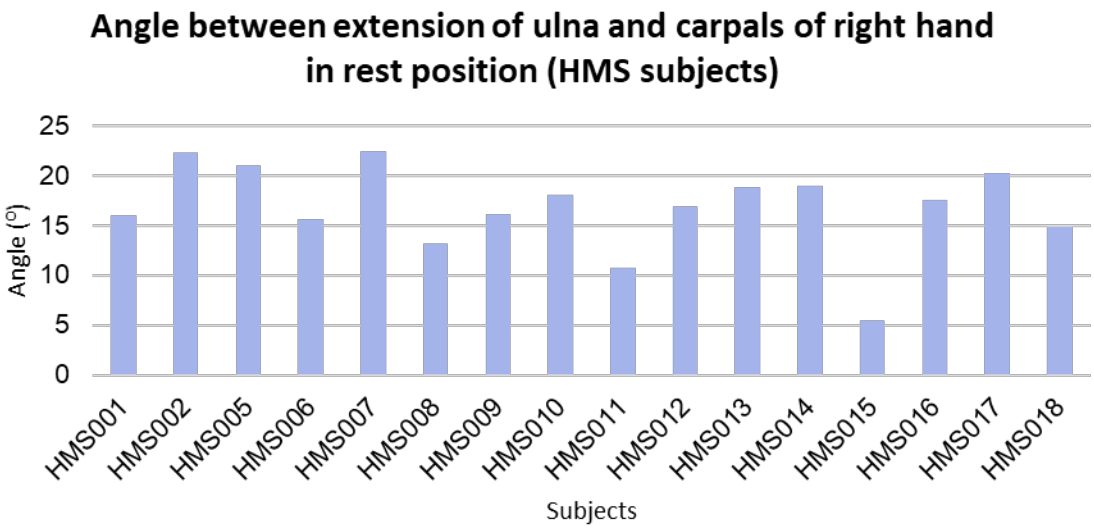


Figure 4.31 Angle between extension of ulna and carpals of right hand in rest position (HMS group)

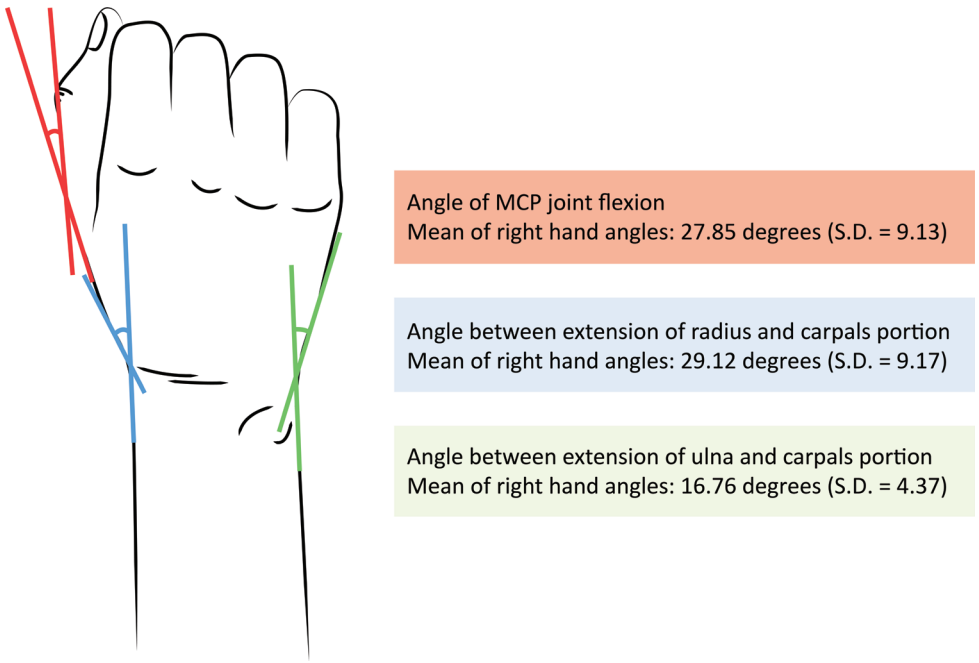
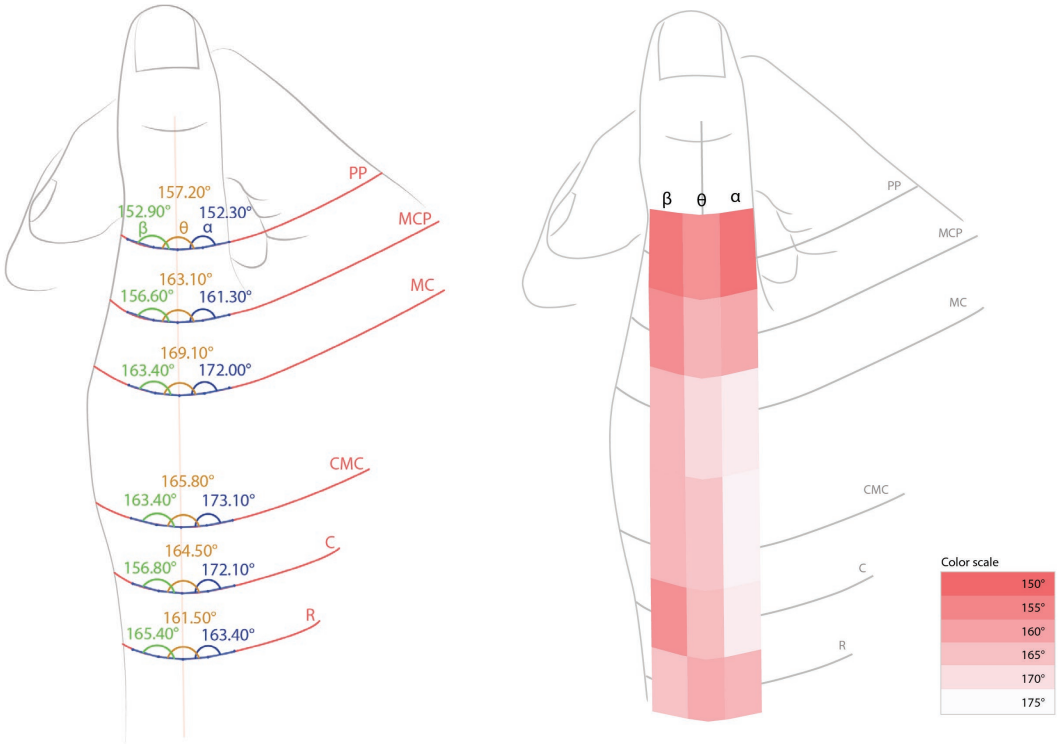


Figure 4.32 Summary of the angle results at the MCP joint and the two sides of wrist (HMS group)

For the HMS group, the measured angles range from approximately 135° to 190°. Similar to the HYS group, the area with the PP is the most curved part of the wrist. The smallest angle is α at the PP with a mean of 152.27°. On the other hand, the largest angle is 173.15° of α at the CMC. The measured angle results are listed in Table 4.4 in and shown as a gradient map in Figure 4.33.

Table 4.4 Means, S.D. and ranges of α, θ and β at different cross section levels along the thumb (HMS group)

Position	Angle	Mean	S.D.	Range
PP	α	152.27°	7.07	137.69°-163.05°
	θ	157.20°	4.92	149.62°-172.42°
	β	152.95°	4.47	145.35°-162.82°
MCP	α	161.26°	7.22	151.83°-173.76°
	θ	163.09°	6.30	152.58°-175.56°
	β	156.63°	3.90	151.72°-168.69°
MC	α	172.04°	6.03	158.75°-182.10°
	θ	169.14°	5.71	156.66°-178.52°
	β	163.45°	6.54	150.44°-172.42°
CMC	α	173.15°	5.61	164.37°-180.90°
	θ	165.81°	6.26	152.49°-175.13°
	β	163.44°	7.41	147.41°-173.81°
C	α	172.06°	9.36	160.59°-192.16°
	θ	164.48°	8.33	144.47°-179.04°
	β	156.78°	10.88	134.41°-169.75°
R	α	163.38°	4.29	155.23°-169.51°
	θ	161.54°	6.14	149.69°-170.62°
	β	165.39°	6.26	151.93°-173.26°



(a) (b)

Figure 4.33 (HMS group)

(a) Summary of mean of α, θ and β at different cross section levels along the thumb and

(b) Gradient map of mean of angles

4.3.2.4 Angle measurement results of the DQVS group

During the scanning process, the subjects in the DQVS group were asked to place their wrist of the right injured hand in the rest position at an extension of 10° to 20°. However, around half of the subjects could not maintain the position and extended their wrist for more than 20° (Figure 4.34). The mean of the angle of the wrist extension is 24.28° (S.D.= 9.34). The reason why the subjects could not maintain an extension of 10° to 20° during scanning might be due to the pain along the radial side of the wrist.

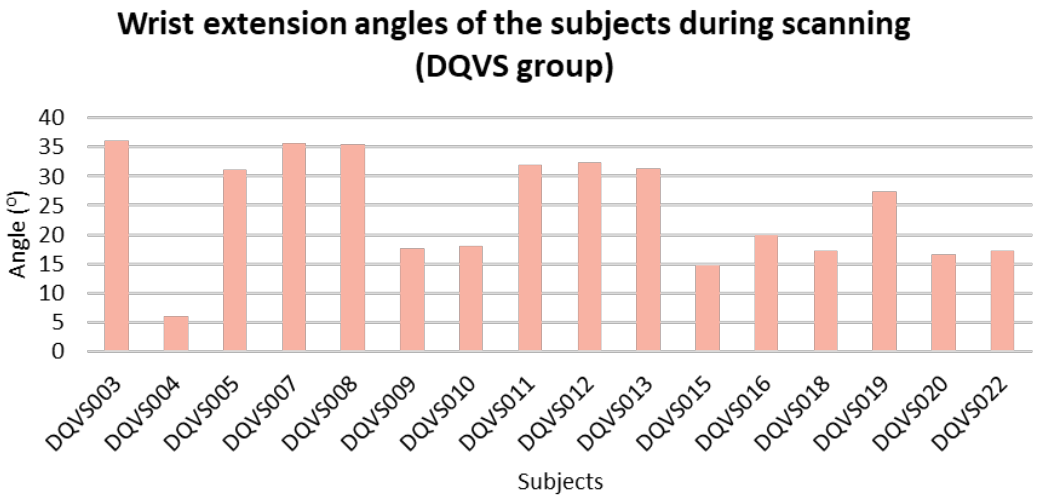


Figure 4.34 Wrist extension angles of the subjects during scanning (DQVS group)

After capturing the 3D hand images, the different angles of the thumb and wrist were measured by using Rapidform software. The flexion angles of the MCP joint were measured and are shown in Figure 4.35. The mean of the flexion angle is 18.99° (S.D.= 7.01). For the two measured angles of the wrist, the mean of the angle between the extension of radius and carpals, and the angle between the extension of the ulna and carpals are 19.76° (S.D.= 5.67) and 19.56° (S.D.= 8.66) respectively. The measured results of the two angles of each subject are shown in Figures 4.36 and 4.37. The mean results of the three different angles are shown in Figure 4.38.

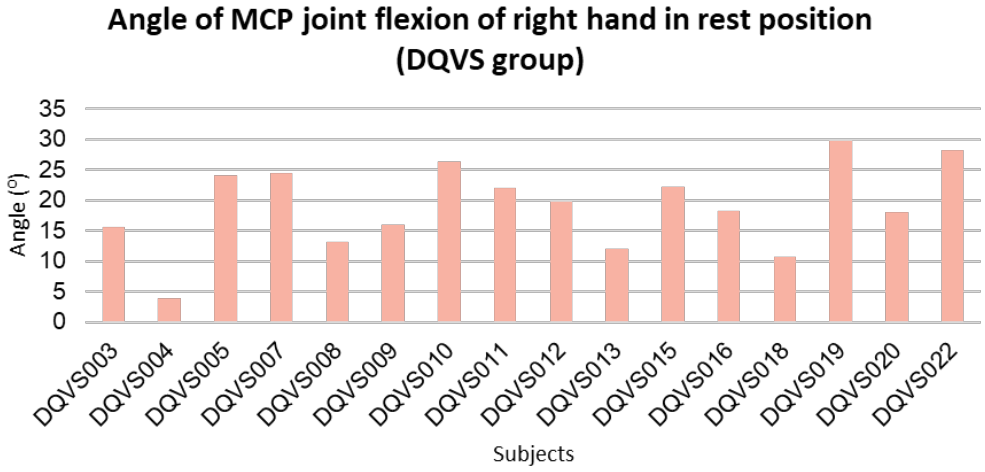


Figure 4.35 Angle of MCP joint flexion of right hand in rest position (DQVS group)

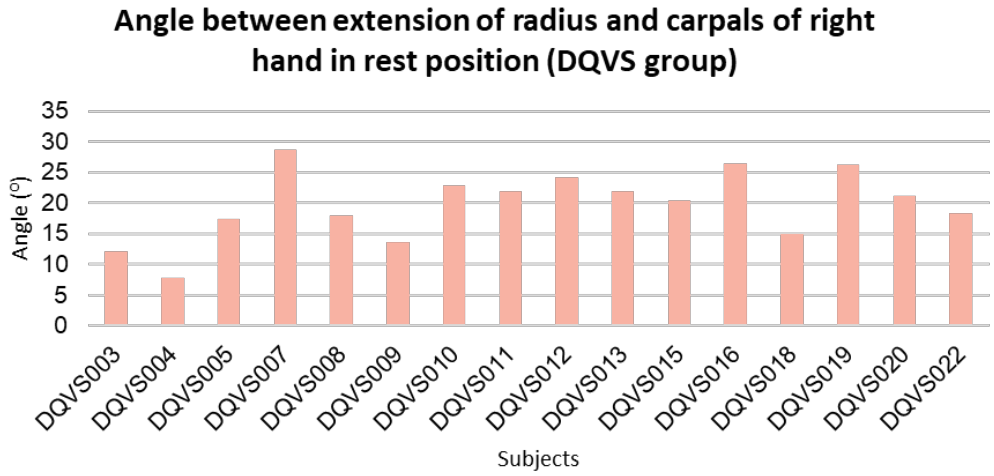


Figure 4.36 Angle between extension of radius and carpals of right hand in rest position (DQVS group)

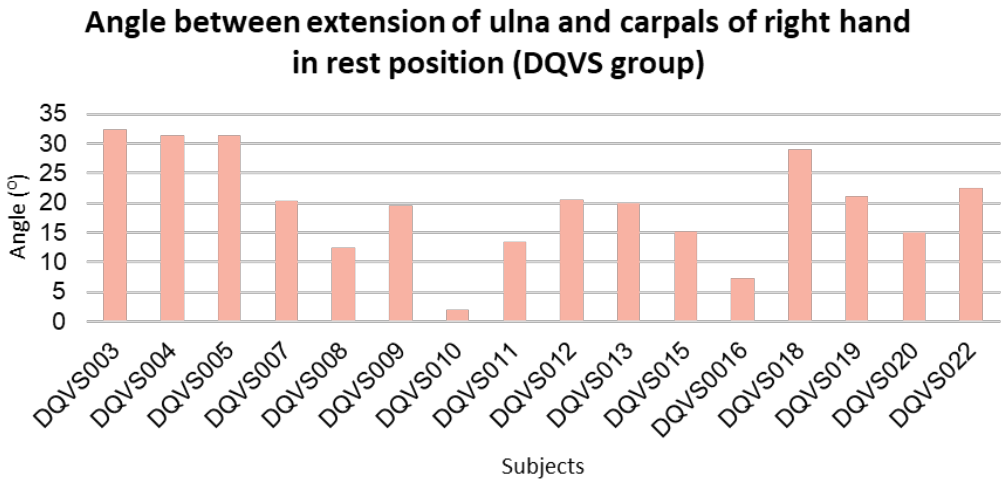


Figure 4.37 Angle between extension of ulna and carpals of right hand in rest position (DQVS group)

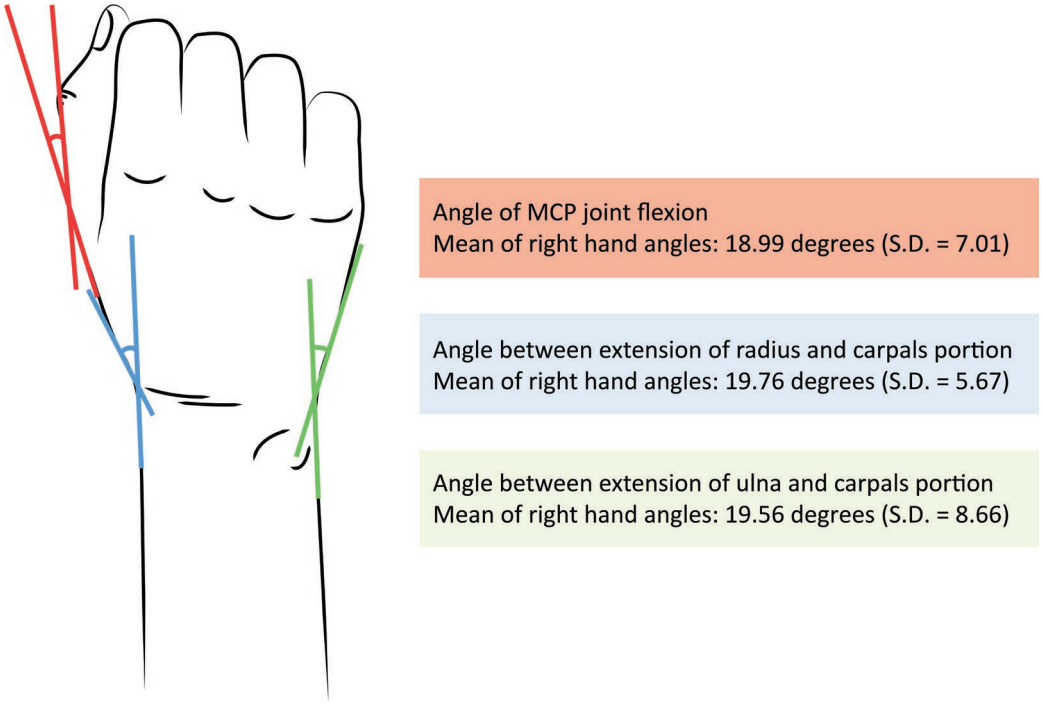
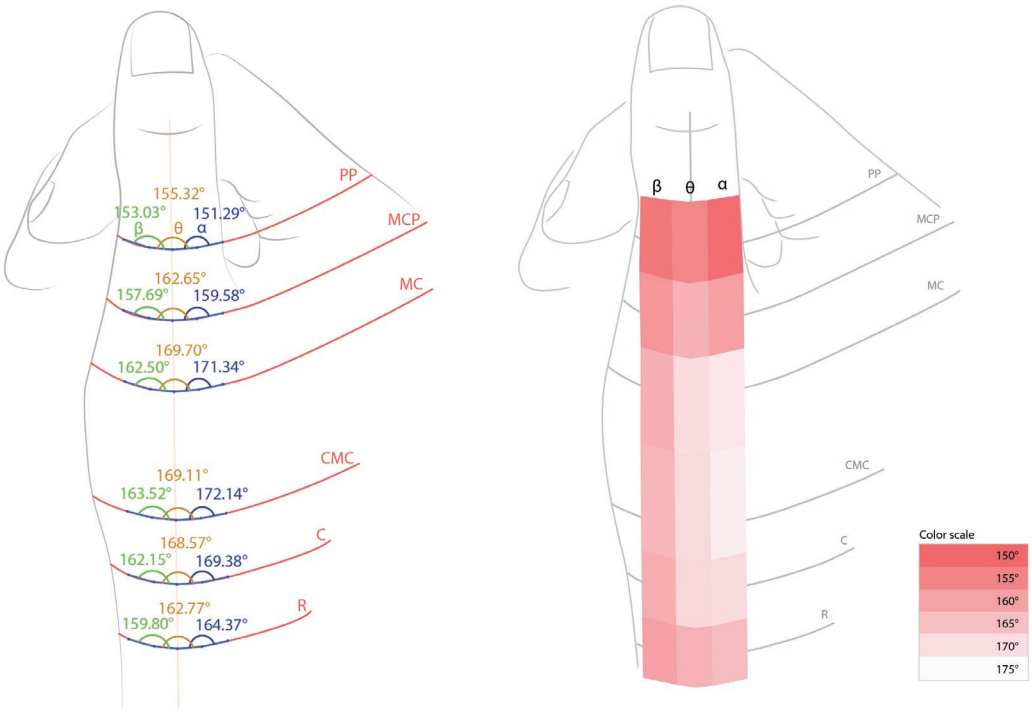


Figure 4.38 Summary of the angle results at the MCP joint and the two sides of wrist (DQVS group)

Unlike the HYS and HMS subjects who do not have DQV, the subjects of DQVS group are patients with DQV. However, the location of the smallest and largest angles is the same as that of the HMS group. The smallest angle (151.29°) is α at the PP and the largest angle (172.14°) is α at the CMC (Table 4.5). The angle results range approximately from 130° to 185°. Figure 4.39 shows the measured angles at different parts sections along the thumb and the degree of curvature through a gradient map.

Table 4.5 Mean, S.D. and range of α, θ and β at different cross section levels along the thumb (DQVS group)

Position	Angle	Mean	S.D.	Range
PP	α	151.29°	9.35	130.40°-162.50°
	θ	155.32°	4.26	147.80°-161.94°
	β	153.03°	5.76	144.07°-161.79°
MCP	α	159.58°	6.01	147.57°-173.71°
	θ	162.65°	4.62	154.19°-174.15°
	β	157.69°	3.94	150.57°-163.76°
MC	α	171.34°	2.70	165.91°-176.84°
	θ	169.70°	6.72	160.81°-181.05°
	β	162.50°	3.73	156.74°-167.66°
CMC	α	172.14°	6.05	161.32°-183.37°
	θ	169.11°	5.13	162.56°-179.01°
	β	163.52°	5.39	150.99°-175.01°
C	α	169.38°	3.87	162.74°-174.44°
	θ	168.57°	5.16	158.30°-175.84°
	β	162.15°	6.07	152.97°-174.32°
R	α	164.37°	3.84	155.81°-174.86°
	θ	162.77°	5.27	153.42°-171.99°
	β	159.80°	5.53	146.51°-167.81°



(a) (b)

Figure 4.39 (DQVS group)

(a) Summary of mean of α, θ and β at different cross section levels along the thumb, and

(b) Gradient map of measured angle results

4.3.2.5 Comparison between the angle results of HYS and HMS

A Mann-Whitney U test, which is a non-parametric independent test, was carried out to compare the measured angles of the HYS and that of HMS groups, all of whom do not have DQV. Since the two groups are in different age groups, the purpose of the comparison is to investigate the differences in the angle of the curvature along the thumb and wrist due to age. The null hypothesis (H_0) proposes that there is no difference between the two groups. After calculating the statistical results with SPSS software, it was found that there are significant differences between the two groups in terms of 6 angles. At the cross-sectional curve of the PP, the θ of the HMS group (mean rank = 15.94) is larger than that of the HYS group (mean rank = 9.60), $U = 41.0$, $Z = -2.056$ and, $p = 0.040$; and the β of the HMS group (mean rank = 15.88) is larger than that of the HYS group (mean rank = 9.70), $U = 42.0$, $Z = -2.003$, and $p = 0.045$. At the cross-sectional curve of the MCP, the α of the HMS group (mean rank = 16.06) is larger than that of the HYS group (mean rank = 9.40), $U = 39.0$, $Z = -2.161$, and $p = 0.031$; and the

θ of HMS group (mean rank = 17.00) is larger than that of the HYS group (mean rank = 7.90), $U = 24.0$, $Z = -2.951$, and $p = 0.003$. At the cross-sectional curve of the MC, the θ of the HMS group (mean rank = 16.22) is larger than that of the HYS group (mean rank = 9.15), $U = 36.5$, $Z = -2.293$, and $p = 0.022$. At the cross-sectional curve of R, the β of the HMS group (mean rank = 16.31) is larger than that of the HYS group (mean rank = 9.00), $U = 35.0$, $Z = -2.372$, and $p = 0.018$. Since the p values of these six pairs of angles are less than 0.05, H_0 is rejected in that the six angles of the HMS group are significantly larger than those of the HYS group. One possible reason for this phenomenon may be that mature adults have enlarged joints with thickened collagenous connective tissues due to years of accumulated joint movement and increase rate of osteoarthritis. Figure 4.40 shows the location of the six angles along the thumb.

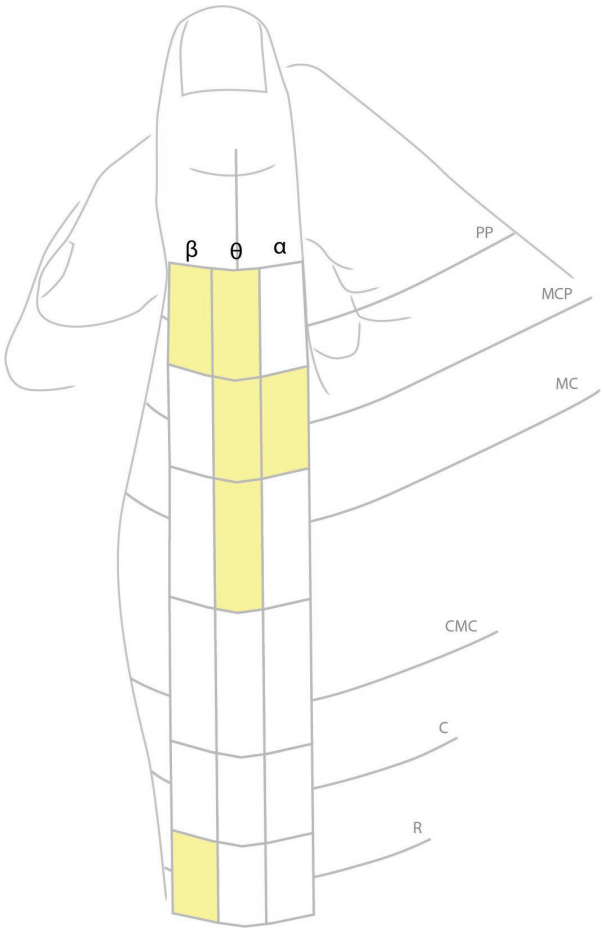
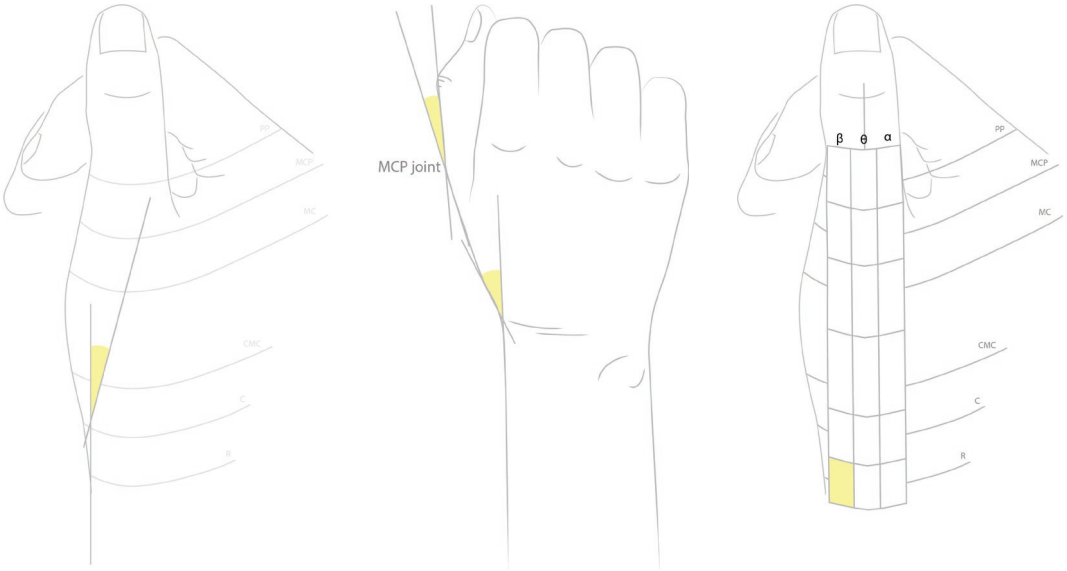


Figure 4.40 Location of the six angles

4.3.2.6 Comparison between the measured angle results of HMS and DQVS Groups

A Mann-Whitney U test was carried out to compare the measured angle results between the HMS groupand DQVS groups. Both groups are in the same age cohort; however, the former do not have DQV. The purpose of the comparison between the measured angle results of these two groups is to investigate the differences in the curvature angles along the thumb and wrist due to DQV. The H_0 proposes that there is no difference between the measured angle results of the two groups. The results indicate that H_0 is rejected for four of the angles as the p values are less than 0.05. The angle of the wrist extension of the DQVS group (mean rank = 20.50) is significantly larger than that of the HMS group (mean rank = 12.50), $U = 64.0$, $Z = -2.412$, and $p = 0.016$. The reason why the DQVS group performed be due to the difficulties of holding their wrist within 10° to 20° of extension with wrist pain. The angle of the MCP joint flexion of the DQVS group (mean rank = 12.00) is significantly smaller than that of the HMS group (mean rank = 21.00), $U = 56.0$, $Z = -2.714$, and $p = 0.007$. The angle between the extension of the radius and carpals of the DQVS group (mean rank = 11.75) is also significantly smaller than that of the HMS group (mean rank = 21.25), $U = 52.0$, $Z = -2.864$, and $p = 0.004$. When the hand of the subjects were in the rest position during scanning, the distal phalanx of the thumb came into contact with the middle phalanx of the index finger. As the more distal part of the tip of thumb touches the middle phalanx of the index finger, the phalangeal joints of the thumb flexes more and the thumb extends more. Since greater extension of the thumb may trigger pain in an injured area of the hand, the DQVS group may tend to put their hand into the rest position with less extension of the thumb and flexion of the MCP joint during the scanning process. The last angle that showed a significant difference between the HMS and DQVS groups is β at the cross-sectional curve of R. The β of the DQVS group (mean rank = 12.44) is significantly less than that of the HMS group (mean rank = 20.56), $U = 63.0$, $Z = -2.450$, and $p = 0.014$. The reason why the β of the DQVS group is less might be its location along the girth of R is where the swollen part of the injured wrist is found. Since the swollen part protrudes from the flatter surface of the wrist, the angle measured along the skin surface of the swollen part might be smaller, thus indicating a more curved surface at the radial side of the wrist which corresponds to one of the possible symptoms of DQV. Figure 4.41 shows the location of the four angles.



(a) (b) (c)

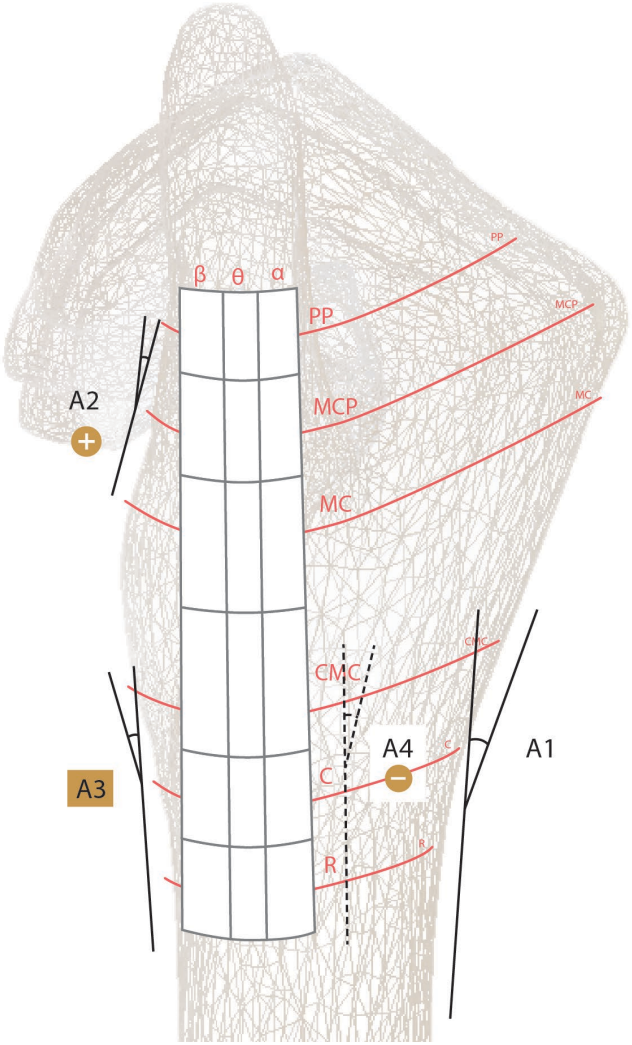
Figure 4.41 Location of four angles: (a) wrist extension;
(b) MCP joint flexion and between extension of radius and carpals; and
(c) β at the cross-sectional curve of R

4.3.2.7 Correlation between measured angle results of DQVS

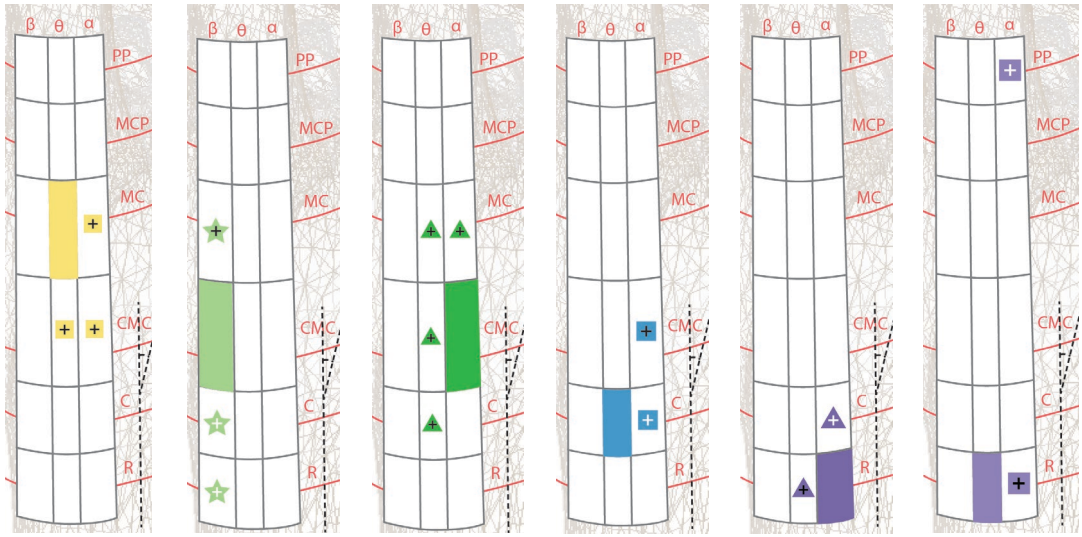
A non-parametric Spearman's rank correlation test was carried out to investigate the correlation between the angle of the curvatures along the thumb of the DQVS group. H_0 proposes that there is no correlation between the two specific angles. The test results showed some correlation with $p < 0.05$, so H_0 is rejected and the two angles are considered to be correlated. Figure 4.42 shows the correlations between the angles. The angles with a circle, triangle, square or star shape logo are those that are correlated to the highlighted angle (fully coloured). Angles with circular logos correlate to the angle at the wrist; angles with triangular logos correlate to α; angles with square logos correlate to θ; angles with star logos correlate to β. A positive sign indicates a positive correlation, while a negative sign indicates a negative correlation. Sign in white represents $p < 0.05$, whereas sign in black represents $p < 0.01$.

Figure 4.42(a) shows that the angle of the MCP joint flexion (A2) is positively correlated to the angle between the extension of the radius and carpals (A3), $r_s = 0.582$, and $p = 0.018$. The angle between the extension of the ulna and carpals (A4) is negatively correlated to the angle between the extension of the radius and carpals

portion (A3), r_s = -0.521, p = 0.039. A possible reason that A2 and A3 have a positive relationship might be the linkages between the MCP and CMC joints by the APL and EPB tendons. During the hand rest position, when the first metacarpal bone is extended outward to a larger degree due to the attachments of the two tendons at the joints, the flexion of the MCP joint would normally be increased. For a negative relationship between A3 and A4, the degree of wrist ulnar deviation would normally be decreased when a patient deviates the hand towards the radial side to a larger extend.



(a)



(b) (c) (d) (e) (f) (g)

Circular logo: correlates to angle at the wrist

Triangular logo: correlates to angle α

Square logo: correlates to angle θ

Star logo: correlates to angle β

Positive sign: positive correlation

Negative sign: negative correlation

White sign: $p < 0.05$

Black sign: $p < 0.01$

Figure 4.42 Correlations between angles of thumb curvature

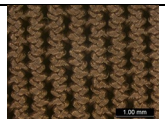
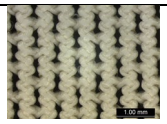
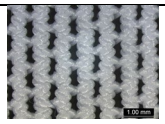
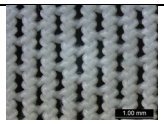
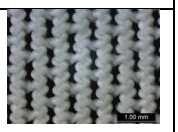
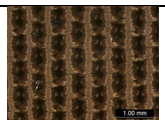
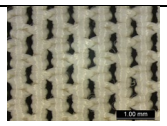
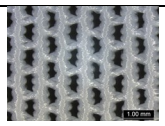
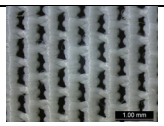
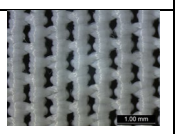
Figure 4.42(b) shows that α at the MC curve ($r_s = 0.744$, $p = 0.001$), and α ($r_s = 0.674$, $p = 0.004$) and θ ($r_s = 0.738$, $p = 0.001$) at the CMC curve are positively correlated to θ at the MC curve. β at the MC, C and R curves is positively correlated to that at the CMC curve, with $r_s = 0.673$, $p = 0.004$; $r_s = 0.586$, $p = 0.017$ and $r_s = 0.521$, $p = 0.039$ respectively (Figure 4.42(c)). α ($r_s = 0.628$, $p = 0.009$) and θ ($r_s = 0.674$, $p = 0.004$) at the MC curve, θ at the CMC curve ($r_s = 0.736$, $p = 0.001$) and θ at the C curve ($r_s = 0.701$, $p = 0.003$) are positively correlated to α at the CMC curve, as shown in Figure 4.42(d). With reference to Figure 4.42(e), there is a positive relationship between α at the CMC curve and θ at the C curve ($r_s = 0.701$, $p = 0.003$), and α at the C curve and angle θ at the C curve ($r_s = 0.527$, $p = 0.036$). α at the R curve is positively associated with α at the C curve ($r_s = 0.558$, $p = 0.025$) and angle θ at the R curve ($r_s = 0.635$, $p = 0.008$) (Figure 4.42(f)). In addition, angle α at the PP curve is positively correlated to α at the R curve ($r_s = 0.582$, $p = 0.018$), as shown in Figure 4.42(g). The correlation patterns shown in Figure 4.42(b) to 4.42(g) indicate that significant positive relationships can be found between the surrounding adjacent angles. Furthermore, it can be observed that the positive correlations between the angles are extended vertically and diagonally from the left side at the bottom to the right side at the top. The diagonal

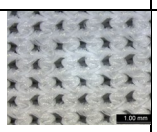
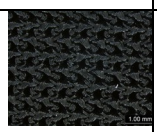
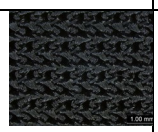
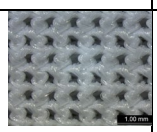
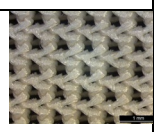
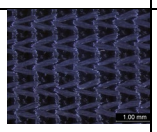
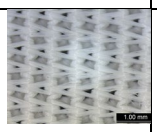
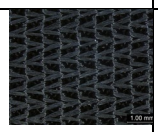
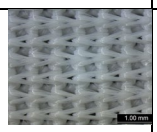
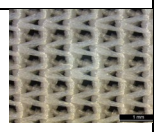
patterns of the angle relationship may be related to the anatomical structure underneath the skin, which the EPB tendon normally passes through the radial side of the wrist and inserts to the dorsum of the base of the proximal phalanx of the thumb.

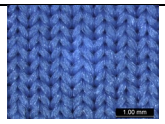
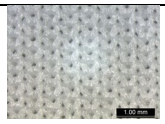
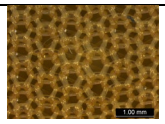
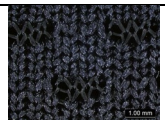
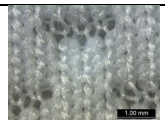
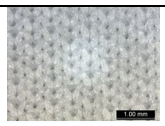
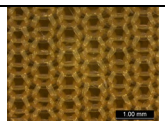
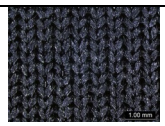
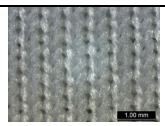
4.3.3 Selection of fabrics for proposed splint development

The selection of fabrics is a critical task for creating a comfortable splint. In this study, fabric samples were tested in terms of the air permeability, thermal conductivity, stretch and recovery, water vapor transmission and moisture management. To fabricate specific parts of the splint with different kind of fabrics, five kinds of powernet fabrics, six kinds of satinette fabrics (including the one used in the clinical splint), and five kinds of spacer fabrics were tested. The spacer fabrics with a sandwiched compressible middle layer could be act as protection layer along the thumb. Powernet fabrics with higher permeability could compose the main part of the splint for better air ventilation. Satinette is a stronger fabric that can be used as the main fabric of the splint to help to control hand movements and maintain the shape of the splint. All sixteen fabrics were observed under microscope and their fabric compositions are shown in Table 4.6.

Table 4.6 Fabric sample information

Fabric type	Powernet fabrics				
Code	Po1	Po2	Po3	Po4	Po5
Technical face					
Technical back					
Fabric compositions	71% polyamide 29% Elastane	59% Polyamide 6 41% Elastane	75% Polyamide 25% Elastane	71% Polyamide 29% Elastane	59% Polyamide 6 41% Elastane

Fabric type	Satinette fabrics					
Code	Sa1	Sa2	Sa3	Sa4	Sa5	SaC
Technical face						
Technical back						
Fabric compositions	77% Polyamide 23% Elastane	80% Polyamide 20% Elastane	80% Polyamide 20% Elastane	80% Polyamide 20% Elastane	91% Polyester 9% Elastane	N/A

Fabric type	Spacer fabrics				
Code	Sp1	Sp2	Sp3	Sp4	Sp5
Technical face					
Technical back					
Fabric compositions	89% Polyester 11% Elastane	93% Polyester 7% Elastane	91% Polyester 9% Elastane	90% Polyester 10% Elastane	90% Polyester 10% Elastane

4.3.3.1 Fabric weight and thickness

The splint for DQV treatment is worn by patients for long hours and even while doing daily tasks. Therefore, the splint should not be excessive in weight. Heavy fabric might also exert forces onto the hand, which may increase the burden on the muscles and tendons. Thus the splint fabric should be thinner if other properties are already optimised. Since the splint is worn on the hand where it is difficult to cover up with

clothing, the splint should be composed of thinner fabrics for most of the components so as to reduce the bulkiness and increase aesthetics. The fabric samples were tested accordance with ASTM D3776 and AASTM D1777 for weight and thickness, respectively. The measured results are shown in Table 4.7.

Table 4.7 Mean weight and thickness of fabric samples

Code	Po1	Po2	Po3	Po4	Po5
Mean fabric weight (g/m^2)	178.7	198.9	217.6	176.4	197.7
Mean fabric thickness (mm)	0.42	0.44	0.50	0.40	0.41

Code	Sa1	Sa2	Sa3	Sa4	Sa5	SaC
Mean fabric weight (g/m^2)	238.5	225.2	225.9	228.3	231.1	209.8
Mean fabric thickness (mm)	0.57	0.62	0.48	0.52	0.55	0.56

Code	Sp1	Sp2	Sp3	Sp4	Sp5
Mean fabric weight (g/m^2)	405.1	403.0	277.6	301.0	313.2
Mean fabric thickness (mm)	3.80	3.76	3.84	1.87	1.89

According to Table 4.7, Po4 is the thinnest and lightest powernet fabric. Among the satinette samples, SaC is the lightest in weight and the fabric used to construct the conventional splint offered by the clinic. However, SaC has a higher thickness than Sa3, Sa4 and Sa5. Among the five satinette fabric samples, Sa3 is the thinnest fabric. The thickness of the spacer fabrics depends on the sandwiched filament layer in between the two layers of knitted fabrics. Sp3 is the thickest but also the lightest among the spacer fabric samples. Sp5 has a moderate weight; however, it is the thinnest spacer fabric.

Although Sp4 has a moderate weight, it might be a good option as the fabric that encompasses the injured areas for protective purposes with a less bulky appearance since it is the thinnest spacer fabric. Po4 is the lightest and thinnest powernet which is potentially suitable for composing the main parts of the splint. Based on the weight and thickness results, it is difficult to determine which satinette fabric sample is more suitable for constructing the splint body; therefore, other properties have to be taken into consideration.

4.3.3.2 Air permeability

In the test that measured the air permeability of the fabric samples, air was blown from the air permeability tester KES-F8-AP1 through the fabric specimens to the external environment along the air hole. The value measured by the tester is the air resistance resultant of the fabric blockage. Therefore, a higher air resistance value denotes lower air permeability of the fabric sample. Figure 4.43 shows the air resistance rate of the fabric samples. Po3 has the lowest air resistance rate in comparison to the other fabrics. For satinette, Sa3 and Sa4 have a similar air resistance value, which is less than that of the other satinette fabrics. Sp3 has significantly less air resistance than the other spacer fabrics. From the results, Po3 might be a better option for constructing the splint in terms of air permeability. As satinette is one of the main fabrics for the body of the splint, Sa3 and Sa4 which have higher air permeability may be good options. Spacer fabric is planned to be used along the thumb for protective purposes. The spacer fabric is used where the thumb stay is attached. Since the thumb stay material probably has a lower air permeability compared to fabric, the fabric used along the thumb should have the highest air permeability as possible, so as to maintain wear comfort along the thumb. Therefore, Sp3 is likely to be used due to its high air permeability.

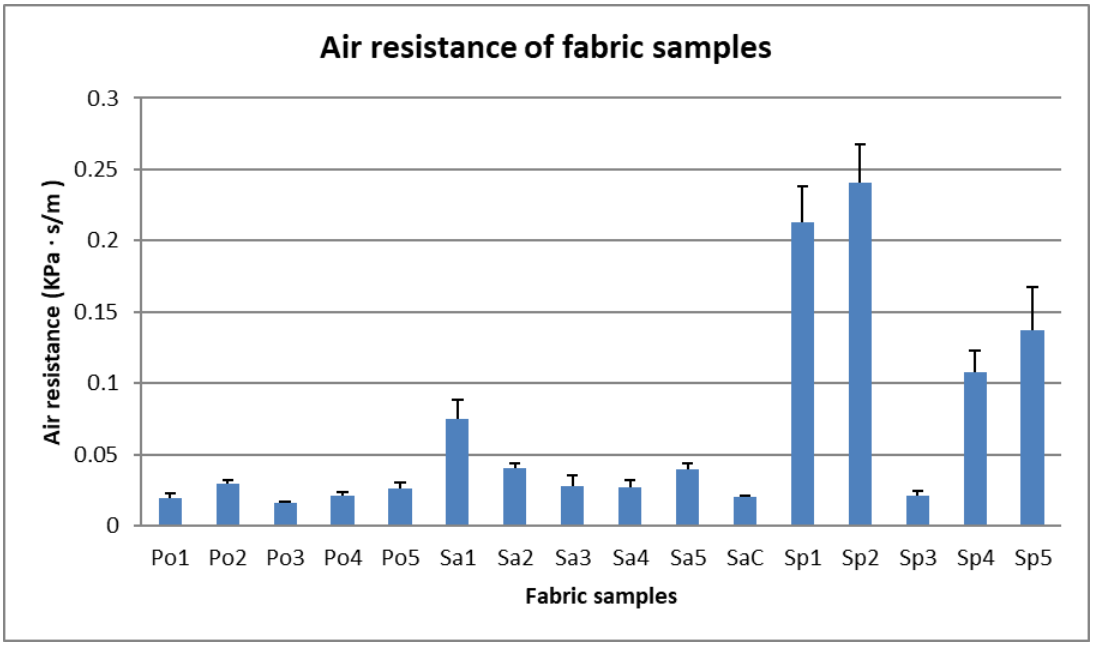


Figure 4.43 Air resistance of fabric samples

4.3.3.3 Thermal conductivity

The thermal conductivity of fabric is a critical factor that affects the quantity of heat transmitted through the material, thus influencing the overall wear comfort of the splint. In the experiment, heat transfer from the human skin to the outer environment is simulated. That is, a test with Thermal Property-Measuring Instrument KES-F7 THERMO LABO II. The amount of heat transferred from the B.T. box to the water box through the fabric specimen was recorded in watts. After obtaining the value of the heat flow loss, the thermal conductivity (K) of the fabric samples was calculated by using:

$$K = \frac{WD}{A\,(\Delta T)}$$

where W is the heat flow loss of the B.T. box, K is the thermal conductivity, A is the area of the heat plate on the B.T. box (25 cm^2), ΔT is the temperature difference between the B.T. and water boxes (10°C) and D is the thickness of the sample measured under a pressure of 6 g/cm^2.

Table 4.8 shows the mean heat flow loss of the heat plate on the B.T. box and fabric mean thickness. Figure 4.44 illustrates the thermal conductivity of the fabric samples in a bar chart.

Table 4.8 Mean heat flow loss and mean thickness of fabric samples

Sample Code	Po1	Po2	Po3	Po4	Po5
Mean heat flow loss of B.T. heat plate (W)	4.11	3.70	3.32	4.25	4.04
Mean thickness (mm)	0.42	0.44	0.50	0.40	0.41

Code	Sa1	Sa2	Sa3	Sa4	Sa5	SaC
Mean heat flow loss of B.T. heat plate (W)	3.21	3.19	3.26	3.07	3.02	2.34
Mean thickness (mm)	0.57	0.62	0.48	0.52	0.55	0.56

Code	Sp1	Sp2	Sp3	Sp4	Sp5
Mean heat flow loss of B.T. heat plate (W)	0.56	0.52	0.51	0.86	0.81
Mean thickness (mm)	3.80	3.76	3.84	1.87	1.89

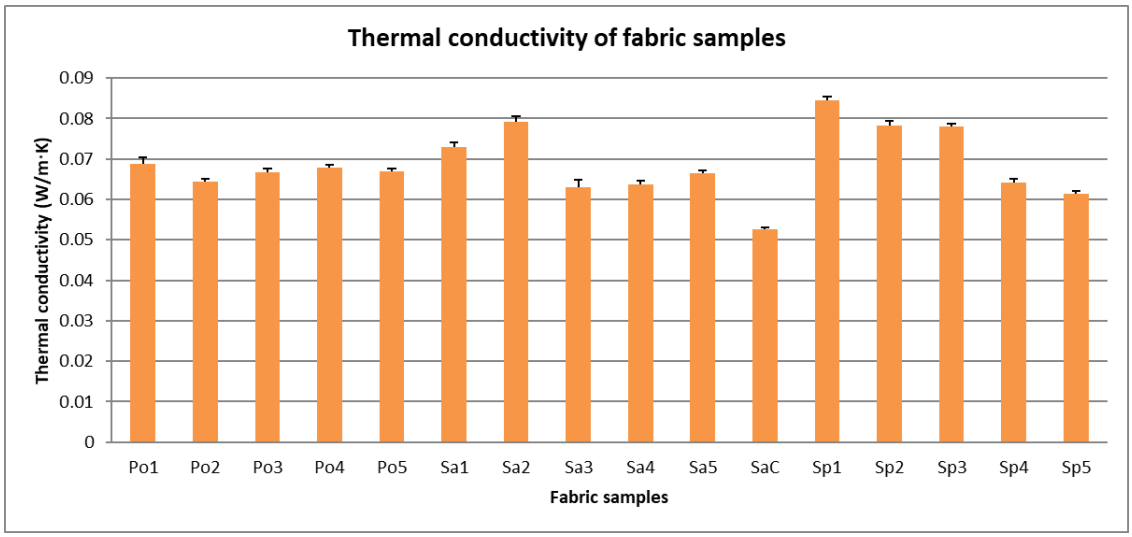


Figure 4.44 Thermal conductivity of fabric samples

Although the heat flow loss is much higher in the powernet and satinette fabrics than the spacer fabric, the differences in the thermal conductivity among all of the fabrics are not substantial. This could be because the mean thickness of the fabric samples are taken into consideration during the calculation. In terms of the powernet, Po1 and Po4 have a relatively higher thermal conductivity than the other powernet samples although the five samples have a similar thermal conductivity. Sa2 has the highest thermal conductivity among the satinette fabrics. Sp1 has the highest thermal conductivity among the spacer fabrics. However, even though the air permeability of Sp1 is much lower than Sp3, Sp4 and Sp5, the latter three may still be used due to much better air permeability and acceptable thermal conductivity.

4.3.3.4 Stretch and recovery

The splint for treating DQV is designed to immobilise the affected hand. The hard thumb supporter is responsible for stabilising the injured parts of the hand, while the main component of the splint which is composed of fabric should have a certain degree of stretchability for ease of inserting the thumb stay, ease of donning the splint, and providing the opportunity for changes in hand shape during the day with a good fit. In addition, since patients are required to wear the splint for 2 weeks or more, during the splinting period, time for donning and doffing the splint may accumulate. The splint fabric should have excellent recovery ability to maintain the size and shape of the splint even when the splint has been donned and doffed for a considerable length of time. The stretchability and recovery of the fabric samples were measured by using the Intron 4411 tensile tester and the results are shown in Figures 4.45 and 4.46.

Since the powernet, satinette and spacer fabrics are warp knitted, all of the stretch in the wale direction is normally higher than that in the course direction. In the construction of garments, the wale direction of powernet and satinette is horizontally along the body girth which would allow more room for the wearer to stretch the garment across the body. According to Figure 4.45, most of the warp knitted samples have higher stretchability across the wale direction than the course direction. Powernet and satinette fabrics were then determined for use as the primary materials of the main part of the splint. In order to allow patients the freedom to perform simple daily activities and for aesthetics purposes, the fabric samples with higher stretchability were chosen. Among the five powernet fabrics, Po1 and Po3 have higher stretchability across the

wale direction. It was observed that Po2, Po4 and Po5 have a more balanced stretchability across both knitting directions. For satinette fabrics, large differences between the stretchability along the wale and coarse directions are observed. Sa3 has the highest stretchability along the wale directions than the other satinnet fabrics. For the spacer fabrics, Sp3, Sp4 and Sp5 have a similar degree of stretchability across both directions, while Sp1 and Sp2 have relatively lower stretchability in both directions in comparison to the former three spacer samples.

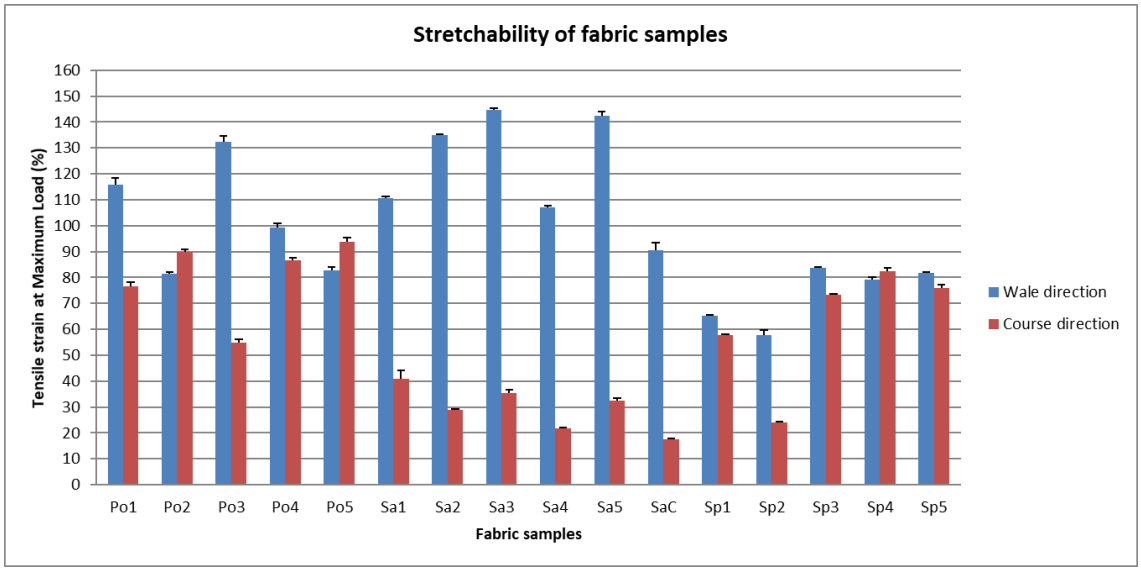


Figure 4.45 Stretchability of fabric samples

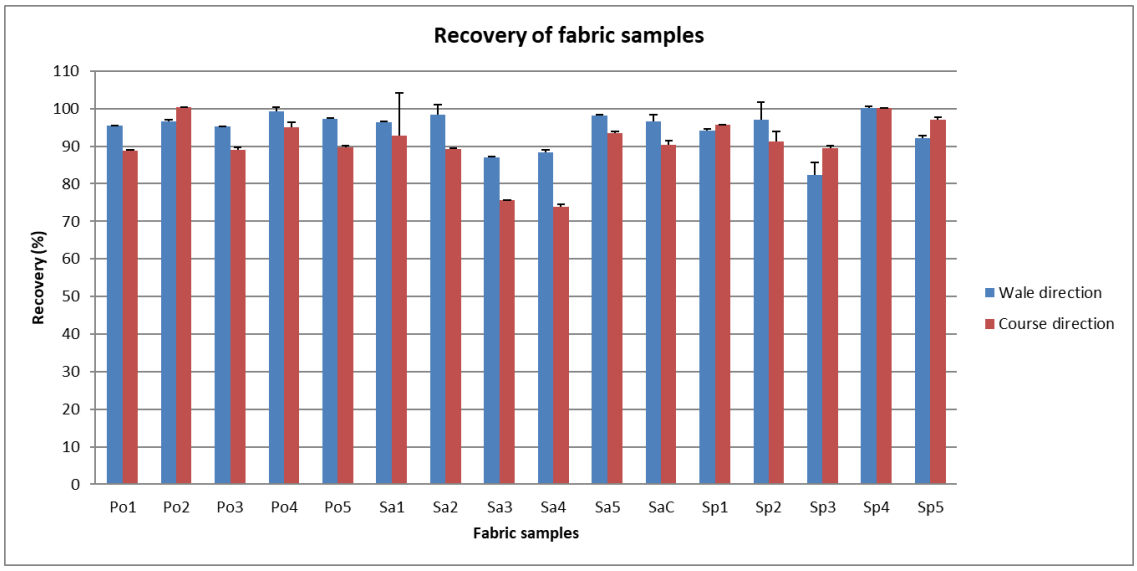


Figure 4.46 Recovery of fabric samples

The recovery percentage of the fabric samples in the wale and course directions is similar. The recovery of fabric across the girth of the hand is important as stretching occurs with each don and doff of the splint. The fabric directions applied across the girth should be considered, which is the wale direction of all three kinds of fabrics. A higher recovery rate in these directions means that the fabric can recover better after deformation. From the perspective of recovery ability, the optimal choices are Po4, Sa2, Sa5, or Sp4.

4.3.3.5 Water vapor permeability

Skin covered by the splint perspires; water is one of the by-products. When water vapor is trapped in the space between the splint and hand, feelings of humidity and discomfort may ensue. Therefore, the fabrics selected for splint construction should have high water vapor permeability. The test results are shown in Figure 4.47. Po2 has the highest water vapor permeability among the powernet fabrics. Sa2 among the satinette samples and Sp3 among the spacer fabrics have the highest water vapour permeability.

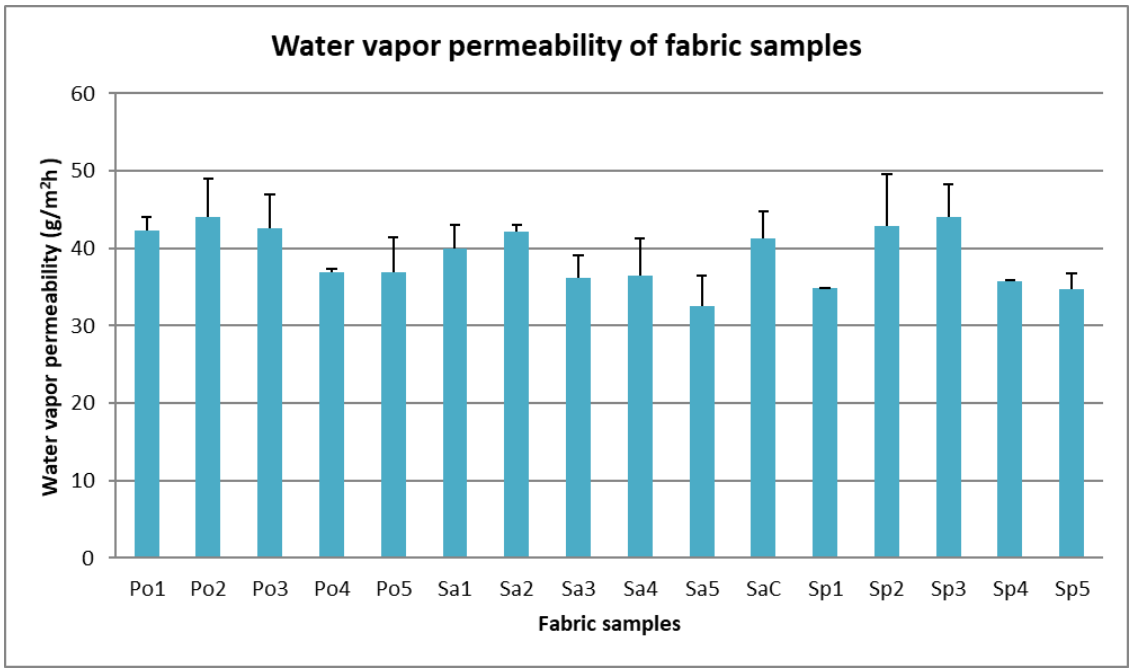


Figure 4.47 Water vapor permeability of fabric samples

4.3.3.6 Moisture management test

The six different satinette samples and five spacer samples were subjected to a moisture management test. Since the testing solution flows through the pores of the powernet fabrics quickly, it can be difficult for the moisture management tester to determine the solution spreading speed and situation at the face and back of the powernet fabrics. Therefore, the powernet fabric samples were not used in the moisture management test. The test replicated the moment when a sweat droplet touches the fabric surface and how this droplet spreads from the top surface to the bottom surface of the fabric. Figures 4.48 and 4.49 show the spreading of solution droplets at the top and bottom surfaces of the satinette and spacer fabrics as detected by the sensor plates of the moisture management tester respectively.

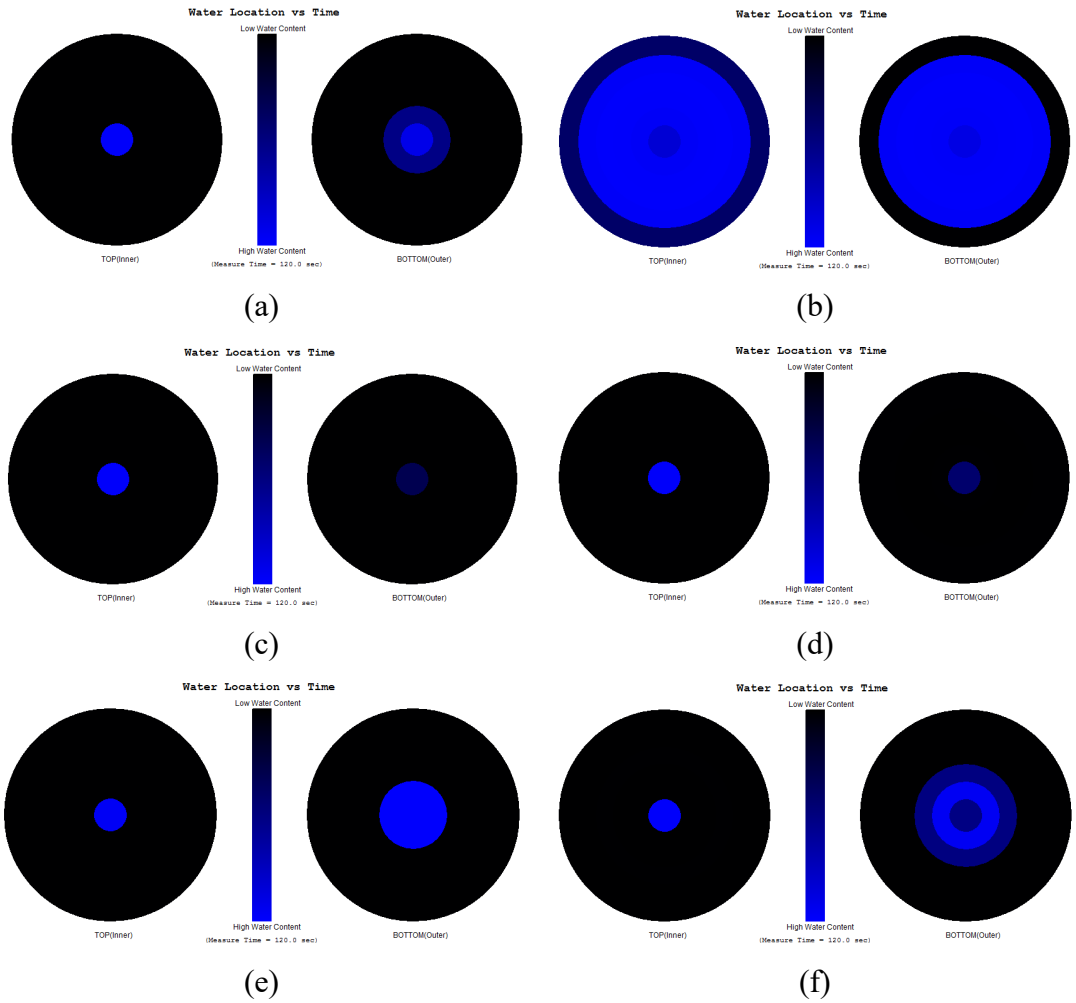


Figure 4.48 Moisture management test results:
(a) Sa1; (b) Sa2; (c) Sa3; (d); Sa4; (e) Sa5; (f) SaC

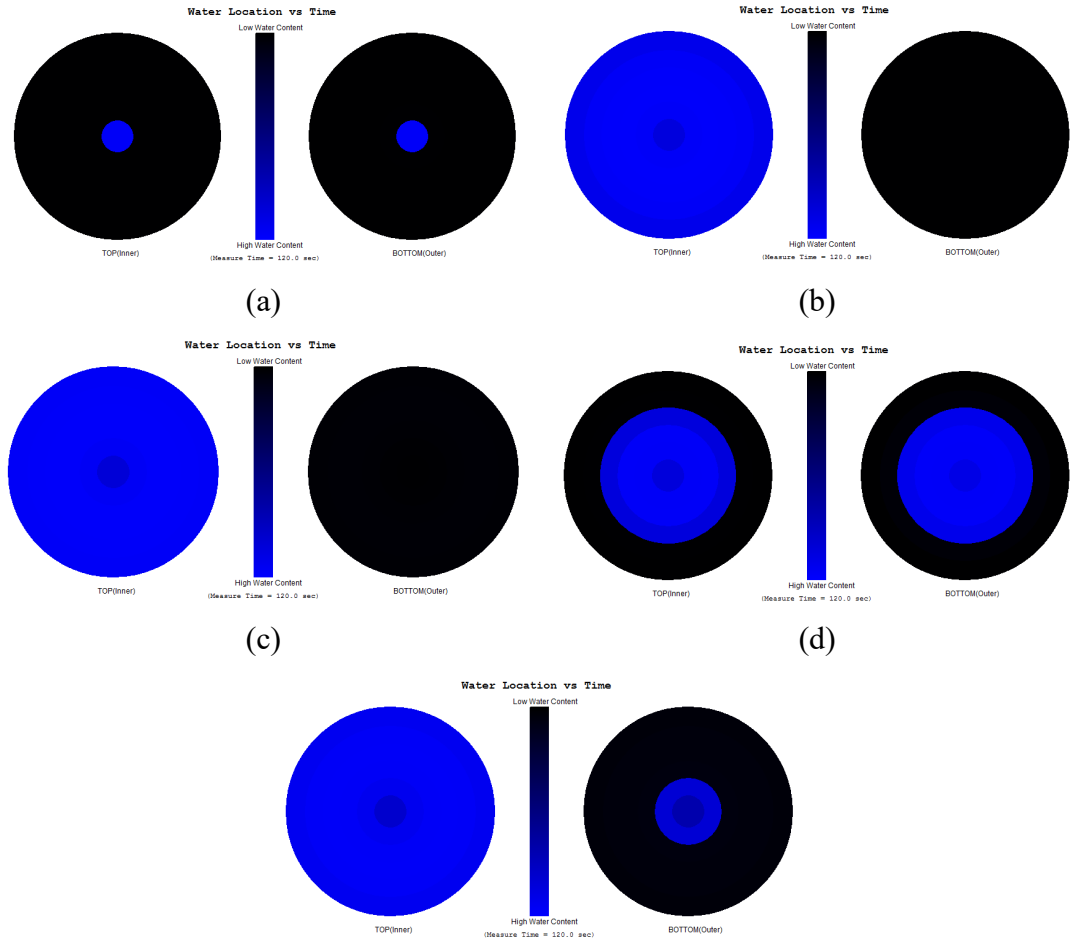


Figure 4.49 Moisture management test results:
(a) Sp1; (b) Sp2; (c) Sp3; (d); Sp4; (e) Sp5

According to Figure 4.48, Sa2 shows better moisture management than all of the other satinette fabrics in spreading the solution droplet at the top and bottom surfaces of the fabric. The solution could spread through Sa2 from the top to bottom efficiently within 120 seconds. For the spacer fabrics, the solution pooled at where it landed on the fabric and did not spread well over the surface of the fabric although the solution could flow across the top and bottom surfaces of Sp1. For Sp2 and Sp3, the solution could not be detected to pass through Sp2 and Sp3. The solution was only able to spread widely at the top surface of both fabrics. In comparing the results of Sp4 and Sp5, both fabrics allow the solution droplets to pass through the sandwich layer, however, the solution spread evenly on both surfaces. Therefore, Sp4 is a good option to construct the proposed splint in terms of moisture management.

4.3.3.7 Score weighting and fabric selection

The fabric samples were rated and given a score based on their performance. For the powernet and spacer fabrics, a score of 1 refers to the fabric with the worst performance while a score of 5 indicates the fabric with the best performance in a specific area. For satinette, a score of 1 is the lowest while 6 is the highest. Table 4.9 shows the ranking of the fabric samples according to their performance in each area. To include the comments of the subjects on the fabric properties, a score weighting system was developed, which was set up based on the scoring of the subjects on different factors of the splint in the questionnaire. The DQVS group completed the questionnaire, in which the importance of specific aspects of the splint was ranked; for example, appearance, functionality, air permeability, cooling effect, fabric stretchability, etc. A score of 1 represents 'not at all important' while a score of 5 represents 'very important'. Table 4.10 shows the mean scores of the importance of each aspect rated by the DQVS group.

Table 4.9 Ranking of fabric samples according to their performance for different aspects: (a) Powernet; (b) Satinette; and (c) Spacer

(a) Powernet					
Area of performance	Po1	Po2	Po3	Po4	Po5
Air permeability	4	1	5	3	2
Thermal conductivity	5	1	2	4	3
Maximum Heat Flux (Q-max)	4	2	1	5	3
Thickness	3	2	1	5	4
Weight	4	2	1	5	3
Bulkiness	1	4	2	3	5
Water vapor permeability	3	5	4	1	2
Stretchability- wale	4	1	5	3	2
Stretchability- course	2	4	1	3	5
Recovery- wale	2	3	1	5	4
Recovery- course	1	5	2	4	3

(b) Satinette						
Area of performance	Sa1	Sa2	Sa3	Sa4	Sa5	SaC
Air permeability	1	2	4	5	3	6
Thermal conductivity	5	6	2	3	4	1
Q-max	5	4	6	3	2	1
Thickness	2	1	6	5	4	3
Weight	1	5	4	3	2	6
Bulkiness	4	1	6	5	3	2
Water vapor permeability	4	6	2	3	1	5
Stretchability- wale	3	4	6	2	5	1
Stretchability- course	6	3	5	2	4	1
Recovery- wale	3	6	1	2	5	4
Recovery- course	5	3	2	1	6	4
Moisture management	4	5	1	2	6	3

(c) Spacer					
Area of performance	Sp1	Sp2	Sp3	Sp4	Sp5
Air permeability	2	1	5	4	3
Thermal conductivity	5	4	3	2	1
Q-max	3	2	1	5	4
Thickness	2	3	1	5	4
Weight	1	2	5	4	3
Bulkiness	2	3	1	4	5
Water vapor permeability	2	4	5	3	1
Stretchability- wale	2	1	5	3	4
Stretchability- course	2	1	3	5	4
Recovery- wale	3	4	1	5	2
Recovery- course	3	2	1	5	4
Moisture management	4	2	1	5	3

Table 4.10 Score weighting system: mean scores (S.D.) of the importance of different aspects

Item	Mean score (S.D.)
Appearance	3.3125 (0.9465)
Functionality	4.4375 (0.6292)
Comfort	4.5333 (0.6399)
Air permeability	4.5000 (0.6325)
Thermal conductivity	4.4375 (0.6292)
Q-max	4.0000 (0.8944)
Thickness	3.8125 (0.7500)
Weight	4.2500 (0.6831)
Bulkiness	4.5000 (0.6325)
Water vapor permeability	4.1250 (0.8062)
Stretchability	4.0000 (0.7303)
Recovery	4.0625 (0.6801)
Moisture management	4.1250 (0.6191)
Durability	4.2500 (0.6831)
Ease of cleaning	4.1875 (0.8342)
Ease of donning	4.5625 (0.5123)

The final score of each item was calculated by multiplying the ranked score with the weighting rate correspondingly. The formula is:

$$Final\ score\ of\ each\ item = Ranking\ score \times weighting\ rate$$

Taking the score of the air permeability of Po1 as an example,

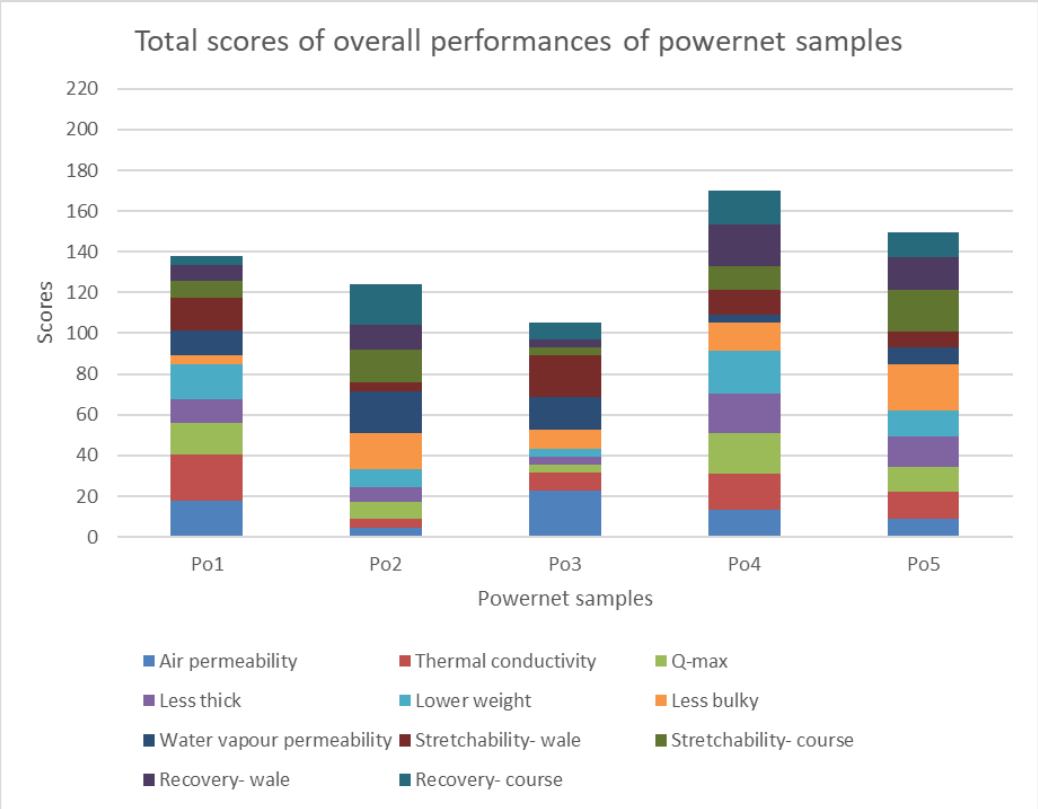
$$Final\ score\ of\ air\ permeability\ of\ Po1 = 4 \times 4.5$$

$$= 18$$

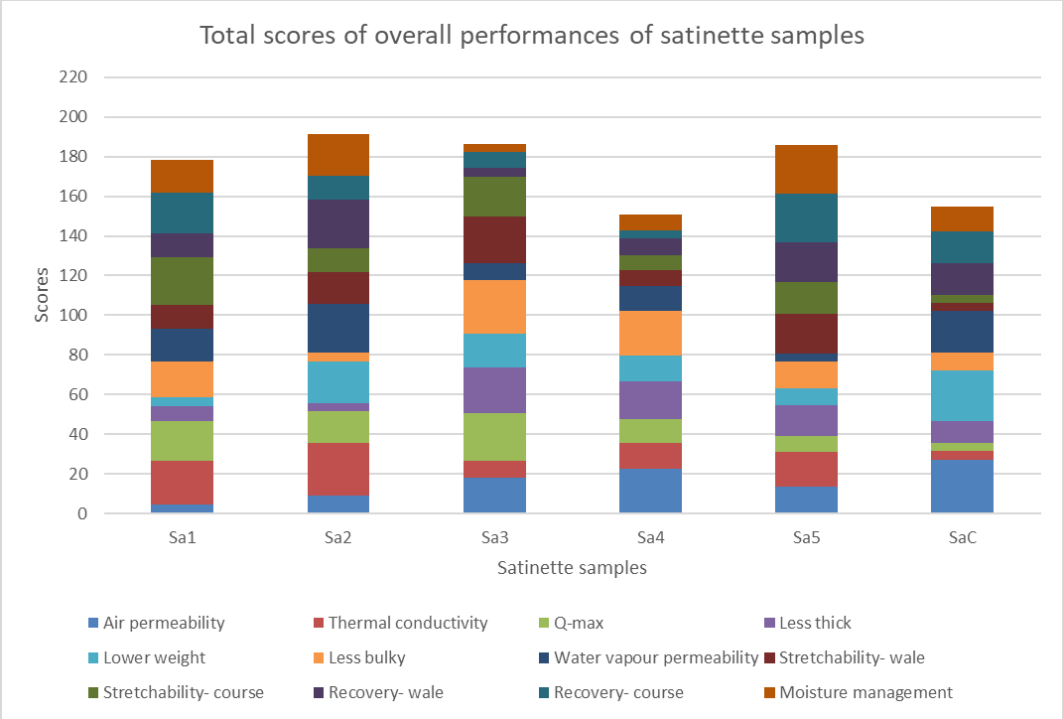
After calculating the final scores of all of the items of each fabric sample, the scores were added up to give the total score of each fabric sample by using the following formula,

$$Total\ score\ of\ fabric\ sample = Sum\ of\ final\ scores\ of\ items$$

The total scores of the fabric samples were calculated and illustrated as bar charts, see Figure 4.50. The results show that Po4 has the best performance among the powernet fabric samples. On the chart of satinette fabrics, it can be observed that SaC, which is the fabric that is being used by the clinic in this study, has a relatively lower total score than the other samples. This shows that other satinette fabric samples could be better options in terms of the overall fabric properties. Sa1, Sa2, Sa3 and Sa5 have similar total scores. Since Sa2 has the highest total score, it is used as one of the primary materials for the main component of the proposed splint in this study. As for the results of the spacer fabric samples, Sp4 has a higher total score than the other samples. Therefore, Po4, Sa2 and Sp4 have the best overall performance and used as the materials for the proposed splint in this study.



(a)



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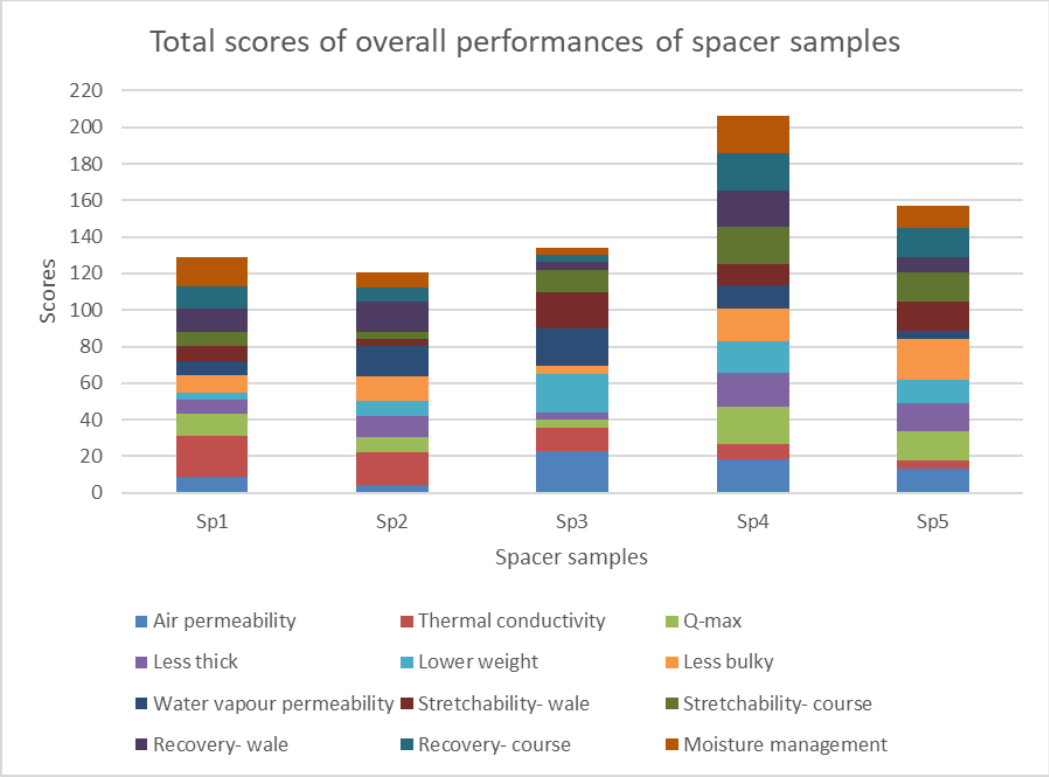


(c)

Figure 4.50 Overall performance of fabric samples:
(a) Powernet; (b) Satinette; and (c) Spacer

4.4 Summary

The currently available splints in the current market and a conventional splint used in a clinic in Hong Kong have been discussed in this chapter. Experiments for investigating the angles at the wrist and curvature of the thumb are carried out. The measured angles are then compared and analysed to gain a better understanding of the ergonomic shape of the hands of the subjects in this study. The gained knowledge and measured angle results could be used as reference to develop the proposed functional splint. Different kinds of fabrics are also tested to determine the most suitable materials for the proposed splint.

Ten splinting products from the online market have been reviewed, and their purpose is to mainly stabilise the wrist and thumb, so as to protect the hand and alleviate the pain of several different types of hand conditions, including DQV. Most of the commercially available splints are embedded with stays that support the thumb or the wrist. Although the splints claim that they could help to stabilise the hand, there is a lack of evidence to show the effectiveness of how they immobilise the hand. Therefore, an experiment for testing the control of the splint over hand movements is necessary. The review also summarised the fabric contexts, fastening systems, colours and sizes of the splints. These components are the elements that relate to the wear experience, which designers have to take into consideration when designing a splint.

An experiment is also conducted to investigate the effectiveness of the splints in controlling the movements of the wrist and thumb. The two splints that have been donned and tested are the Futuro and Medex splints. The results show that these two splints allow a large range of IP joint movement, which makes sense as the IP joint does not trigger the APL and EPB tendons of the DQV disease. However, the effectiveness of the Futuro and Medex splints in controlling the hand movements, such as wrist flexion, extension and ulnar deviations is low. Insufficient restriction of thumb abduction and over restriction of the MCP joint flexion are also observed. Therefore, a proposed functional splint with sufficient and appropriate restrictions on hand movements is timely and needed.

A clinical visit to the Occupational Therapy Department of the David Trench Rehabilitation Center in Sai Ying Pun, Hong Kong, has been done to observe the flow of clinical check-ups of patients with DQV and the fabrication process of customised splints. During the check-up, procedures such as diagnostic, grip strength and pinch strength tests, and the prescription and fabrication of the splint are carried out. In the clinic, short and long splints are prescribed to patients with minimal and moderate symptoms respectively. The fabrication methods and components of the two splints are different. Possible problems of the splints are noted. For the short splint, the neoprene fabric is not air permeable which may cause feelings of warmth during the use of the splint. For the long splint, fabric folds and bulkiness of the splint are observed. Therefore, the proposed functional splint should use fabrics with higher air permeability with a good fit.

Three groups of subjects are then recruited and labelled as the HYS, HMS and DQVS groups. The hand of the subjects is maintained in the rest position and scanned by using a 3D scanner. The angles of their wrist and curvature of their thumb are measured and recorded. The curvature along the thumb is illustrated with a gradient map and displayed in a numerical form. The results of the two groups who are in two different age ranges without DQV or the HYS and HMS groups, were compared statistically. Angles θ and β at the curvature of the PP, α and θ at the curvature of the MCP, θ at the curvature of the MC, and β at the curvature of R of the HMS group are significantly larger than those of the HYS group. Moreover, comparisons made between the results of the non-DQV and DQV subjects who are in a similar age range are conducted. The angle of the wrist extension of the DQVS group is significantly larger than that of the HMS group. On the other hand, the angle of the MCP joint flexion, angle between the extension of the radius and carpals and β at the R curve of the DQVS group are significantly smaller than those of the HMS group. Correlations of the angles of the DQVS group are also worth mentioning. The angles are correlated in the vertical and diagonal patterns, which may be related to the anatomical structure across the radial side of the wrist. The measured angle results could be used as reference for the development of the proposed functional splint in the next stage of this study.

The selection of appropriate fabrics for fabricating the proposed functional splint is important. Five types of powernet fabrics, six types of satinette fabrics, including the one constructed by the clinic, and five types of spacer fabrics are tested by using different fabric tests, such as air permeability, thermal conductivity, stretch and recovery, etc. A score weighting system of the fabric properties is developed according to the questionnaire results completed by the DQVS group. After calculating the fabric test results with the score weighting system, Po4, Sa2 and Sp4 have the best overall performance and are selected as the materials for the proposed functional splint. These fabrics likely can provide adequate wear comfort to the splint users.

Chapter 5 Design and development of proposed functional splint

5.1 Introduction

After conducting a literature review in Chapter 2 which discusses the different types of splints currently found in the market and available in clinics for treating DQV, several problems related to the splint are found, as follows: 1) low treatment compliance rate, 2) fit problems, 3) bulkiness and 4) ability to stabilise the hands. This study aims to design and develop a proposed splint to remedy the aforementioned problems. In this chapter, the design concept and pattern development processes are explained in detail. The processes of developing the splint and supporter prototypes are also discussed.

5.2 Design concept

The concepts of instrumental, non-instrumental and non-physical interactions have been discussed in Section 2.4.3 of Chapter 2. Different parts of the splint that might affect the perceived satisfaction of the patient towards the splint are also discussed. Design elements of the splint, such as aesthetics, comfort, durability, functional performance and efficacy, are important and taken into consideration as the design criteria for the proposed splint in this study. Figure 5.1 shows the design criteria of the proposed splint and Figure 5.2 shows the details of each criterion.

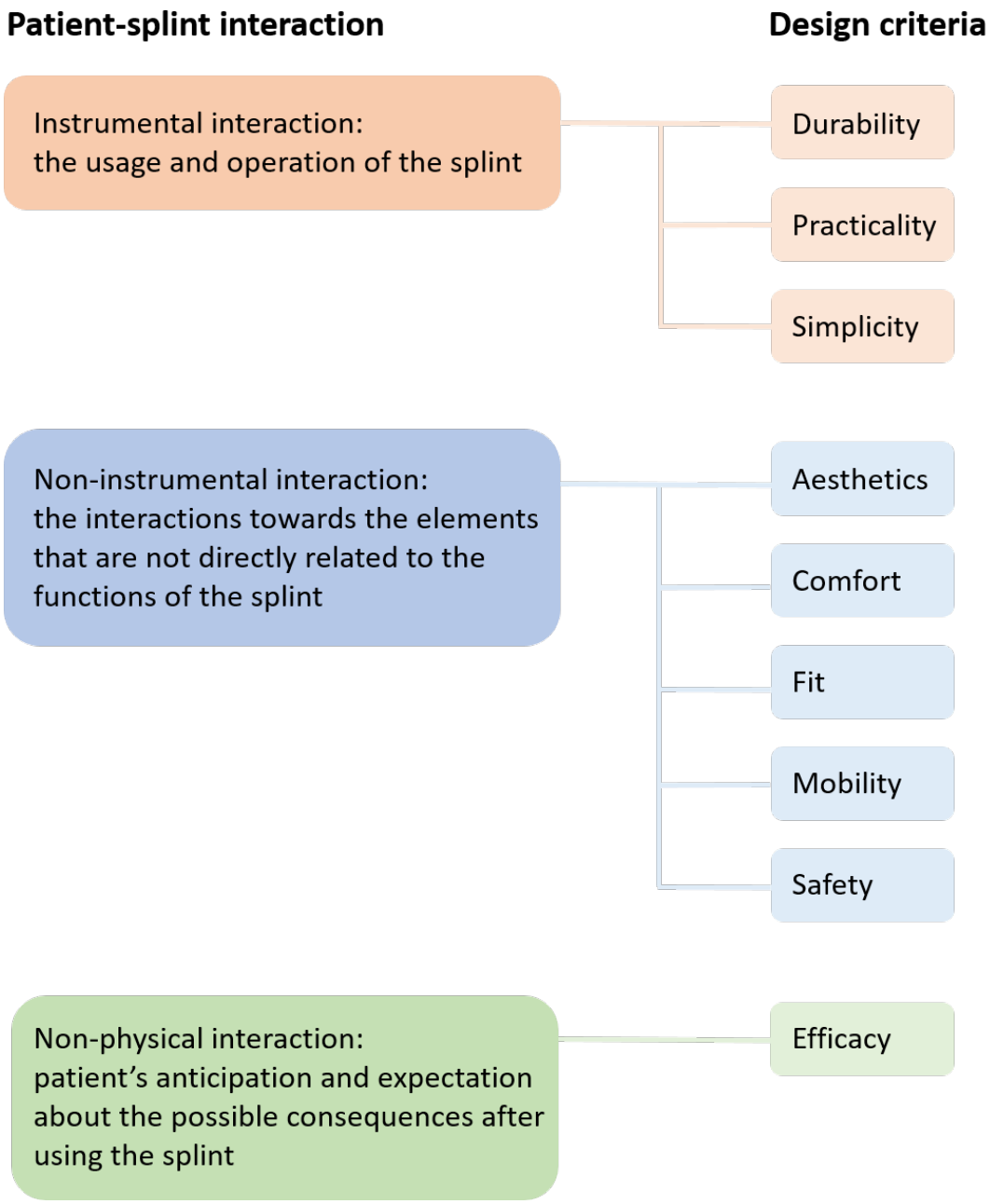


Figure 5.1 Patient-splint interaction and design criteria of the proposed splint

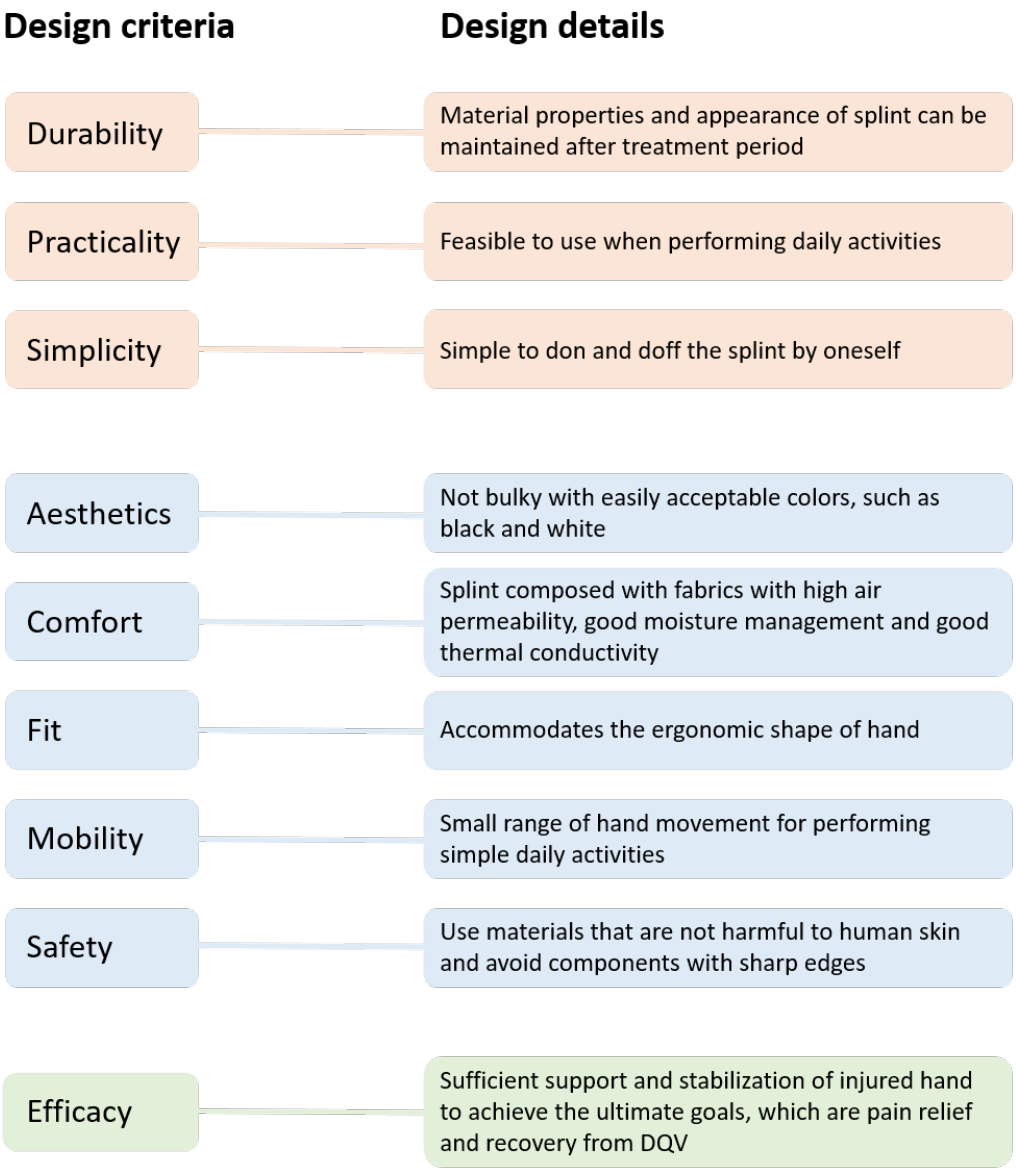


Figure 5.2 Design criteria and design details of the proposed splint

The instrumental interaction between patients and a splint is the usage and operation of splint by the patients. During the usage of a splint, the three critical design elements that are taken into consideration are ‘durability’, ‘practicality’ and ‘simplicity’. Generally, patients are required to wear the splint for 2 weeks or more. During the treatment period, the splint should be durable enough to withstand basic hand movements since patients have to wear the splint every day and perform different tasks. The splint should be practical and feasible for use during daily life instead of causing too much inconvenience. Since patients have to don and doff the splint every day for showering and washing their hands, the steps to don the splint should be simple enough so that patients can don and doff the splint easily and quickly by themselves.

Non-instrumental interaction is the interaction with elements that are not directly related to the functions of the splint, for instance, ‘aesthetics’, ‘comfort’, ‘fit; ‘mobility’ and ‘safety’. In terms of the aesthetics, the appearance of the splint might affect how patients perceive the splint and feel about it. Patients might find pleasure from the splint and are more willing to wear it if the splint is form fitting and aesthetically pleasing. Patients may also consider the colour of the splint. For example, some patients may prefer a neutral colour that matches the skin pigment, whilst others may prefer darker colours so that grime is not apparent on the splint. The wear comfort is also a critical element that may affect the compliance rate as patients would just take off the splint if it causes discomfort. Therefore, the proposed splint should be composed with fabrics that are equipped with high air permeability, good moisture management property and good thermal conductivity. The splint should fit well to the ergonomic shape of the patient’s hand as poor fitting splint with inappropriate pressure distribution may lead to hand pain and discomfort. Although the purpose of splint wearing is to support and stabilise the injured wrist and parts of thumb, simple daily activities within a small range of hand movement should still be feasible. Therefore, after the splint is donned, an appropriate range of mobility should be given to the patients for hand opposition and finger movements. Since the movement of the distal IP joint of the thumb would not trigger contraction and extension of the APL and EPB tendons, the IP joint of thumb should be free to move after the splint is donned. Moreover, the splint should be safe for patients to wear which requires some safety considerations; for example, the materials should not irritate the skin, and there should not be sharp edges of the splint components.

The last patient-splint interaction is non-physical interaction. This interaction involves the anticipation and expectations of the patient about the possible results after using the splint, which are related to the functions of the splint. The efficacy of splinting treatment is to protect and stabilise the injured hand, and consequently relief the symptoms of DQV, which are the most important areas of concern of patients. During splinting, improvements in hand condition may have impacts on the compliance rate in the later stages. After the splint is worn daily for a month or longer, patients normally expect a certain degree of pain relief or even full recovery from DQV.

5.3 Splint pattern development

The patterns of the thumb spica splint and the radial gutter immobilisation orthosis show that the orthoses protect the thumb and radial side of the hand, respectively, and mainly cover one-third to half of the forearm. Orthoses with a larger coverage area can reduce the level of pressure distributed from the splint to the forearm and hand. As for the glove pattern, the thumb piece is separately drawn and sewing onto the main part of the glove so as to fabricate a glove that fits the shape of the thumb and other parts of hand well. The patterns shown in Figure 5.3 can be used as reference for the development of the pattern pieces of the proposed splint. The main body of the splint consists of 5 smaller patterns with specific curved shapes that can be combined to create 3D contours to fit the hand well. The pattern pieces of the proposed splint (Figure 5.4) include 2 for the inner layer of the ulnar side of the main body of the splint (material: powernet), 2 for the outer layer of the ulnar side of the main body of the splint (material: satinette), 1 for single layer of the radial side of the main body of the splint (material: spacer), 1 for the thumb piece (material: spacer), and 2 for the pockets of the supporters in which a larger rectangular piece is designed for inserting the thumb supporter and smaller rectangular piece for inserting of ulnar supporter.

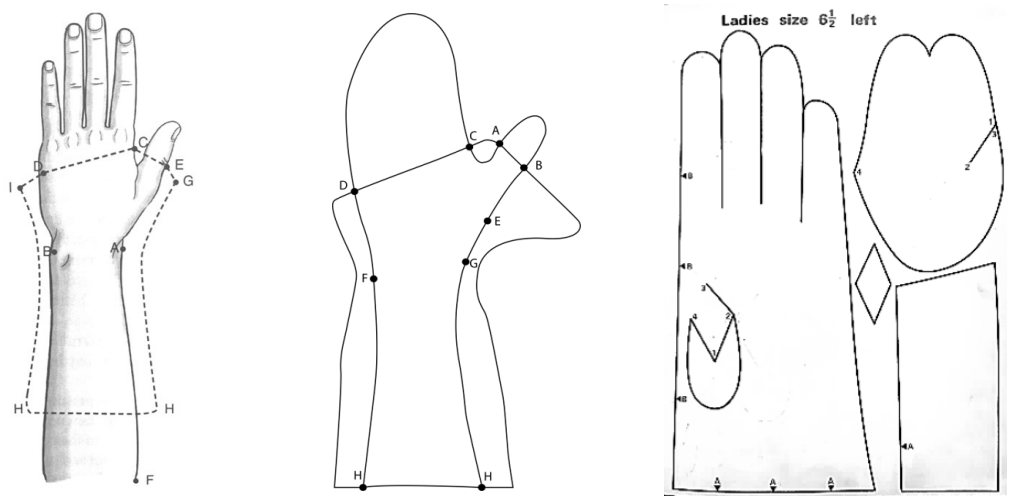


Figure 5.3 Orthoses and glove patterns
(Coppard & Lohman, 2014; Emlyn-Jones, 1974; Mahle & Ward, 2018)

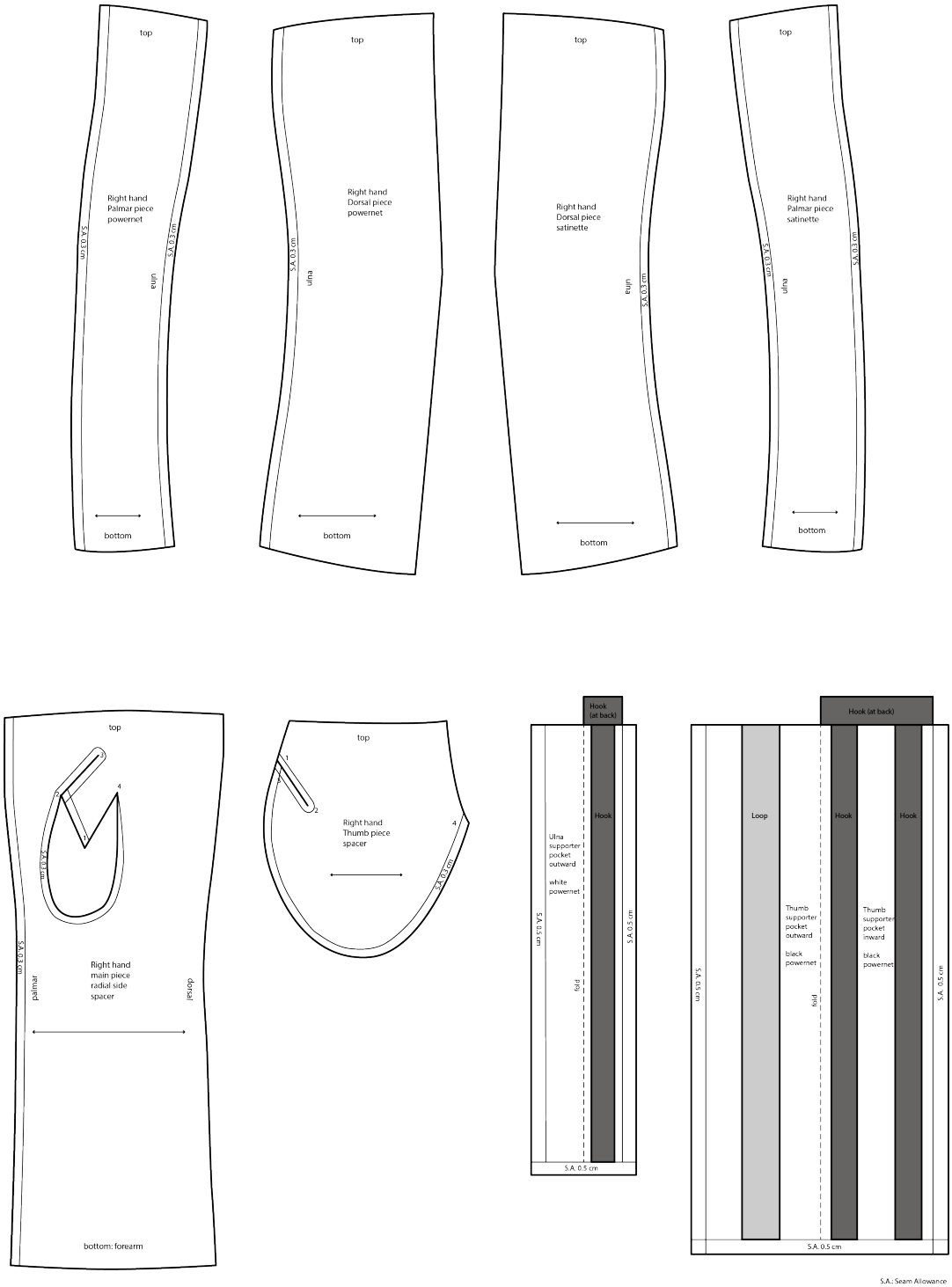


Figure 5.4 Patterns of the proposed splint for treating DQV

5.4 Splint prototypes

5.4.1 First prototype

As mentioned in Section 5.3, spacer fabric is used in the thumb area along the radial side of the hand. Spacer fabric was used due to its high air permeability and ability to eliminate the pressure of the rigid thumb supporter exerted onto the skin, which acts as a protective layer. Powernet fabric was used for the inner side of the splint as it has high air and water vapor permeabilities, which means that it is suitable for use as the fabric layer next to the skin of the hand. The high stretchability of powernet fabric can accommodate different hand shapes and facilitate the splint to offer a good fit. Satinette fabric was used as the outer layer of the splint. With the relatively higher stability, the satinette fabric layer may help to control the shape of the splint. The net structure of the satinette fabric allows the splint to be breathable. The double layers composed of powernet and satinette at the ulnar side of the body of the splint may reinforce the overall shape of the splint. Figure 5.5 shows the location of the spacer, powernet and satinette fabrics in the proposed splint.

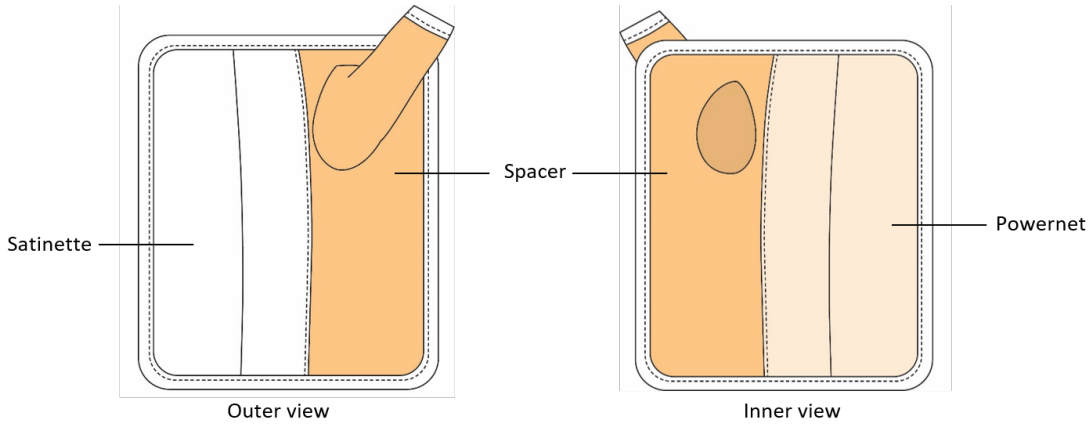
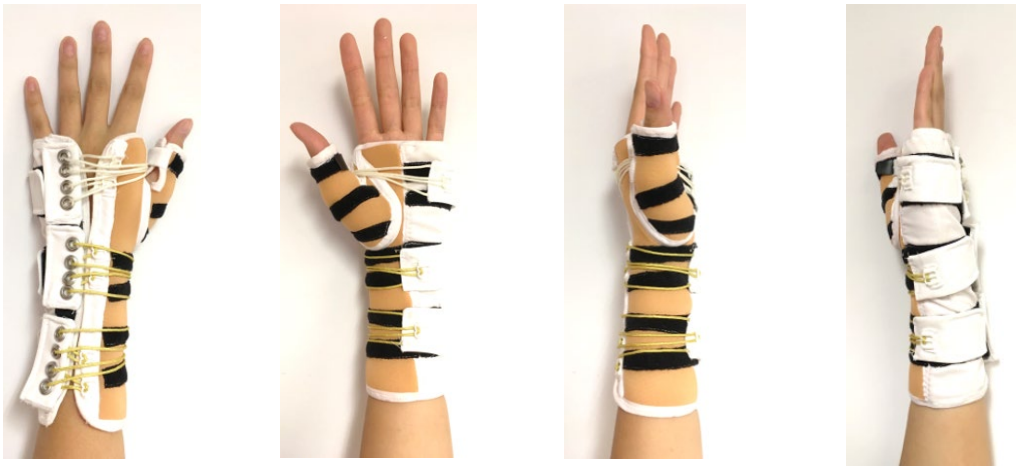


Figure 5.5 Placement of different types of fabric in the splint

Figure 5.6 shows the dorsal, palmar and side views of the first prototype. The fastening system is composed of Velcro strips (loop) which surround the girth of the hand and forearm for free attachment of the closing components (hook), three sets of narrow threads at the top, middle and bottom parts are used for size adjustment and metal eyelets for thread insertion and allow the mobility of the threads. Figure 5.7 show the placement location of the fabric materials and the fastening system.

After donning the first prototype, the subjects found some problems. First, the splint is difficult to construct with the complicated steps of eyelets attachments. Second, since the width of the closing components with the eyelet attached are too short that they could not attach to the Velcro loop securely, they easily detached during size adjustment. Thirdly, the narrow adjustable threads may easily hook onto by other objects when the subject is performing different daily tasks, hence causing inconvenience. Lastly, the splint appearance is messy and aesthetically unpleasing.



(a) (b) (c) (d)

Figure 5.6 First prototype of the splint
(a) dorsal; (b) palmar; (c) radial side; and (d) ulnar side views

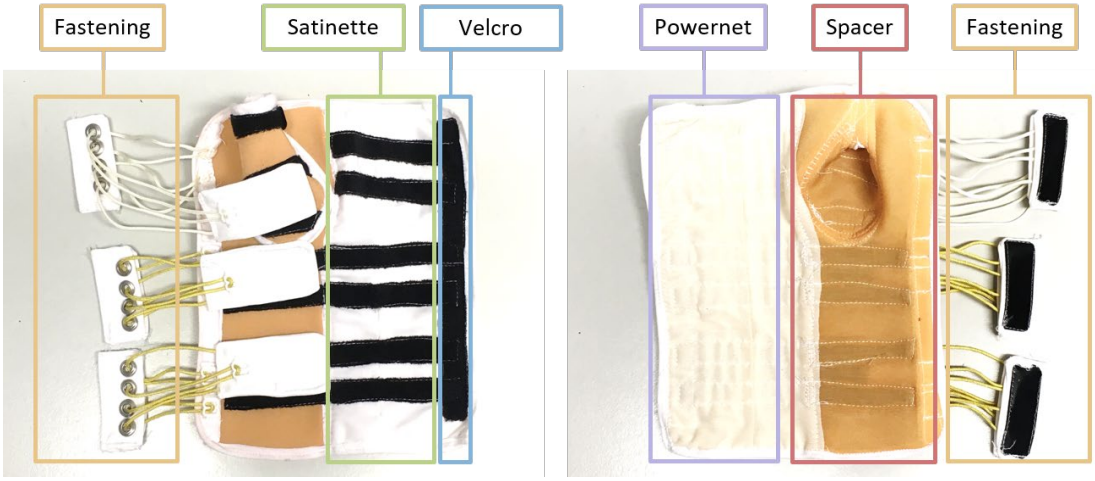


Figure 5.7 Placement of materials in the first prototype

5.4.2 Second prototype

The fabric components of the second prototype are the same as those of the first prototype. However, the fastening system was modified. To eliminate the complexities of the steps that involved inserting the eyelets, adjustment sliders were chosen to replace the eyelets. Since the holes of the sliders are flat and wider than those of the eyelets, narrow straps can be use which fit well in the holes. Replacing the narrow threads with straps gives the splint a neater appearance. In addition, the risk of catching onto other objects is reduced with the use of straps instead of a number of narrow threads. As with the narrow threads, the straps can be pulled easily to adjust the size of the splint. Figure 5.8 shows different views of the prototype and Figure 5.9 shows the overall appearance of the body of the splint and the fastening system is clearly shown in the technical drawings.

(a) (b) (c) (d)

Figure 5.8 Second prototype of the splint:
(a) dorsal; (b) palmar; (c) radial side; and (d) ulnar side views

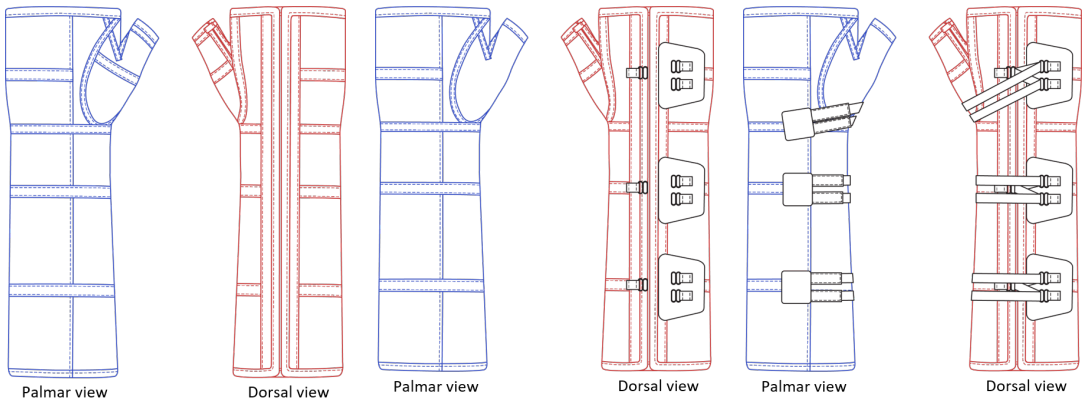


Figure 5.9 Technical drawings of second prototype:
(a) body of splint, (b) body of splint with fastening components; and
(c) body of splint with fastening components and adjustable straps

The fastening systems were designed to have two ways for opening and closing them. All were attached onto the main body of the splint with Velcro tape. The first way to access the splint is to detach the closing parts at the end of the adjustment straps, as shown on the left of Figure 5.10. This way of opening allows the wearers to pull the closing parts of the adjustment straps so that they can adjust the tightness of the splint components that surround their hand and forearm. On the other hand, the second way of opening is to detach the slider parts, so that the splint would be open along the mid-line at the dorsal side of the hand without changing the attached length of the adjustment straps, as shown in the right of Figure 5.10. This unique way of opening the splint is suitable for patients whose splint is adjusted by professional clinicians because they may not want to adjust the splint each time that they don the splint.

As for the aesthetics of the second prototype, some problems were observed. First, there are too many Velcro strips at the thumb piece which should be reduced. Secondly, in order to create a detachable fastening system, the closing pieces are attached separately onto the main body of the splint. The attachment of the closing pieces causes the splint to appear bulky which might also cause inconvenience so that wear compliance might be an issue.

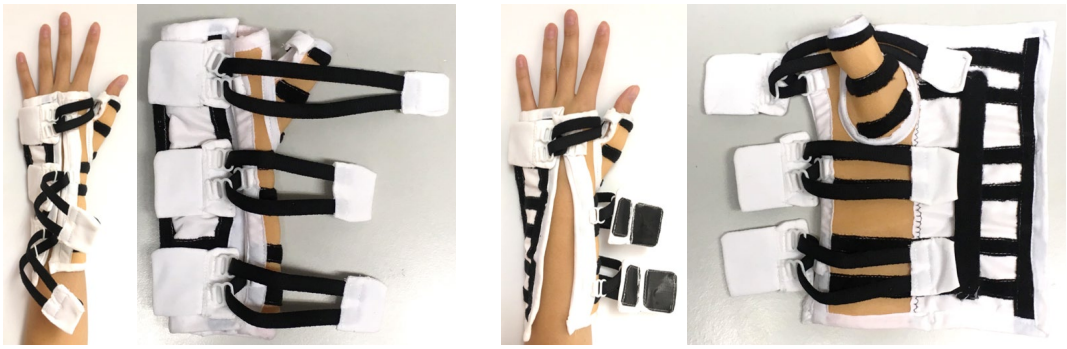


Figure 5.10 Two opening systems of the second prototype

5.4.3 Final prototype

Different views of the final prototype are shown in Figure 5.11. Since the detachable fastening system imparts bulkiness to the second prototype, the fastening components were reverted back to the original version, which gives the splint a neater appearance that accommodates the ergonomic shape of the hand. Black spacer, white satinette and white powernet fabrics were used to construct the final prototype. Black and white are common colours which are well received by patients. The colours of the fabrics divide the splint into two parts - the radial and the ulnar parts. The thumb and ulna supporters are then inserted into the black and white pockets respectively, so that patients can easily attach the supporters onto the correct side of the splint based on the colour. Furthermore, the attachable concept of the supporters allows slight adjustment of their placement in accordance with the changes in the shape of the hand of the patients. Figure 5.12 shows a technical drawing of the final version of the body of the splint with details of the type of fabric used and placement of the different components. Figure 5.13 shows a subject who is wearing the splint with the two supporters attached at both sides of the splint.

(a) (b) (c) (d)

Figure 5.11 Final version of the splint

(a) dorsal; (b) palmar; (c) radial side; and (d) ulnar side views

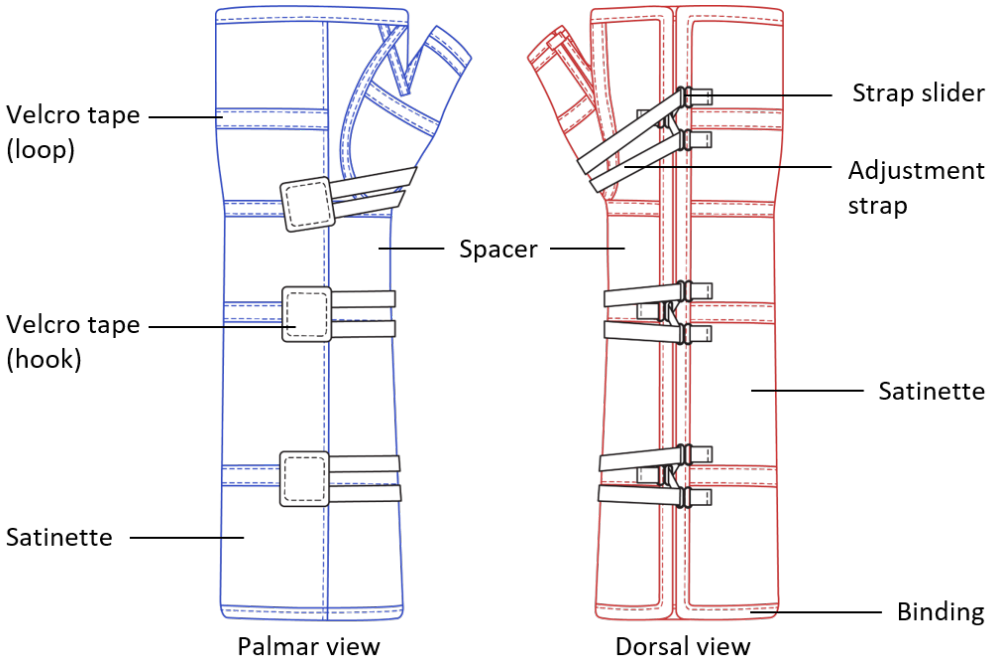


Figure 5.12 Technical drawing of the final version of the splint with details of components

(a) (b)

Figure 5.13 Final version of the proposed splint with attached supporters
(a) dorsal and (b) palmar views

5.5 Development of the supporter

5.5.1 Design ideas for the thumb supporter

In Chapter 4, the reviews of the splint products currently available in the market showed that most of the samples have a thumb supporter to protect the thumb. Some include a wrist supporter to further stabilise the hand. The traditional orthosis used by the clinic in this study also has both thumb and wrist supporters. For the proposed splint, a thumb supporter and an ulna supporter are used to control thumb movement, support the wrist, and prevent over ulnar deviation of the injured hand. Figure 5.14 shows the function of the two supporters.

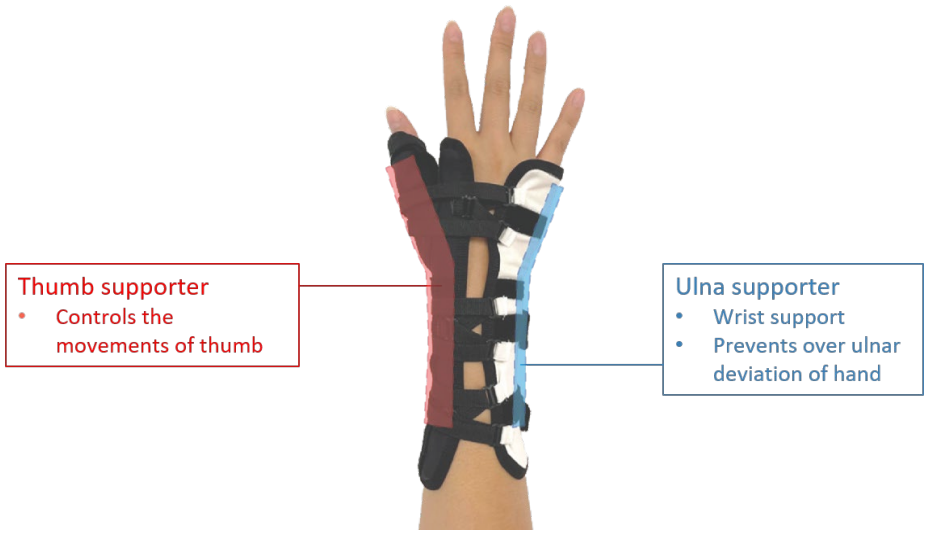


Figure 5.14 Functions of thumb and ulna supporters

The idea behind the design of the thumb supporter is to divide the supporter into three parts: the top, middle and bottom pieces, as shown in Figure 5.15. The reason for dividing the supporter into three different components is so the middle piece can be constructed with different lengths. With the length variations, the supporter can have different lengths which accommodate different hand sizes. The ability to make fine adjustments to the length of the thumb supporter is meant to accommodate the shape of the hand. The 3D models of the thumb supporter pieces and the ulna supporter were created by using Solidworks software. The dimensions and the specific angles at different parts of the supporters were based on the measured angle results of the group of DQV patients (DQVS group) (Figure 5.16) as discussed in Section 4.3.2.4 of Chapter 4. Figure 5.17 shows the drawing process of the supporter components with Solidworks.

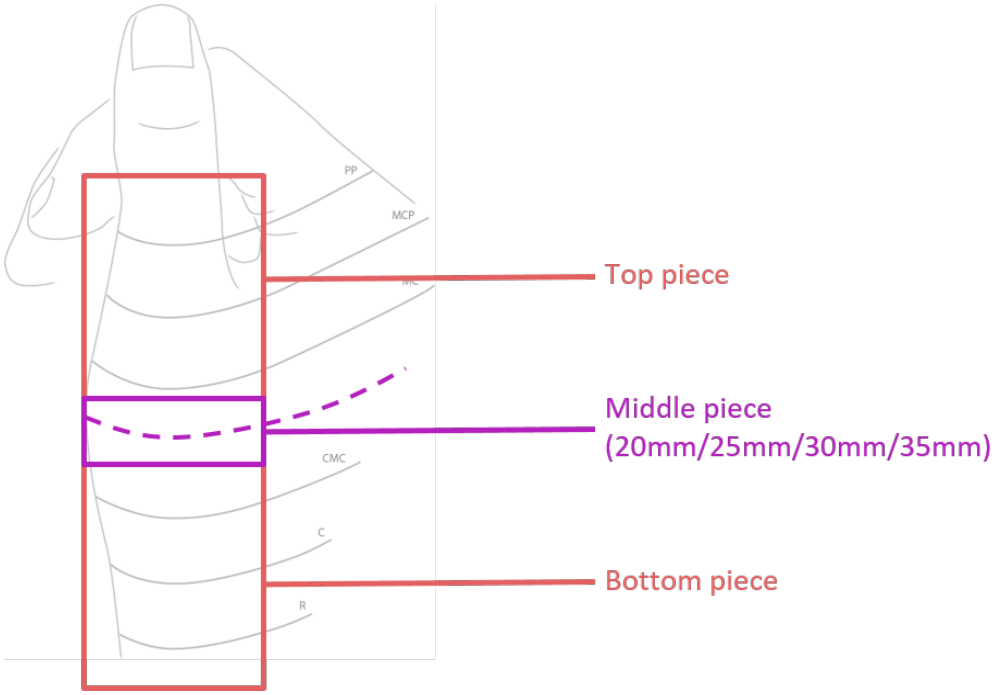


Figure 5.15 Details of design of thumb supporter

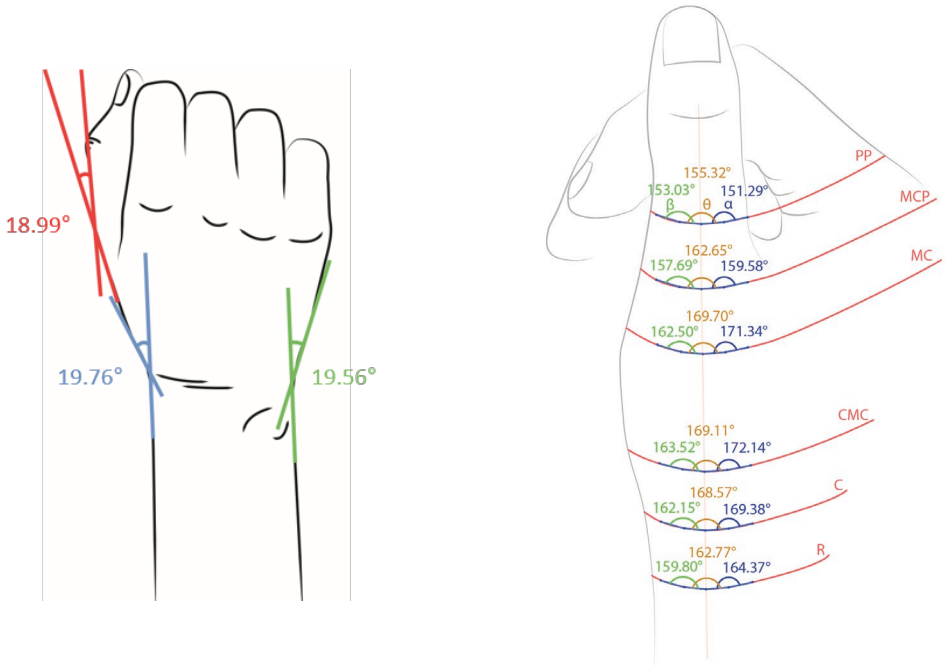


Figure 5.16 Measured mean angle results of DQVS group

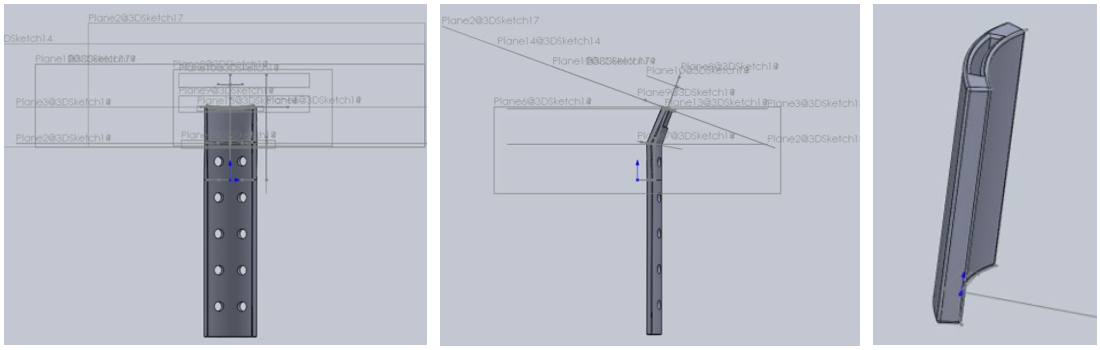


Figure 5.17 Drawing process of supporters with Solidworks

5.5.2 Supporter Prototype I

The 3D printed pieces of the first supporter prototype are shown in Figure 5.18. The printed material is transparent resin. The longest piece is the ulna supporter, which is designed to be attached to the ulnar side of the splint. The other pieces are the different components of the thumb supporter. The top and bottom pieces are designed to be inserted into the perforations in the centre of the middle pieces so that together, they make up the thumb supporter. Different lengths of the middle piece allow the total length of the thumb supporter to accommodate different hand sizes. The pieces are 2.5 mm in thickness and the protruding parts of the top and bottom pieces are 1 mm in thickness. The aligned circular perforations along the pieces are designed to enhance

the air ventilation of the thumb supporter. After combining the pieces, it was found that the inserted parts of the top and bottom pieces are fragile and easily break (Figure 5.19). The protruding parts are perhaps too thin, which might have caused this problem. Therefore, the first supporter prototype is not strong enough to support the hand.

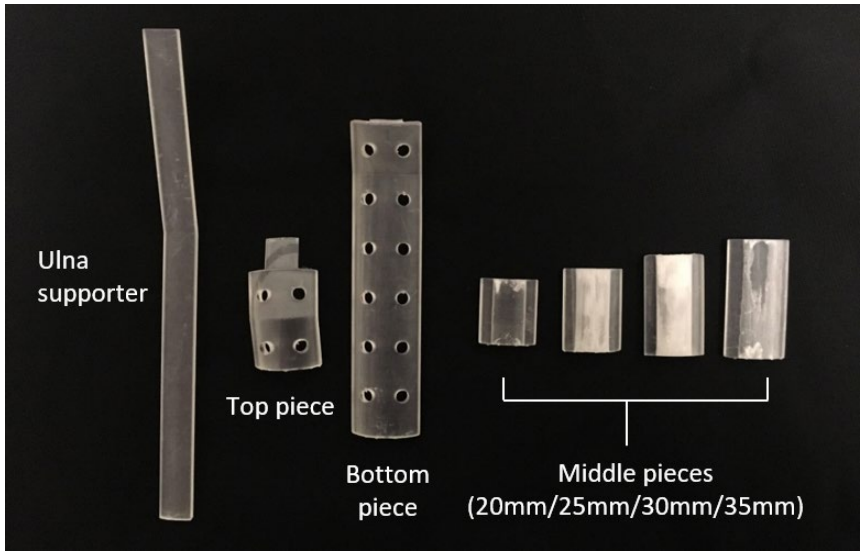


Figure 5.18 Parts of the first supporter prototype

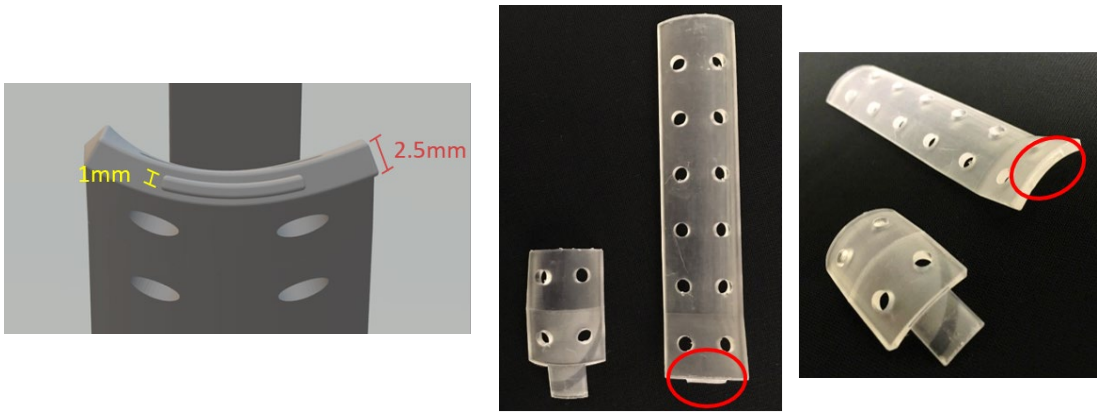


Figure 5.19 Design details of the bottom piece and broken part

5.5.3 Supporter Prototype II

The problem with the first prototype is that it is too fragile due to the thickness of the protruding part. To solve this problem, the second prototype (Figure 5.20) is 0.5 mm thicker than the first prototype. The thickness of the protruding part is increased from 1 mm to 1.5 mm, as shown in Figure 5.21. The reason why 0.5 mm of material was added is to strengthen the pieces, but at the same time, minimise the bulkiness of the

overall splint. Additional parts were extended from the middle pieces (Figure 5.22), to provide better connection and a better match between the pieces, thus better supporting the performance of the splint.

After producing the components of the second prototype, some parts are still brittle and could be broken easily, such as the extended parts of the middle pieces even though the middle pieces can match the top and bottom pieces better, and the strength of the pieces is higher with an increase in the total thickness (Figure 5.23).

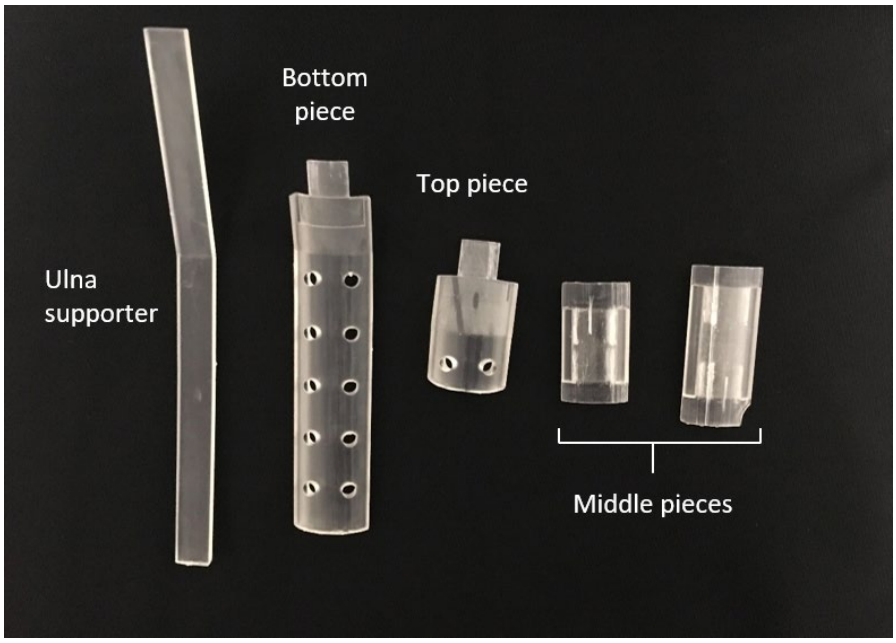


Figure 5.20 Parts of second supporter prototype

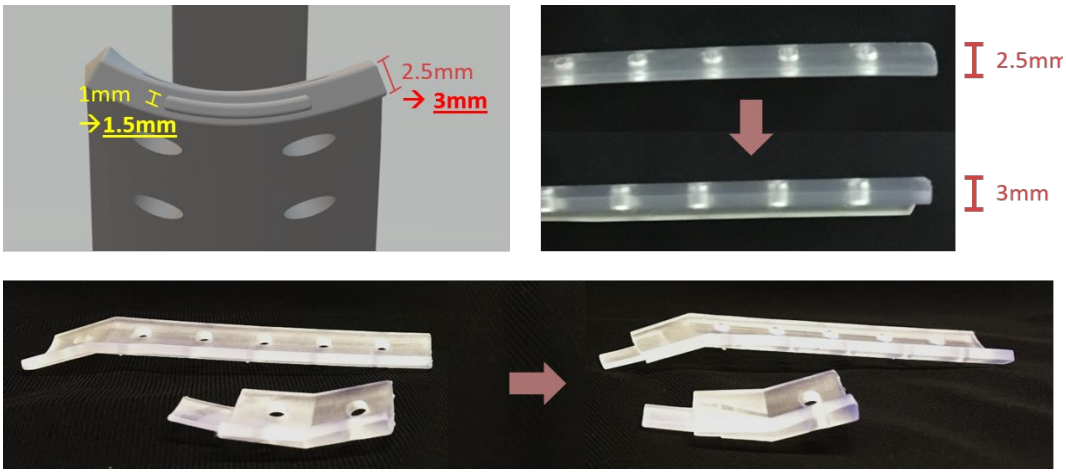


Figure 5.21 Modifications: Second prototype based on first prototype

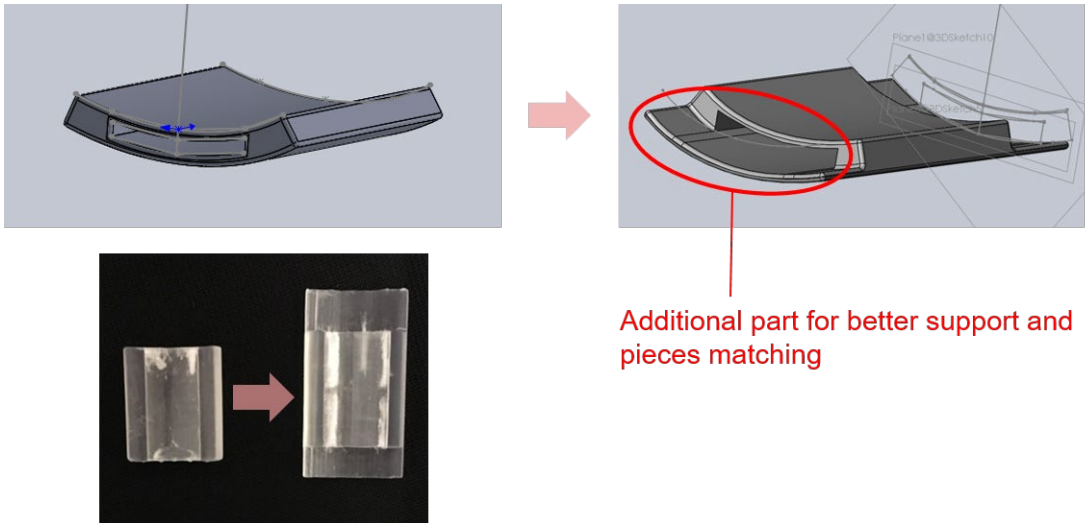
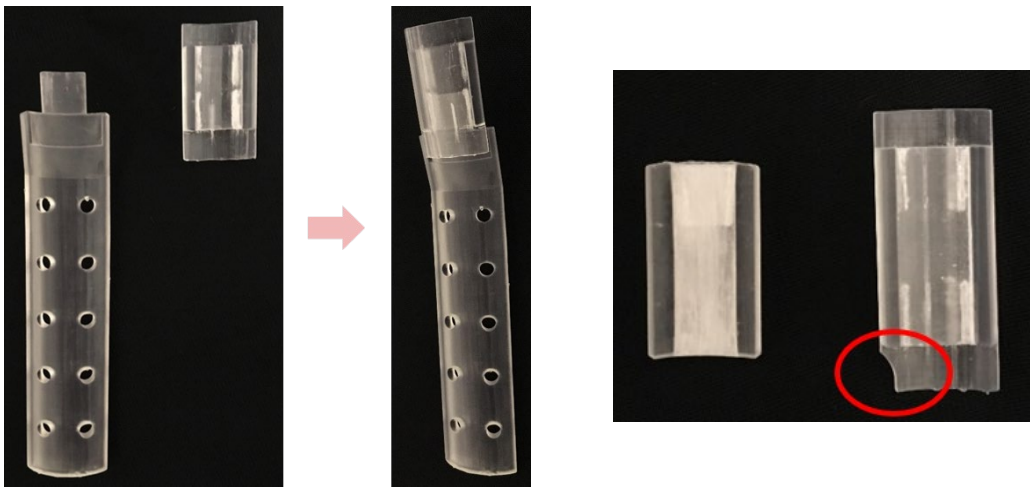


Figure 5.22 Extension of parts of middle pieces



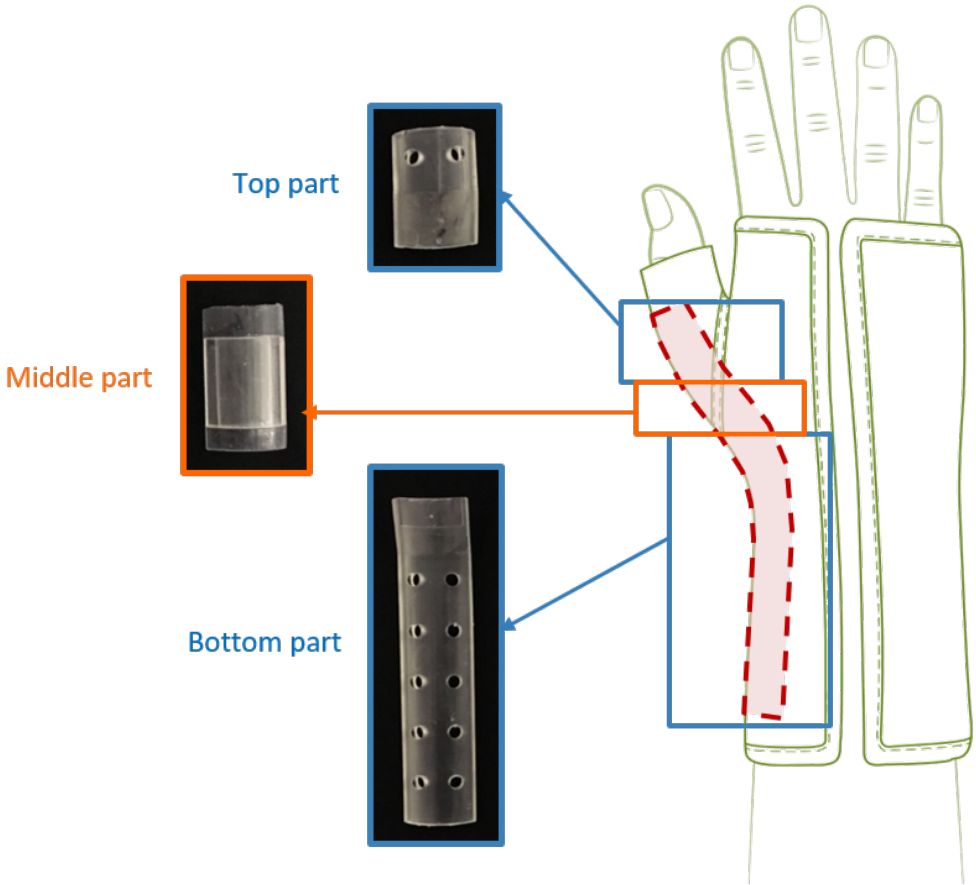
(a) (b)

Figure 5.23 (a) Matching of pieces and (b) broken part

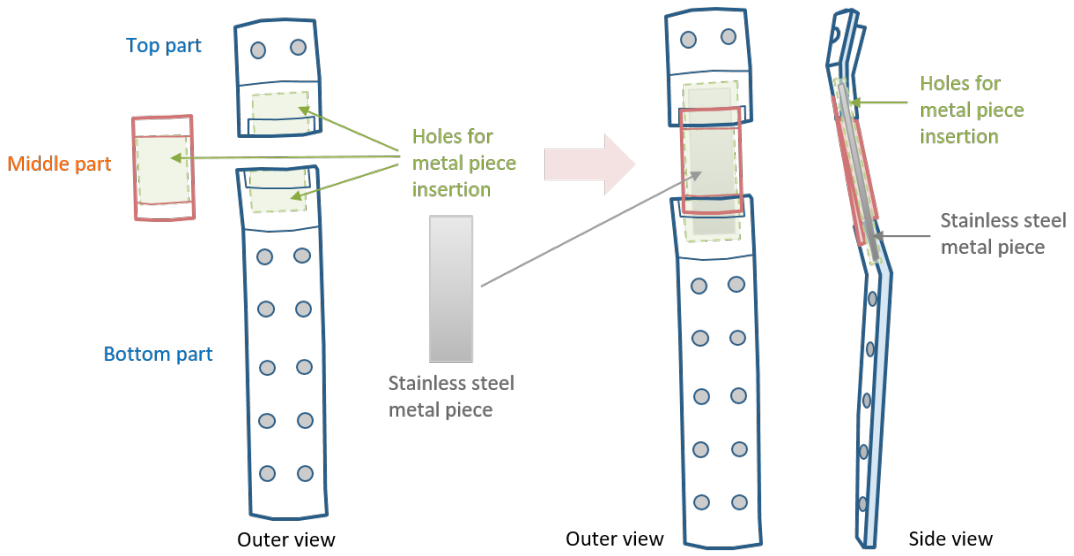
5.5.4 Supporter Prototype III

The different ways of inserting the protruding parts of the top and bottom pieces into the perforations of the middle pieces were successful enough to form thumb supporters with different lengths. The purpose of the thumb supporter is to support the injured thumb and control its movements. Therefore, the weight of the thumb may be partially exerted onto the supporter. Since the supporter has to protect and minimise the movement of the thumb, the supporter should be strong enough to withstand the forces of the patient's thumb when the patient wants to perform movements that exceed the movement range of the splint. As the first and the second prototypes were printed with resin materials, some of the pieces are fragile and could not withstand the force of the

thumb during movement. To solve this problem, a new idea to replace the materials at the points of connection between the different pieces with stronger materials was proposed. The original protruding parts of the top and bottom pieces were first removed. Similar to the middle pieces, narrow perforations were created at the top and bottom pieces. Then, a strong metal piece was inserted which passed through all three pieces, so that the entire thumb supporter, including the points of connection, would be strong enough to support the thumb. The idea behind the design of connecting the top, middle and bottom pieces with a metal piece is illustrated in Figure 5.24.



(a)



(b)

Figure 5.24 Design concept of the third prototype
(a) placement of the top, middle and bottom pieces along the radial side of hand, and
(b) three pieces connected with a metal piece

The parts of the third prototype that are printed with resin material are shown in Figure 5.25. Two different perforation heights of 0.5 mm and 0.7 mm were experimented for inserting the metal pieces. However, since the perforations are too narrow, and the resin material was printed in a liquid bath, some of the excess resin became stuck in the narrow perforations (Figure 5.26). As a result, the metal pieces could not pass through the middle pieces.

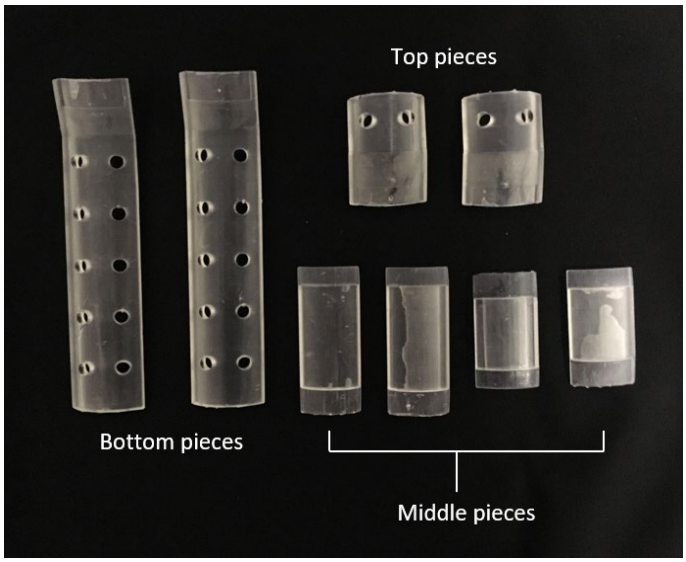
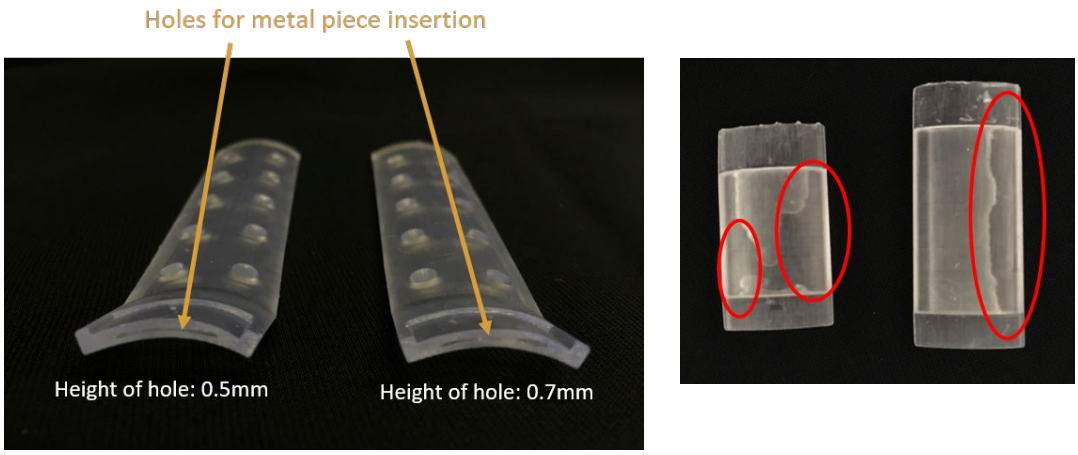


Figure 5.25 Parts of third prototype of thumb supporter



(a) (b)

Figure 5.26 (a) Height of perforations for metal piece insertion and (b) parts merged with the perforations of the middle pieces

5.5.5 Supporter Prototype IV

The pieces of Supporter Prototype IV were printed with black resin material (Figure 5.27). To solve the problem of resin sticking in the narrow perforations, the height of the perforations was increased from 0.5 mm and 0.7 mm to 1.1 mm for the fourth prototype. After inserting the metal pieces through the perforations and exerting some force onto the supporter, it was found that the panel of perforations became damaged. The damage to the material might be that the panel of perforations, which is only 0.6 mm in thickness, is not thick enough, as shown in Figure 5.28.

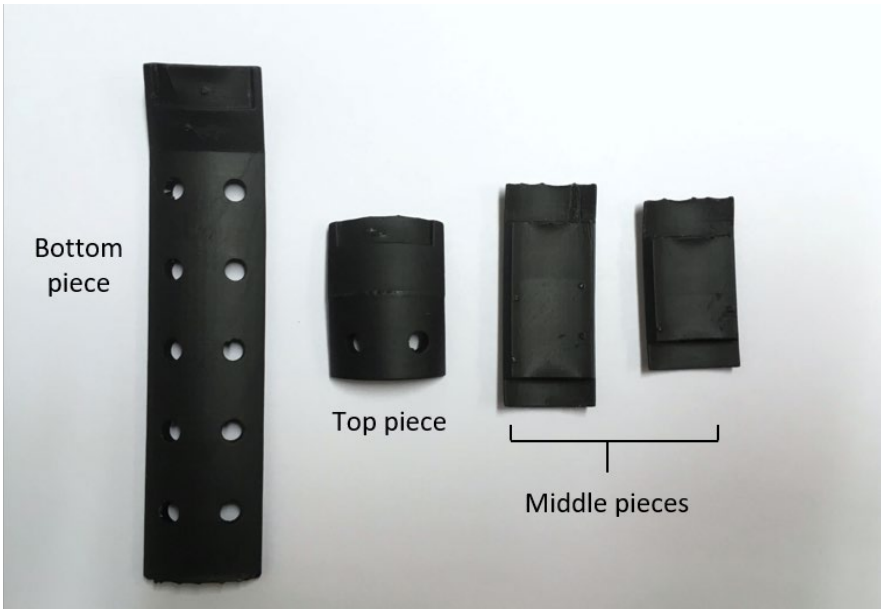
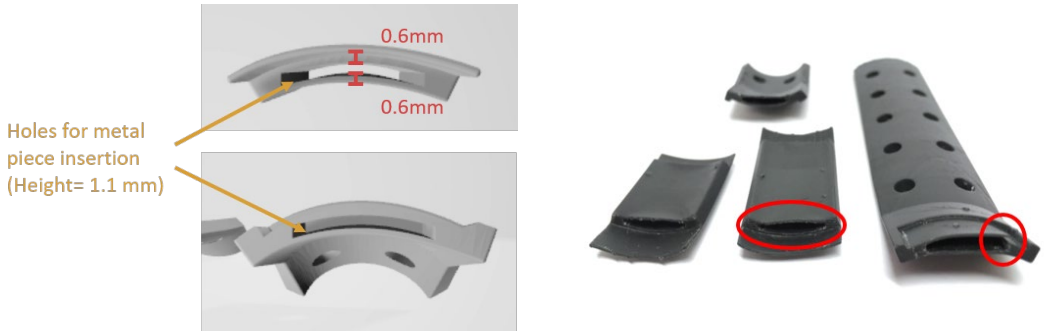


Figure 5.27 Pieces of fourth prototype



(a) (b)

Figure 5.28 (a) Height of perforations for metal piece insertion and (b) damage to the panel of perforations

5.5.6 Supporter Prototype V

The pieces of the fifth prototype are shown in Figure 5.29. The extended parts of the middle piece are eliminated in the fifth prototype as they contribute too much to the overall thickness of the piece, which results in an overly thin panel of perforations and other extended parts. Therefore, the focus of the fifth prototype is to create a perforation for the metal piece insertion of 1 mm in height, and surrounded by material at least 0.7 mm in thickness. Figure 5.30 shows that the metal piece could successfully pass through the top, middle and bottom pieces to form the thumb supporter. Figure 5.31 shows the different views of the combined thumb supporter.

The width of the perforations and metal piece is a critical factor that affects the thickness of the surrounding parts and the strength of the supporter. Prototype pieces with two perforation heights of 7 mm and 10 mm were prepared for inserting the metal pieces, respectively. During the trials that examined the different possible combinations, problems like damage to the panel of perforations could be found (Figure 5.32). Therefore, experiments to determine the most suitable type of 3D printing material and the appropriate size of the metal pieces were carried out and are discussed in the next two sections.

Figure 5.29 Pieces of fifth prototype

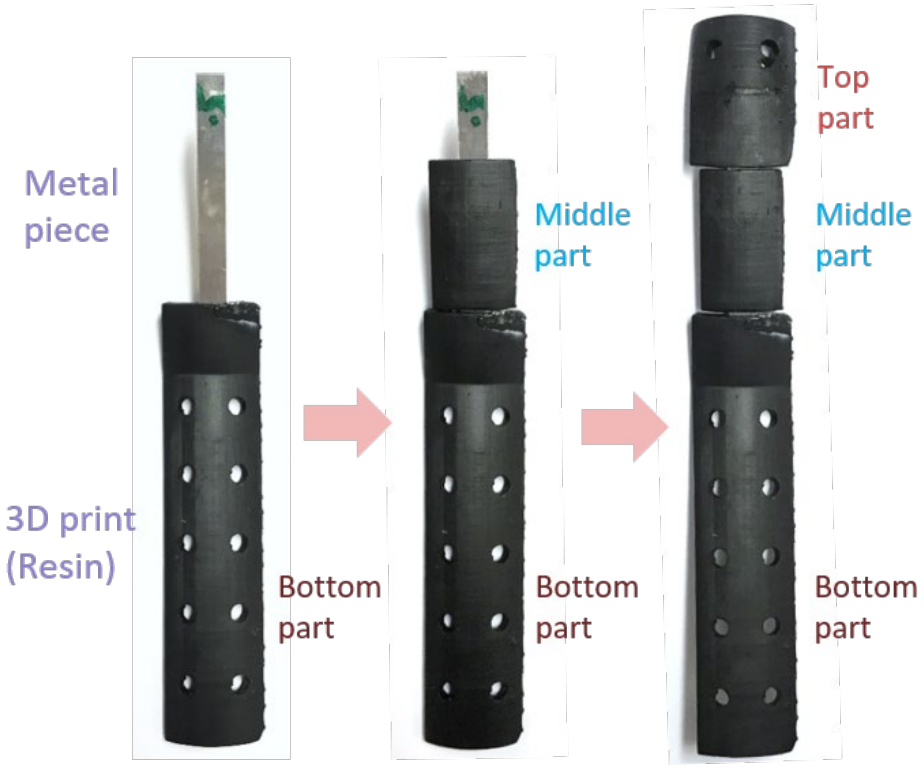


Figure 5.30 Steps to build thumb supporter

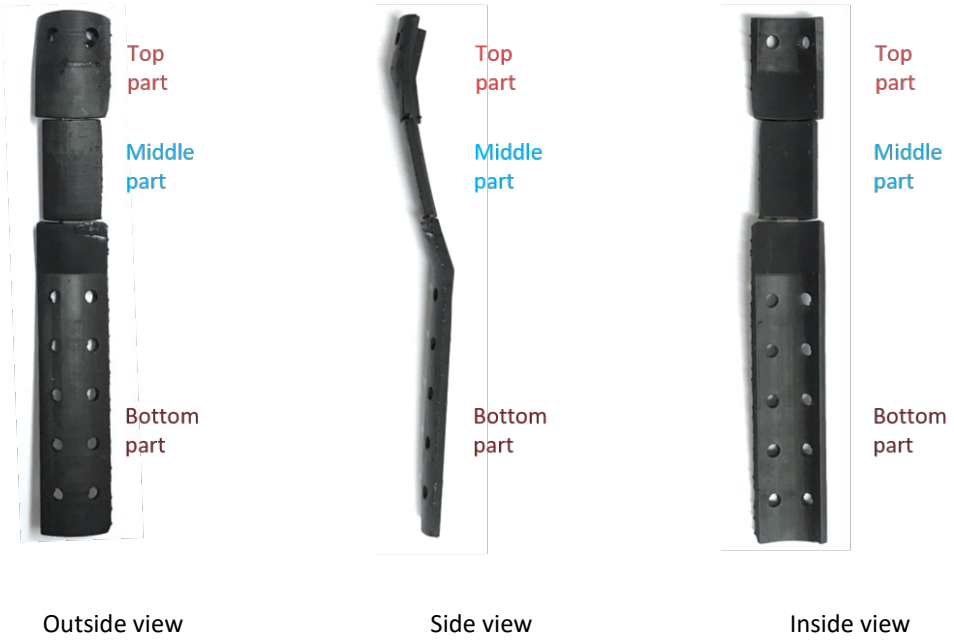


Figure 5.31 Different views of thumb supporter with different parts

(a) (b)

Figure 5.32 (a) Pieces of prototype with 7 mm and 10 mm perforations and (b) damage

5.5.7 Material selection to construct supporter

After evaluating the five prototypes made of resin materials, it was found that the pieces are relatively fragile. This means that the material chosen for printing the thumb supporter pieces and ulna supporter is very important. To determine the optimal material, three-point bending and recovery tests were carried out on several different kinds of 3D printing materials in order to select the optimal material that can withstand the forces exerted by the hand during movement. Figure 5.33 shows the printed materials and the sample during the test.

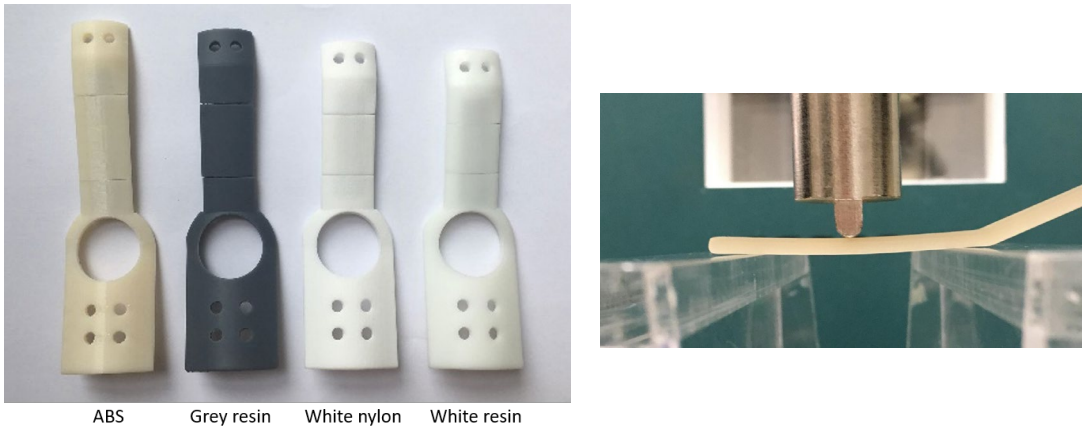


Figure 5.33 Printed materials and testing process

After testing the printed samples, the results show that sample made with white resin sustains the highest compressive load at the set maximum compressive extension, which indicates that the white resin sample has the highest strength among the four samples (Figure 5.34). Similar to the white resin sample, the acrylonitrile butadiene styrene (ABS) sample can also sustain a high compressive load at maximum compressive extension.

Since DQV patients have to wear the splint for long hours each day, the thumb and ulna supporters should be able to recover back to their original position to support the hand after numerous movements apart from being sturdy enough to support the affected thumb. Therefore, it is important for the supporters to have high recovery. Figure 5.35 shows that the ABS sample has the highest recovery ability. In reviewing the overall performances of the samples, ABS was used for the 3D printing as the ABS sample has relatively high strength and the highest recovery among the samples.

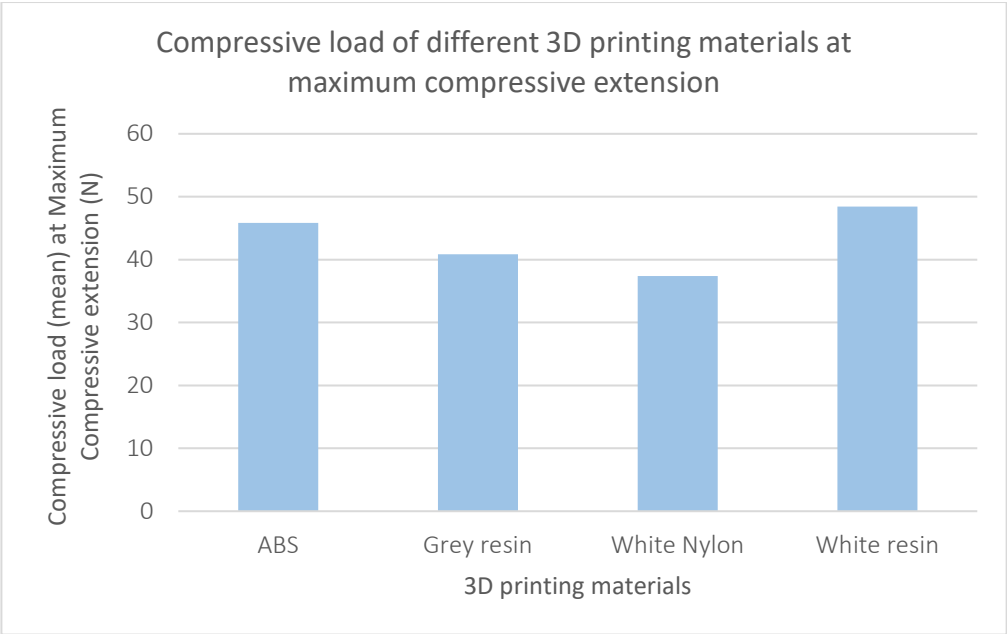


Figure 5.34 Compressive load of different 3D printing materials at maximum compressive extension

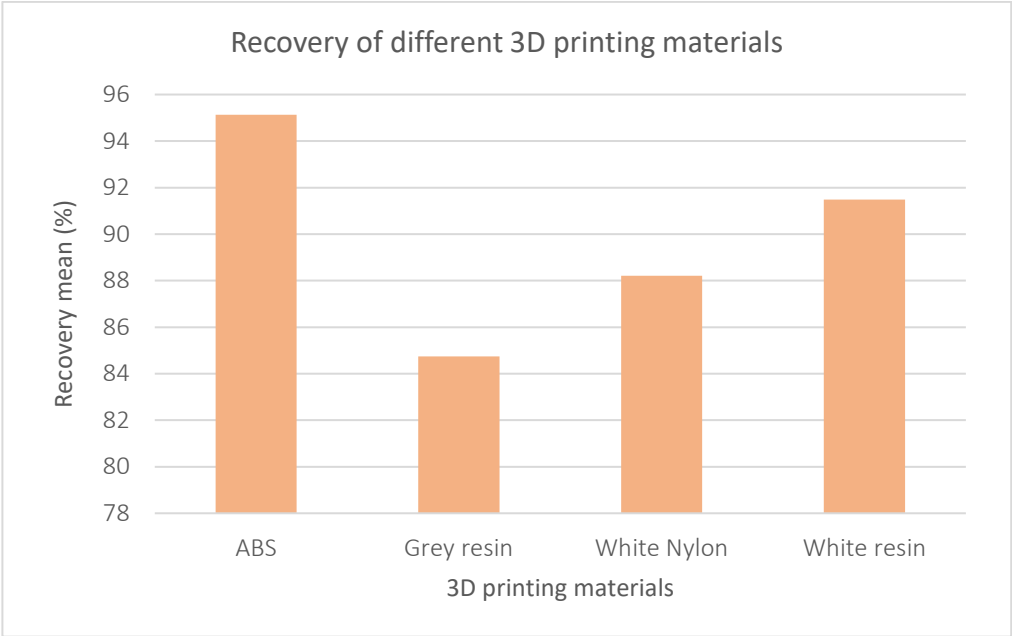


Figure 5.35 Recovery of different 3D printing materials

5.5.8 Metal component for supporter

The material and size of the metal piece of the supporter might affect the overall strength of the supporter as it is the main component that connects all the pieces together. As mentioned in Section 3.5.3.2 of Chapter 3, eighteen different metal sample pieces made of aluminium (A) or stainless steel (SS), with different thicknesses and widths were tested through three-point bending and recovery tests. The three-point bending test results, as shown in Figure 5.36, indicate that the SS sample with a thickness of 1 mm, and width of 6 mm or 10 mm sustains the highest load when the mid-point of the sample is extended to the set point. This shows that the two samples have the highest strength among all of the samples with the same width. For the results of the recovery test (Figure 5.37), SS samples with a thickness of 0.5 mm and width of 6 and 10 mm have the best performance. Besides, the SS samples with a thickness of 1 mm and width of 10 mm, and thickness of 0.3 mm and width of 10 mm have the second best recovery ability. In reviewing the overall results of both tests, the SS sample with a thickness of 1 mm and width of 10 mm has the highest strength and relatively high recovery ability. Therefore, this sample is used for the connective part of the thumb supporter.

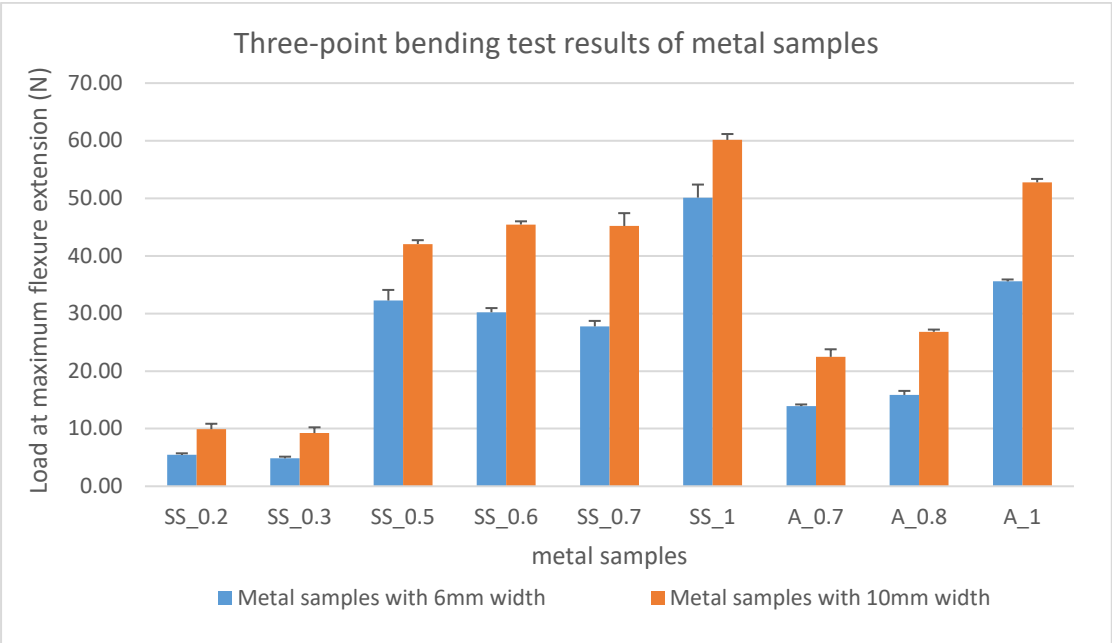


Figure 5.36 Three-point bending test results of metal samples

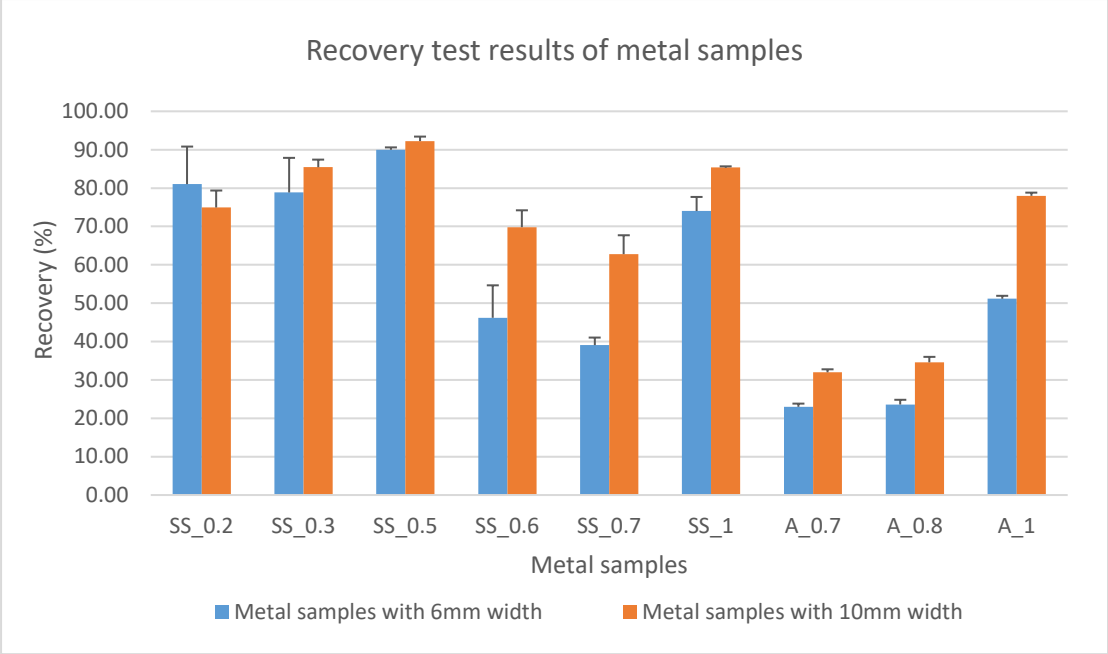


Figure 5.37 Recovery test results of metal samples

5.5.9 Final supporter prototype

Patients with DQV may feel pain, tenderness and soreness near the radial styloid process. Chow (2009) found that patients may complain about the pain at the protruding bony area when wearing a hard splint. Therefore, considering the pressure given by the splint to the bony structure of the hand, a design that would eliminate the contact pressure at the protruding region, such as the radial styloid process, is developed. In observing the 3D images of the hands of the DQVS group with a gradient map, seven patients were found to have larger curvature near the radial head, which is shown in red in Figure 5.38. The region with larger curvature may indicate swelling, which is one of the symptoms of DQV. By drawing circles of the regions in red, the diameter of the largest circle is found to be about 27 mm. Referring to the observed results of the hand images, a design that uses circular perforations of 27 mm in diameter at the cross-sectional curve R of the thumb supporter was produced. By designing an opening at the radial head, the swollen area would not come into contact with the supporter, and no pressure would be exerted onto the injured part of the hand. Furthermore, the surrounding printed rigid structure could act as a barrier to protect the swollen area from external impacts.

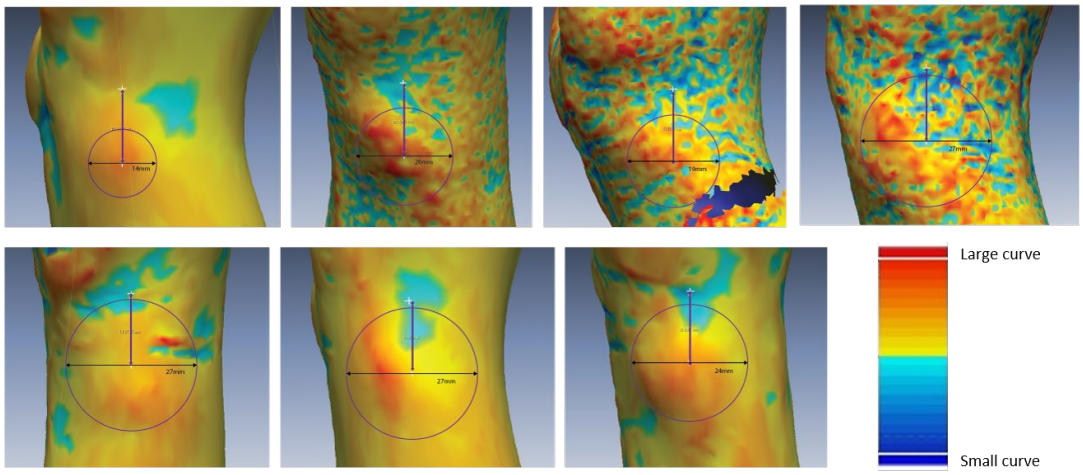


Figure 5.38 3D gradient maps of hands of DQVS group

The aforementioned design was implemented for the final prototype of the thumb supporter. After creating a circular opening at the radial head, the supporting part that is lower than the cross-sectional curve C was widened and extended along the girth of the hand, so that protection and stabilisation along the radial side of the hand could be enhanced. The small circular perforations for air ventilation were rearranged. Based on the results of the three-point bending and recovery tests, the final version of the thumb and ulna supporters was printed by using ABS, and SS metal pieces with a thickness of 1 mm and width of 10 mm were prepared in accordance with the length of the middle pieces. The components of the final prototype are shown in Figure 5.39.

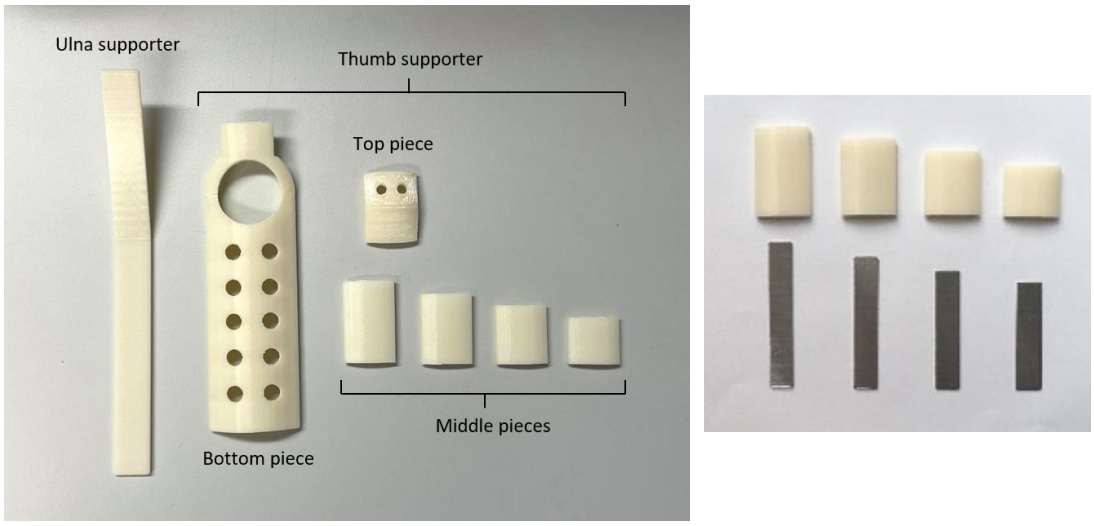


Figure 5.39 Pieces of final prototype

5.6 Summary

The first part of Chapter 5 discusses the design concepts of the proposed splint. The development of the design concepts is based on three 'patient-splint interactions'. The three interactions include 'instrumental interaction', 'non-instrumental interaction' and 'non-physical interaction'. Based on the type of interaction, different design criteria can be identified. To use the splint, elements such as 'durability', 'practicality' and 'simplicity' are essential. In terms of the expectations of patients towards the splint, the effectiveness of the splint to relieve their DQV symptoms is an important point which needs to be demonstrated through the functions of the splint. Elements apart from function that wearers are also concerned about include 'comfort', 'aesthetics', 'fit' etc. The details for implementing the design criteria onto the splint for DQV treatment are then explained.

The patterns for the proposed splint are developed based on the design criteria and the patterns of existing thumb orthoses. There are in total eight pattern pieces for the splint. Dividing the splint into two halves, four pattern pieces form the ulnar side of the splint, whilst two pattern pieces form the radial side of the splint, including the thumb part. The two remaining pattern pieces form the pockets for the ulna supporter and thumb supporter respectively. The two pockets are constructed of powernet fabrics and Velcro tape, which allow clinicians to attach the supporters onto the two sides of the patient's hand, based on the ergonomic shape of each hand which is a somewhat tailored solution.

Two prototypes and the final version of the splint have been discussed. Sketches that show the placement locations of the selected fabrics are provided. Problems with the splint prototypes, such as overly complex fastening system and bulkiness, have been identified. Apart from the development process of the splint, the process of constructing the thumb and ulna supporters is also explained in this chapter. Five prototypes of thumb supporters are designed before finalising the last prototype of the supporter. Problems of the previous prototypes, such as insufficient supporting force, ease of damage, and fusion of materials, have been identified. To select the optimal 3D printing materials and metal pieces to construct the proposed splint, three-point bending and recovery tests are conducted. According to the test results, ABS is chosen to print the supporters. The SS piece is selected for connecting pieces of the thumb supporter

together. In summary, the final version of the proposed splint is composed of two main components, the body of the splint which is fabric and the supporters. The body of the splint is fabricated with spacer, satinette and powernet fabrics. The fastening system is composed of narrow straps and Velcro tape. There are both thumb and ulna supporters to stabilise the two sides of the hand. The ulna supporter is simply printed out as a single piece, whilst the thumb supporter is composed of top, middle and bottom pieces with a metal piece connector along the middle of the inside of the structure. Four different sizes of the middle pieces have been designed for accommodating different hand sizes. The evaluation of the performance of the proposed splint is discussed in the next chapter.

Chapter 6 Clinical study of the proposed functional splint

6.1 Introduction

The design concept and pattern development processes of the proposed splint have been explained in Chapter 5. In this chapter, the results of a 3-month clinical study are discussed. First, the profile of the recruited subjects for the wear trial is provided. Then, the clinical study results including the overall hand conditions of the patients, the grip and pinch strengths of both the healthy and affected hands, pressure distribution exerted by the splint onto the hand of the patient, amount of hand movement controlled by the proposed splint and the input from the patients towards the splint, are discussed. Finally, a summary of the study results is provided.

6.2 Subject recruitment

During the period of July 2020 to Jan 2021, 13 female subjects (WTS) between the ages of 49 to 67 years old were recruited from the Queen Mary Hospital, Hong Kong after being diagnosed with DQV by a professional clinician. Of the 13, 12 of the subjects underwent a three-month splinting treatment with the proposed splint. The remaining subject underwent two months of the intervention as her DQV was successfully treated in the second month of the treatment and she did not feel that it was necessary to continue the splinting treatment. The demographics of the subjects are listed in Table 6.1.

Table 6.1 Demographics of recruited subjects in the clinical study (WTS group)

Subject code	Gender	Age	Injur-ed hand	Injection for DQV	Surgery for DQV	Period of pain	Period of intervention	Other hand conditions during intervention	Other treatment during intervention
WTS001	F	66	L	N	N	6 months	3 months	Trigger finger	PT
WTS002	F	59	R	N	N	7 months	3 months	N	N
WTS003	F	64	R	N	N	6 months	3 months	Trigger finger	TCM
WTS006	F	66	R	N	N	6 months	3 months	N	N
WTS010	F	65	R	N	N	5 months	3 months	Trigger finger	Steroid injection in the region of trigger finger
WTS016	F	53	R	N	N	6 months	3 months	N	N
WTS021	F	67	L	N	N	3 years and 1 month	3 months	N	Massage
WTS030	F	58	R	N	N	1 year	3 months	Adhesive capsulitis, Tennis elbow	PT
WTS034	F	58	R	N	N	3 years	3 months	N	N
WTS038	F	49	L	N	N	1 year and 1 month	3 months	N	N
WTS040	F	60	R	N	N	2 years	3 months	Trigger finger	PT
WTS041	F	55	L	N	N	6 months	3 months	N	N
WTS043	F	58	R	N	N	4 months	2 months	N	N

Notes: PT: Physiotherapy and TCM: Traditional Chinese Medicine

6.3 Clinical study results

6.3.1 Hand conditions of patients

Each subject underwent a total of four clinical sessions which included one before the intervention and three during the splinting treatment. In each session, the subject was instructed to perform different hand movements and score the level of perceived pain from 1 to 10 by using the VAS. The two hand movements that the subjects were instructed to carry out were thumb and finger extensions and hand opposition. The extension movement requires the extension of the thumb and the hand opposition involves thumb abduction, which may trigger pain.

The mean values of the pain level score of the two hand movements are calculated and plotted in Figures 6.1 and 6.2. As mentioned, since one of the patients was successfully treated of her DQV in the second month of intervention, the pain score of her third month follow-up is shown as 1, which is the lowest score on the VAS, that is, no pain at all. Both graphs show that the pain scores of patients when performing the thumb and finger extensions or hand opposition are reduced over time, from a rating of over 4.5 to 2.5 or lower. A non-parametric Friedman test was conducted which found a significant difference between the pain level of patients when extending their thumb and fingers before and after the intervention, χ^2 (3) = 26.705, and p = 0.000. There is also a significant difference between the pain level of patients when opposing their hand before and after the intervention, χ^2 (3) = 18.300, and p = 0.000.

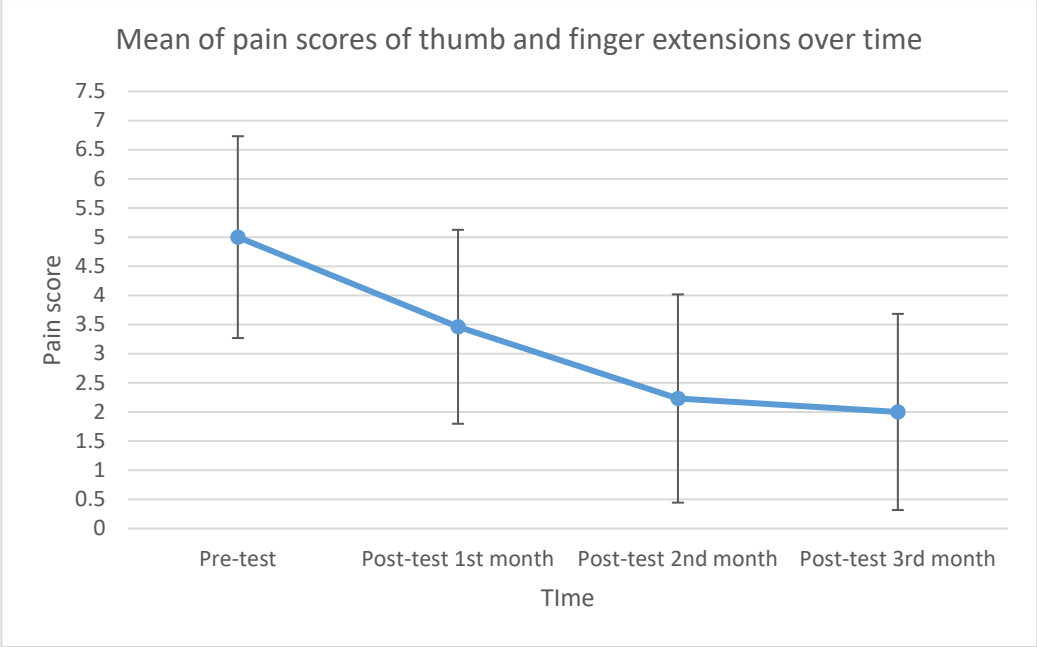


Figure 6.1 Mean of pain scores of thumb and finger extensions over time

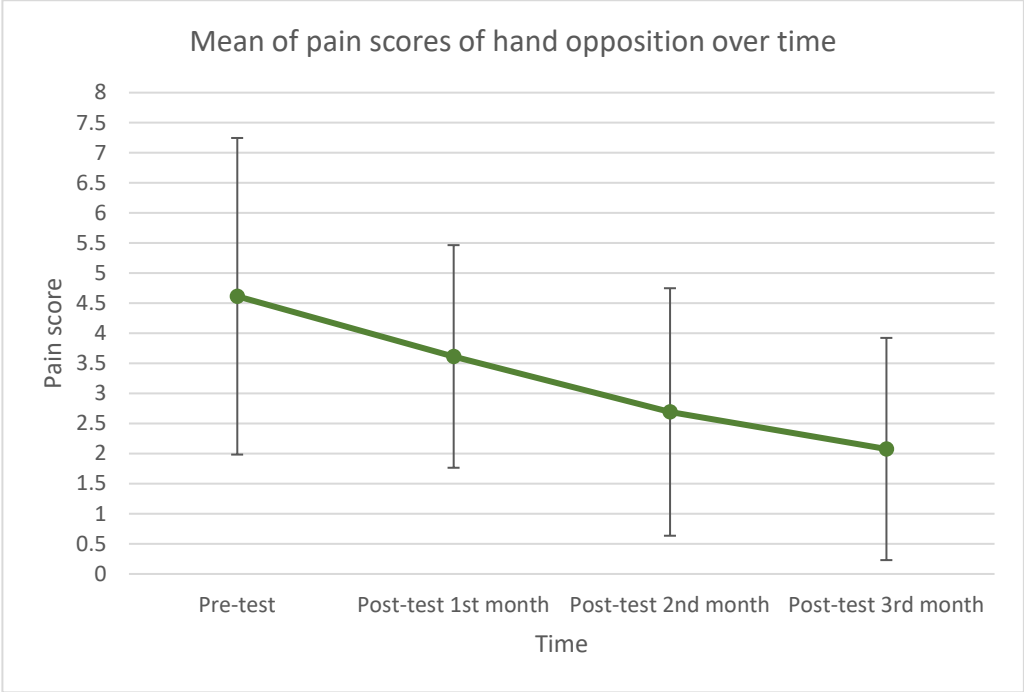


Figure 6.2 Mean of pain scores of hand opposition over time

The pain scores of these two hand movements of each subject are plotted in Figures 6.3 and 6.4. For the thumb and finger extensions, 92.3% of the subjects feel less pain after the treatment. Figure 6.4 shows that 76.9% of the subjects have a reduced pain score during opposition of the hand. On the other hand, the pain score of the remaining 23.1% of the subjects is the same. Overall, none of the subjects indicated a higher pain score after the splinting treatment for both types of hand movements.

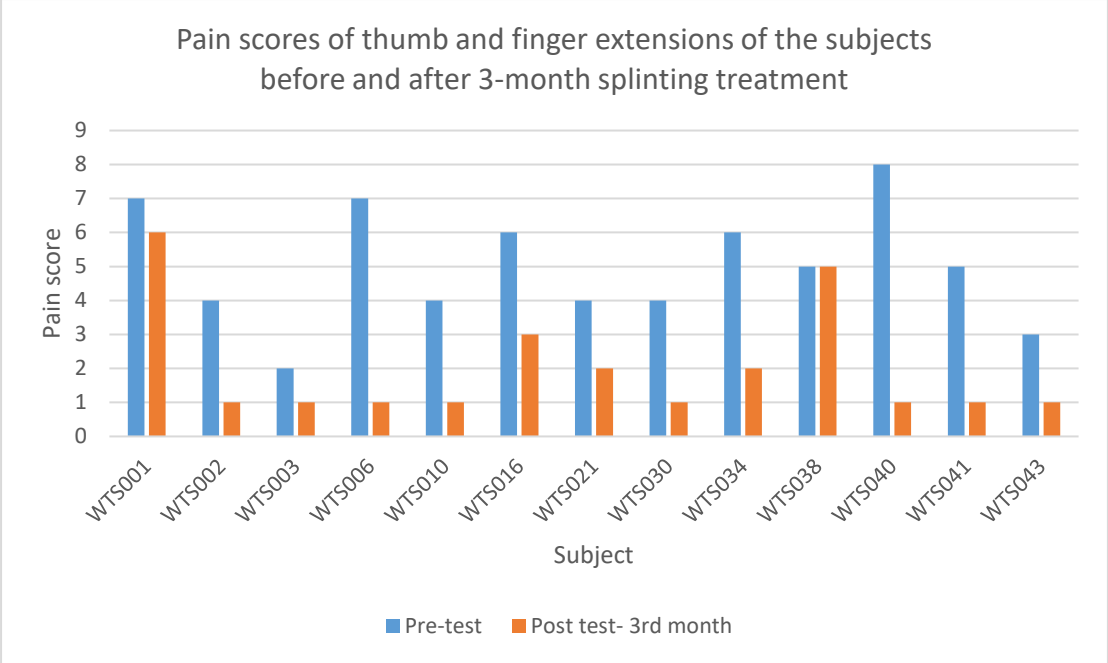


Figure 6.3 Pain scores of thumb and finger extensions of subjects before and after 3-month splinting treatment

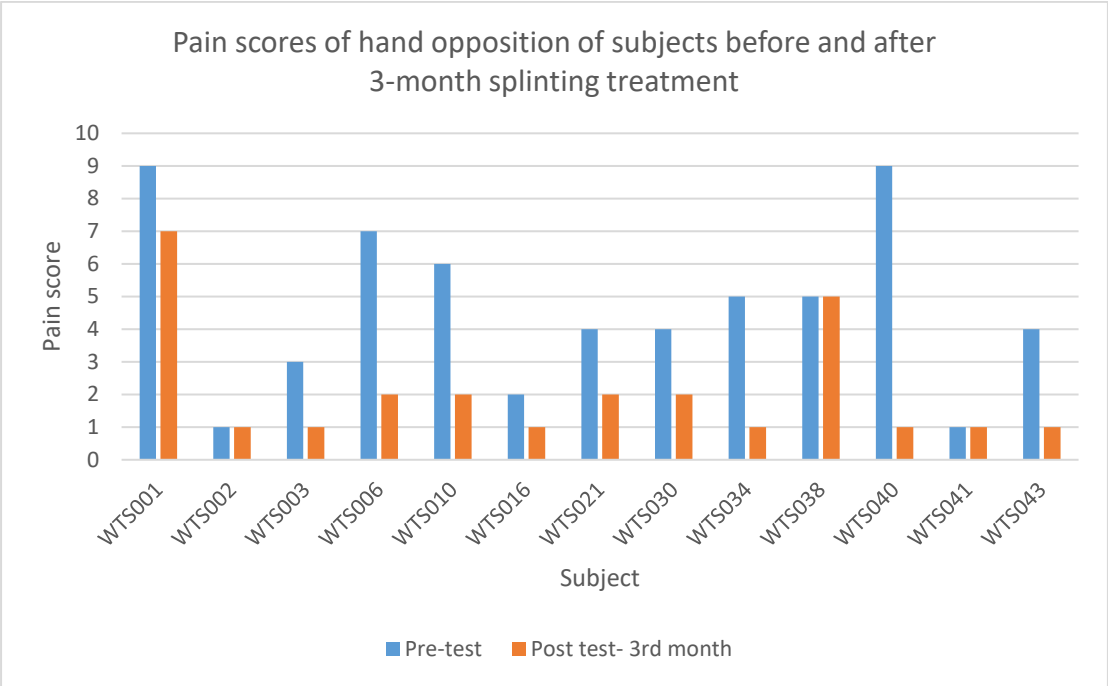


Figure 6.4 Pain scores of hand opposition of subjects before and after 3-month splinting treatment

In the session prior to testing, each patient was instructed to list three daily activities that gave them pain due to DQV. They scored the pain level of the mentioned activities in each follow-up session in order to observe the progress of healing of their injured wrist. Activities that patients listed were classified into nine categories: hand twisting, cooking, holding lightweight objects, holding heavy objects, handcrafting, donning and doffing clothing, fine motor skills, baby caring and other. The daily frequency of these activities is plotted in Figure 6.5. 'Donning and doffing clothing' is the most frequently mentioned among the subjects. The second most frequently mentioned activity is 'cooking'. It makes sense that these are the two most frequently mentioned activities as they are the most common and unavoidable activities in daily life. On the other hand, the frequency of the implementation of other specific activities like handcrafting can be comparatively reduced and limited.

The mean values of the pain level of each activity category are calculated and the change in pain over time is presented in Figure 6.6. It can be observed that the pain scores of some of the activities fluctuate over the intervention period; for example, those for 'baby caring' and 'handcrafting'. However, a comparison of the final scores in the third month of treatment with the initial scores before the treatment showed that the pain scores in all of the categories are reduced.

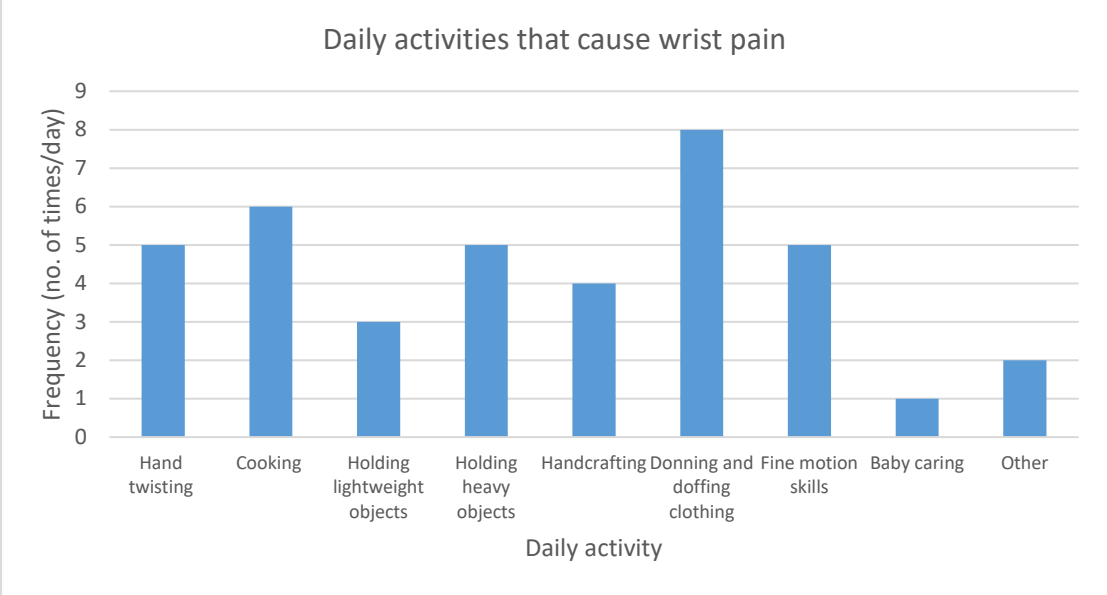


Figure 6.5 Daily activities that cause wrist pain

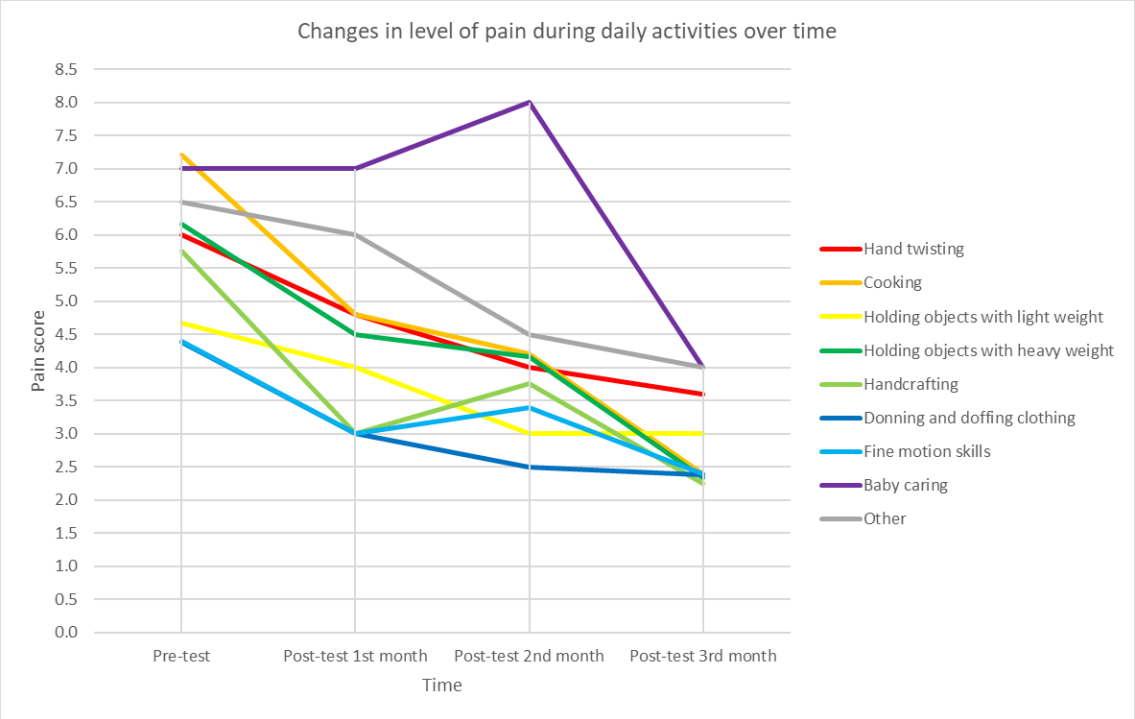


Figure 6.6 Changes in level of pain during daily activities over time

6.3.2 Grip and pinch strengths

As mentioned in Section 3.6.3.2, the grip and palmar pinch strengths are the secondary outcome of this study. With the reduction of pain over the treatment period, it is anticipated that these DQV patients could increase their grip and pinch strengths. The mean values of the grip and pinch strengths of the hands of the patients are calculated and shown in Figures 6.7 and 6.8 respectively. The results of the affected versus the healthy hand are compared and plotted in the graphs. The grip strength of the patients is gradually increased, while the pinch strength fluctuates over time. However, both strengths are increased overall after undergoing the splinting treatment. The healthy hand of the patients generally has a higher strength than their affected hand. It is interesting that, similar to the affected hand, the strength of the healthy hand is increased over the time of the intervention. The reason might be that the patients avoided the use of the injured hand due to wrist pain, and increased the use of the healthy hand for daily tasks, which strengthened the corresponding muscles. According to the Shapiro-Wilk test, the data are approximately normally distributed. A repeated measures ANOVA was conducted to determine the differences before and after the intervention. Only twelve subjects provided data as one of them left the study after the second month following a successful treatment. Therefore, her information is

considered to be missing data during the statistical analysis. No significant difference between the grip strengths of the affected hands before and after treatment is found, $F(3, 33) = 0.739$, $p = 0.536$. While, the pinch strengths are significantly different during the intervention, $F(3, 33) = 4.075$, $p = 0.014$. Follow up comparisons indicate that the difference between the pinch strength of pre-test and that of post-test 2nd month is significant, with $p = 0.007$.

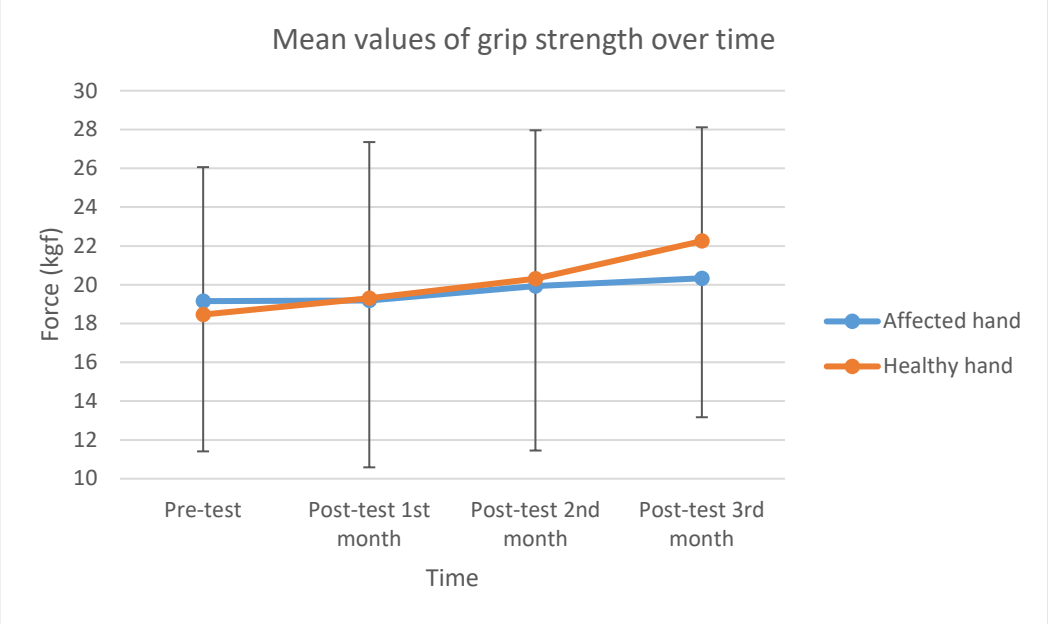


Figure 6.7 Mean values of grip strength over time

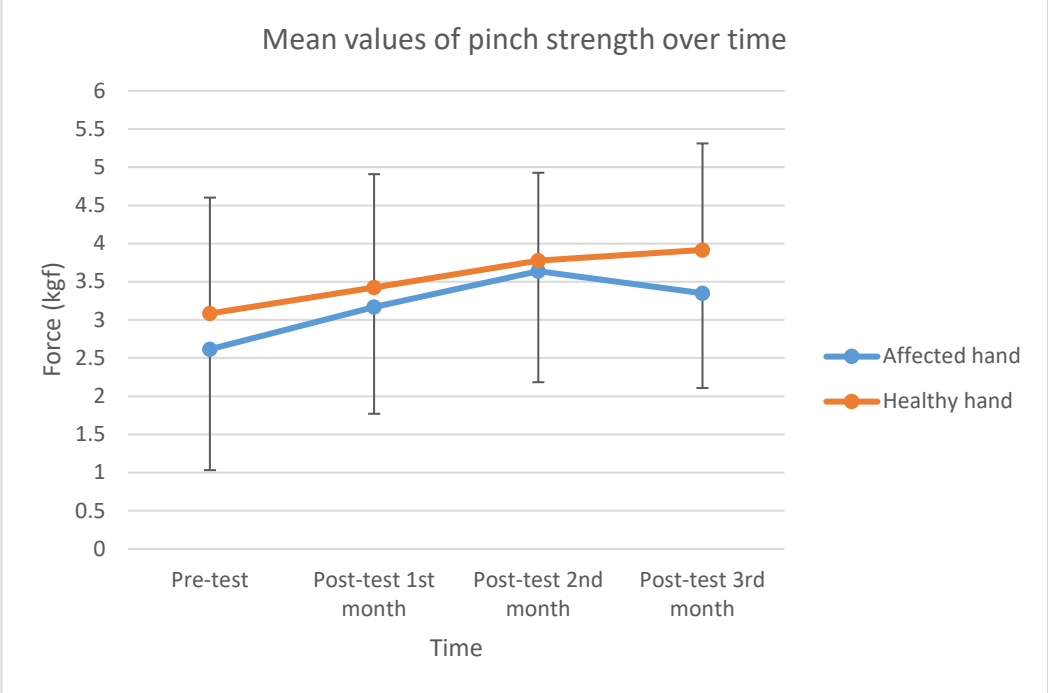


Figure 6.8 Mean values of pinch strength over time

The grip and palmar pinch strengths of the affected hand of each subject before and after the 3-month splinting treatment are plotted in Figures 6.9 and 6.10. As for the patient who left the study after two months, the measurements of her grip and pinch strengths in the second month follow-up session were used again for the third month and plotted in the chart. It is shown in Figure 6.9 that the grip strength of 53.8% of the subjects is increased while 23.1% of the subjects maintained the same grip strength of their affected hand. As for the palmar pinch strength, 76.9% of the subjects showed an increase in pinch strength after the treatment.

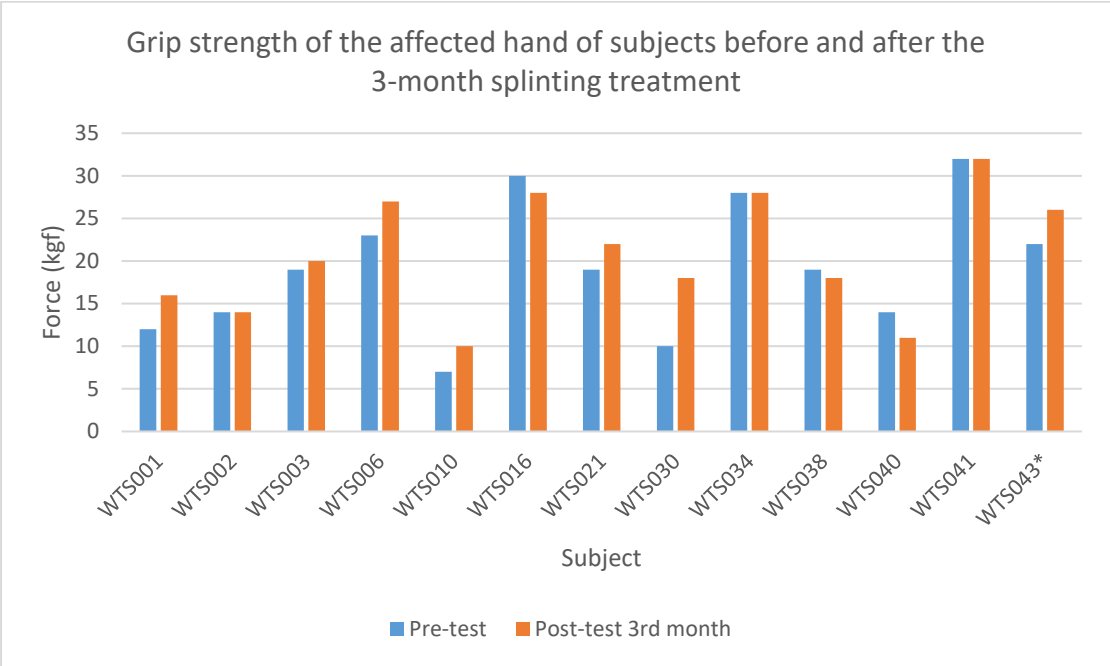


Figure 6.9 Grip strength of the affected hand of subjects before and after the 3-month splinting treatment

** As subject WTS043 left the study after two months, the measurements of her grip and pinch strengths in the second month follow-up session were used again for the third month*

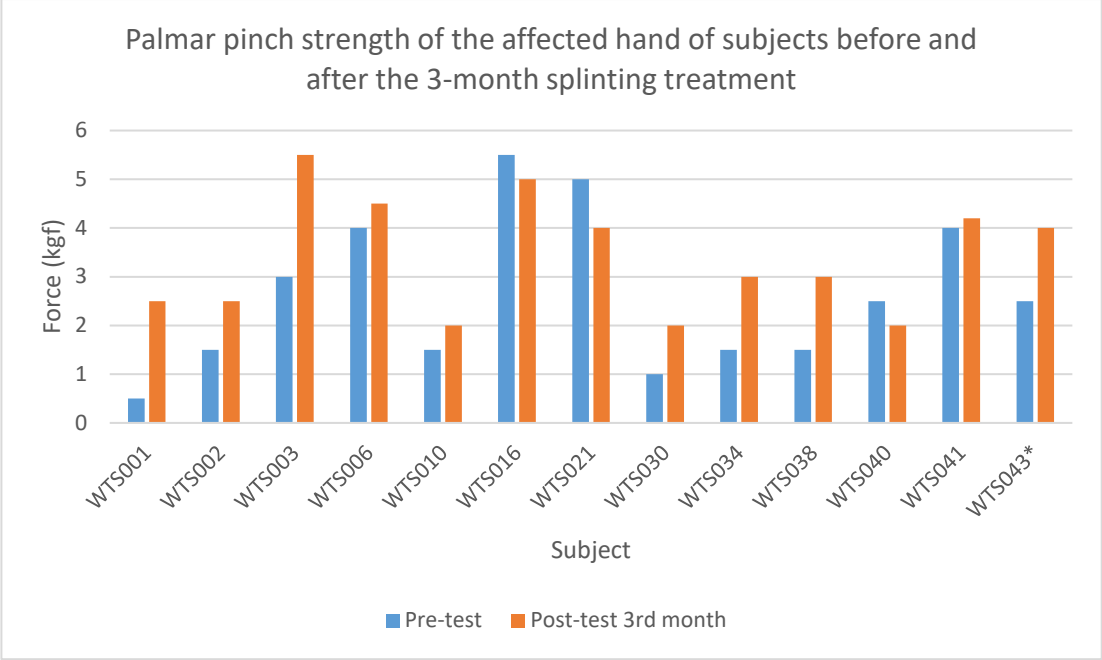


Figure 6.10 Palmar pinch strength of the affected hand of subjects before and after the 3-month splinting treatment

** As subject WTS043 left the study after two months, the measurements of her grip and pinch strengths in the second month follow-up session were used again for the third month*

6.3.3 Pressure test

Long thumb spica splints, which are used to treat DQV, are usually composed of hard materials. The rigidity of the splint can help to prevent over flexion of the thumb and ulnar deviation of the wrist of the affected hand (Nemati et al., 2017). Although the rigid part contributes to controlling hand movement, it may cause pain when high amounts of pressure are exerted onto some parts of the hand, especially the areas with a protruding bony structure (Chow, 2009). Furthermore, a high amount of pressure may lead to pressure ulcers. Agrawal and Chauhan (2012) indicated that a normal capillary pressure ranges from 16 mmHg (2.1 kPa) to 33 mmHg (4.4 kPa). When an external pressure that exceeds 4.4 kPa is exerted onto the skin, blood may not be able to pass through the blood vessels underneath the skin smoothly. After a certain duration of time, the surrounding soft tissues may become anoxic, which consequently leads to the necrosis of soft tissues and occurrence of pressure ulcers. Therefore, pressure given by the splint to the DQV affected hand is one of the important factors that should be considered during treatment. Although the pressure exerted by the splint is necessary to be considered, research studies that have examined the pressure distribution on

different parts of the hand of DQV patients from the splint are limited. In this study, the pressure distribution on six specific areas of hand is measured when the hand of the patients is in different positions and doing different movements with the proposed splint. The pressure at the different areas of the hand, particularly those with bony structures like the MCP joint and radius head (Figure 6.11), is identified and measured as a hard thumb supporter would be applied along the radial side of wrist for movement control.

In this experiment, the subjects are instructed to perform a set of hand movements, which include two static and two dynamic movements. The two static movements include the original rest position and the rest position with extended thumb and fingers. The two hand movements include moving a bottle and writing characters. The details of the movements have been clearly explained in Section 3.6.3.3. The entire set of hand movements were performed twice by each subject. During the first set of movement, the gap of the splint opening (Figure 6.12) was adjusted to be 1 cm in width (hereinafter Splint 1). Then for the second set of movement, the width was increased to 2 cm (hereinafter Splint 2). The purpose of the experiment is to investigate the pressure distribution from the proposed splint on the hand of the subjects in different situations and suggest an appropriate opening width and proper tightness of the splint for each subject.

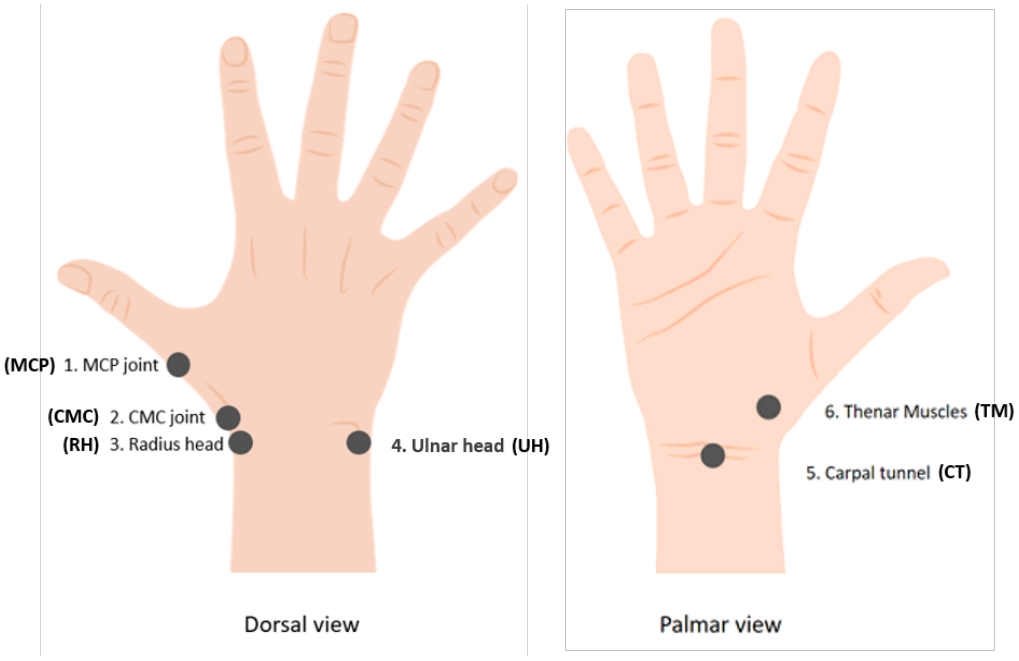


Figure 6.11 Location of pressure sensors

Figure 6.12 Width of gap of opening of the proposed splint

The maximum amount of pressure at different points during the implementation of hand movements was identified for comparison purposes. For the two static positions, the pressure recorded from the 15th to the 20th second was extracted from the 30 second recording. The maximum pressure points were identified from the extracted data. Figure 6.13 shows that the maximum pressure received by the CMC joint is the highest at 6.6 kPa (S.D. = 6.6) with Splint 1. The ulnar head receives the second highest amount of pressure from the splint, which is 5.6 kPa (S.D. = 4.3). It was observed that both parts have bony areas. Similar to the results of the static rest position, the top two areas of pressure for the static rest position with extended thumb and fingers are the CMC joint and ulnar head, in which the latter experiences the highest amount of pressure at 9.8 kPa (S.D. = 7.0) and the CMC joint is the second highest at 9.1 kPa (S.D. = 9.0) with Splint 1. Both Figures 6.13 and 6.14 show that the maximum pressure among the six regions with Splint 1 varies more than that with Splint 2. Furthermore, in the three bony areas, the ulnar and radius heads and CMC joint, the maximum pressure with Splint 1 is double to triple of that with Splint 2. The maximum pressure in the carpal tunnel area of both postures is the lowest among all of the measured spots. This might ensure that there is little change of exerting too much pressure to the median nerve and other tendons that pass through the carpal tunnel region and minimise the occurrence of related adverse hand conditions, such as carpal tunnel syndrome.

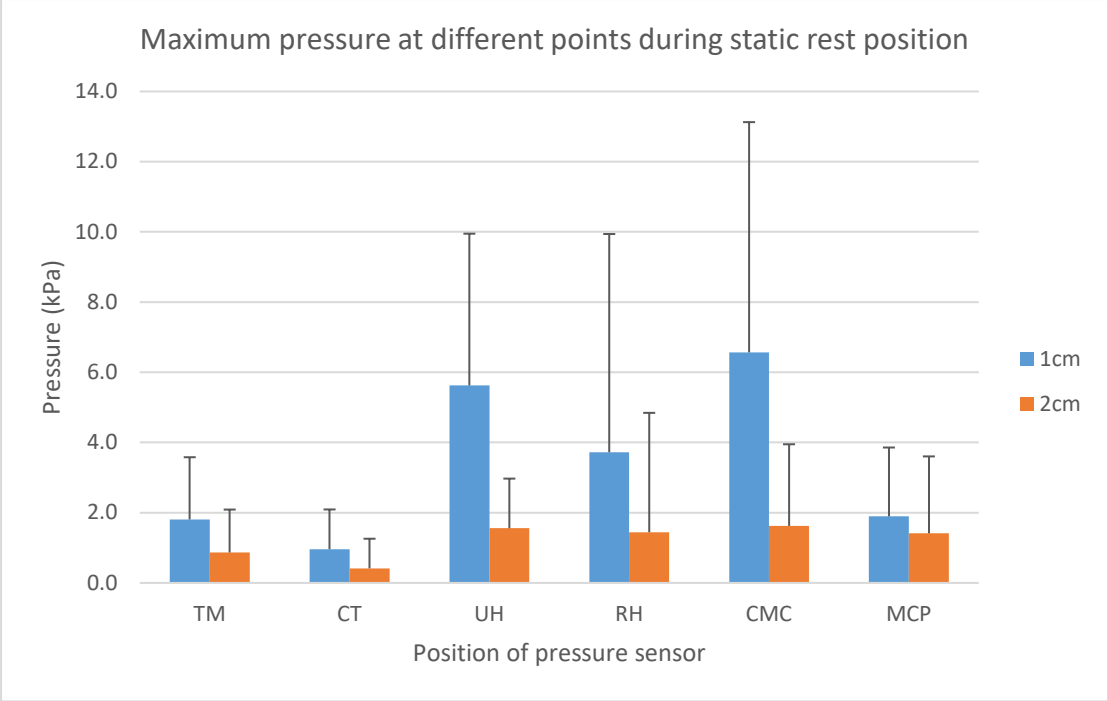


Figure 6.13 Maximum pressure at different points during static rest position

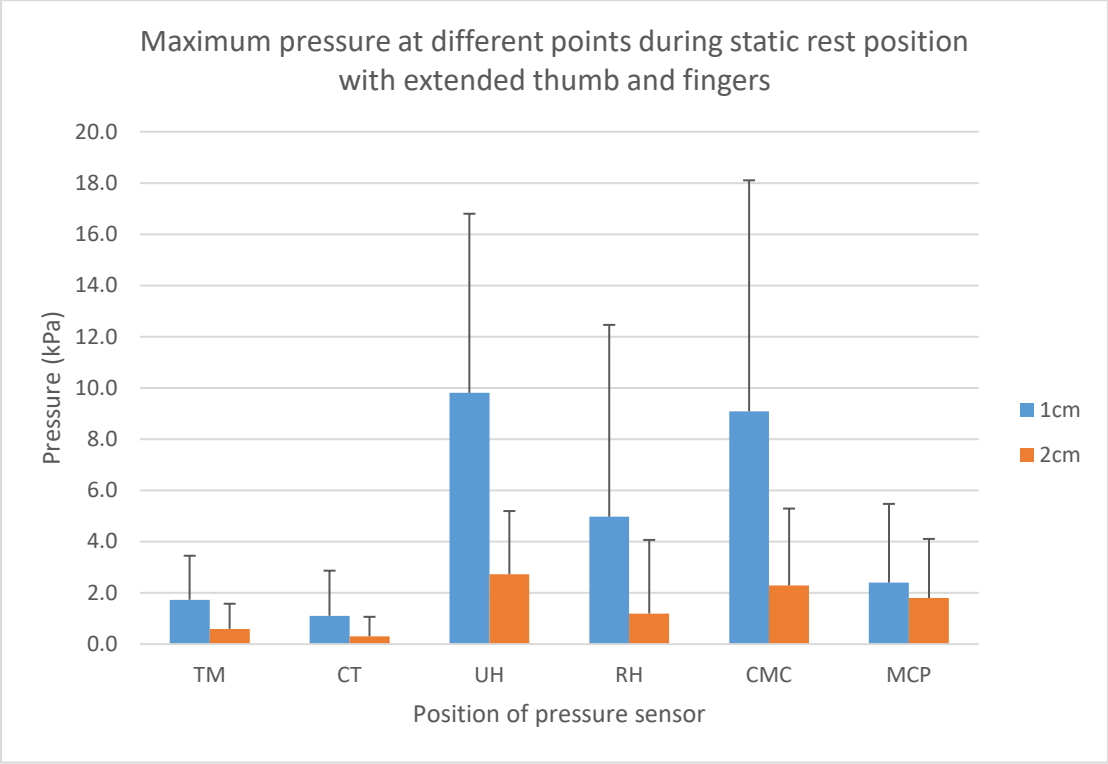


Figure 6.14 Maximum pressure at different points during static rest position with extended thumb and fingers

Apart from the static positions, the subjects were required to perform two sets of hand movements, which are moving a bottle (500 ml) and writing characters. Each subject was asked to move a bottle between two points thrice, in which the distance between the points is 40 cm. A ten second break was given between each movement. Similarly, each subject was instructed to follow and write the three ‘a’s printed on paper, from the smallest to the largest one. A ten second break was given between each writing task. After recording the movements, the data from the third time that the bottle is moved and the last and largest written letter ‘a’ of each subject were extracted. The maximum pressure of each sensor point was identified from the extracted data for comparison purposes. With Splint 1, the CMC joint is subjected to the highest maximum pressure (13 kPa, S.D. = 7.9) during the bottle movement task; see Figure 6.15. On the other hand, the carpal tunnel area received the lowest maximum pressure (2.6 kPa, S.D. = 2.3). With Splint 2, the CMC joint and carpal tunnel area also receive the highest and lowest maximum pressures of 6.2 kPa (S.D. = 5.5) and 1.3 kPa (S.D. = 2.1) respectively. These results are about half of the values of the corresponding results of Splint 1. According to Figure 6.16, the area that receives the highest maximum pressure during writing of the characters is the CMC joint, which is subjected to 14.5 kPa (S.D. = 8.6) and 8.9 kPa (S.D. = 8.0) of pressure with Splints 1 and 2, respectively. The area that receives the lowest maximum pressure during writing of the characters is the same as that for the bottle moving task, which is the carpal tunnel area.

Both graphs show similar patterns. The three bony structures are subjected to a higher maximum pressure, including the ulnar and radius heads and CMC joint. Areas with softer tissues, which are the thenar muscles and carpal tunnel area, are subjected to a lower maximum pressure during both types of movements. It is interesting to see that the maximum pressure at the MCP joint with Splint 2 is higher than that with Splint 1 for both types of movements. This result might be because the former is not as tight, and offers more room for the thumb to flex at the MCP joint, so that the flexed bony MCP joint might hit the inner surface of the rigid thumb supporter during movement.

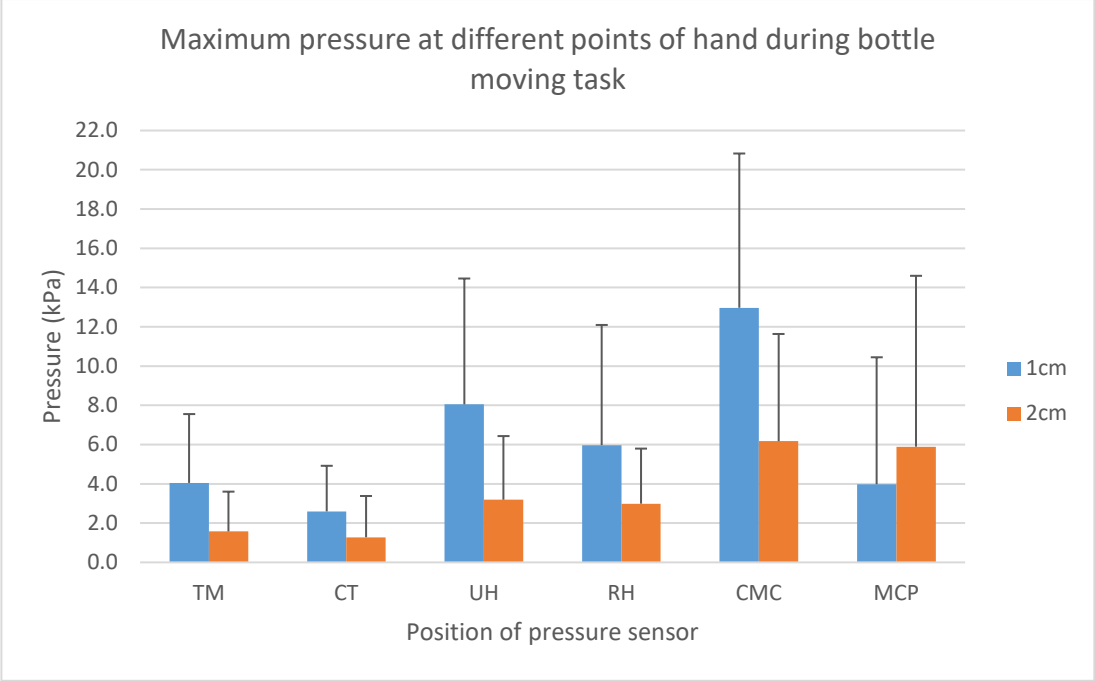


Figure 6.15 Maximum pressure at different points of hand during bottle moving task

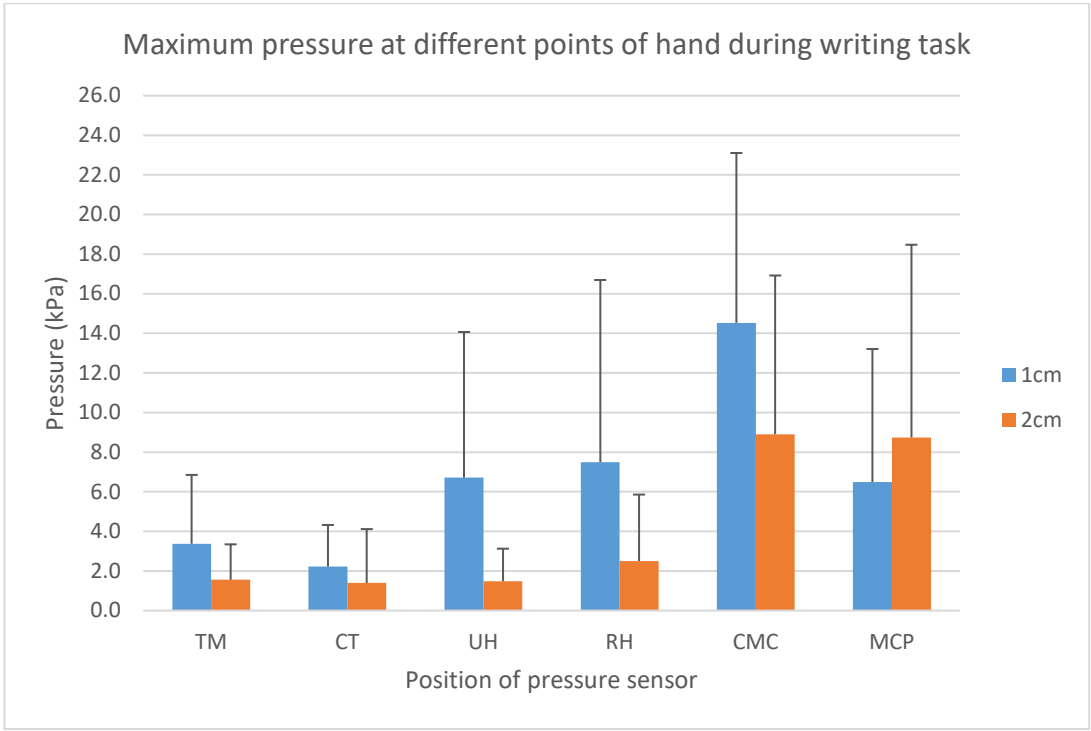


Figure 6.16 Maximum pressure at different points of hand during writing task

As mentioned, an external pressure that exceeds 4.4 kPa on human skin will cause the surrounding soft tissues to become anoxic, which then leads to necrosis of the soft tissues and occurrence of pressure ulcers. Patients with DQV are generally required to wear a hand splint for at least 8 hours each day. Therefore, it is important to ensure that

the maximum pressure exerted by the splint is less than 4.4 kPa. Table 6.2 shows that when subjects are performing the two rest positions, the maximum pressure at the CMC joint and the ulnar head with Splint 1 exceeds 4.4 kPa. On the other hand, the corresponding pressure results with Splint 2 are less than 4.4 kPa, which is acceptable. Since the subjects need to perform different daily activities with the splint donned, and holding a bottle and writing are common daily tasks, the results of the tasks are important. Table 6.2 shows that the maximum pressure at the CMC joint during the two movements with Splint 1 is much higher than 4.4 kPa, while the pressure results of Splint 2 are slightly higher than the acceptable range. Even though moving a bottle and writing are common daily activities, the duration of the exerted maximum pressure on the CMC joint is still relatively short. Therefore, it may be reasonable for subjects to use Splint 2, however, patients may still need to pay some attention to the CMC joint when performing movements. Moreover, to avoid insufficient control of hand movements with a loose splint, the subjects are advised to wear the proposed splint with an opening width of 2 cm or slightly more than 2 cm during the treatment.

Table 6.2 Maximum pressure point on different areas of hand with different tasks

Task	Resting position	Resting position with extended thumb and fingers	Moving of bottle	Writing of characters
Maximum pressure point	CMC joint	Ulna head	CMC joint	CMC joint
Maximum pressure (Splint 1)	6.6 kPa	9.8 kPa	13 kPa	14.5 kPa
Maximum pressure (Splint 2)	1.6 kPa	2.7 kPa	6.2 kPa	8.9 kPa

6.3.4 Hand restriction test with the proposed splint

6.3.4.1 Clinical study

As the purpose of splinting is to restrict the hand movement of DQV patients, it is important to evaluate the hand immobilisation function of the proposed splint. The subjects were instructed to perform four wrist and two thumb movements with their

bare hand and with the use of the proposed splint respectively. The four wrist movements are wrist flexion, wrist extension, and radial and ulnar deviations. The two thumb movements are CMC joint extension and thumb abduction. The range of motion (ROM) of each movement was measured with a goniometer and recorded for comparison purposes.

Figures 6.17 to 6.20 show the ROM results of the four wrist movements for each subject. The mean ROM of the bare hand for wrist flexion is 47.8° (S.D. = 9.6), but after wearing the proposed splint, the mean ROM is maintained at 17.1° (S.D. = 10.0). The mean ROM of the bare hand for wrist extension is 47.2° (S.D. = 9.4). As mentioned in Nemati et al. (2017), the hand of the patient should be placed in a rest position with a wrist extension of 10° to 20° when moulding the splint. After donning the proposed splint, the mean ROM for wrist extension is 22.2° (S.D. = 10.0), which is close to the suggested range. As for the results of the wrist radial deviation, the mean ROM of the bare hand is 7.2° (S.D. = 3.4). As shown in Figure 6.19, the mean ROM with the splint donned is 0° (S.D. = 0.0), which indicates that the rigid thumb supporter can fully support the radial part and thumb of the hand, and prevent the hand from radial deviation. The mean ROM of the bare hand for ulnar deviation is 22.2° (S.D. = 7.6). Since ulnar deviation of the wrist is part of the movement in the Finkelstein's test, which will pull the DQV related tendons and trigger pain for disease diagnosis, the ulnar deviation of the affected hand should be inhibited. After wearing the splint, the mean ROM for ulnar deviation is held at 13.2° (S.D. = 5.9).

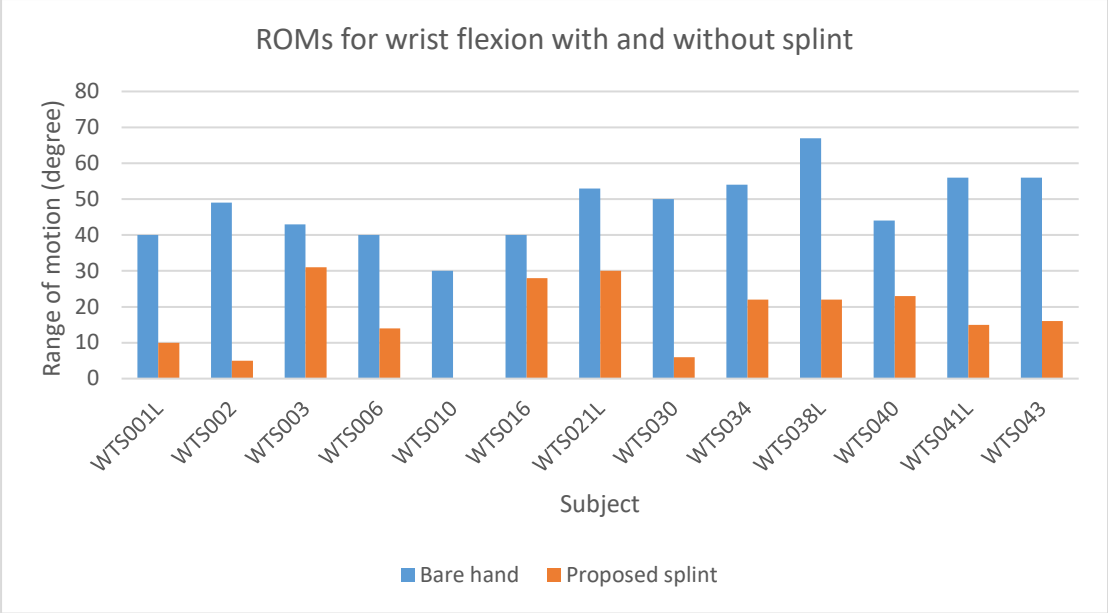


Figure 6.17 ROMs for wrist flexion with and without splint

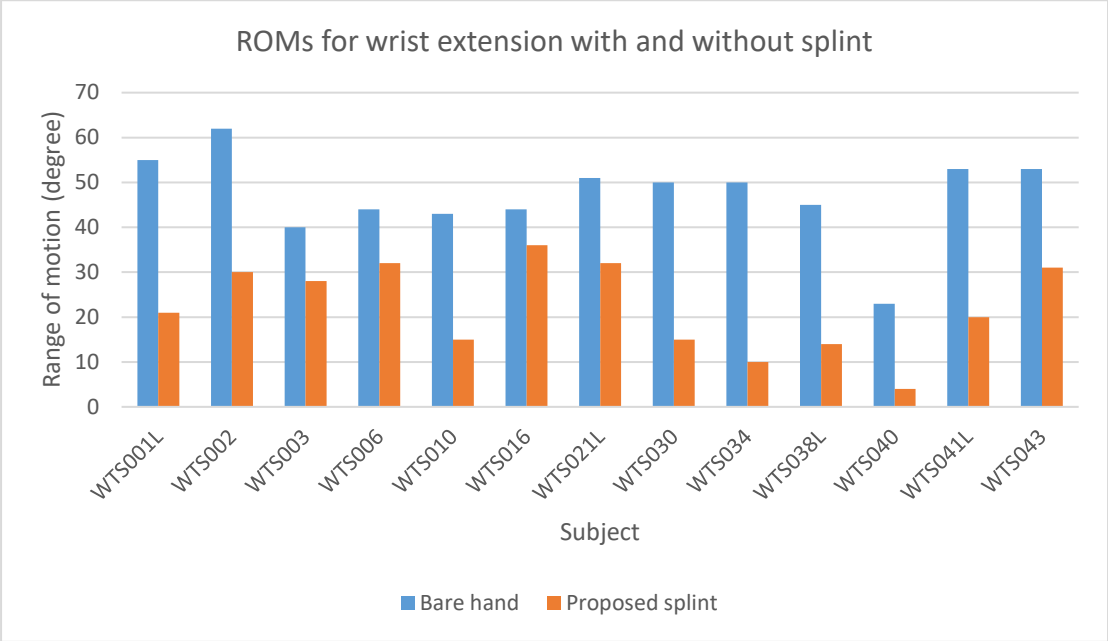


Figure 6.18 ROMs for wrist extension with and without splint

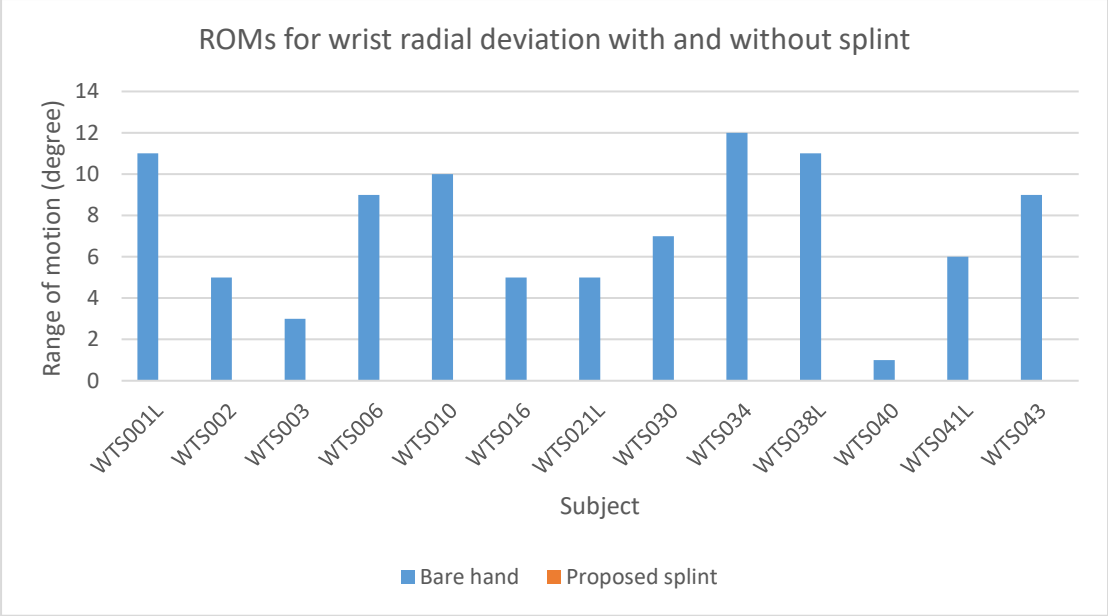


Figure 6.19 ROMs for wrist radial deviation with and without splint

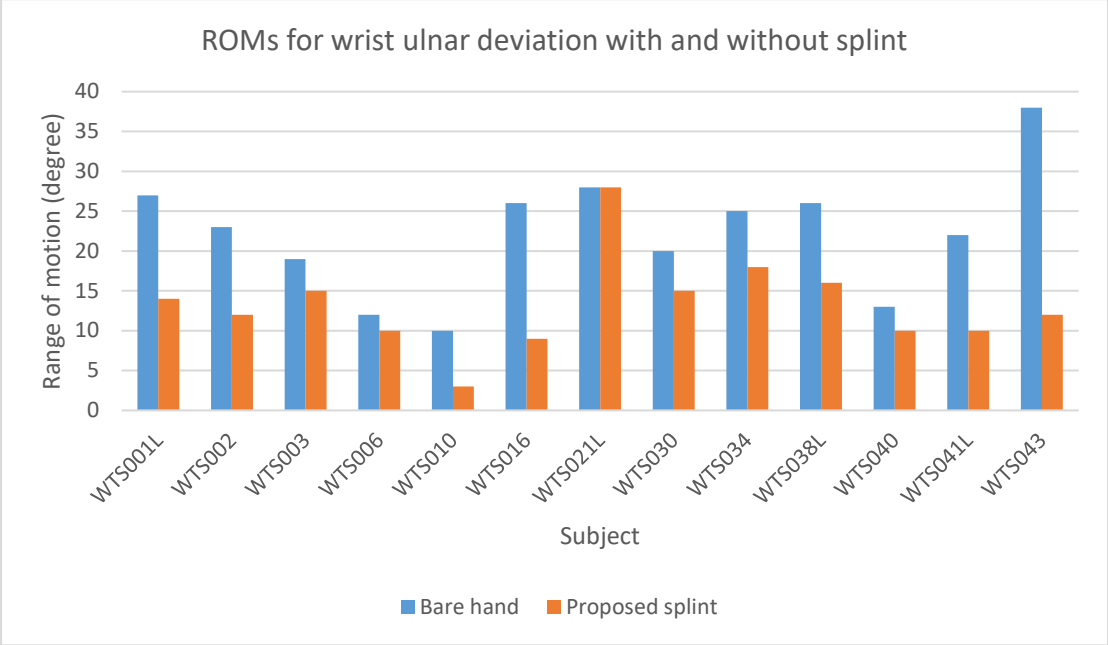


Figure 6.20 ROMs for wrist ulnar deviation with and without splint

According to Nemati et al. (2017), 45% to 60% of daily activities require the use of the thumb. Therefore, it is important to allow an adequate ROM to carry out different tasks that require thumb movement. Wilton (2014) indicated that splinting for hand immobilisation and resting allow slight abduction of the thumb at the CMC joint. The mean ROM of the bare hand for the CMC joint extension is 42° (S.D. = 9.0). With the use of the proposed splint, the degree of extension is reduced to 36.7° (S.D. = 5.0). For the thumb abduction, wearing the proposed splint can reduce the mean ROM from 38.6° (S.D. = 7.9) to 32.4° (S.D. = 9.6). It is evident that the proposed splint is able to reduce the movement of the thumb and protect the thumb from over extension and abduction. At the same time, the splint allows a suitable range of thumb movement to implement daily tasks. Figures 6.21 and 6.22 show the ROM results for the CMC joint extension and thumb abduction with and without the use of the splint for each subject.

A non-parametric Wilcoxon signed ranks test was conducted to investigate the differences between the ROMs of the six movements with and without the splint. The differences between the two sets of data are all significant in which the p values range from 0.001 to 0.005. Table 6.3 shows the details of the statistical results which indicate that the proposed splint can significantly reduce hand movement.

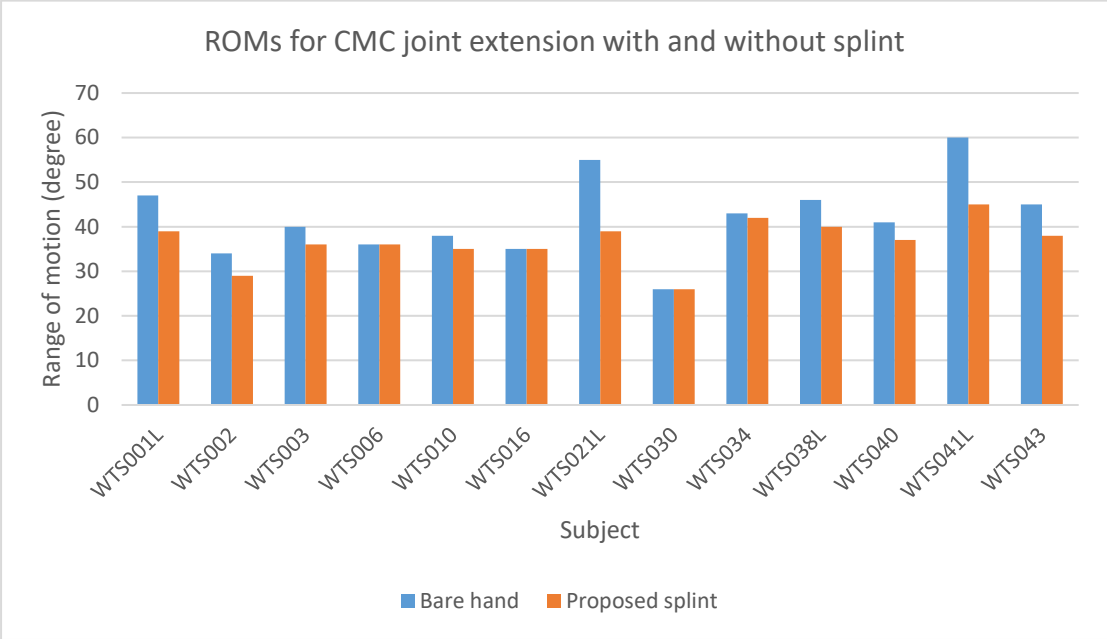


Figure 6.21 ROMs for CMC joint extension with and without splint

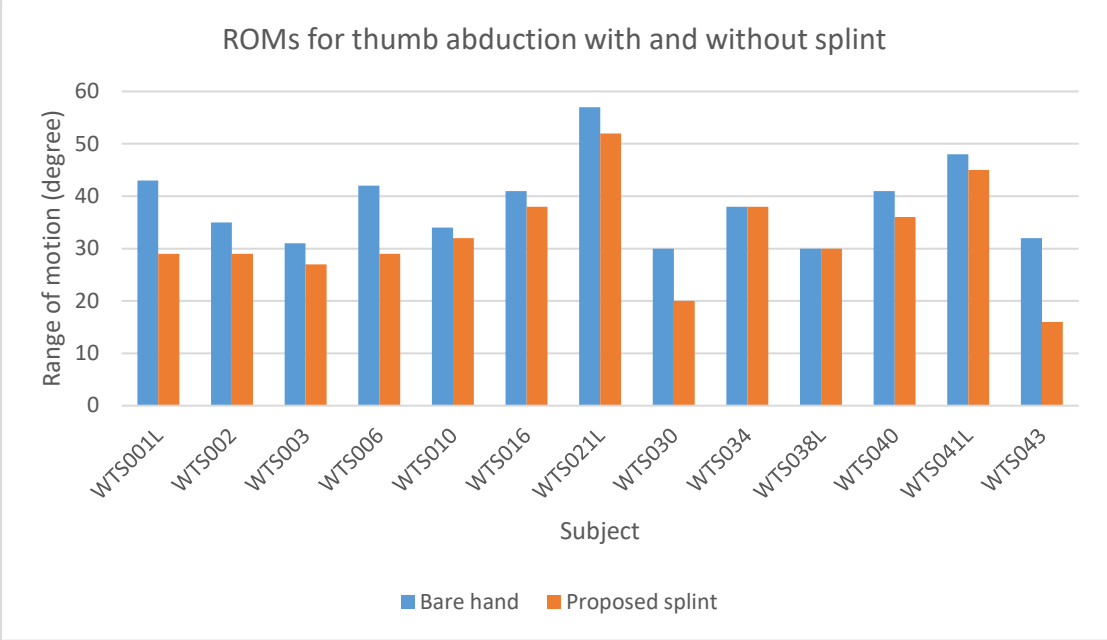


Figure 6.22 ROMs for thumb abduction with and without splint

Table 6.3 Wilcoxon signed ranks test results of ROMs

Wilcoxon signed ranks test results		
Hand motion	Z value	p-value
Wrist flexion	-3.183	0.001
Wrist extension	-3.182	0.001
Wrist radial deviation	-3.186	0.001
Wrist ulnar deviation	-3.061	0.002
CMC joint extension	-2.805	0.005
Thumb abduction	-2.937	0.003

Note: ROM results with proposed splint significantly lower than those of bare hand

6.3.4.2 Further study with existing splints in market

To further evaluate the ability of the proposed splint to control hand movement, an experiment was carried out to compare the ROMs of the hands of the subjects. The experiment focused on the following conditions: bare hand, use of two existing splints found on the market, and use of the proposed splint. The two purchased splints are the Futuro and Medex splints. Details of these two splints are found in Table 3.1. In this experiment, 15 healthy female subjects between 20 and 29 years old were recruited. They were instructed to perform the same four wrist and two thumb movements as done by the subjects in the clinical study. All of the splints were tested on the right hand. Figure 6.23 shows the images of the Futuro, Medex and proposed splints.

Splint appearance			
Name:	Deluxe Thumb Stabilizer	De Quervain's Thumb Splint	Proposed splint
Brand:	Furuto	Medex	/

Figure 6.23 Splints used in ROM study

The mean ROM of the bare hand for wrist flexion among the 15 subjects is 61.4° (S.D. = 8.2). Figure 6.24 shows that the Futuro splint can somewhat control the wrist flexion with a mean ROM of 45.7° (S.D. = 8.6). The Medex splint can better control the wrist flexion with a mean ROM of 32.9° (S.D. = 9.3). The proposed splint however shows optimal control of the wrist flexion, with the lowest mean ROM of 21.0° (S.D. = 7.9). As for the wrist extension (Figure 6.25), the mean ROM of the bare hand is 61.9° (S.D. = 5.9). All three splints show similar reduction of wrist extension, with a mean ROM of 49.3° (S.D. = 6.1), 48.5° (S.D. = 9.5) and 42.1° (S.D. = 11.1) for the Futuro, Medex and proposed splints, respectively.

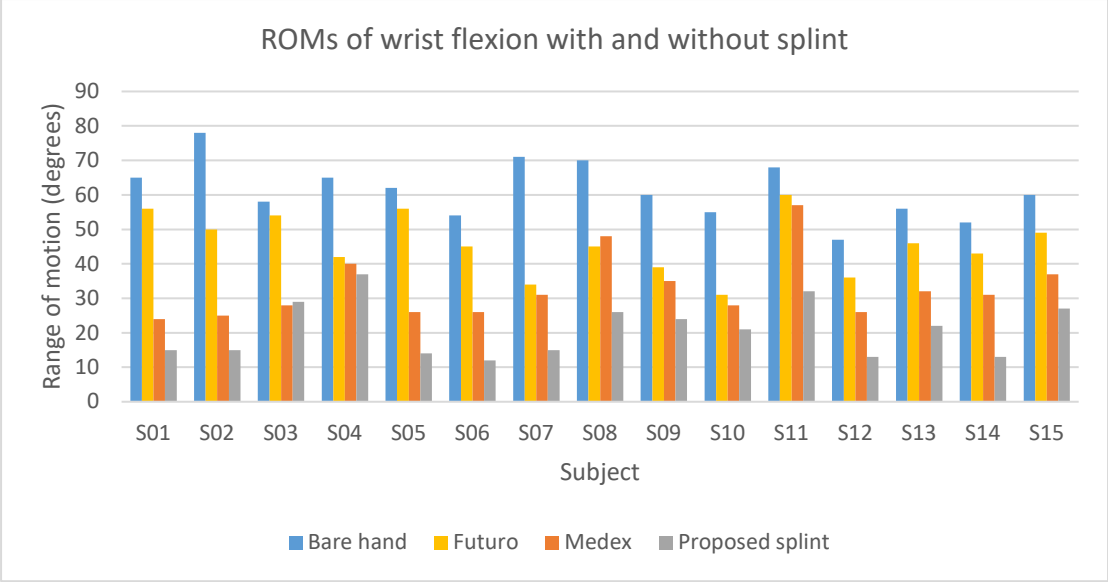


Figure 6.24 ROMs for wrist flexion with and without splint in ROM study

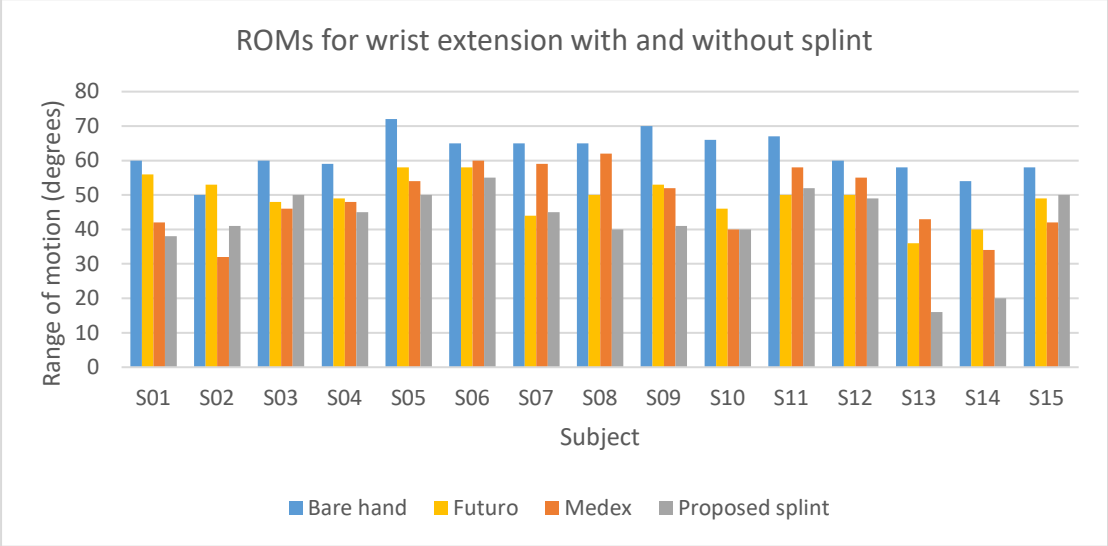


Figure 6.25 ROMs for wrist extension with and without splint in ROM study

The results of wrist radial and ulnar deviation are shown in Figures 6.26 and 6.27 respectively. The mean ROMs of the bare hand for the wrist radial and ulnar deviations are 15.7° (S.D. = 4.9) and 39.5° (S.D. = 7.2) respectively. Among the three splints, the Futuro shows the least reduction in ROM in which the mean ROMs for the wrist radial and ulnar deviations are 11.9° (S.D. = 2.4) and 32.2° (S.D. = 7.4), respectively. The Medex splint shows a moderate reduction while the proposed splint shows the highest reduction of ROM. The mean ROMs for the wrist radial and ulnar deviations with the Medex are 8.3° (S.D. = 3.9) and 26.2° (S.D. = 6.2) respectively, and 6.1° (S.D. = 3.0) and 21.8° (S.D. = 5.5) with the proposed splint, respectively. The reason why the Futuro

splint has the least reduction in ROM might be the insufficient coverage of the splint along the forearm area for wrist support and stabilisation. The Medex and the proposed splints show the highest reduction which may be due to the design that covers the forearm along with a rigid thumb supporter on the radial side of the hand. As for the proposed splint, the ulnar support complements the thumb supporter which further stabilises the hand.

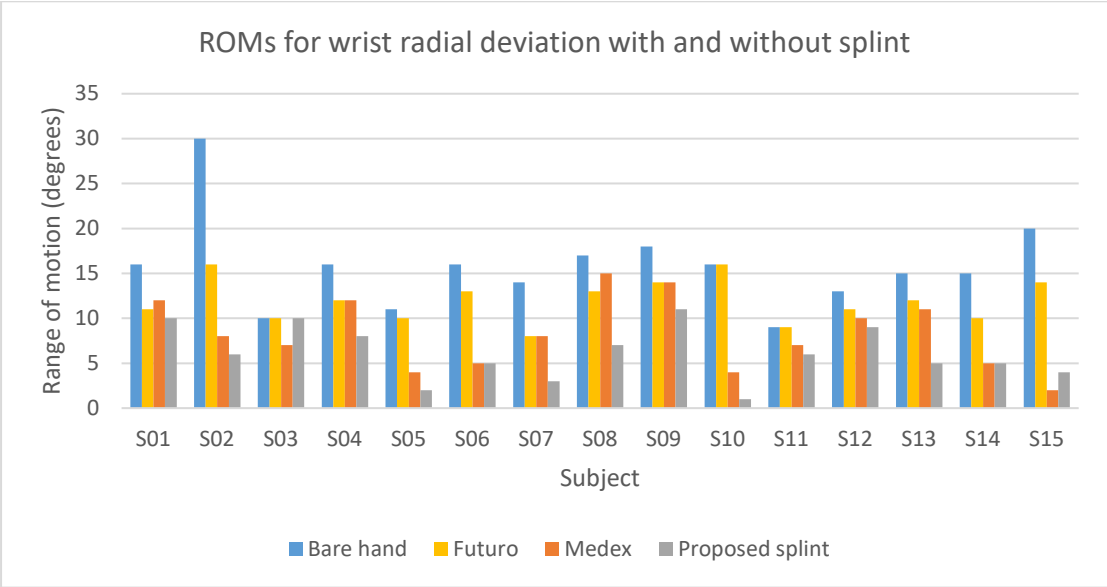


Figure 6.26 ROMs for wrist radial deviation with and without splint in ROM study

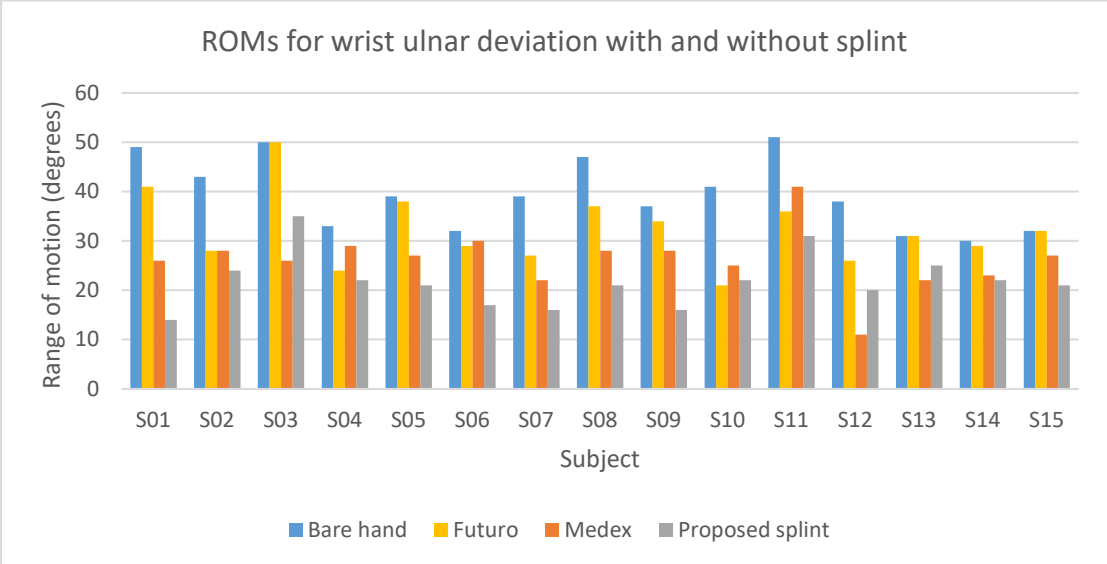


Figure 6.27 ROMs for wrist ulnar deviation with and without splint in ROM study

The ROM results for the CMC joint extension and thumb abduction are presented in Figures 6.28 and 6.29. Without a splint, the mean ROMs for the CMC joint extension and thumb abduction are 54.9° (S.D. = 10.4) and 49.9° (S.D. = 8.1) respectively. The Futuro and Medex show a similar performance in reducing the ROMs. The former reduces the mean ROMs for the CMC joint extension and thumb abduction to 40.3° (S.D. = 7.80) and 41.7° (S.D. = 5.8) respectively. The mean ROMs with the use of the Medex splint are 42.5° (S.D. = 7.7) for the joint extension and 40.2° (S.D. = 7.2) for the thumb abduction. The proposed splint shows the best performance in reducing the extension and abduction of the thumb, with a mean ROM of 38.4° (S.D. = 6.0) for the former and 37.9° (S.D. = 5.3) for the latter. Consistent with the results of the clinical study, the mean ROMs for thumb extension and abduction are reduced to a range of 30° to 40°. This would allow sufficient movement for subjects to perform tasks that require the thumb but at the same time, prevent the tendons along the thumb from overstretching.

A non-parametric Friedman test was conducted which showed statistically significant differences in the ROMs for all six movements depending on whether a splint was used. The statistical results are listed in Table 6.4.

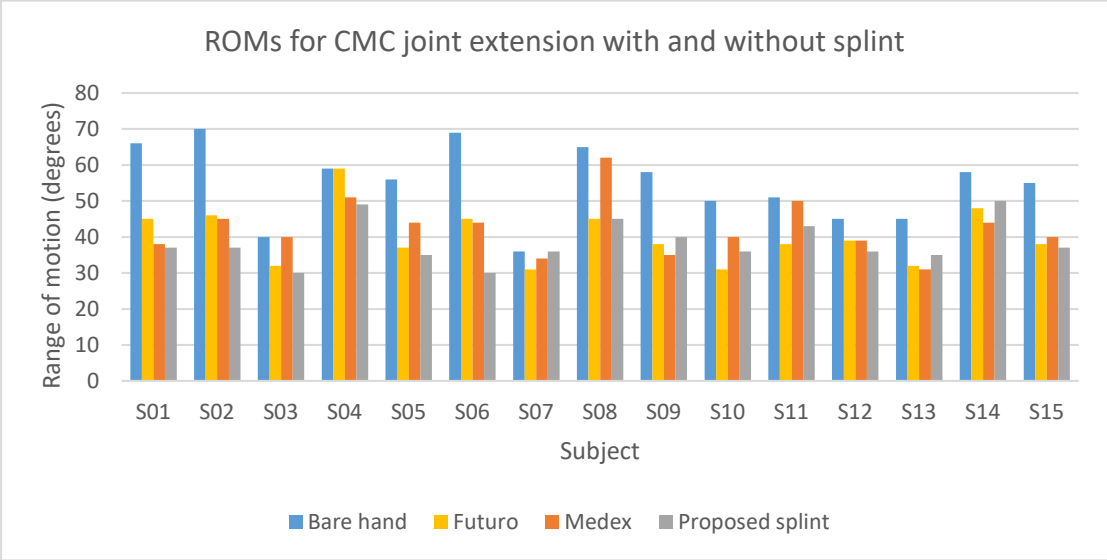


Figure 6.28 ROMs for CMC joint extension with and without splint in ROM study

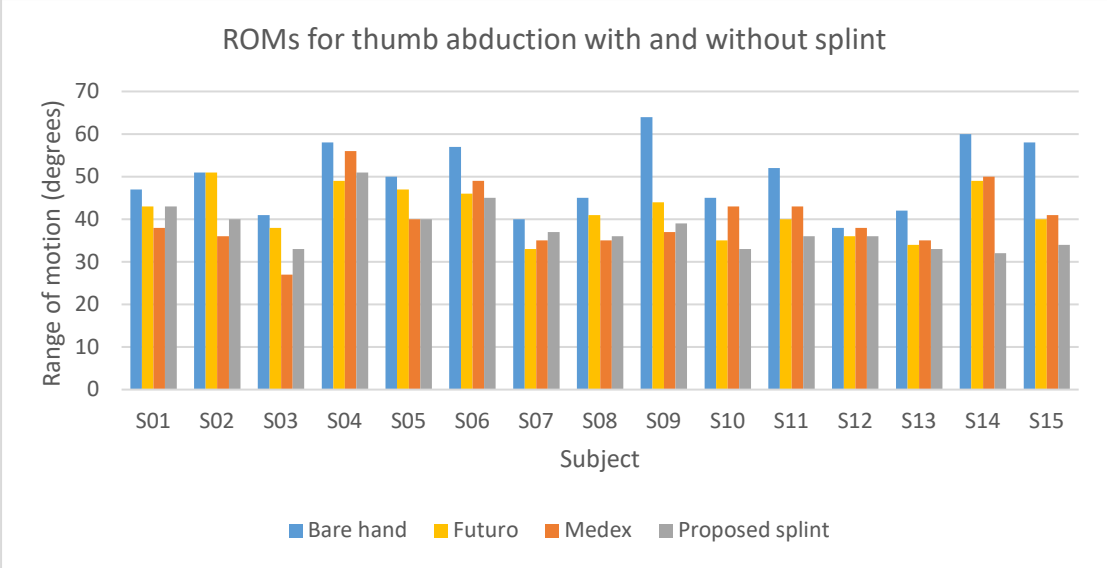


Figure 6.29 ROMs for thumb abduction with and without splint in ROM study

Table 6.4 Friedman test results of ROM results in ROM study

Hand movement	χ^2 value	Degree of freedom	p-value
Wrist flexion	42.680	3	0.000
Wrist extension	28.772	3	0.000
Wrist radial deviation	36.108	3	0.000
Wrist ulnar deviation	34.171	3	0.000
CMC joint extension	25.717	3	0.000
Thumb abduction	27.621	3	0.000

6.3.5 Splint evaluation questionnaire

During the clinical study, a questionnaire was given to the patients at each follow-up session. The questionnaire aims to understand the splint wearing conditions of the subjects and their comments on different aspects of the proposed splint, for example, the function of the splint, problems during splinting and the properties of the splint. As mentioned in Section 6.2, one of the subjects ended her participation in the study in the second month because she no longer had any symptoms, and since she did not attend the third follow-up session, her information is shown as missing data.

At the beginning of the intervention, the subjects were given a recommendation to wear the splint for at least 8 hours each day. It can be observed in Figure 6.30 that the subjects did not adhere to this wear standard. The mean wear time is 6.4 hours (S.D. = 2.9) in the first month, then dropped to 4.8 hours (S.D. = 3.0) in the second month and increased to 5.3 hours (S.D. = 2.4) in the third month. Since almost half of the subjects are housewives, they self-reflected and indicated that they are responsible for much of the housework every day, in which many require the use of water. These tasks include washing dishes, preparing food and cleaning with wet towels, which make it difficult to carry out during splinting as the subjects wanted to avoid getting the splint wet. Therefore, they removed the splint, which resulted in a mean wear time that is less than the suggested time.

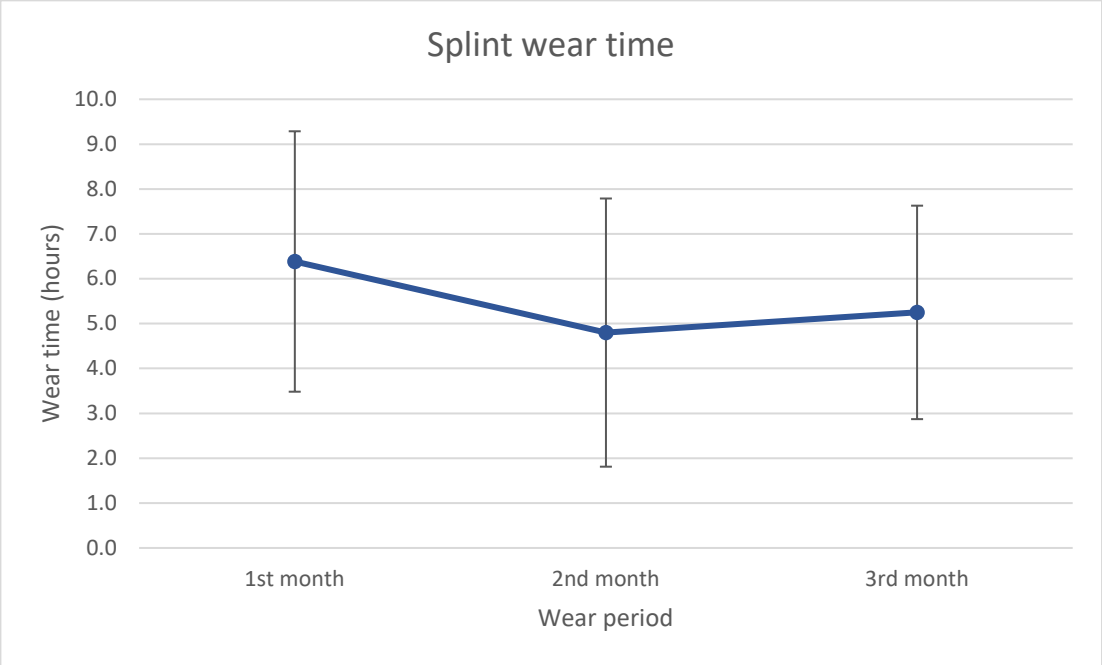


Figure 6.30 Mean wear time of splint

In the first part of the questionnaire, the subjects were instructed to use a Likert scale to rate their agreement with four statements that are related to the functions of the proposed splint and four statements that are related to the problems caused by wearing the splint. Figure 6.31 is a graph that shows most of the subjects 'neither agree nor disagree' or 'agree' that the splint relaxes their hand and relieves their pain, and that the performance of the splint to cure DQV is effective at the beginning of the treatment.

They agree that wearing the splint can remind them to rest their affected hand. At the end of the intervention, the agreement of the subjects towards all four functions is increased. They mostly agree that the splint can remind them to rest their hand. Furthermore, they agree that the splint could relieve their pain.

As for the problems caused by wearing the proposed splint, the patients rated either 'disagree' or 'neither agree nor degree' for all four listed problems at the beginning of the treatment (Figure 6.32). Throughout the intervention, they tended to disagree that wearing the splint is worrisome and troublesome. In general, they also disagree that there is a 'decrease in sleeping quality' and 'reduction in self-confidence'. In summary, the subjects have positive feedback about the proposed splint. They agree that the splint can reduce the pain of their hand and at the same time, wearing the splint would probably not cause any issues or concerns.

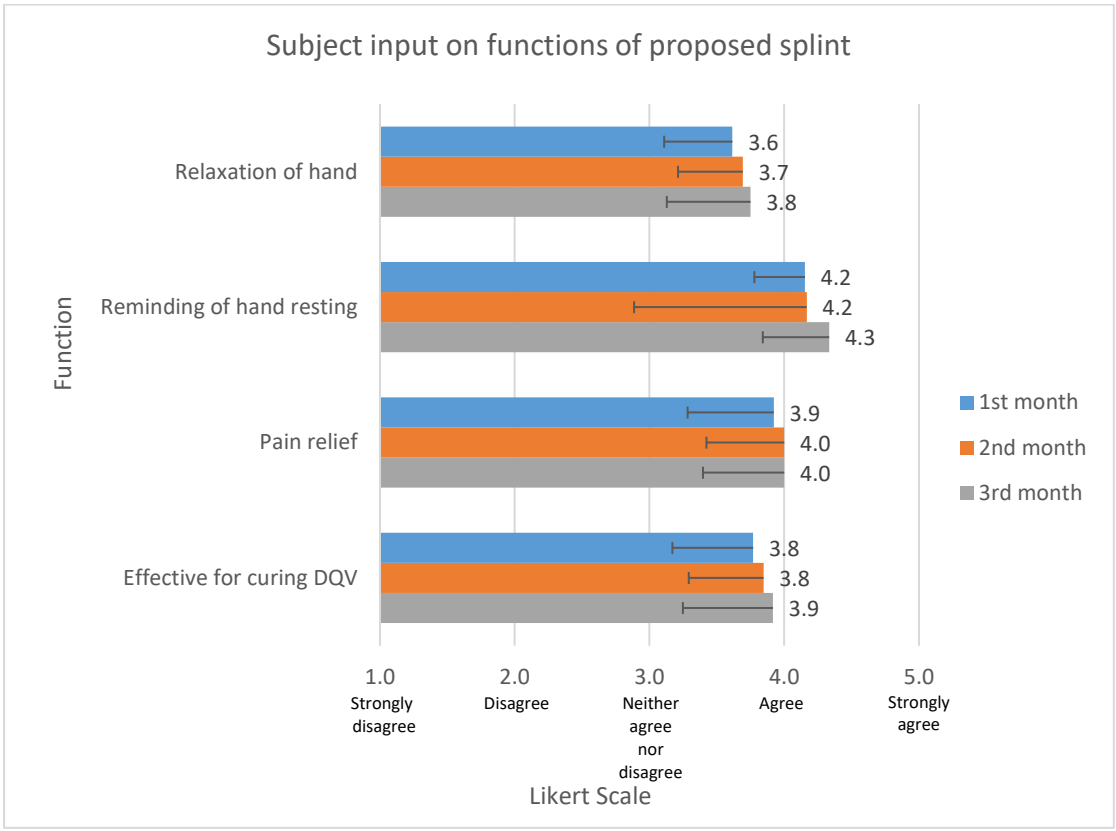


Figure 6.31 Subject input on functions of proposed splint

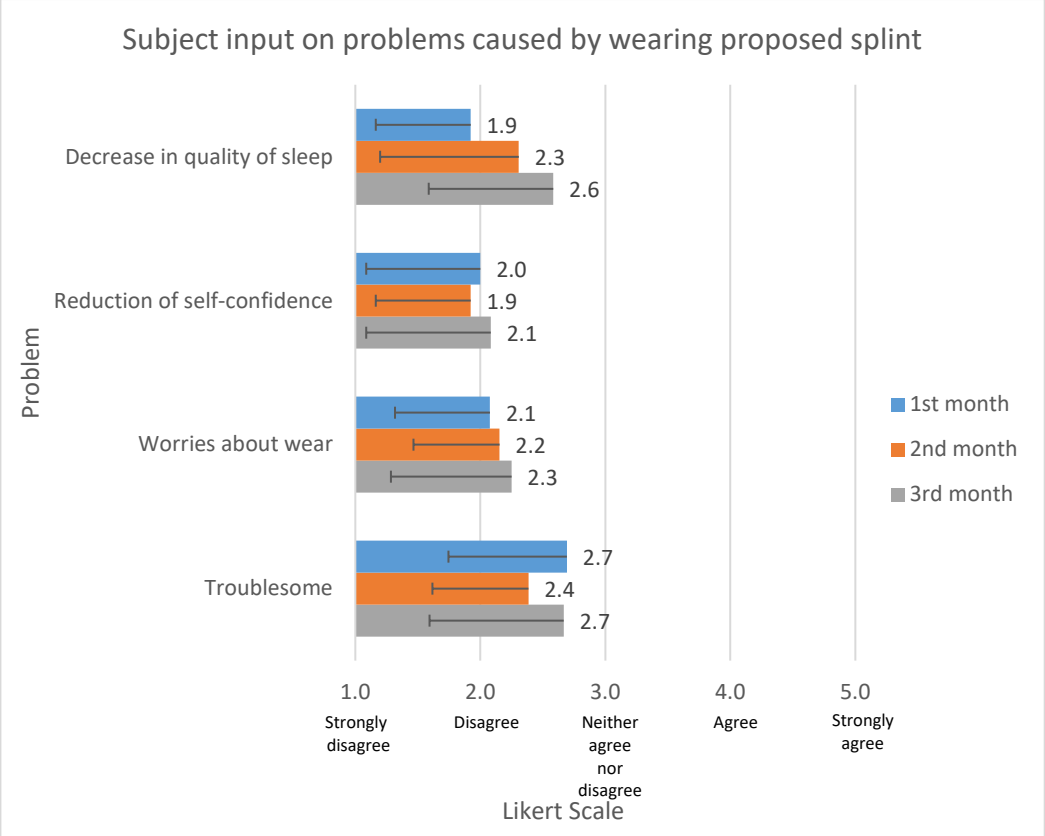


Figure 6.32 Subject input on problems caused by wearing proposed splint

In the second part of the designed questionnaire, the subjects were instructed to score their level of satisfaction towards different aspects of the proposed splint, for example, the appearance, durability, wear comfort, functionality, etc. Figure 6.33 shows that the subjects are quite satisfied with all of the properties of the proposed splint after wearing the splint for a one month period. Overall, their satisfaction with the splint increased in all aspects over the three-month period of intervention. The reason might be that they have become more used to wearing the proposed splint with time. They may also have experienced improvement of their symptoms over time. At the end of the intervention period, the three items that the subjects are most satisfied with include: the 'convenience' of the splint, which is related to its weight and bulkiness; the 'wear comfort' of the splint, which is about its hand feel and air permeability; and the 'functionality' of the splint, which is related to reducing the symptoms and relieving the pain of the injured hand.

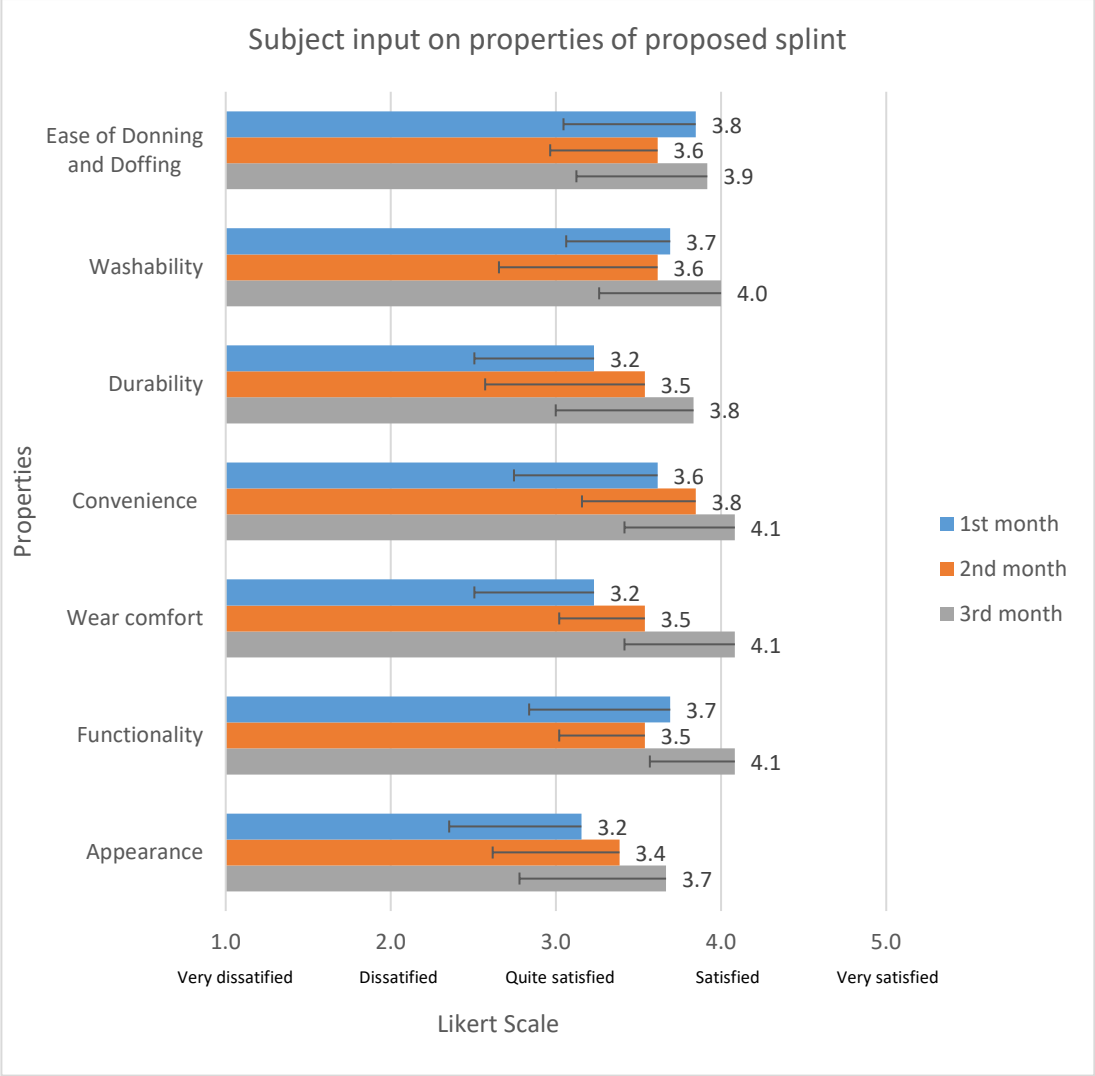


Figure 6.33 Subject input on properties of proposed splint

6.3.6 *Quick*DASH

The *Quick*DASH questionnaire was also used as an outcome measure to understand the physical function and symptoms of DQV. The questionnaire design, modules and scoring system are shown in Figure 6.34. The subjects were required to complete the first two modules, so that their ability to perform specific daily tasks and their severity of DQV symptoms at different points in time throughout the intervention could be compared. On the other hand, since the work and sport/ performing arts modules were optional for completion, and some of the patients are housewives without an official paying job and do not play any sport or musical instruments, they did not complete these two modules. Thus, the results collected from the two optional modules cannot be used for comparison purposes.

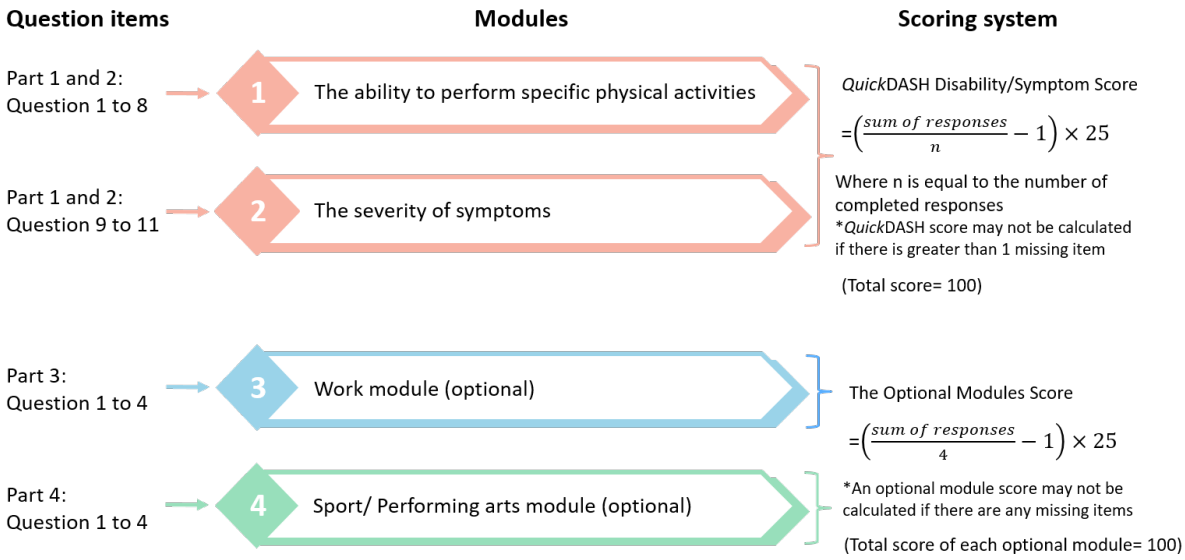


Figure 6.34 Structure and scoring system of *Quick*DASH questionnaire (Chan et al., 2019)

The overall score for the '*Quick*DASH Disability/Symptom Score' can be calculated from the first two modules. The subject who left the study early was given a score of 0, which represents no pain and disability. The overall mean scores and scores of each subject are plotted in Figures 6.35 and 6.36 respectively. The mean score at pre-test is 52.9 (S.D. = 15.5) and reduced to 28.8 (S.D. = 19.9) in the third month of treatment. A non-parametric Friedman test was conducted and there is a significant difference between the scores before and after the intervention, χ^2 (3) = 19.016, and p = 0.000.

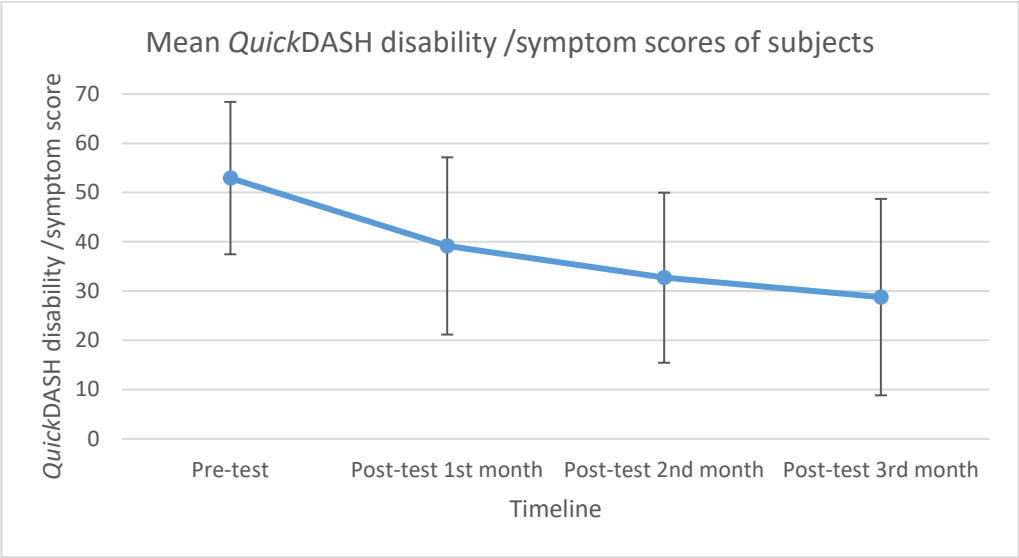


Figure 6.35 Mean *Quick*DASH disability/ symptom scores of subjects

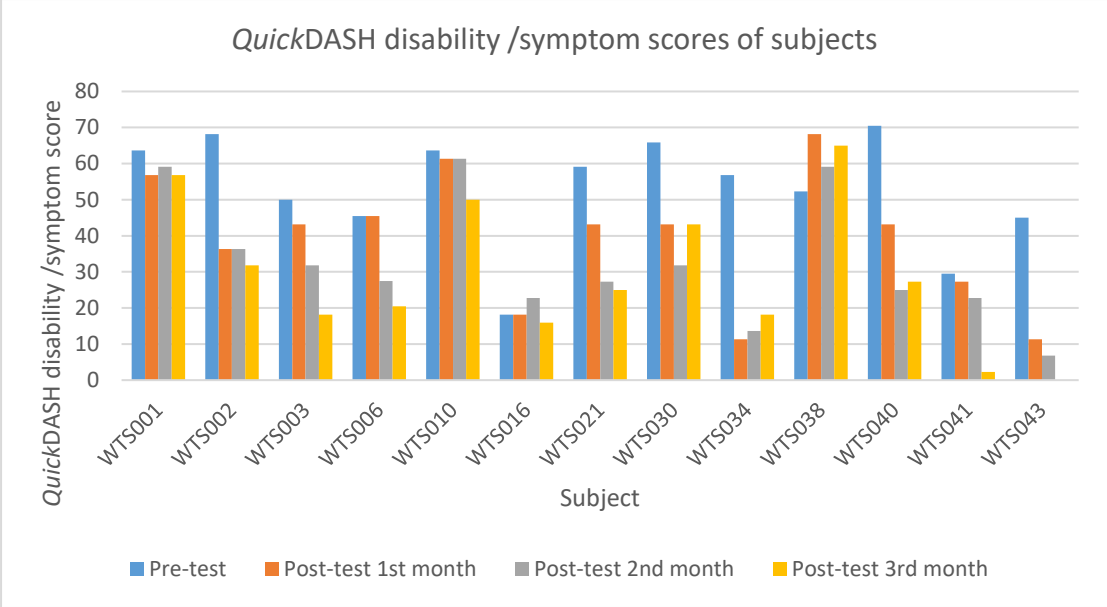


Figure 6.36 *Quick*DASH disability/ symptom scores of subjects

Gummesson et al. (2006) validated the *Quick*DASH questionnaire and indicated that the results have a similar accuracy as that of a full-length DASH questionnaire. Williams (2014) stated that both the DASH and *Quick*DASH are reliable and responsive tools that are suitable for research and clinical studies. However, he also pointed out that a corresponding system between the DASH score and specific severity level of disability has not yet been clearly developed. He mentioned a study found that participants with a DASH score that ranges from 0 to 29 probably do not consider the disorder of their upper-limbs as a problem. After calculating the *Quick*DASH disability/ symptom scores of each subject, the scores were grouped into two groups, which are those between 0 and 29 and those that are 30 or higher. The distributions of the two groups before and after the treatment are plotted as pie charts in Figure 6.37. At the pre-test stage, 8% of the subjects have a *Quick*DASH disability/ symptom score less than 29 which means that they may feel pain of their injured hand but not consider DQV as a significant problem. On the other hand, 92% of the subjects have a score higher than 29 which mean they may suffer more with DQV. It can be observed in Figure 6.37 that the number of patients with a score higher than 29 is reduced over the course of the treatment. In the end, more than 60% of the patients have a score less than 29. This shows that DQV has much fewer impacts on the daily life of these subjects after the splinting treatment.

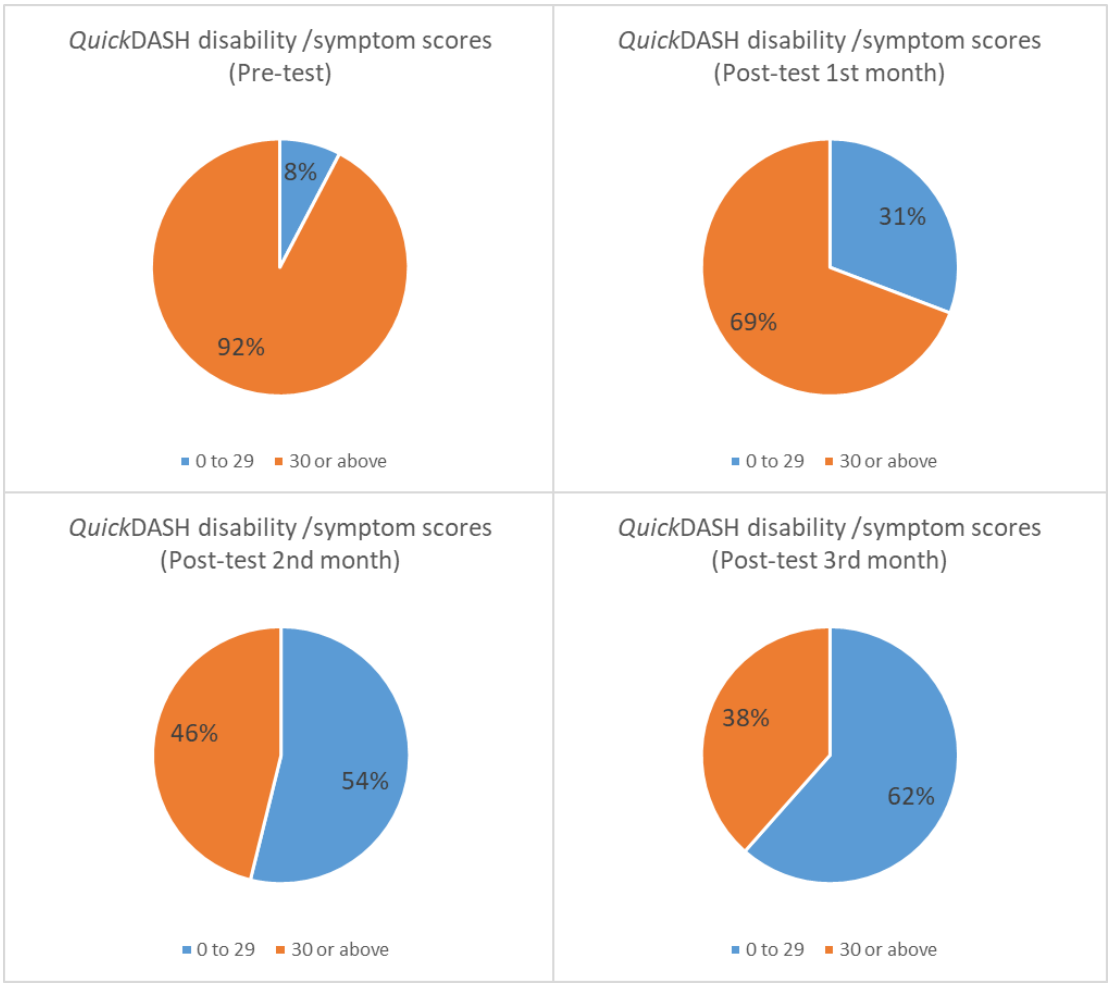


Figure 6.37 Distribution of *Quick*DASH disability/ symptom scores of subjects ≤ 29 or >29 with time

6.3.7 Health-related quality of life

In the second month of the intervention, it was determined that the quality of life of the patients in this study might be worthwhile of further study. The Short Form 12-item Health Survey version 2 (SF-12 v2) was given to each subject for completion during the second and third follow-up sessions. The subject who left the study early was considered to be missing data. The collected answers were calculated through a designed algorithm for score comparison (Ware, 2002).

After following the scoring procedures of the SF-12 v2, the scoring results of the eight domains were calculated based on a 0 to 100 scale. A higher score represents less pain and impairment and fewer dysfunctions of the body. On the other hand, the two main summary scales were transformed to t-scores with a mean of 50 and a standard deviation of 10 (Larson, 2002). The scores of all the domains, except 'Role-Physical',

are increased from the second to third month of treatment; see Table 6.5. Lam, Wong, Lam, Lo, and Huang (2010) stated that the scores of the two role related domains and the 'Social functioning' domain might be affected by the changes in employment environment and economic situation of the living society. On the other hand, the scores of other domains such as 'General Health' and 'Vitality' may mainly depend on personal feelings instead of social and economic factors. Therefore, a lower score of the 'Role-Physical' domain may be due to the employment demands on the subjects during that month and the difficulties in work completion owing to wrist pain. On the other hand, increases in the scores of the other domains indicate enhancement of quality of life, which may be due to the healing of the wrist after one more month of splinting. The increased PCS and MCS scores, as shown in Table 6.6, further show that the subjects demonstrate an increase in both physical and mental health in their daily life over the last month of the splinting treatment.

Table 6.5 Scoring results of eight domains

	Second month				**Third month**			
Scale	**Mean**	**Std. Dev.**	**Min.**	**Max.**	**Mean**	**Std. Dev.**	**Min.**	**Max.**
General Health	40.4	26.5	0.0	85.0	52.9	27.6	25.0	100.0
Physical Functioning	55.8	25.3	0.0	100.0	70.8	31.7	0.0	100.0
Role-Physical	63.5	18.7	25.0	87.5	60.4	19.1	25.0	87.5
Bodily Pain	57.7	21.4	25.0	100.0	58.3	22.2	25.0	75.0
Role-Emotional	70.2	20.1	37.5	100.0	77.1	17.5	50.0	100.0
Mental Health	70.2	14.9	50.0	100.0	74.0	17.2	50.0	100.0
Vitality	48.1	21.6	25.0	75.0	56.3	24.1	25.0	100.0
Social Functioning	73.1	23.9	25.0	100.0	83.3	22.2	50.0	100.0

Table 6.6 Scoring results of PCS and MCS

	Second month				Third month			
Summary Measure	**Mean**	**Std. Dev.**	**Min.**	**Max.**	**Mean**	**Std. Dev.**	**Min.**	**Max.**
Physical component summary scale	38.9	6.5	30.2	50.1	41.2	8.9	23.1	53.0
Mental component summary scale	48.9	8.5	38.9	67.2	51.9	8.8	40.4	64.4

6.3.8 Correlations between comments of subjects

A non-parametric Spearman's test was conducted to investigate the correlations between the comments of the subjects. Correlations with a p value less than 0.05 are considered to be significant. The results indicated that the satisfaction of the ease of donning and doffing the proposed splint is significantly and positively correlated to pain relief and the effectiveness of the splint, which r_s= 0.743, p = 0.004 and r_s = 0.749, p = 0.003 respectively. When the splint is easy to use, the subjects might be more willing to wear the splint so that the compliance rate is then increased. Thus, a longer splinting period may allow for a longer time of resting the wrist and healing the injured tissues. Furthermore, the satisfaction with the functionality of the proposed splint is significantly and positively correlated with the relaxation of the hand and negatively correlated with the worries about the wear of the splint, which r_s = 0.879, p = 0.000 and r_s = -0.730, p = 0.005 respectively.

6.4 Chapter Summary

In the final stage of the research project, a clinical study is carried out to evaluate the performance of the proposed splint. The study design is pre- and post-test interventions, which includes one pre-test clinical session for the evaluation of the hand conditions and the prescription of a splint, and three post-test follow-up sessions. The splint intervention lasted for three months. A total of 13 female subjects who range between 49 and 67 years old and diagnosed with DQV are recruited for the study. One subject terminated treatment early after the second month because her DQV is successfully treated while the other 12 subjects participated for all three months.

To evaluate the hand conditions, thumb and finger extension and hand opposition are carried out. Pain level is evaluated based on a VAS scale from 1 to 10. The results show that the level of pain with the two hand movements is significantly reduced after the splinting treatment. The subjects also listed three daily activities that are most difficult and painful to implement and score the degree of pain. The activities are classified into nine categories: hand twisting, cooking, holding lightweight objects, holding heavy objects, handcrafting, donning clothing, fine motor skills, baby caring and other. The pain scores for all of categories at the third month of follow-up are lower than those at pre-treatment. The changes in the palmar pinch and grip strengths are the secondary outcome of the study. Although there are no significant difference of grip strengths between the pre- and post-treatment results, the pinch strengths are significantly increased during the treatment.

The pressure given by the splint on the injured hand is sometimes neglected by splint manufacturers. To investigate the pressure distribution of the splint and ensure that the patients are wearing the splint properly without excessive tightness, a set of pressure tests are conducted. Patients are asked to perform two static rest positions while wearing the splint. Two hand movements are also carried out with the splint, which include moving a bottle and writing characters. The testing is repeated, once with Splint 1 and then with Splint 2. The results show that the maximum pressure point with Splint 1 for all of the tasks is higher than 4.4 kPa, which is the pressure value that may affect the blood flow across the hand. For the results of Splint 2, the maximum pressure received during the moving tasks is slightly higher than 4.4 kPa, while the maximum pressure received during the static rest positions are less than 4.4 kPa. Therefore, the recommendation is to wear Splint 2, which has an opening width of 2 cm or slightly more than 2 cm, so that the hand can be held in the appropriate position without excessive pressure.

The aim of a DQV splint is to support the affected hand of patients and limit hand movement. To evaluate the hand immobilisation function of the proposed splint, the subjects perform six hand movements with and without the splint, and the ROMs of each movement are then recorded. The six movements are wrist flexion and extension, wrist radial and ulnar deviations, CMC joint extension and thumb abduction. The results show that the ROMs of all of the movements with the proposed splint are

significantly smaller than that with the bare hand. This shows that the proposed splint can prevent the hand from over extension and excessive deviation. A ROM study to compare the ability of existing splints on the market to reduce hand movement in comparison to the proposed splint has also been carried out. Fifteen healthy female subjects between 20 to 29 years old performed six movements in four hand conditions respectively. The hand conditions include: bare hand, wearing the Futuro splint, using the Medex splint and wearing the proposed splint wearing. The test results are in agreement with the ROM results of the patients that there are significant differences between the four conditions for all six movements.

A splint evaluation questionnaire is specially designed for the subjects so that they can comment on their wear experience of the proposed splint. The self-reported splint wear time each day is around 5 to 6 hours, which is less than the recommended 8 hours each day. The reason might be that almost half of the subjects are housewives so they find it difficult to wear the splint while doing housework that involves the use of water. The subjects also increased their positive views on the functions of the splint, such as pain relief and effectiveness of treating the ailment, over the 3-month period of treatment. They indicate that they 'neither agree nor disagree' or 'disagree' that there are problems caused by wearing the splint throughout the intervention. Overall, the subjects are satisfied with all of the listed properties of the proposed splint, that is, the appearance, durability, wear comfort and convenience of donning and doffing.

The *Quick*DASH Disability/Symptom Score is used here to reflect the condition of the hand in the past week in terms of pain level and severity of disability. A higher score indicates higher levels of pain and disability. Changes in the score are considered as the primary outcome of this study. The result shows that the mean *Quick*DASH Disability/Symptom scores of the subjects are reduced over the intervention period. The statistical analysis indicates that there is a significant difference between the scores before and after the splinting treatment.

The SF-12 v2 is a validated questionnaire to evaluate the health-related quality of life (HRQOL) of the patients. The SF-12 v2 was given to the patients to fill in during the intervention, in the second and third follow-up sessions. The overall results show that the summary scores for both physical and mental aspects increases after one month of

treatment, which reveals that the quality of life of subjects has been enhanced over the last session of intervention.

Finally, the correlation between the inputs of the subjects is investigated. The results show that when the subjects are more satisfied with the donning and doffing of the splint, they are more willing to wear the splint, which may be correlated with the ability of the splint to treat the injured hand. Furthermore, the satisfaction of the patients with the functions of the splint may allow the patients to relax their affected hand and feel less worried about the ailment.

To conclude, the proposed splint can stabilise and support the hand of DQV patients, and contribute to speeding up the healing process of the DQV affected hand. The outcomes of the clinical study show that the proposed splint is effective enough to reduce the pain level and severity of disability of the injured hand. With the gradual healing of the hand, the grip and the palmar pinch strengths are increased. The HRQOL of patients can also be enhanced after undergoing the splinting treatment.

Chapter 7 Finite element model of proposed functional splint

7.1 Introduction

Finite element analyses (FEAs) can be used to simulate various phenomena by using finite element models (FEMs) to provide numerical solutions for problems in different fields, such as land surveying, physics and engineering. FEMs can be used to analyse displacement, and pressure and thermal distribution problems. During the past years, more and more researchers in the medical field have been utilising FEAs to build simulation techniques for treatments, such as operations, needle injections and orthotic therapies, to gain a better understanding on the treatment processes and outcomes. In this study, a FEM that simulates the wearing of the proposed splint has been built to investigate the pressure distribution given from the splint onto the patient's hand. The purpose of wearing this splint is to stabilise the injured hand in the resting position. The fastening system of the splint allows tightening with an appropriate degree of tightness, which maintains the supporters in the proper positions. Over-tightening should be avoided as exertion of high pressure onto the surface of the skin for certain periods of time may lead to the formation of pressure ulcers. Compared to the limited data obtained through measurements by using the Pliance®-xf-16 pressure point sensors, the use of a FEM can provide a full picture of the pressure distribution over the entire hand. Investigation of the pressure distribution of the proposed splint can be repeatedly carried out in the future with this model, which may save time and costs as opposed to conducting multiple human wear trials.

7.2 Development of geometric model

In this study, a FEM has been developed to simulate the pressure distribution of the splint on the patient's hand. The model consists of three main parts, which are the patient's hand, and soft materials and hard supporters of the splint. In the initial stage, a hand with bones was constructed. Then, the soft materials were built to surround the model of the hand. The two supporters were aligned at the radial and ulnar sides of the hand respectively. In the second stage, the fabric and supporting materials were tested to obtain information on the properties to build the material data set in the model system. Element types were selected for mesh formation of the modelled parts. In the

third stage, the interactions between the different parts were established. The boundary conditions and displacement of specific areas were defined. In the final stage, the system setting for running the model was adjusted. The modelling task was then submitted to generate the results.

7.2.1 Construction of hand and lower arm model

A female subject (Subject code: WTS002) who is 59 years old was recruited for the clinical study of the proposed splint. Her injured right hand was scanned by using an Artec Eva handheld scanner to obtain a 3D image. The subject had not received any injections nor surgical treatment of the affected hand before the intervention. Furthermore, the subject did not have other hand diseases and did not undergo other types of treatment during the intervention, as shown in Table 7.1. Her injured hand was selected to form the simulation model as the swelling symptoms of DQV near the radial styloid were very obvious, which is highlighted in red in Figure 7.1.

Table 7.1 Demographics of WTS002

Subject code	Gender	Age	Injured hand	Injection for DQV	Surgery for DQV	Period of pain	Period of intervention	Other hand diseases during intervention	Other treatments during intervention
WTS002	F	59	R	N	N	7 months	3 months	N	N

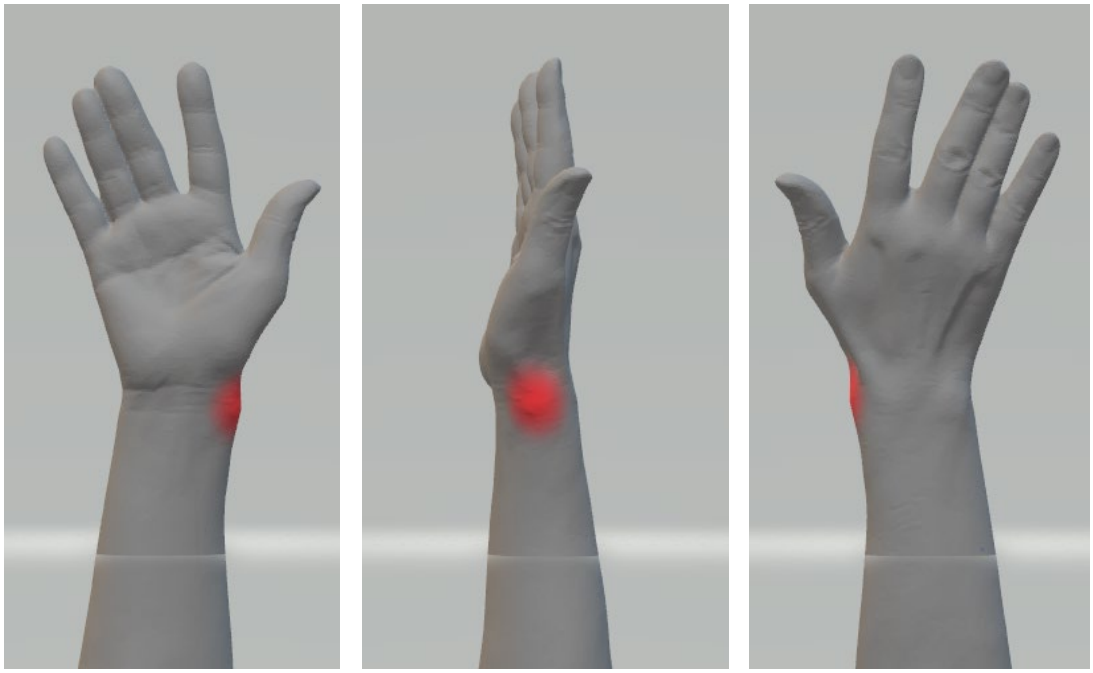


Figure 7.1 Swelling near radial styloid of injured hand due to DQV (highlighted in red)

The model of the hand was first re-oriented by using Artec Studio to align the position of the model based on the x, y and z axes, as shown in Figure 7.2. Then, the model of the hand was edited with Geomagic Studio software. Unnecessary parts of the model, such as the fingers, were cropped to reduce the computational time of the model. The model was then divided into different grids, so as to generate gridlines and form patches on the hand. The formed patches also facilitate recognition of the hand contours with the use of software, which contribute to the meshing process in later steps. The formation process of gridlines and patches is shown in Figure 7.3. After defining the patches on the model of the hand, an ordered u-v grid was generated. When the software identified components with over-creased features or over-irregular shapes, these components would be shown in red (Figure 7.4). Fixation of the model of the hand was carried out and the surface was mapped (Figure 7.5). The final model of the hand and lower arm is shown in Figure 7.6.

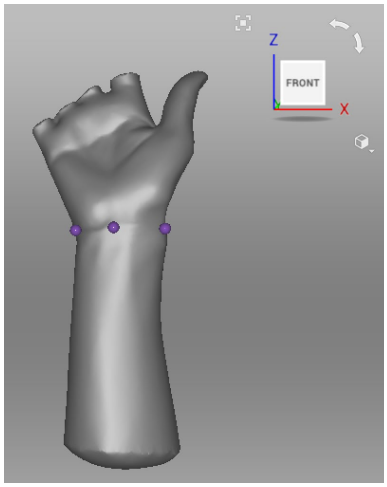
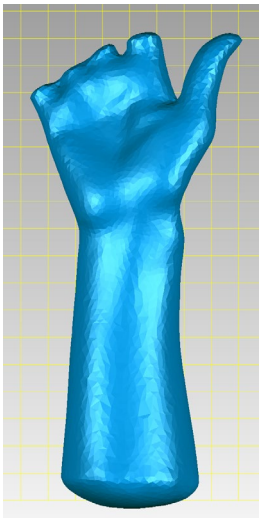
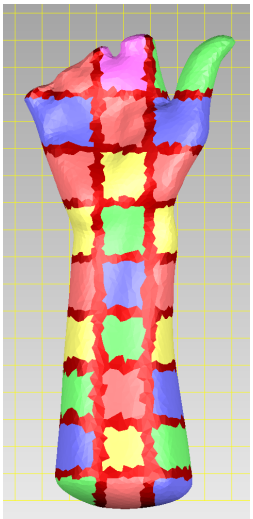


Figure 7.2 Re-orientation of model of hand



(a)



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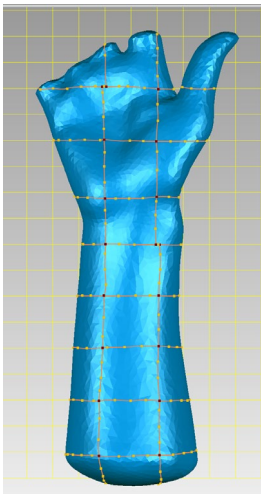

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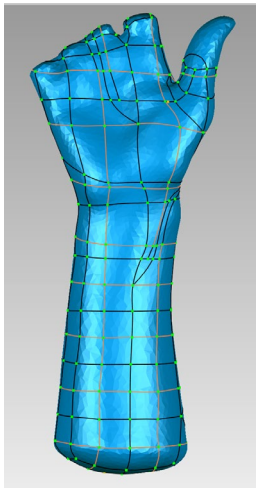


(d)

Figure 7.3 Construction process of model of hand (a) Polygonal model;
(b) Division of model into grids; (c) Formation of gridlines; and (d) Formation of patches

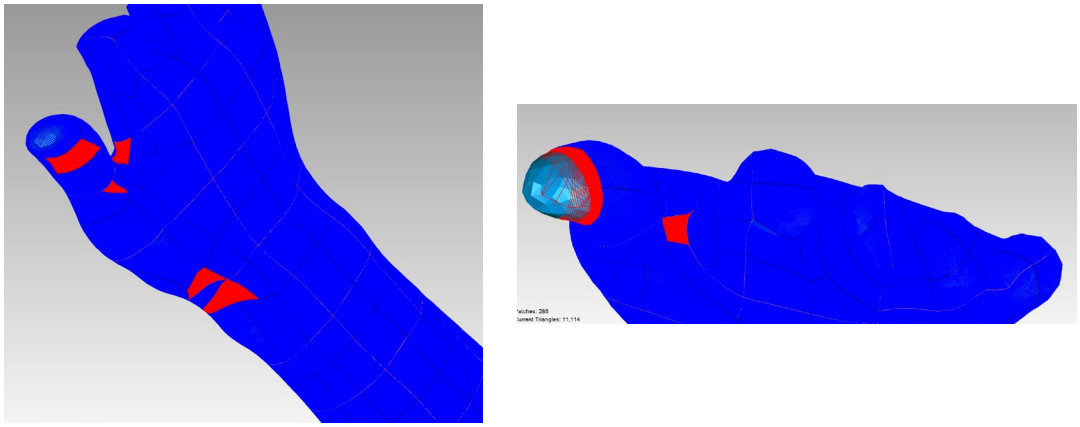


Figure 7.4 Identifying parts with improper features

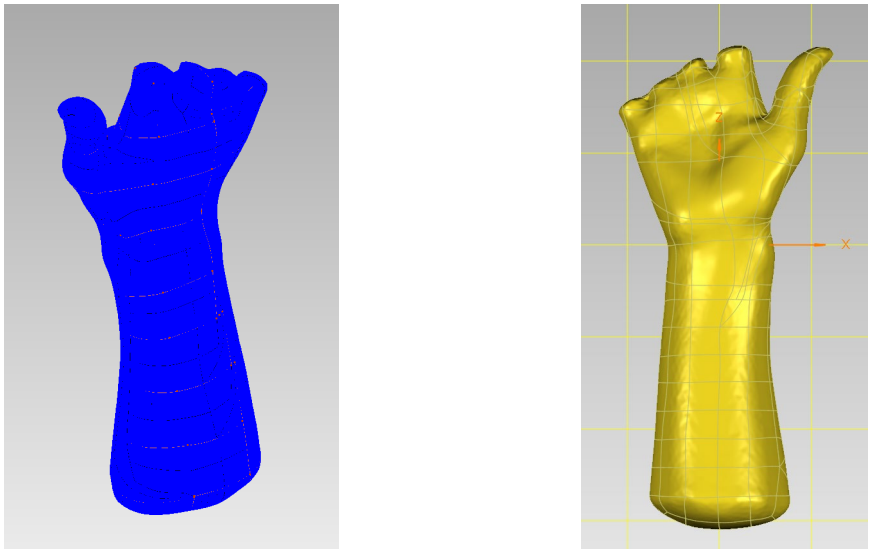


Figure 7.5 Fixation of grids and mapping of model surface

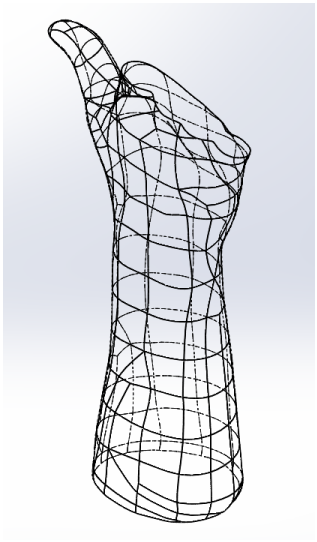
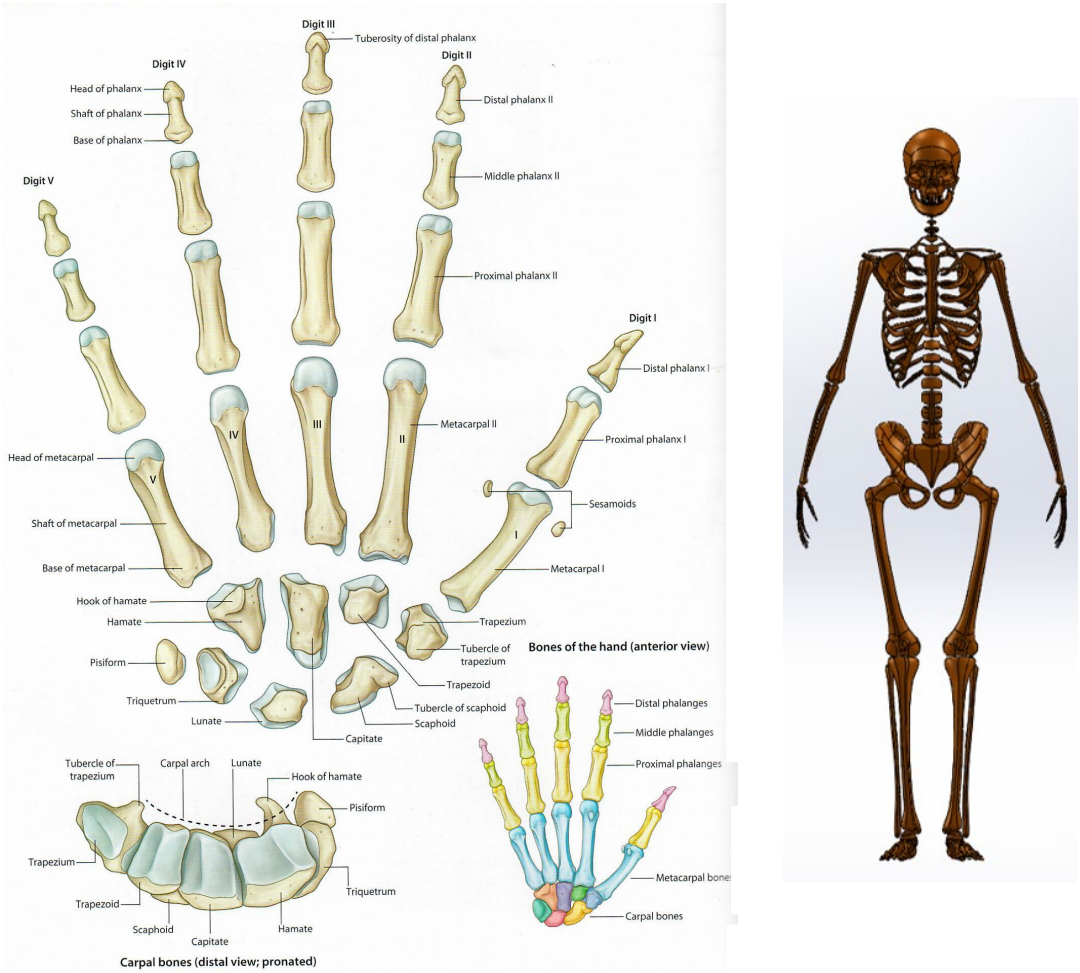


Figure 7.6 Final geometric model of hand and lower arm

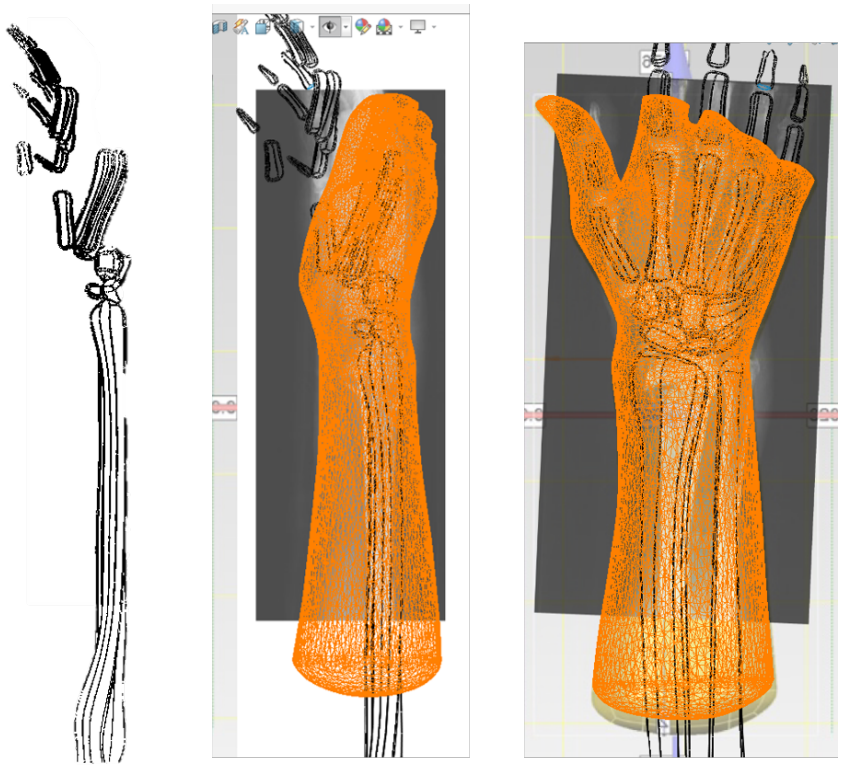
7.2.2 Construction of bone model

The human hand consists of 27 bones, which include the bones of the wrist, palm and fingers (Drake, 2015). First, the bones of the right hand (Fig. 7.7a) were extracted from the 3D model of the bones of the body (Figure 7.7b). The models of the hand bones were inputted into Solidworks software to edit and develop the bone components of the FEM. The bones that were not covered by the hand and lower arm were deleted so as to reduce the total size of the bone model. With the use of Solidworks, each bone was re-oriented and re-scaled to correspond with the volume and shape of the hand and lower arm. The position of the bone was aligned according to the contours of the hand, as shown in Figure 7.8. After editing the bones, the entire bone model was inputted into Geomagic software. Similar to the processing steps of the hand and lower arm model, contour lines and grids of the bones were formed. The final model of the bones is shown in Figure 7.9.

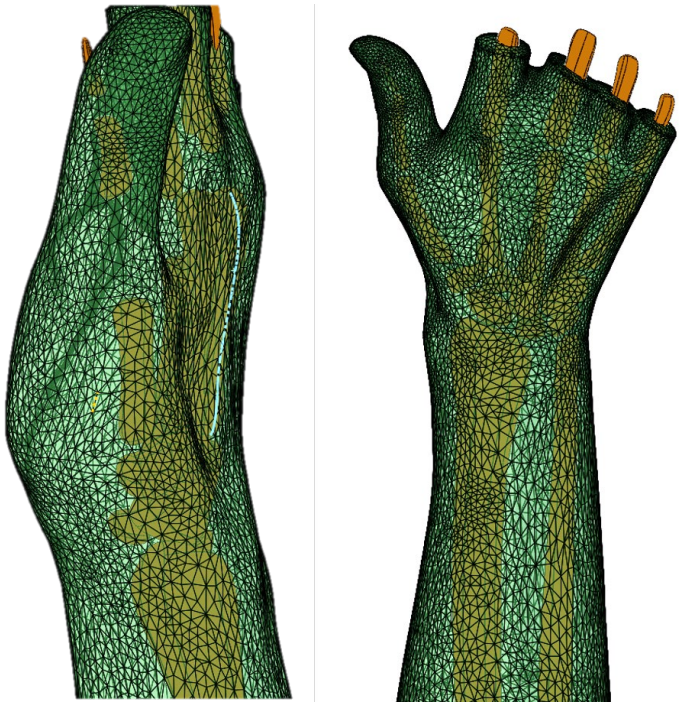


(a) (b)

Figure 7.7 (a) Bones of human hand, and (b) 3D model of human body bones



(a)



(b)

Figure 7.8 Development of model of bone:

(a) Re-orientation and re-scaling of parts with bones;

(b) Alignment of bone with the contours of hand

Figure 7.9 Final geometric model of bones of hand

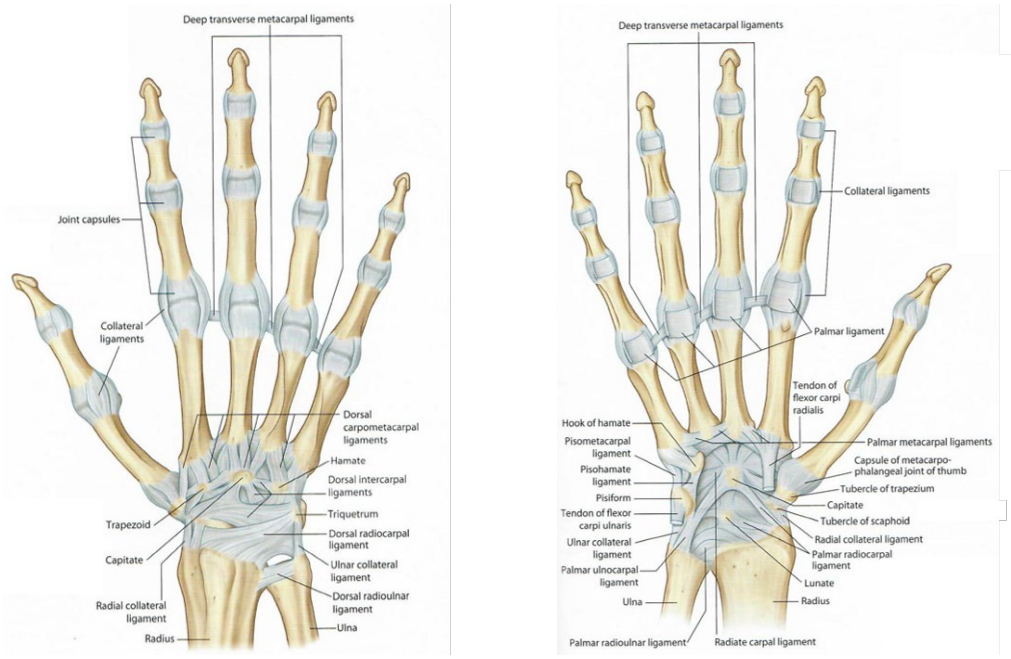
7.2.3 Construction of model of the ligaments

The human hand is composed of flesh, bones and connective tissues, such as ligaments and tendons. Images of the connective tissues of the hand are shown in Figure 7.10. An enlarged version that shows the position of the ligaments in the wrist region is shown in Figure 7.11. The figures of the hand anatomy indicate that there are numerous ligaments that connect all the different bones together to form the fundamental shape of the hand. In terms of the anatomical images, a simplified model of the ligaments was built. The main idea behind the model of the ligaments is to simulate the connective tissues between the bones. Figure 7.12 shows the construction process of a ligament between two bones by using Solidworks. Similar to the editing of the models of the hand and bones, the shape of the set of ligaments was defined for better contour recognition with Geomagic (Figure 7.13). Matching the model of the ligaments with that of the bones, the final outcome of the two models is shown in Figure 7.14.

In this study, the software used to run the FEM is Abaqus. The model of the ligaments was successfully inputted into the Abaqus software, however, further processing steps of the model was not possible due to the occurrence of errors. The problems of the model of the ligaments might be that the ligaments are too thin with irregular shapes,

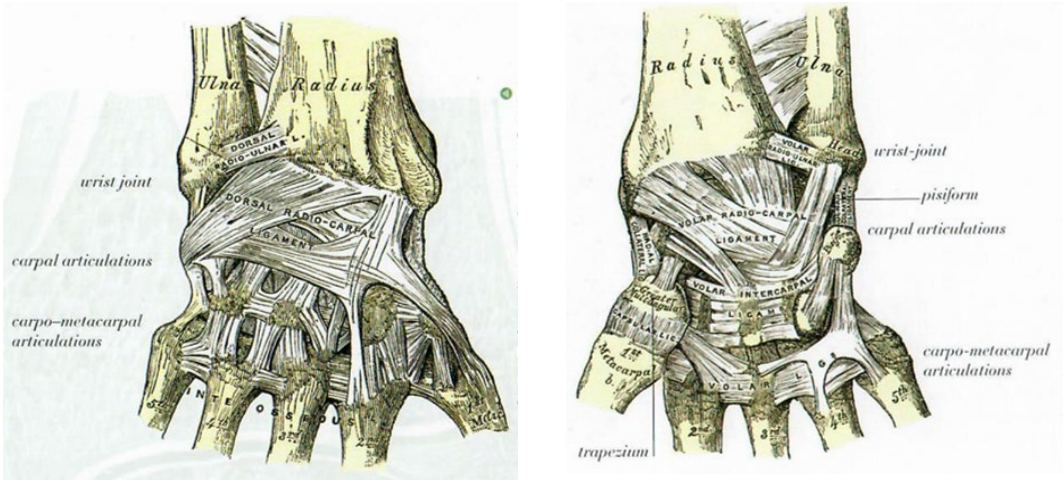
which made it difficult for the software to mesh all the pieces properly. Furthermore, compared to the models of the hand and bones, the components of the model of the ligaments are more disperse which made it difficult for the software to work with the intricate 3D images. Figure 7.15 shows the unsuccessful result of the removal of ligaments from the model of the hand. Since numerous errors occurred from modelling the ligaments, which may further affect the meshing and calculation of the simulated results, a decision was made to remove the model of the ligaments from the final FEM.

With the absence of the ligaments, a Young's modulus of the skeletal muscles was applied to the model of the hand which would represent the general properties of the flesh of hand.



(a) (b)

Figure 7.10 Connective tissues of hand: (a) dorsal and (b) palmar views (Drake, 2015)



(a) (b)

Figure 7.11 Ligaments in wrist region: (a) dorsal and (b) palmar views (Joseph, 2006)

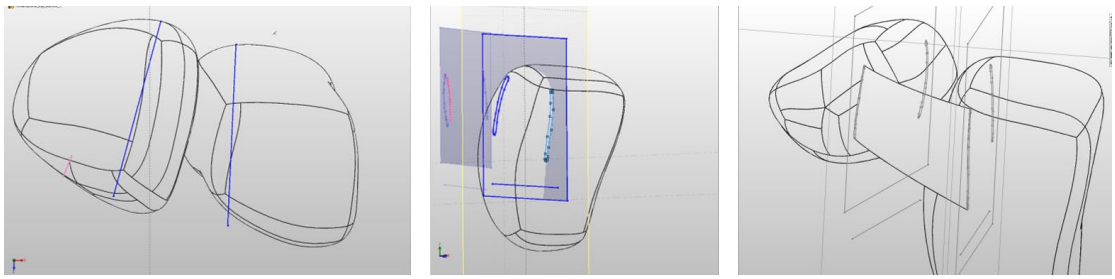


Figure 7.12 Construction of ligament pieces between two bones

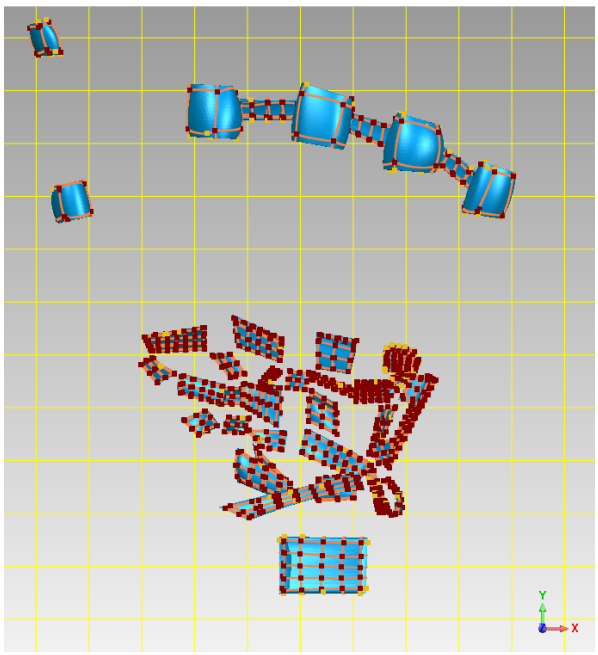


Figure 7.13 Contour definition of model of ligaments

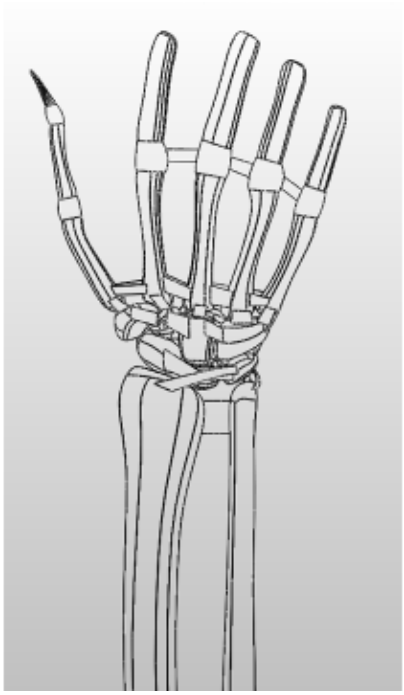


Figure 7.14 Matching model of ligaments and that of bones

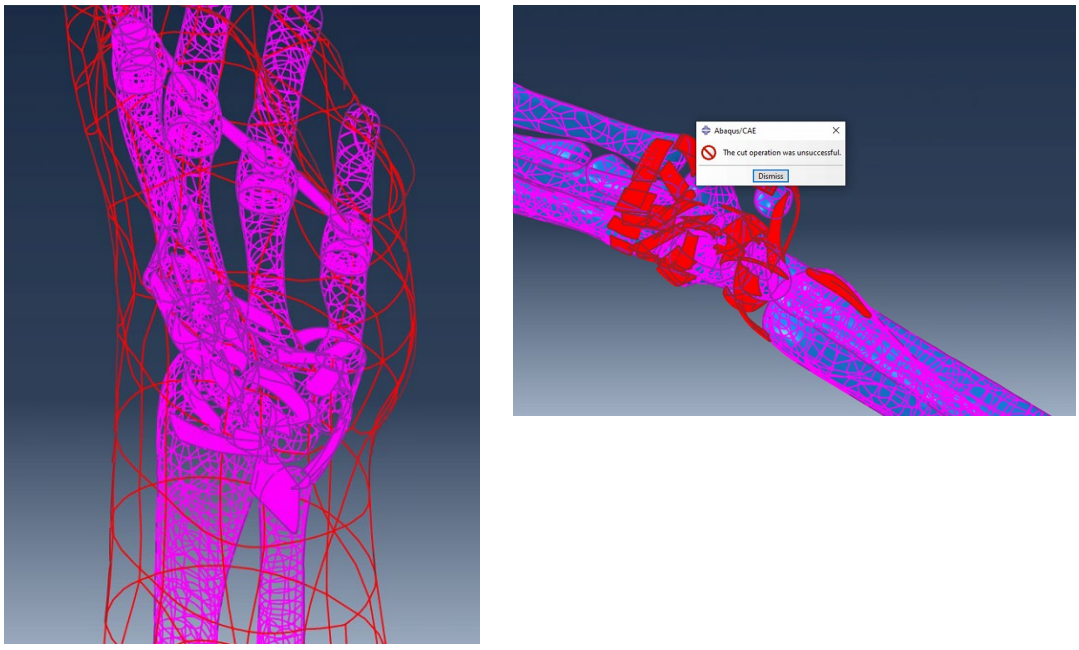


Figure 7.15 Unsuccessful removal of ligaments from model of the hand

7.2.4 Construction of model of splint

7.2.4.1 Splint fabric

The model of the splint comprised two main parts; the soft materials and the hard supporters. The materials for the splint were developed based on the model of the hand. A thin layer of fabric was built by increasing the thickness of the outer surface of the model of the hand in Solidworks. Using the design of the proposed splint, three different kinds of fabrics were used to form the body of the splint. Spacer fabric was used at the radial side of the splint so as to protect the injured area and reduce the pressure given by the thumb supporter to the thumb. On the other hand, a combination of satinette and powernet fabrics was used for the ulnar side of the splint to impart an appropriate degree of stretchability that would offer good contour fitting features, and high air permeability for enhanced comfort. Therefore, the fabric part of the model of the splint was divided into two parts, the radial and the ulnar parts. For the latter, the two different fabrics were simplified as a single layer. The width of the models of the fabric at the radial and ulnar sides of the hand is 2 mm and 1 mm respectively. The process of forming the model of the fabric is shown in Figure 7.16.

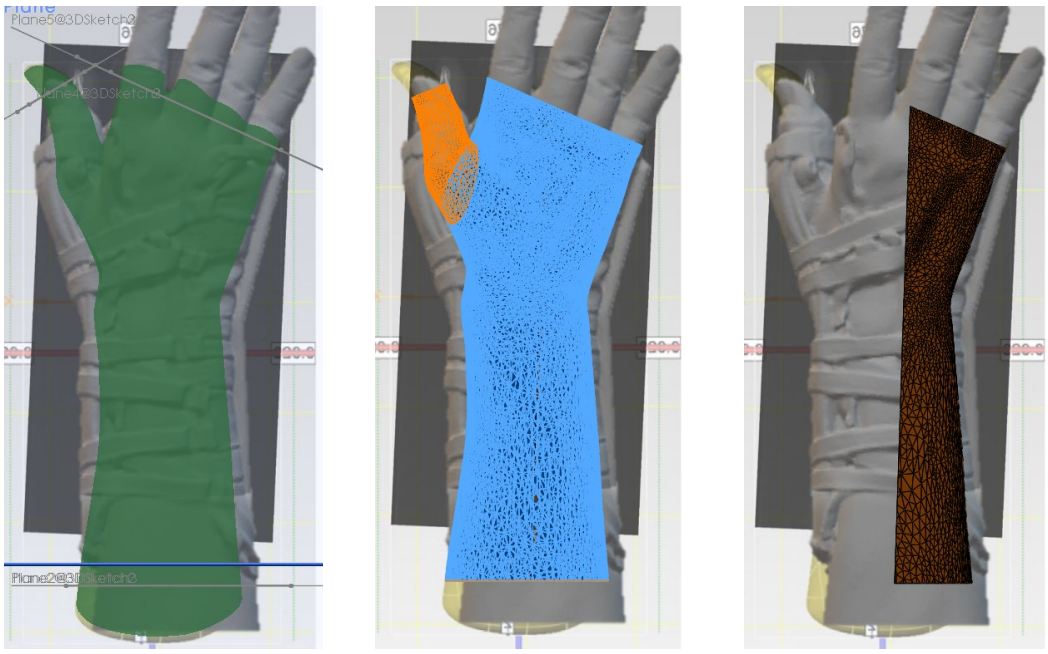


Figure 7.16 Formation process of model of fabric

Several problems of the models of the fabrics were noticed during the operation process. First, the shape of the webbing between the thumb and index finger is overly irregular so that meshing was difficult. Second, since the elements at the webbing are too close to each other, the elements may crash during the simulation process, which ultimately causes errors during the calculation of the results. Lastly, the fabric edges of the models are irregular and wavy which would cause difficulties when selecting a specific region to move the displacement (Figure 7.17). Therefore, the fabric components were modified by removing the elements at the webbing between the thumb and index finger and straightening the edges of the fabrics. A small piece of fabric was added at the middle of each fabric component which replicates the fastening strap that holds the supporter in position. The modified models are shown in Figure 7.18 and the final geometric models of the fabric are shown in Figure 7.19.

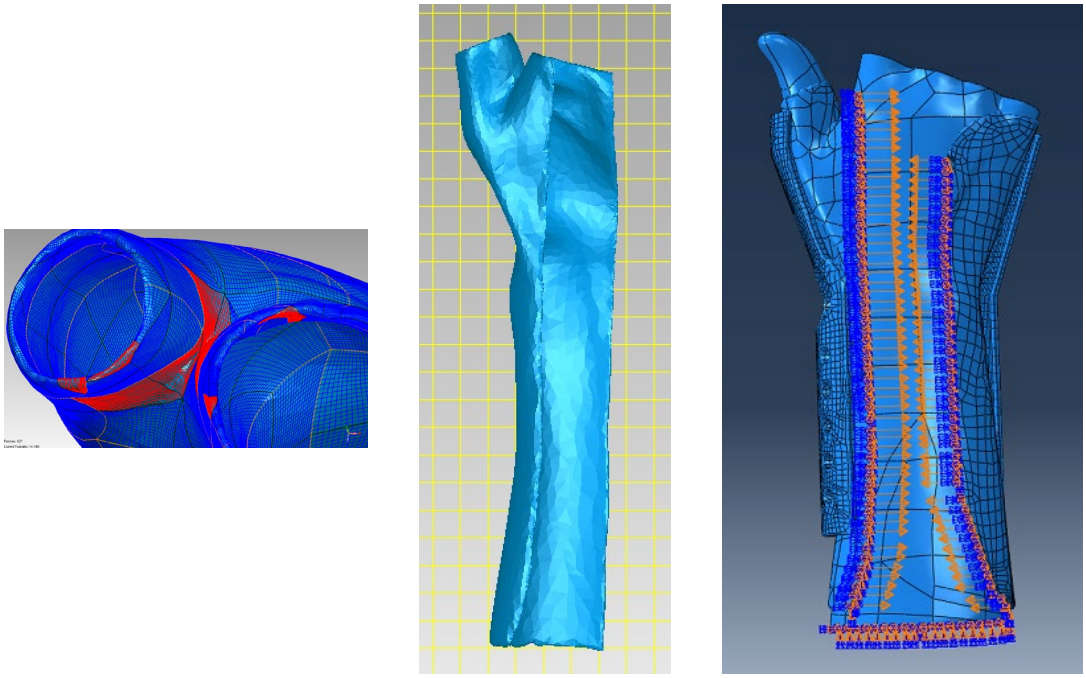


Figure 7.17 Problems with models of fabrics

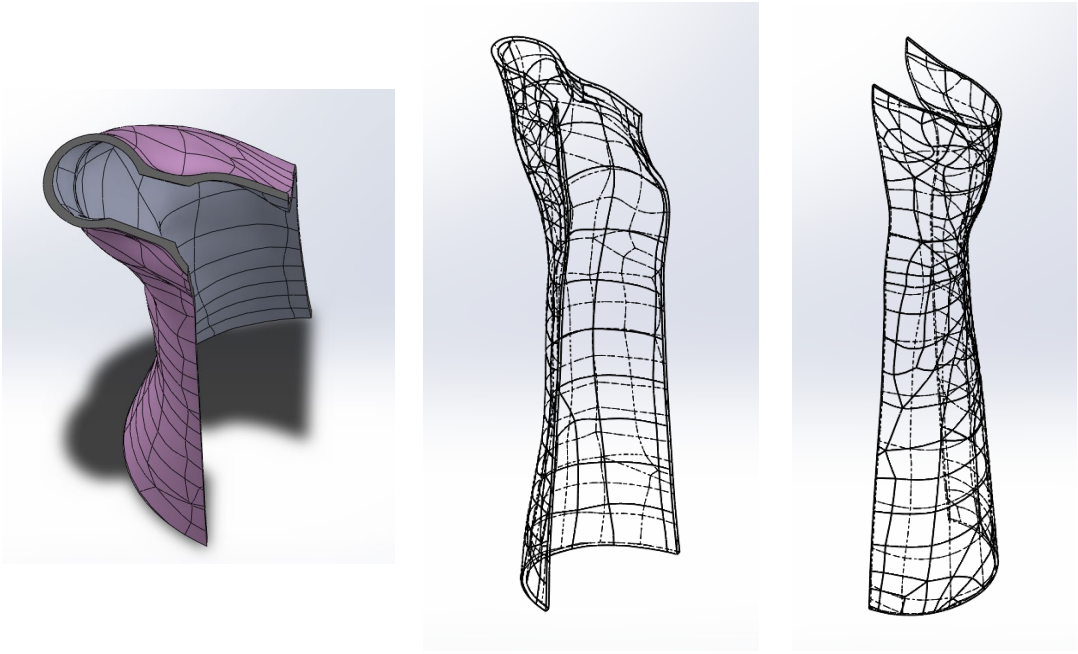


Figure 7.18 Modified models

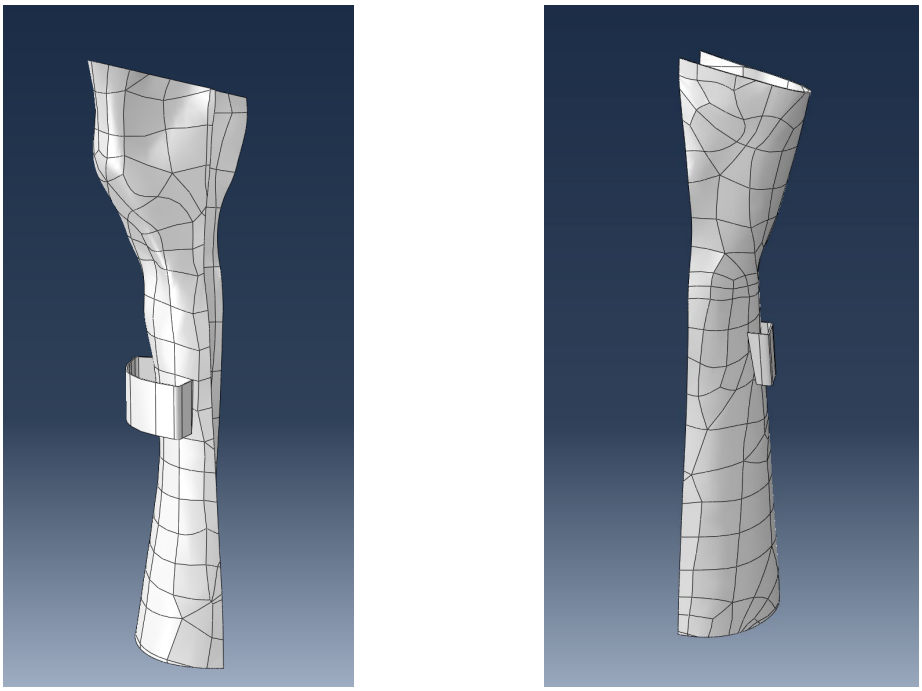


Figure 7.19 Final geometric models of fabric

7.2.4.2 Supporters

Apart from fabric, there are other components of the splint which are rigid; they are the supporters. The models of the supporters were built by using Solidworks. The models were developed from the model files used for 3D printing with acrylonitrile butadiene styrene (ABS) in the clinical study. In the original file, the top, middle and bottom parts of the thumb supporter were separated for later combining to accommodate the different sizes of the hand (Figure 7.20). For the FEM simulation, it is not necessary to separate the thumb supporter. Therefore, the parts were aligned and matched to form an entire thumb supporter (Figure 7.21). The contour lines of both supporters were defined in Geomagic, and their geometric models were created, as shown in Figure 7.22.

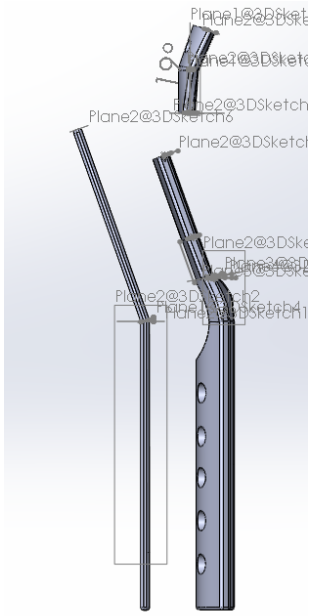


Figure 7.20 Separated parts of model of thumb supporter in the original file

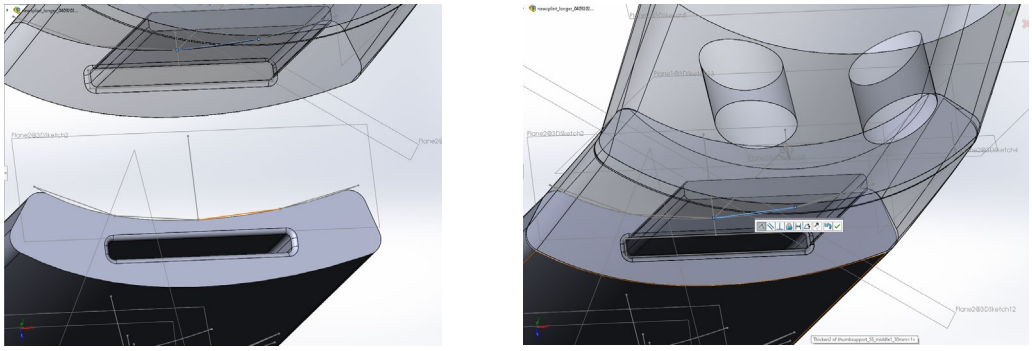


Figure 7.21 Alignment of parts of thumb supporter

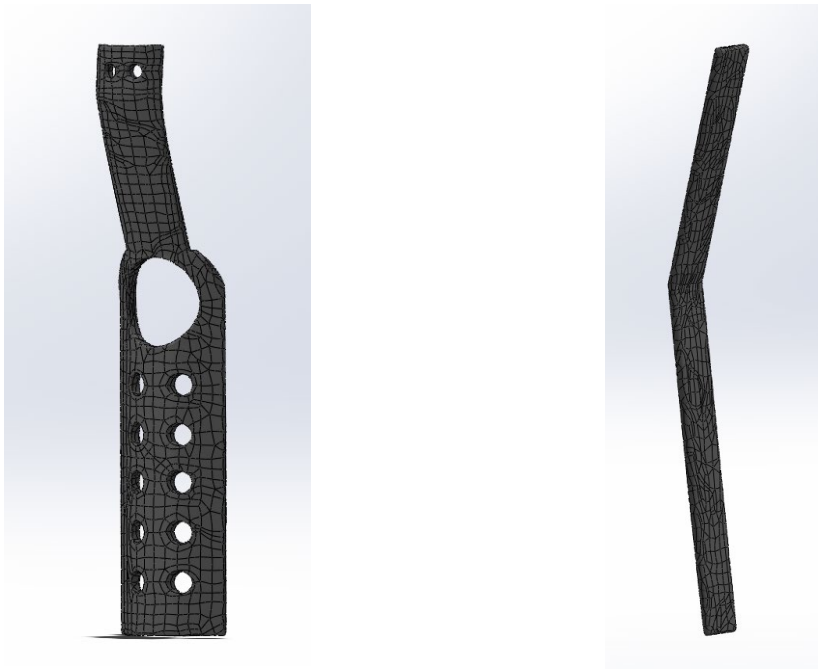


Figure 7.22 Final geometric models of supporters

7.3 Defining material properties, mesh element type and boundary conditions

7.3.1 Defining material properties

In this study, the FEM is composed of six models; that is, models of the: 1) hand and lower arm, 2) bones, 3) fabric for the radial side of the splint, 4) fabric for the ulnar side of the splint, 5) thumb supporter and 6) ulna supporter. All six models were inputted into Abaqus and the material properties of each model were applied to set up the FEM. According to Cox and Erler (2011), the Young's Modulus of skeletal muscle and bone are around 0.012 MPa and 2000 MPa respectively. Wheatley, Morrow, Odegard, Kaufman, and Haut Donahue (2016) assumed the Poisson's ratio of skeletal muscle was 0.47. Lai et al. (2015) indicated that the Poisson's ratio of cortical bone was 0.3. This information was used as the material properties of the FEM in this study.

Tensile tests were carried out to determine the Young's modulus of the fabric. With reference to the design of the proposed splint, the girth of the patient's hand needs to be parallel to the wale direction of the fabric. Therefore, the wale direction of the fabric was tested. Five samples of spacer and satinette fabrics were prepared respectively for the tensile tests. After collecting the results, the mean values were calculated. The test

results indicated that the Young's modulus of the spacer fabric is 0.02654 MPa and that of the satinette fabric is 0.01518 MPa. Both fabrics are warp knitted fabrics. According to Razbin, Jeddi, Semnani, and Ramzanpoor (2020), the Poisson's ratio of warp knitted fabric is around 0.7. However, a Poisson's ratio of 0.7 cannot be inputted into the Abaqus system, as the system suggests a maximum Poisson's ratio of 0.48. Therefore, the Poisson's ratio was set to 0.48. Figures 7.23 and 7.24 show the tensile stress-strain results of the spacer fabric and satinette fabric samples.

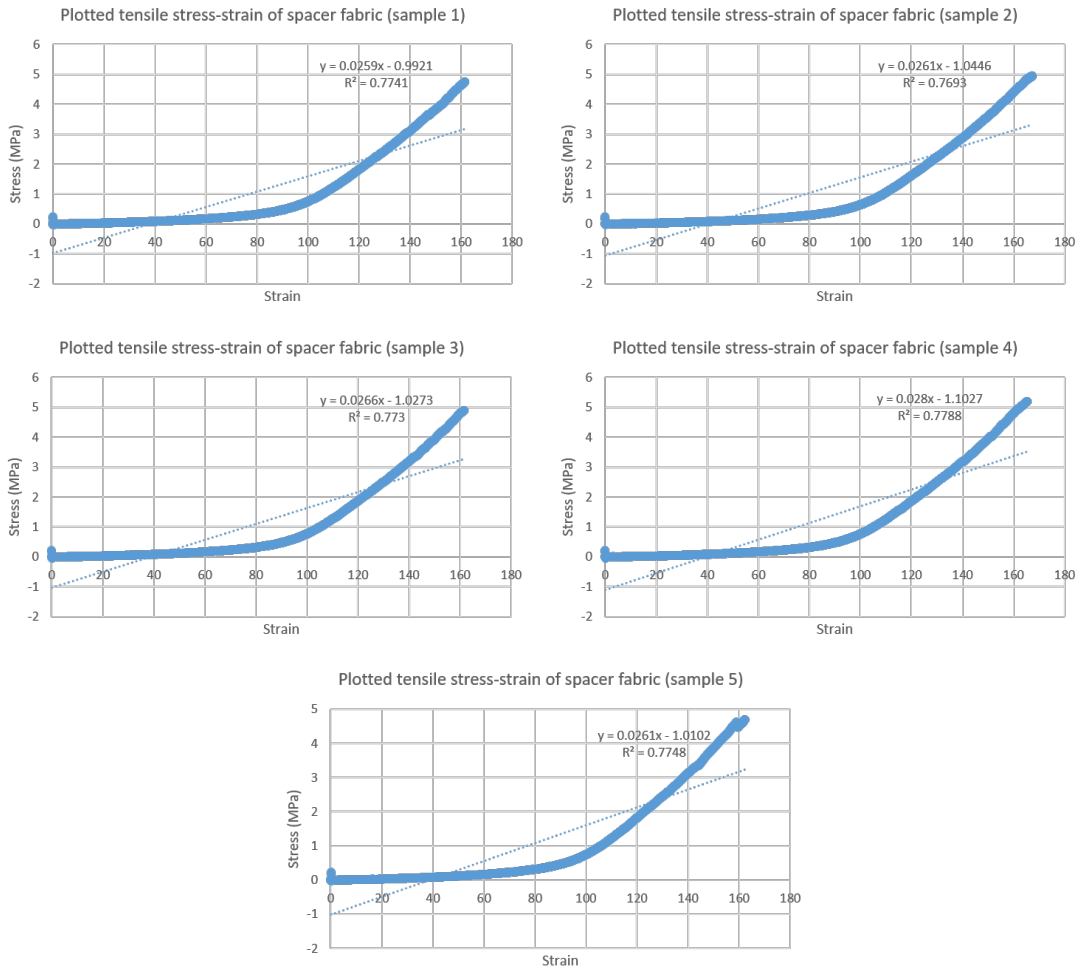


Figure 7.23 Plotted tensile stress-strain of spacer fabric samples

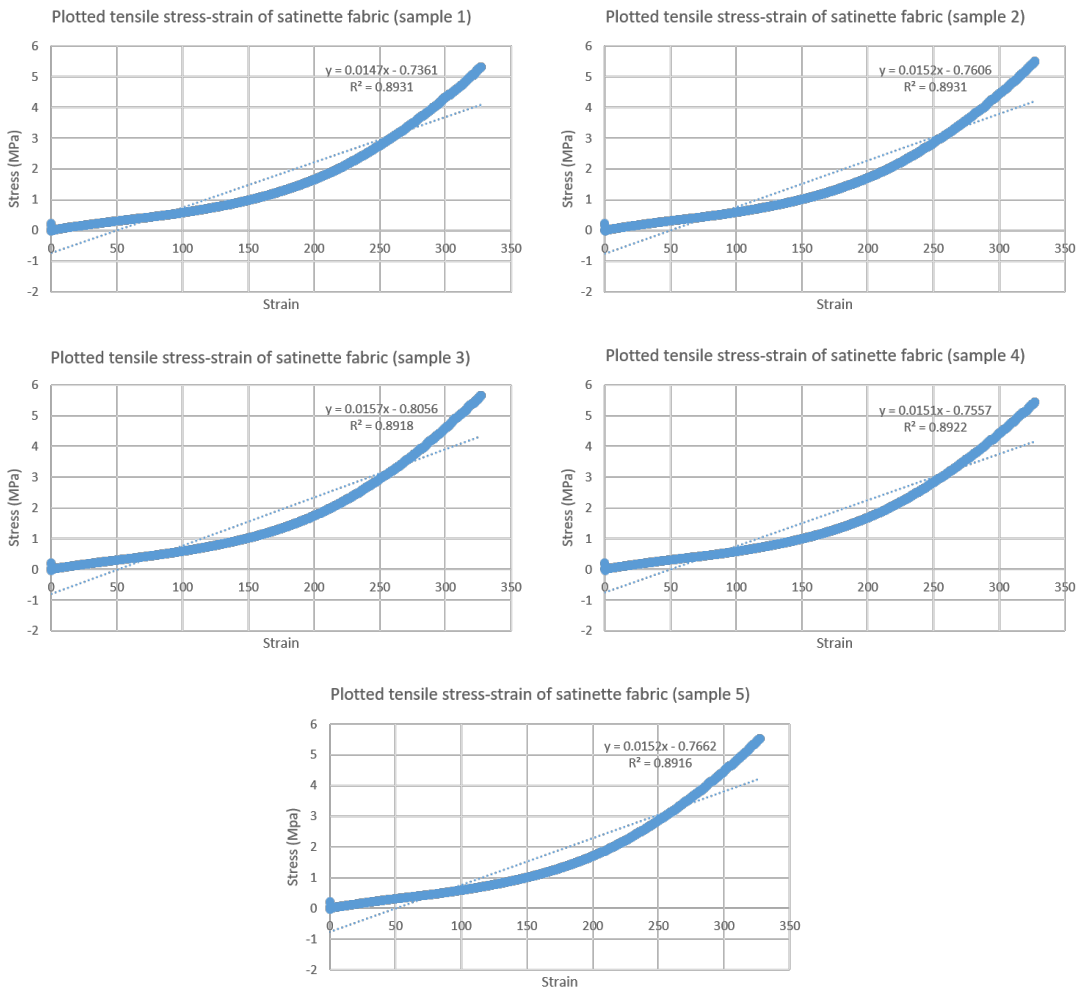


Figure 7.24 Plotted tensile stress-strain of satinette fabric samples

The material used to print the supporters is ABS. In accordance with ASTM D638 Standard Test Method for Tensile Properties of Plastics, five specimens were printed with ABS and subjected to tensile testing. The result indicated that the Young's modulus of the 3D printed ABS is 18.6838 MPa. Using the measured data, the Poisson's ratio of the 3D printed ABS is calculated to be 0.29368. Figure 7.25 shows the plotted tensile stress-strain of the 3D printed ABS samples. The Young's modulus and Poisson's ratio of the six models of the body parts are summarised in Table 7.2.

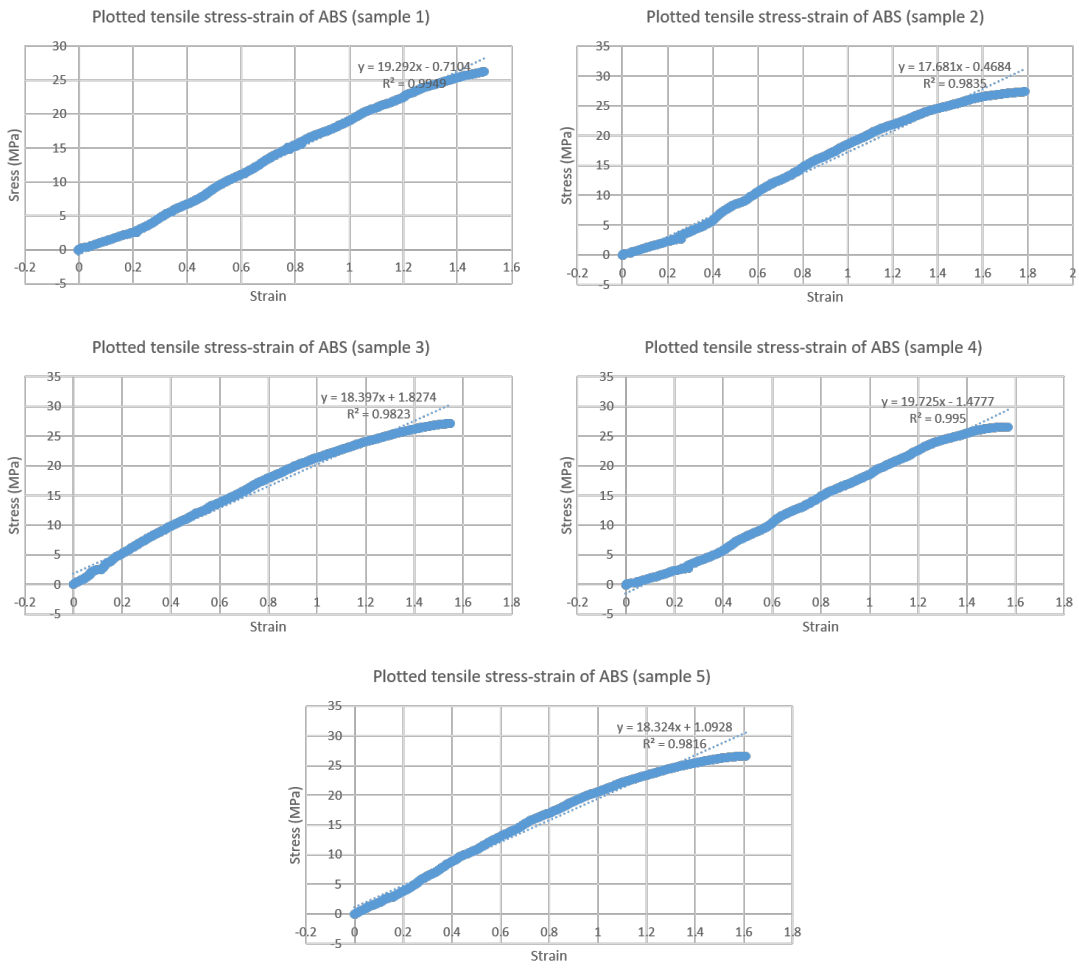


Figure 7.25 Plotted tensile stress-strain of 3D printed ABS samples

Table 7.2 Young's modulus and Poisson's ratio of the six models of the body parts

	Young's modulus (MPa)	Poisson's ratio
Flesh of hand	0.012	0.47
Bone	2000	0.3
Fabric of radial side (Spacer)	0.02654	0.48
Fabric of ulnar side (Satinette)	0.01518	0.48
Thumb supporter (ABS)	18.6838	0.29368
Ulna supporter (ABS)	18.6838	0.29368

7.3.2 Assembly of parts

The six models were classified into three groups. Each group was assembled together to form a new part. The first group formed a new model of the hand that included the flesh and bones. In this group, the model of the bones was first subtracted from the original model of the hand, so as to produce a model with holes where the bones should be located. Afterwards, the model of the flesh was merged with that of the bones to give a new model of the hand (Figure 7.26). The assembly of the second group of models gave a new model of the radial part of the splint. This model was formed by merging the fabric of the radial side of the splint with the thumb supporter (Figure 7.27). The third new model, which is the model of the ulnar part of the splint, was composed of the fabric of the ulnar side of the splint and the ulna supporter, as shown in Figure 7.28.

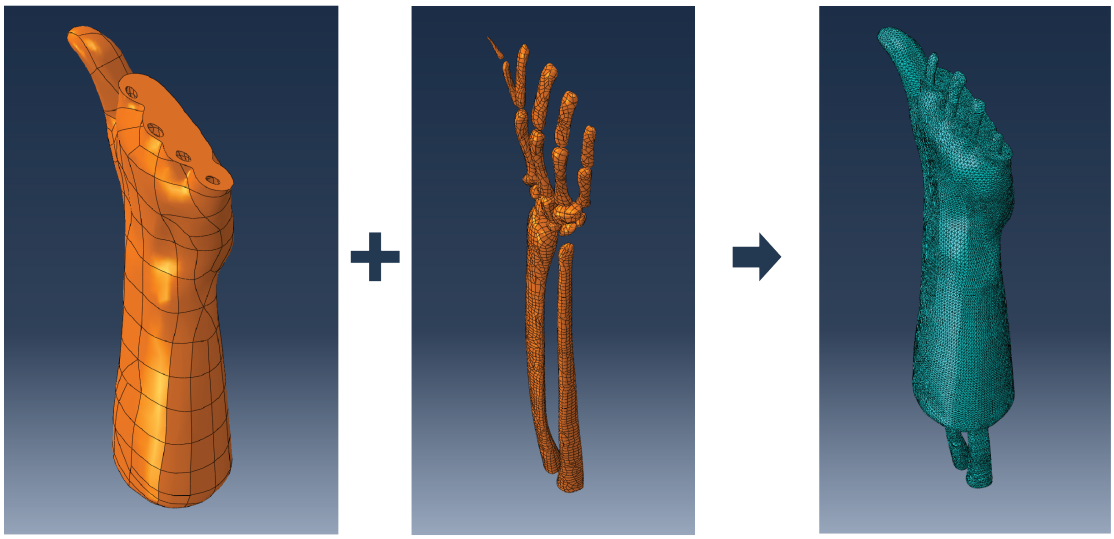


Figure 7.26 Formation process of new model of hand

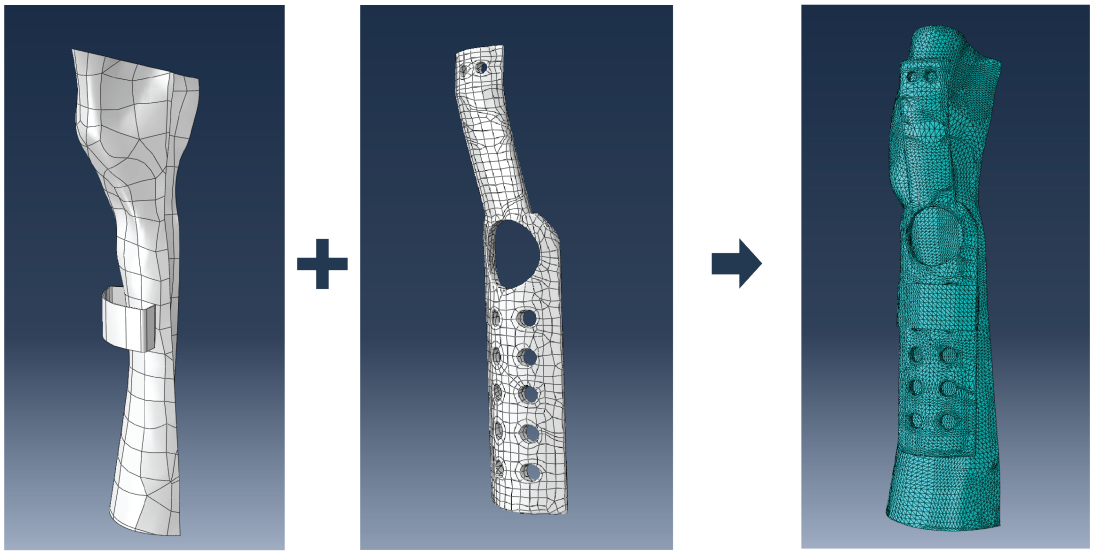


Figure 7.27 Formation process of model of radial side of splint

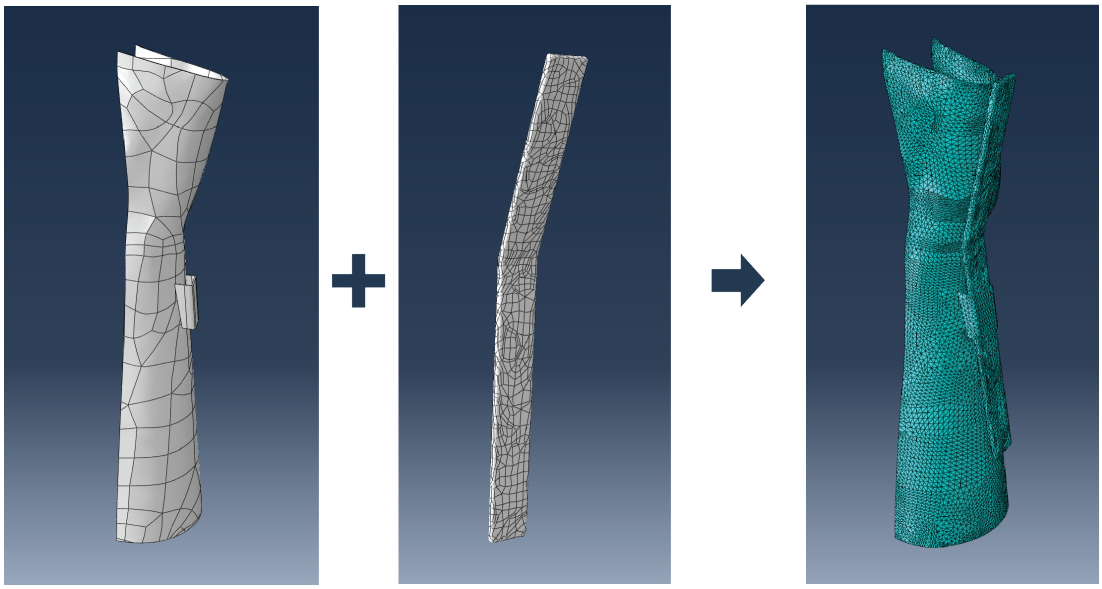


Figure 7.28 Formation process of model of ulnar side of splint

7.3.3 Defining mesh element type

A necessary step for converting a 3D model into a FEM is 'meshing'. The mesh element used in this study is a 10 node linear quadratic tetrahedral element (type C3D10), as shown in Figure 7.29 (Dhatt et al., 2012). A free meshing method was adopted to map the meshes of the three new models. The mesh size is 2 for all of the models. The number of nodes and elements of the new model of the hand are 1,105,322 and 759,916 respectively. The model of the radial side of the splint consisted of 308,273 nodes and 179,278 elements. On the other hand, the model of the ulnar side of the splint consisted of 150,363 nodes and 76,473 elements. Figure 7.30 shows the meshed versions of the three new models. Table 7.3 summarises the number of nodes and elements of the models.

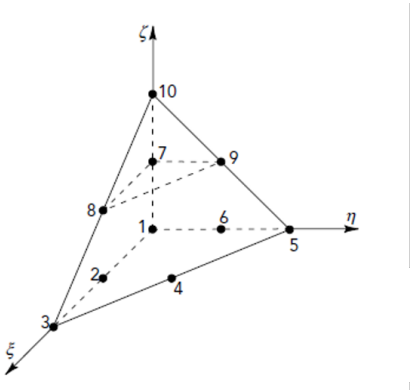
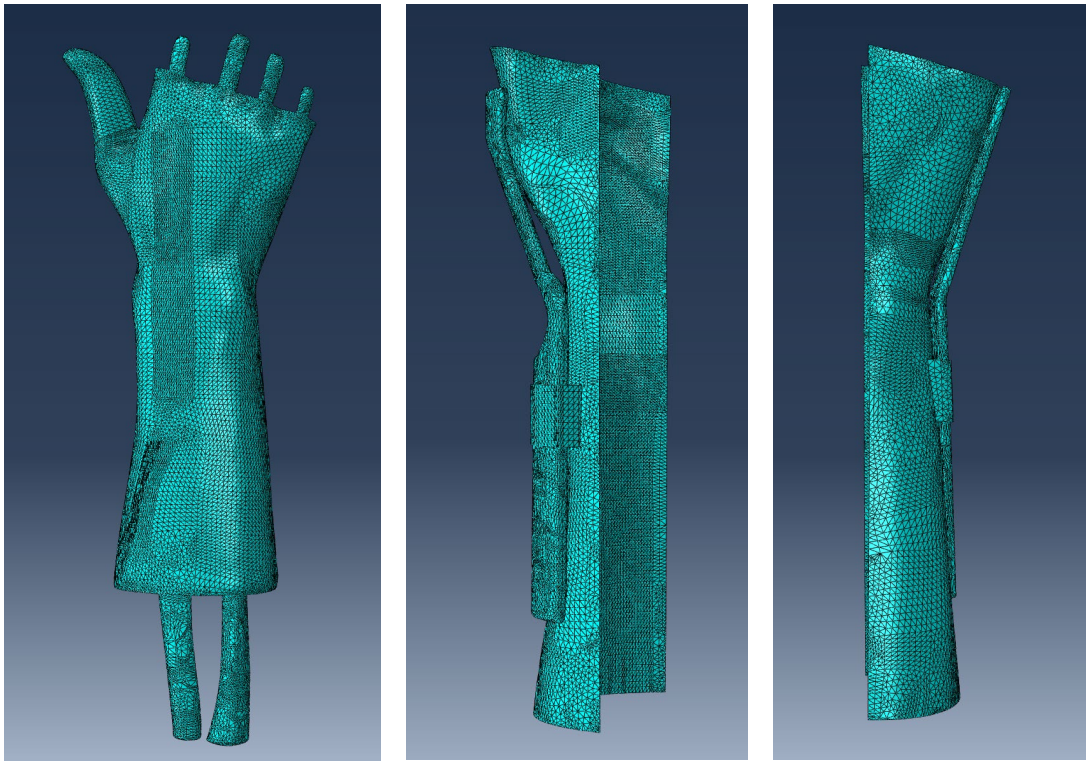


Figure 7.29 A 10 nodes linear quadratic tetrahedral element
(Dhatt et al., 2012)



(a) (b) (c)

Figure 7.30 Meshed versions of the three models:
(a) New model of hand;
(b) Model of radial side of splint;
(c) Model of ulnar side of splint

Table 7.3 Number of nodes and elements of the models

Model	Number of nodes	Number of elements
New model of the hand	1,105,322	759,916
Model of the radial side of splint	308,273	179,278
Model of the ulnar side of splint	150,363	76,473

7.3.4 Defining boundary conditions and surface interactions

Defining the boundary conditions, determining the movement of the parts and establishing the surface interactions between models are important steps in FEM analyses. The first step of the simulation process was to fix the model of the hand into position. Since the purpose of this FEM is to focus on the wear process of the proposed splint, the entire model of the hand was assumed to be fixed in position. Therefore, the elements at the top and bottom of the modelled flesh of the hand were anchored by setting the displacements of x, y, z positions of those elements to 0 throughout the entire simulation process. The boundaries at the fabric edges along the midline of the palm were also fixed so as to show the presence of a seam between the two fabrics. Anchoring symbols appeared at the selected parts once the regions were fixed, as shown in Figure 7.31.

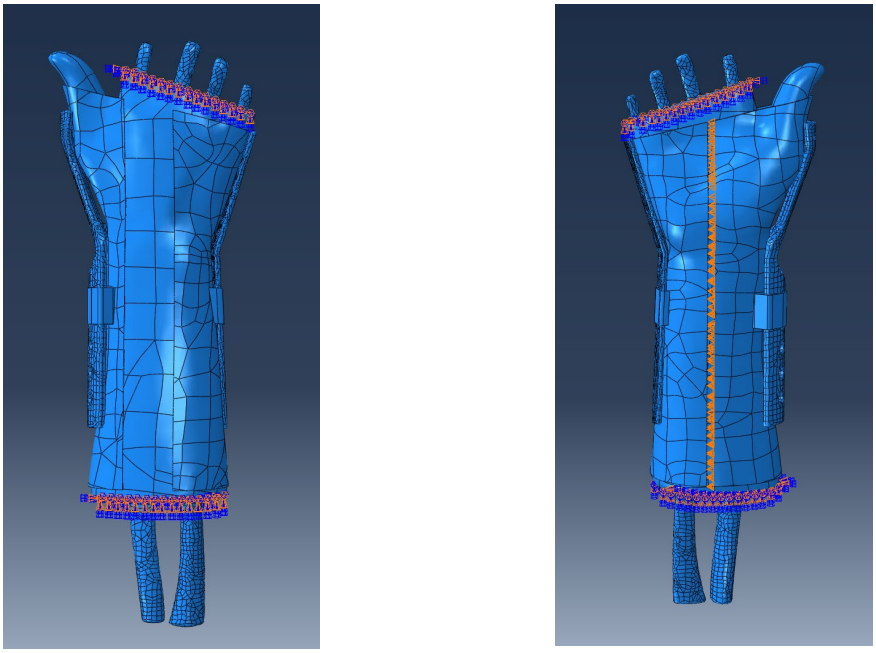


Figure 7.31 Location of fixed boundaries:
(a) Top and bottom of the flesh of the new model of the hand;
(b) Seam between the two fabrics along the midline of the palm

To simulate the wear process of the splint, the displacements of the elements along the edges of the two fabrics at the dorsal side were set to move towards the central line. The orange arrows in Figure 7.32 along the edges of the two fabric indicate how the edges move during the simulation process.

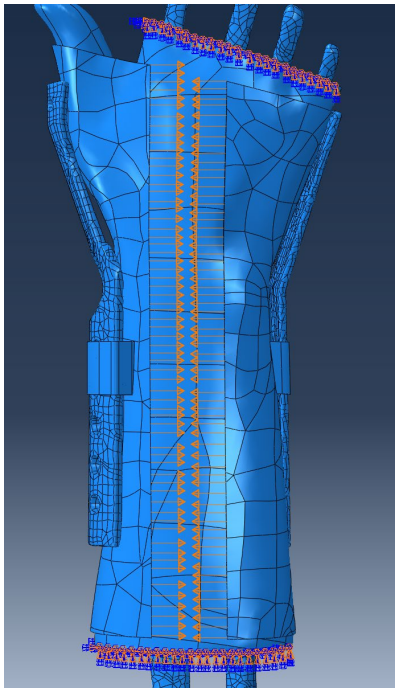
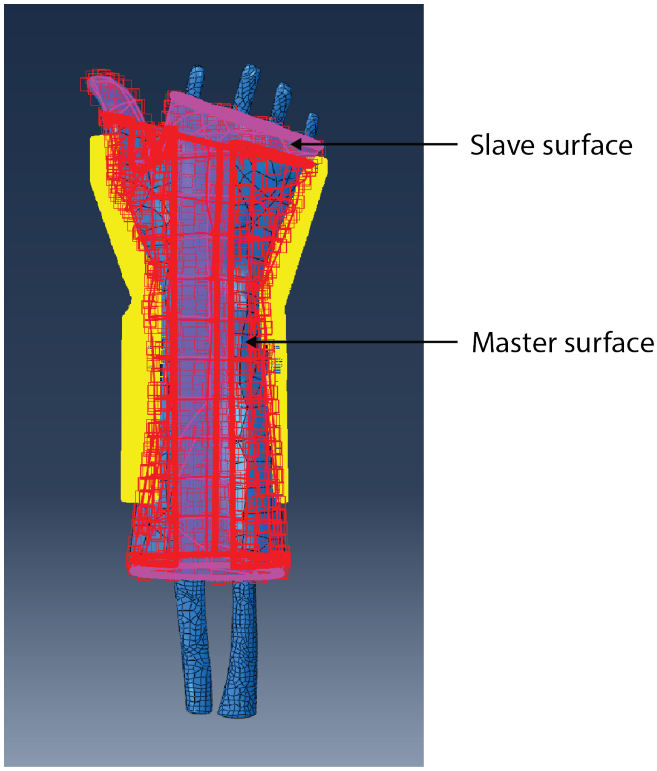
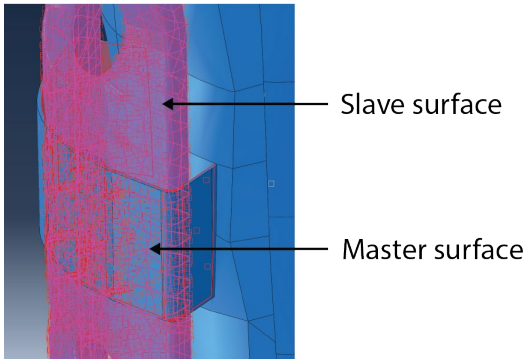


Figure 7.32 Orange arrows indicate movement of edges of fabric during simulation process

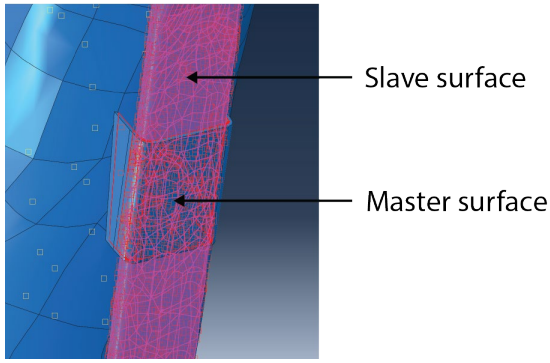
After setting the displacements of specific regions, the interactions between the surfaces were defined. The first surface-to-surface contact was made between the hand and the splint fabric. During the splint wearing process, the splint fabric comes into contact with the skin of the hand. Therefore, the inner surface of the splint fabric was set as the master surface, while the deformable hand surface was set as the slave surface. With these setting of interactions, when the master surface comes into contact with the slave surface, the former would not penetrate through the latter. Instead, the slave surface might be pushed away or deformed according to the pre-set material properties. The second interaction takes place between the fastening strap at the radial side of the splint and the thumb supporter. The master surface is the inner surface of the fastening strap, while the slave surface is the surface of the thumb supporter. Similarly, the third interaction takes place between the fastening strap at the ulnar side of the splint and the ulna supporter. The master surface is the inner surface of the fastening strap, whereas the slave surface is the surface of the ulna supporter. Figure 7.33 shows the locations of the surface-to-surface interactions.



(a)



(b)



(c)

Figure 7.33 Location of surface-to-surface interactions:
(a) Between inner surface of splint fabric and outer surface of hand;
(b) Between inner surface of fastening strap at the radial side of splint and outer surface of thumb supporter
(c) Between inner surface of fastening strap at the ulnar side of splint and outer surface of ulna supporter

7.4 Simulation results and validation

Validation is an important step to verify the accuracy of the simulated results generated from a FEM analysis. In this study, the predicted pressure distribution results from the FEM are compared with the measured results in the clinical study. With reference to the experimental design of the pressure test (see Section 3.6.3.3), six pressure points on the hand of the subject were measured by using the Pliance®-xf-16 system. The six measured points are the metacarpophalangeal (MCP) joint of the thumb, carpometacarpal (CMC) joint, radius head (RH), ulna head (UH), carpal tunnel (CT) and thenar muscles (TM). The six locations are shown in Figure 7.34.

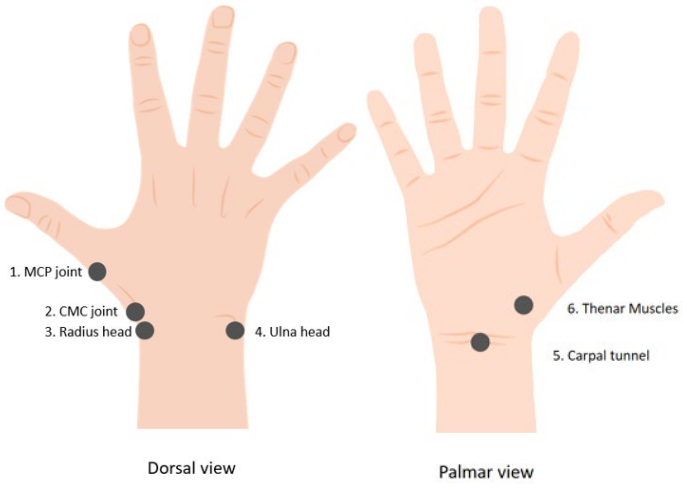


Figure 7.34 Location of six pressure points

The FEM in this study reflects and simulates the pressure distribution on the hand of the subject during the splint wearing process, during which the hand was maintained in a static rest position with extended thumb and fingers. The pressure level at the six locations on the FEM was measured and compared with the clinical results of the subject. Other observed results of the FEM are also discussed in the following sections.

7.4.1 Simulated pressure distribution and displacement of splint

The predicted results of the pressure distribution of the splint are shown in Figure 7.35. In the figure, areas with higher stress are in red colour, whereas areas with lower stress are in blue colour. The colours change gradually in correspondence to the level of stress. From the results, it can be observed that higher stress is found around the wrist. A possible reason could be the fastening straps that hold the rigid supporters close to the

splint body are positioned at the wrist level of the hand. Furthermore, higher stress is found at both the radial and ulnar sides of the splint fabric, or underneath the two supporters. It is interesting that high levels of stress are found at the seam of the two fabrics in the area of the palm. This indicates that when the subject is fastening the splint on her hand, the two fabrics in the region of the palm are subjected to higher pulling forces that pull them apart. This could serve as a reference for splint designers who may have to pay more attention to this specific area, and ensure the stitches along the seam at the palm should be strong enough to withstand the pulling forces.

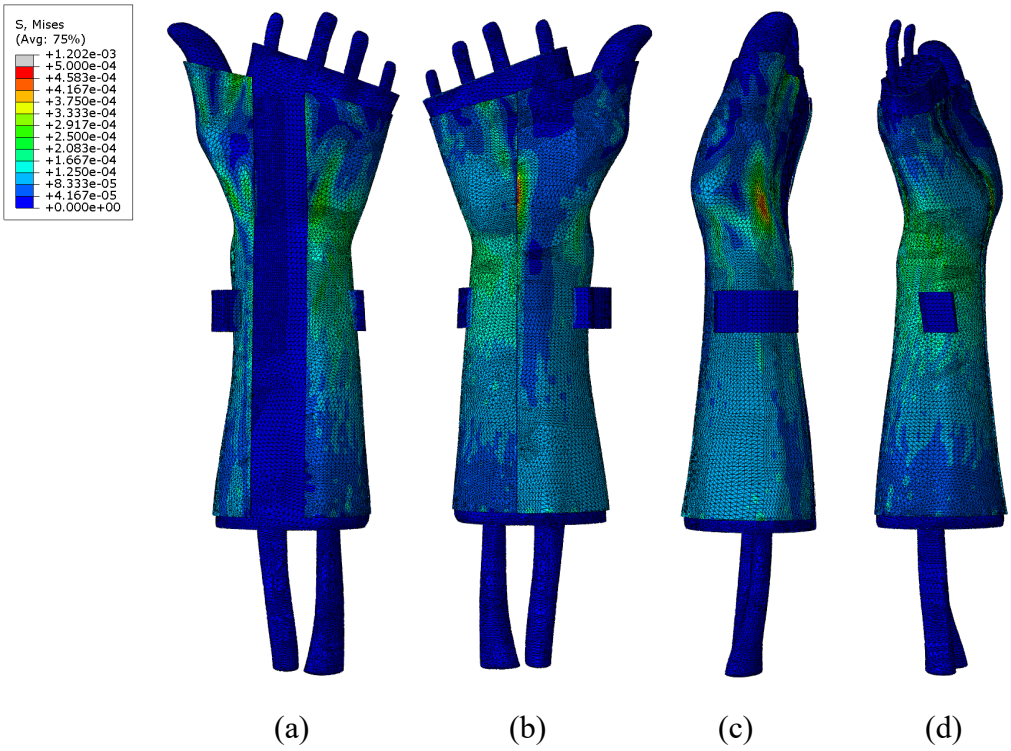
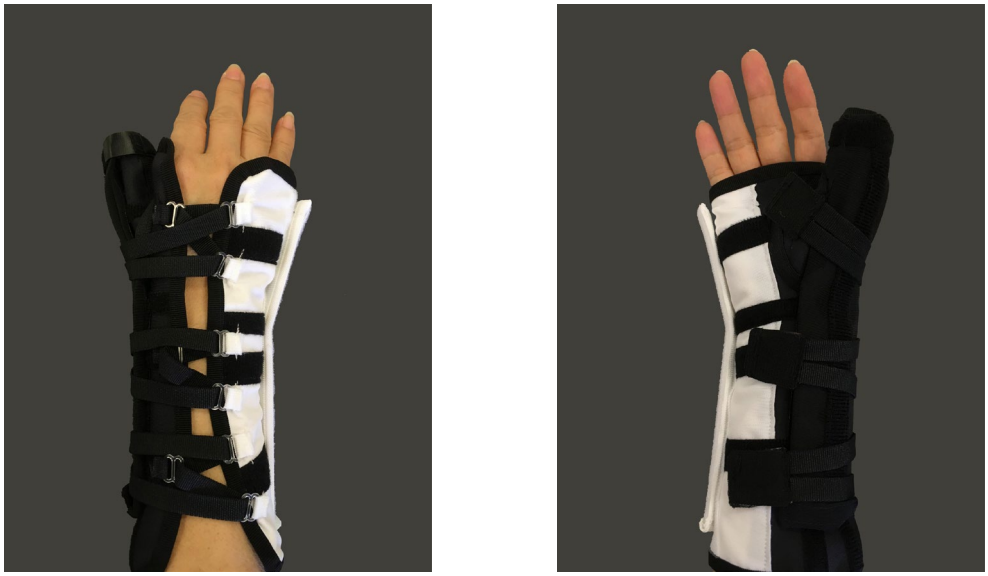


Figure 7.35 Stress distribution of the splint: (a) Dorsal; (b) Palmar; (c) Radial; and (d) Ulnar views

The simulated displacement of the different parts of the splint is shown in Figure 7.36. From the dorsal view of the model, the red colour indicates positive movement to the right side, while blue colour indicates negative movement to the left side. Since the edges of the fabric in the dorsal view were set to move towards the center, which replicates the fastening process of the splint, it is reasonable to see blue colour appear along the edge of the fabric at the ulnar side and red colour along the fabric edge at the radial side. It is interesting to see blue colour in the thumb region of the fabric and some yellow at the ulnar side of the palm, as this indicates both sides of fabric move slightly

to the center of the palm. A possible reason could be the presence of a fixed seam between the two fabrics. Another interesting point is the movement of the two supporters. The ulna supporter remained in a similar position during the simulation as it appears in green. However, the top of the thumb supporter moved to the palm side, and the middle part remained in a similar position, while the bottom moved to the dorsal side of the hand. A possible reason could be that the inner surface of the thumb supporter is slightly curved and covers a larger area along the thumb. A part of the supporter held, while some of the other parts shifted due to the movement of the fabric underneath. Referring to the simulated result, the shifting at the top and bottom parts of the thumb supporter shows that adding fastening straps at the top and bottom of the splint is necessary for supporter positioning. The sewn splint used in the clinical study was equipped with three sets of fastening straps, which were located at the top, middle and bottom levels of the splint, so as to secure the position of the thumb supporter and control the motions of the injured thumb (Figure 7.37).

Figure 7.36 Displacement of the splint: (a) Dorsal;
(b) Palmar; (c) Radial; and (d) Ulnar views



(a) (b)

Figure 7.37 New functional splint with three sets of fastening straps:
(a) Dorsal and (b) Palmar views

7.4.2 Simulated pressure distribution of hand

Apart from the pressure distribution results of the splint, those on the hand surface are also reviewed. Figure 7.38 shows the simulation process of the model of the hand. Numerous pressure spots were found based on the analysed result of the model of the hand (Figure 7.39). Denser pressure spots appeared along the thumb regions and the edges of the fabric at the dorsal side of the hand. The presence of denser pressure spots may be due to the stress exerted by the rigid thumb supporter during its shifting, and the pressure given by the edges of the fabric during the closing motion. Yet, in general, the pressure spots were evenly distributed all over the hand surface, and the areas that were covered by the splint. Since the purpose of wearing a splint for DQV treatment is to stabilise the patient's hand and control the movements of the affected thumb, instead of adding excess pressure to the hand, it is exciting to stimulate an even pressure distribution on the model of the hand. These predicted results may indicate that patients could wear the proposed splint comfortably, instead of experiencing pain or even occurrence of pressure ulcers due to the exertion of high pressure in particular areas.

During the stages of model setting and simulation trials, it was found that running errors appeared when large closing displacements of the two edges of the fabric were set. Therefore, only small closing steps of the fabric could be produced so as to ensure a

smooth and successful implementation of the model analysis. As a result, the readings of the predicted stress distribution results are much smaller than the actual pressure results measured in the real-life case. However, it is still worthwhile to collect the predicted results from the analysed model as the readings could at least act as references to show the pressure distribution on different parts of the hand. Furthermore, a simple comparison between the simulated and the actual results can be made. Based on the six measured points in the pressure test, the specified locations on the model of the hand can be pointed out (Figure 7.40) and the corresponding pressure readings are listed in Table 7.4. Among the six locations, the amount of pressure was predicted at the four bony areas, while no pressure was predicted at the two other softer areas. The predicted pressure at the MCP joint is the highest at 0.102 kPa. The area that receives the second highest pressure is the radius head at 0.083 kPa. The predicted pressure of the CMC joint and the ulna head is 0.077 kPa and 0.044 kPa respectively.

Since the predicted pressure values are too small, the readings were increased by 10 times (Table 7.5), and plotted into a line chart for comparison with the experimental pressure data (Figure 7.41). The area that was predicted to receive the highest amount of pressure is the MCP joint. However, the pressure at the MCP joint in the experimental results is not the highest. Nevertheless, focusing on the pressure data of the other three bony regions, both results show that the radius head has the highest pressure among the three areas, the CMC joint receives the second highest amount of pressure, while the ulna head receives the least amount of pressure. Furthermore, both results indicated that the carpal tunnel and thenar muscles did not receive any pressure. It was found that the majority of both results show similar trend. Possible reasons of the differences between the predicted and the experimental results could be only attributed to the small closing steps of the splint in this study. Thus, the situation of fastening the splint more tightly has not been investigated yet. Moreover, some of the anatomical structures, such as ligaments, tendons and blood vessels have been neglected in this model. Nevertheless, a more detailed model of the hand could predict results with higher accuracy.

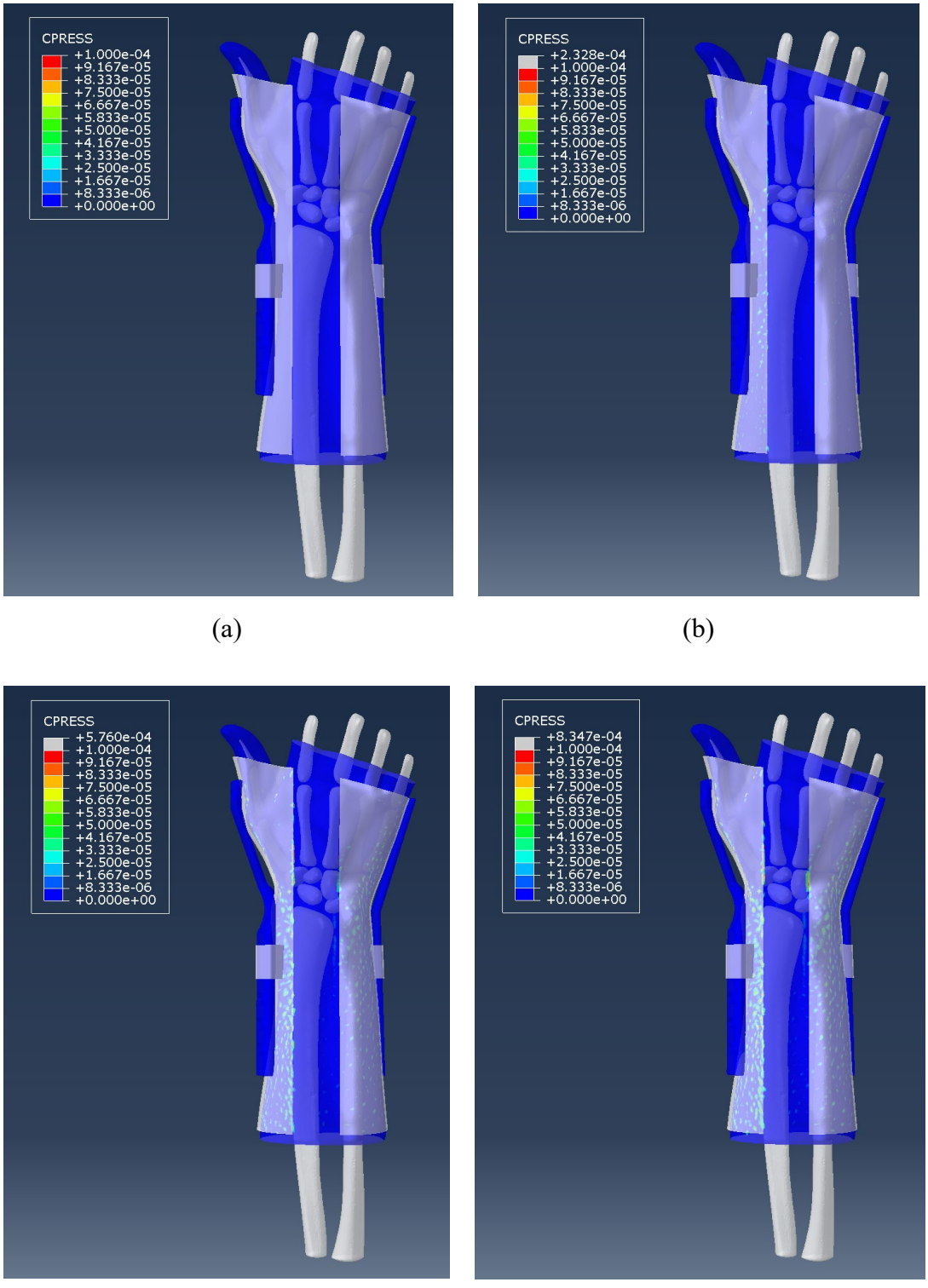


Figure 7.38 Finite element analysis process:

(a) Initial stage; (b) – (c) Middle stages; and (d) Final stage

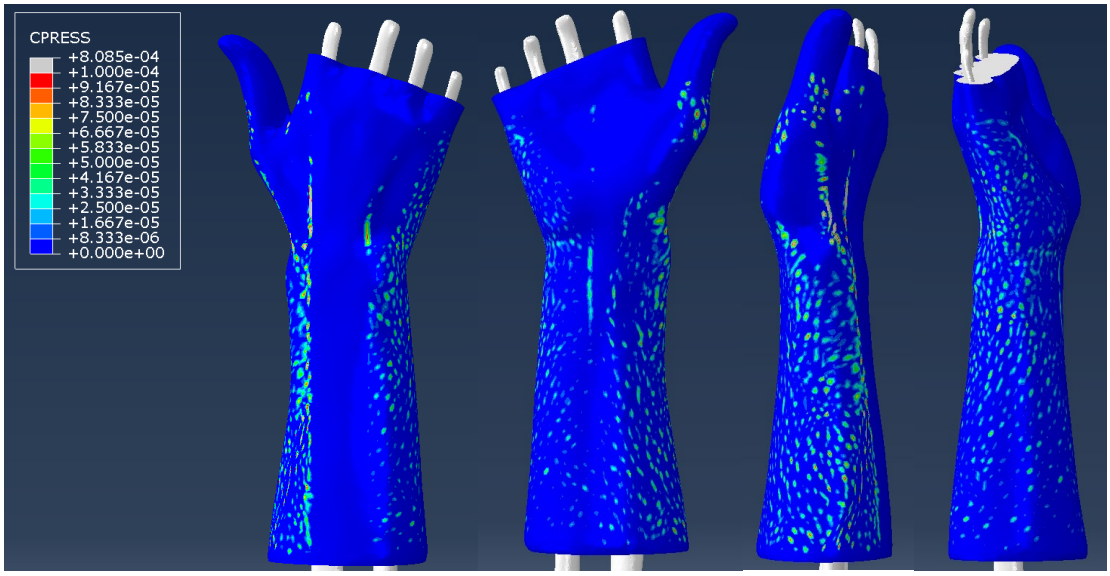
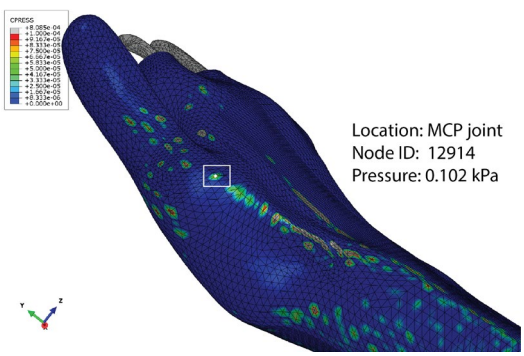
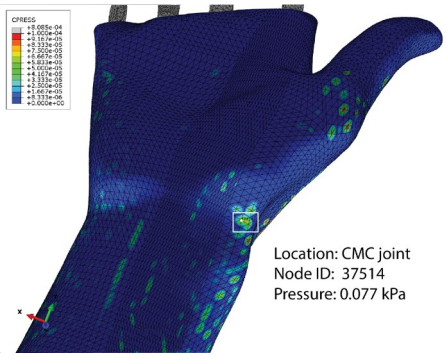


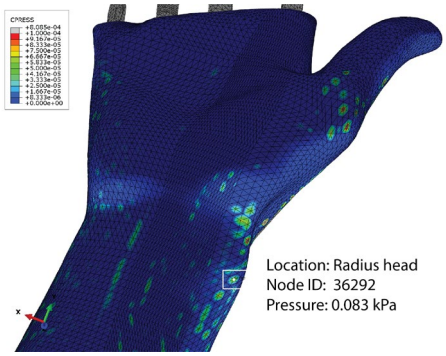
Figure 7.39 Final analysed result of the model of the hand



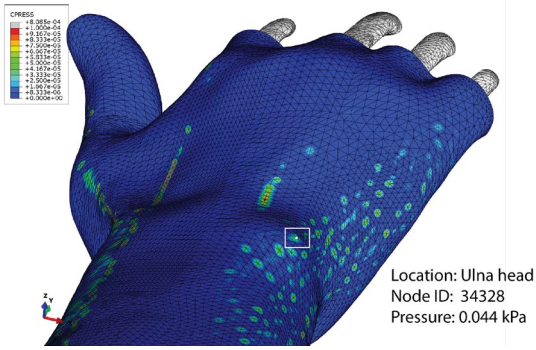
(a)



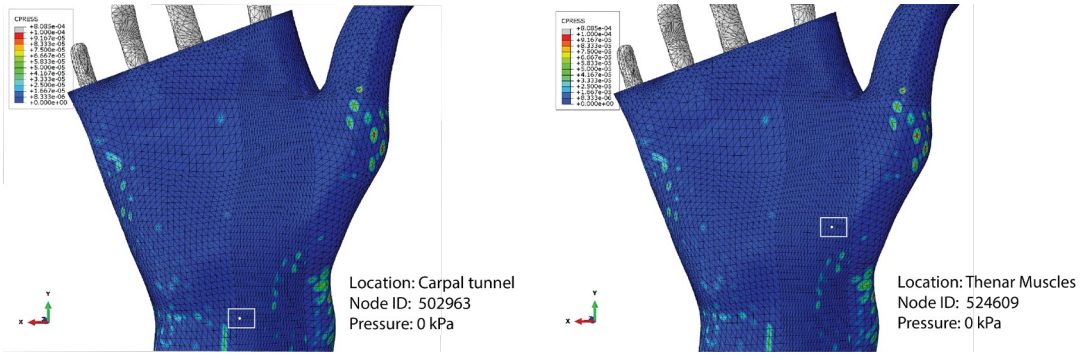
(b)



(c)



(d)



(e) (f)

Figure 7.40 Locations of the six measured points of pressure on the model of the hand and the corresponding results: (a) MCP joint; (b) CMC joint; (c) Radius head; (d) Ulna head; (e) Carpal tunnel; and (f) Thenar Muscles

Table 7.4 Predicted pressure results of the six locations on the model of the hand

Pressure sensor location	Node ID	Predicted pressure (kPa)
MCP joint	12914	0.102
CMC joint	37514	0.077
Radius head	36292	0.083
Ulna head	34328	0.044
Carpal tunnel	502963	0
Thenar Muscles	524609	0

Table 7.5 Comparison of FEM predicted and experimentally measured pressure values

Pressure sensor location	Experimentally measured pressure (kPa)	FEM predicted pressure (kPa)	FEM predicted pressure 10x (kPa)
MCP joint	3.625	0.102	1.02
CMC joint	6.5	0.077	0.77
Radius head	10	0.083	0.83
Ulna head	5.5	0.044	0.44
Carpal tunnel	0	0	0
Thenar Muscles	0	0	0

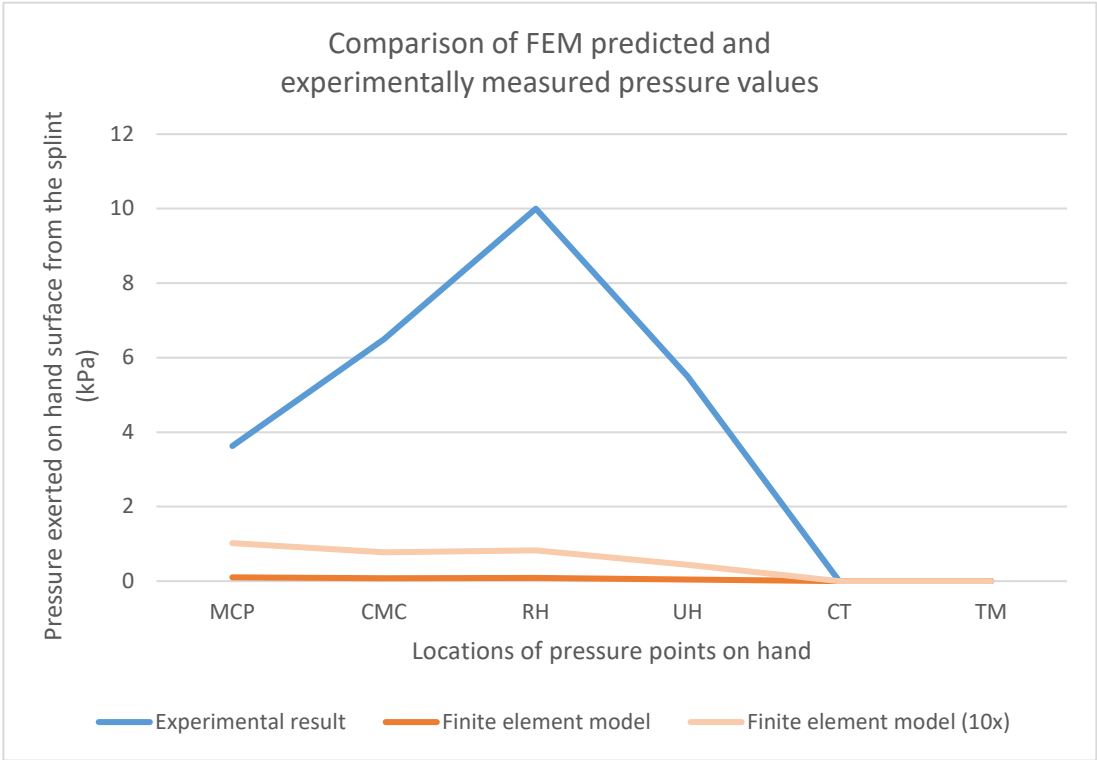


Figure 7.41 Comparison of FEM predicted and experimentally measured pressure values

7.5 Chapter summary

In this chapter, a FEM has been developed to simulate the wear process of the proposed functional splint for DQV treatment. The purpose of conducting the FEM analysis is to understand the pressure distribution on the subject's hand from the proposed splint during and after the splint wearing process. The FEM consists of six components: the flesh of the hand, bones, fabric of the radial and ulnar sides of the splint, thumb supporter and the ulna supporter. Originally, the FEM included the ligaments but due to the difficulties of modelling these intricate parts, the ligaments have been omitted. This limitation means that future studies should build a model of the ligaments that can successfully fit into the FEM since connective tissues are one of the main construction components of the hand. The thin and irregular shapes of the 3D ligaments could be the reason for failure to process the model in FEA software. Therefore, future studies are recommended to build the ligaments in a more organised way with more regular shapes, which may increase the success of processing the model in the FEA software.

The six parts are further assembled into three main models, which comprise the new model of the hand, radial side of the splint, and ulnar side of the splint. Apart from the construction of the models, other elements such as the mesh properties, boundary conditions and surface interactions are defined and discussed.

The predicted results of the stress distribution on the splint fabrics show that higher stress is found around the wrist area. This could be due to the location of the fastening straps, which are used to hold the supporters, and found at the wrist level of the splint. Higher stress is also found in the fabric area underneath the supporters. The rigid supporters exert pressure onto the fabrics underneath during the closing of the splint. An interesting finding is that there is high levels of stress along the seam between the two fabrics in the palm area. Splint designers should pay more attention to this area, and ensure secure stitching is used.

According to the measured points in the pressure test, six specific areas on the FEM are identified and the readings are recorded. Since only small displacements of closing of the fabrics can be successfully simulated in this study, the predicted pressure results are too low in comparison to the actual pressure results. However, apart from the pressure result of the MCP joint, those of the other five areas of the FEM and the real-life cases

appear to have a similar pattern. The analysed outcome also shows that the pressure given by the splint is evenly distributed onto the subject's hand. With this result, patients with DQV can wear the proposed functional splint comfortably without experiencing pain caused by excessive pressure in a particular region.

Chapter 8 Conclusion and recommendations for future work

8.1 Conclusion

DQV is the inflammation of the tendon sheaths, which cover the abductor pollicis longus (APL) and extensor pollicis brevis (EPB) tendons, in the first dorsal compartment of the hand (Ilyas et al., 2007). With this hand condition, other connective tissues in the compartment, such as the tendons and extensor retinaculum may also be inflamed and swollen (Goel & Abzug, 2015). Patients with DQV usually feel pain, soreness and tenderness at the radial side of hand (Goubau et al., 2014). Patients with painful symptoms of DQV may feel difficult to perform daily activities, particularly tasks that require forceful movements of the thumb and twisting of the wrist.

A conservative and non-invasive treatment for DQV is splinting. Splints for DQV are mainly hard or soft. The former, which is usually made of thermoplastic, can effectively control the hand of the patient from making excess movement. However, patients sometimes find fault with the thermal warmth, bulkiness and discomfort of the hard splint. Soft splints, which are made of flexible materials, may solve the problem of discomfort due to the rigidity of hard splints. However, since soft splints are flexible, they may not be able to control the movement of the hand.

A new functional splint is therefore proposed in this study, which is fabricated with both soft and hard components, to treat DQV patients. The design of the proposed splint aims to provide wear comfort to patients during splinting and effectively maintain the injured hand in the proper position for resting and healing. To develop the new functional splint, the objectives of this study are as follows: 1) to understand background information of DQV and review the corresponding treatments, especially splinting; 2) to review and evaluate existing splinting products in the market; 3) to investigate the ergonomic shape of human hands; 4) to design and develop a new functional splint which: a) provides a comfortable wear experience with selected fabrics, b) provides good fitting properties with specially designed supporters and fabric patterns, c) maintains the injured hand in a resting position and prevent large movements of the wrist and thumb without over-exertion of pressure onto the skin; 5) to carry out wear trials of the proposed functional splint to evaluate its performance in function and wear comfort; and 6) to develop a finite element model to simulate the

wear process of the splint, and hence to investigate the pressure distribution on the hand from the splint. All of the objectives have been realised and the study results are summarised as follows.

First, after reviewing previous studies in the literature, background information of DQV including the epidemiology, etiology and pathology of DQV has been obtained. The symptoms, diagnostic methods and treatments of DQV are also reviewed. Principles of the splinting treatment and different range of motion of the hand are studied. Several proposed splints in previous studies are reviewed and the corresponding problems are identified. Previous papers that are related to the finite element modelling of hand splints have been reviewed to understand the construction of 3D models and the simulation process. In addition, a citation network analysis has been conducted to classify the DQV related articles into groups, and hence to understand the distribution of the articles and identify the research gaps of the topic.

Secondly, the design of splints with ten products from online markets is reviewed. The purpose of these products is overall to stabilise and protect the user's hand, so as to relieve the symptoms of a hand condition. However, there is the lack of evidence on their effectiveness. Therefore, two splint samples are purchased from the market and tested for their abilities to control the wearer's hand. The subjects are then instructed to don the samples and perform different hand movements. The ROM results indicate that generally, the splint samples cannot provide sufficient control of the wearer's hand during movement. On the other hand, some parts of the splint are overly restrictive on a particular joint. Furthermore, the short and long splints that are being used in clinics are collected and evaluated. Possible areas of improvement are then identified, for example, enhancing the air permeability of the splint materials, reducing the bulkiness of the splint, and enhancing the fit of the splints. Therefore, a new splint that can stabilise the user's hand, and provide comfort and good fit is needed to be developed.

Thirdly, three groups of subjects, namely the healthy young subject (HYS), healthy mature subject (HMS) and DQV subject (DQVS) groups, are recruited. The shape of their hand was scanned and the angles of the wrist and thumb were measured. The results of HYS and HMS who are both healthy but fall in different age ranges are then compared. The results of the HMS and DQVS groups who are comparable in age are also compared. Significant differences of specific angles are found between the two

groups in both sets of comparisons. In terms of the angle measurements of the DQVS group, significantly correlated angles are found in vertical and diagonal patterns. The measured angle results of the DQVS group reflect the shape of the affected hands, which are explored and used as reference to create the structure of the thumb supporter with 3D modelling software.

Fourth, a new functional splint is proposed and designed in this study. The splint aims to control the hand movement, protect and rest the injured hand for healing purposes, and provide wear comfort and well-fitting features. The splint is composed of both soft and hard materials. The body of the splint is divided into two halves and constructed of fabric. Spacer fabric is used on the radial side of the hand to protect the thumb and relieve interface pressure. On the other hand, the ulnar side of the splint is composed of two kinds of thinner fabrics: satinette and powernet. Two layers of fabric can enhance the durability of the splint. Samples of the spacer, satinette and powernet fabrics are subjected to fabric tests, so as to select the most suitable fabrics with good stretchability for a good fit and high air-permeability for wear comfort. Apart from the soft fabrics, hard supporters are designed for tendon support and hand restriction purposes. The thumb and ulna supporters are developed based on the collected angle measurements in order to provide a well-fitting shape. Several 3D printing materials are then tested, and ABS is selected to print the supporters. Prototypes are fabricated and the final version is then confirmed for a wear trial.

Fifth, a pre- and post-test clinical study is conducted to evaluate the performance of the proposed splint. A total of 13 female DQV patients are recruited for the wear trial. The results show that the pain level of the patients in performing two motions, that is, thumb and finger extension and hand opposition, is significantly reduced after undergoing the treatment. The pain scores of the patients when performing selected daily activities at the 3rd month follow-up are also lower than those of pre-intervention. Furthermore, both the grip and pinch strengths of the patients are increased after the treatment. The pressure test conducted during the follow-up session provides information on splint wearing with proper tightness for each patient. ROM tests are carried out and the results indicate that the proposed splint can control the patient's hand from over extension and deviation. A splint evaluation questionnaire was given to the wearers and the results generally show that they are satisfied with the properties of the proposed splint, such

as its appearance, durability and wear comfort. The *Quick*DASH results show that the pain level and severity of disability of patients are significantly reduced after intervention. Moreover, the SF-12 v2 questionnaire results show that the quality of life of the subjects is enhanced at the last session of intervention.

Sixth, a FEM is formulated to simulate the wear process of the proposed splint with a DQV patient. The FEM is composed of six modelled parts: the flesh of the hand, bones, fabric of the radial and ulnar sides of the hand, thumb supporter and ulna supporter. With reference to the predicted results, a higher pressure is observed at the fabrics that surrounds the wrist area and underneath the rigid supporters. Higher levels of stress are also found along the seam in the palm section. Since only small closing motions can be successfully simulated in this study, the predicted pressure results are too low when compared to the actual pressure results. However, apart from the result for the MCP joint, the predicted results of the other measured points of the FEM and the actual measurements have a similar trend. The predicted results also show that pressure is evenly distributed on the subject's hand.

8.2 Limitations of the study

After conducting the study, some limitations are found which may prevent the generalization of the results. The limitations are discussed as follows.

1) In the design of the splint, the shape of the thumb supporter is built in 3D software based on the angle results obtained from the first group of DQV patients (DQVS group). The 3D shape of the affected hand of the 16 patients in the DQVS group is scanned in order to generate the angle results as reference to construct a thumb supporter. Since the number of recruited subjects in the scanned group is low, the angle results may not be generalized. Furthermore, as a full 3D image of the patient's hand is collected, a more in-depth investigation of the ergonomic shape of the hand can be carried out.

2) Material selection for printing the supporters is conducted in this study. The materials of the supporter prototypes include resin, nylon and ABS. The printing methods used are stereolithography (SLA), selective laser sintering (SLS) and fused deposition modelling (FDM) respectively. Since only three kinds of materials are tested, the variation of the supporter materials being tested is limited.

3) In the clinical study, 13 DQV patients are recruited for the wear trial of the proposed splint (WTS group). The sample size is small and there is no control group. The pre- and post-test designs of the intervention in this study can provide a preliminary outcome and understanding of the efficacy of the proposed splint. However, since there was no control group, comparisons of the results between two subject groups cannot be obtained yet.

4) With limitation of the equipment, only simplified versions of the hand model and small steps of movements can be successfully analyzed. In the FEM of this study, a simplified hand model and splint model are included. On the other hand, other detail components, such as tendons, ligaments, muscles and fastening straps are neglected. This could be the reason why the predicted pressure results are much lower than the actual results. The predicted results in this study act as a reference to understand the pressure distribution on the subject's hand during splinting, stress distribution on the splint fabrics and the displacements of different splint components.

8.3 Recommendations for future work

Based on the established research findings, some recommendations for future works are as follows.

1) To further optimize the detailed parts of the thumb supporter for a good fit, a more in-depth investigation on the ergonomic shapes of DQV patients is suggested. A larger sample size of patients should be recruited for 3D scanning of their hand. Larger number of scanned data could provide more reference for understanding hand shapes, which designers can further use to enhance the fitting performances of the supporters.

2) With the development of 3D printing technologies in the past decades, different kinds of printing materials, for instance, resin, nylon and metal, have been available in the market. Furthermore, apart from SLA, SLS and FDM, other printing methods such as Direct Metal Laser Sintering (DMLS) and Electron Beam Melting (EBM) have been developed. Therefore, with sufficient resources, supporter prototypes constructed with different kinds of materials or by other printing methods can be prepared and tested for comparison. Combination of methods or materials may also bring new ideas for the design of the supporters.

3) A more convincing treatment outcome can be obtained with an increase in the sample size. A randomized control trial (RCT) is recommended for future studies, so as to further evaluate the efficacy of the proposed splint. Apart from comparing the results of the splinting group with the proposed splint to that of the control group, a comparison of the results between the splinting group with the proposed splint and another splinting group with the traditional clinical splint is recommended. Thus, a more comprehensive evaluation on the proposed splint can be achieved.

4) A precise model with details should be developed in the future to predict more accurate results. With enough capacity of the modelling computer, the FEM should include more detailed components, such as the hand and forearm muscles, ligaments, tendons, two separate fabric layers at the ulnar side of the splint and the fastening systems of the splint. Larger closing steps of the splint should also be simulated in order to reflect a more similar condition with the actual wear process in real-life cases. Furthermore, by changing the material inputs of the FEM, the performances of the proposed splint with various kinds of materials can be investigated. As a result, the splint with an optimal selection of materials and design can be generated with the help of the formulated model.

Appendix I. Information sheet for participant in research

INFORMATION SHEET

Project title: Development of Functional Splint for De Quervain's Disease Treatment

This research study is supervised by Dr. YIP Yiu Wan, Joanne, a staff member of Institute of Textiles and Clothing, The Hong Kong Polytechnic University and her team members. Please take time to read the following information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask us if there is anything that is not clear or if you would like to have more information. Take time to decide whether or not you wish to take part.

Purpose of the study

The purpose of this study is to gain the clinical information necessary for the design of functional splint as mechanical therapeutic treatment for patients with de Quervain's disease. The new design of splint would be developed for providing an excellent fitting performance towards the patient's hand with appropriate amount of pressure. The splints would be able to restrict the patient's thumb and wrist movements in order to rest the abductor pollicis longus and the extensor pollicis brevis tendons, and to provide a stable condition for healing. The splint would be equipped with high breathability and excellent wicking property so as to give a comfort wearing experience to the patient, hence to increase the compliance rate. Information such as participant's age and occupation, conditions of the affected hand, for example, how long the participant has de Quervain's disease, his or her feelings and pain level towards the affected area, any problems participant has experienced due to the hand condition, effectiveness and comfortability of the current splint he or she is using, criteria and demands towards the new design of splint etc. will be recorded in order to optimize the splint design with respect to the comfort and functional performances.

Who will be invited to participate in this study?

People who have been diagnosed with de Quervain's disease and advised by doctors or clinicians to wear splint as treatment will be invited to participate in a thorough evaluation.

Exclusion criteria included minor age (<18), presence of other orthopaedic diseases in hand and wrist such as rheumatoid arthritis, having steroid injection for De Quervain syndrome in last 3 months and with history of hand surgery.

What will happen if you decide to take part?

First, a questionnaire will be filled by participant in order to assess the conditions of de Quervain's disease. The questionnaire will include questions related to the condition of the affected hand and splint treatment, for instance, pain level and problems experienced by the participant due to de Quervain's disease, effectiveness and comfortability of the current splint he or she is using, demands towards the new design of splint etc. Other important factors, such as participant's age and occupation will also be recorded.

During the clinical check-up, digital photos and infra-red photos of the participant's affected hand and the clinical procedure of de Quervain's disease splint treatment may be taken as references for clinical studies. Measurements and three-dimensional shape of participant's hand and wrist may be captured as data records. Temperature and level of humidity within the splint, and pressure given by the splint during patient's splint wearing may also be recorded. All the results obtained will be analyzed and helpful to the development of the new functional splint for participants.

After the development of new splint, participant may be invited to participate in the wear trials of new designed splint. A simple questionnaire related to the comfort and functional performances of the new splint will be conducted. Photos of the splint wear trials will be taken for documentation and further improvement works.

Do you have to take part?

It is your freedom to decide whether or not to take part in this study. If you do decide to participate, this information sheet will be given to you as record. Furthermore, you will be asked to sign the consent form. After you have joined the study, you are still free to withdraw at any time without giving a reason. The standard of the follow-up appointment with clinician will not be affected by your choice of participating this study. During the study period, if you failed to turn up at appointments, your participation in this study will be immediately terminated without further notice.

What is the functional splint being tested?

People with de Quervain's disease can feel pain at the first compartment of wrist. The pain and tenderness around the radial styloid process may affect patients' hand performances during daily life. They may feel difficulties in doing some actions that involve movements of thumb and wrist, for example pinching and opening jar lid. Serious pain at the wrist may also affect patients' sleeping quality at night. Therefore, an effective splint aiding to rest the patients' wrists and relieve the pain is important. A good fitting of splint towards the patients' hands with appropriate amount of pressure, which would not affect the blood circulation along the wrist, but can hold the thumb and wrist in correct position, is also significant. However, studies related to the appropriate amount of pressure given by the splint towards different parts of patient's hand for de Quervain's disease treatment are limited.

Comfort, breathability and moisture management of the splint are critical to patients' wearing compliance. Some splints provided in current market or clinic may be constructed with neoprene and large pieces of thermoplastic, which are with poor wicking property and low air ventilation, may lead to discomfort of wearing, especially during hot seasons. Since patients are required to wear the splint for long period of time, fabrics and materials of splint should be breathable, with good moisture management and good hand feel.

The project aims to design and develop functional splint as the mechanical therapeutic treatment for patients with de Quervain's disease. The new designed splint will be able to fit the patient's hand well with proper amount of pressure. The splint will be able to give proper restrictions to the patient's thumb and wrist of the affected hand. Furthermore, the splint will be fabricated with advanced fabrics and suitable materials so as to provide comfortable condition to user's hand.

What are the disadvantages and risks of taking part?

All the evaluations methods are no risk.

The fabrics and materials used in the new splint are safe and comfortable. The splint has been tested in human subjects for short durations during its design and production periods. It demonstrated that it would not cause skin allergy and/or discomfort. In such, there are no special compensation arrangements in this study.

What are the benefits of taking part?

The potential benefit is to provide a new option to patients with de Quervain's disease, with better design, fitting and comfort splint that could carry out optimum mechanical therapeutic treatment towards the affected hand.

What if something goes wrong?

There are no special compensation arrangements in this study. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, you can also contact The Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o M1303, Human Resources Office of the University).

Will my taking part in this study be kept confidential?

If you agree to take part in this study, the measurement results will only be reviewed by the research team to obtain essential information. All information collected will be kept confidential*.

***Confidentiality**

You have the rights of access to personal data and publicly available study results, if and when needed.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Privacy Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorize:

- the principal investigator and her research team and the ethics committee (Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster) responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and

- the relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

What will happen to the results of the research study?

The results will be published in referred journal.

What will happen to the results of the research study?

The results will be published in referred journal.

Who is organizing and funding the research?

The research is organized by Institute of Textiles and Clothing, The Hong Kong Polytechnic University.

Who has reviewed the study?

The study has been reviewed by Departmental Research Committee of Institute of Textiles and Clothing, The Hong Kong Polytechnic University.

Please keep this information sheet for your reference, together with a signed consent form.

If you have any query, please do not hesitate to contact Dr. YIP Yiu Wan at 2766 4848 or email (joanne.yip@). Thank you very much in helping us to improve our patients' care.

Updates of this study will only be informed, if necessary.

Dr. YIP Yiu Wan, Joanne

Principle Investigator/Chief Supervisor

Appendix II. Consent form (English version)

PARTICIPANT CONSENT FORM

Title of Project: Development of Functional Splint for De Quervain's Disease Treatment

Name of Researchers: Dr. YIP Yiu Wan, Dr. Fang Christian, Dr. YICK Kit Lun, Dr. NG Sun Pui and Miss Tam Eunice Wai-si.

1. I confirmed that I have read and understand the content stated in the information sheet for the above study.
2. I agree to take part in the above research.
3. I understand that my participation in the project is voluntary that I am free to withdraw the project at anytime without reasons.
4. I understand that sections of any of my medical documents may be reviewed by responsible individuals from the researcher's team or from regulatory authorities where it is relevant to my taking part study. I give permission for these individuals to have access to my records.
5. I understand that the results obtained from the study may be used in future research and published in referred journal. All information and personal details collected will be kept confidential.
6. I acknowledge that I have the right to ask questions related to the study.

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of witness (if applicable)	Date	Signature
_____	_____	_____
Name of Researcher	Date	Signature

Copies to:

- Participant
- Researcher's file

Appendix III. Consent form (Chinese version)

參與研究項目同意書

研究題目: 設計及改良「狹窄性腱鞘炎」手架研究

研究人員名稱：葉曉雲博士，方欣碩醫生，易潔倫博士，吳新培博士及譚慧詩小姐

1. 本人確定已詳細閱讀並了解提供之研究資料單張。
2. 本人同意參加此項研究。
3. 本人明白是次參與全是自願性質，並知道本人能在沒有原因的情況下隨時退出研究。
4. 本人明白及知道本人的醫療及個人資料可能會被與此研究有關的人員閱讀。本人同意及允許有關人員取得本人的醫療及個人資料，但是，本人之私隱權會被保留，例如本人的個人資料不會被公開。
5. 本人明白及同意本人之研究資料將會發佈在日後的學術報告及刊物內。但是，本人之私隱權會被保留，例如本人的個人資料不會被公開。
6. 本人確認本人有權利發問有關此研究的問題。

_____	_____	_____
參加者姓名	日期	簽名
_____	_____	_____
見証人(如適用)	日期	簽名
_____	_____	_____
研究員	日期	簽名

Appendix IV. Tables for measurement results of ROM tests

For testing the effectiveness of splint samples in limiting hand movement

	Bare hand	Medex splint	Futuro splint
Wrist ROMs			
Flexion			
Extension			
Radial deviation			
Ulnar deviation			
Thumb ROMs			
CMC joint extension			
Thumb abduction			
MCP joint flexion			
IP joint flexion			
IP joint extension			

For clinical study

	Bare hand	Proposed splint
Wrist ROMs		
Flexion		
Extension		
Radial deviation		
Ulnar deviation		
Thumb ROMs		
CMC joint extension		
Thumb abduction		

For further study with existing splints in market

	Bare hand	Medex splint	Futuro splint	Proposed splint
Wrist ROMs				
Flexion				
Extension				
Radial deviation				
Ulnar deviation				
Thumb ROMs				
CMC joint extension				
Thumb abduction				

Appendix V. Questionnaire for collection of comments from the subjects (DQVS group) on the importance of splint properties

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

有關設計及改善「狹窄性腱鞘炎」手架研究問卷

你好! 感謝您撥空填這份問卷，您寶貴的意見，將作為設計及改良「狹窄性腱鞘炎」手架研究之參考。

此問卷的目的是了解及得取更多關於狹窄性腱鞘炎的資訊，以及穿戴手架者的日常情況及意見，從而改善及設計新手架。

本問卷的內容會問及有關你的病徵，你進行某些活動的能力，以及對手架設計的意見。

治療手架的設計條件

你認為手架設計中各方面的重要性

		非常不重要	不重要	頗重要	重要	非常重要
1.	外觀	1	2	3	4	5
2.	功能性	1	2	3	4	5
3.	舒適度	1	2	3	4	5
4.	布料厚度	1	2	3	4	5
5.	手架重量	1	2	3	4	5
6.	手架輕型度	1	2	3	4	5
7.	透氣度	1	2	3	4	5
8.	散熱度	1	2	3	4	5
9.	涼感度	1	2	3	4	5
10.	布料廷伸性	1	2	3	4	5
11.	布料回彈性	1	2	3	4	5
12.	水氣穿透度	1	2	3	4	5
13.	排汗性	1	2	3	4	5
14.	耐用性	1	2	3	4	5
15.	容易清洗	1	2	3	4	5
16.	容易穿戴	1	2	3	4	5

個人資料及背景

姓名：_____ 性別：_____

年齡： 18 – 25 歲 □ 26 – 35 歲 □ 36 – 45 歲 □ 46 – 55 歲 □ 56 – 65 歲 □

手腕感到痛楚時間 (如 3 個月、1 年 8 個月等)：_____

電話號碼：_____ 電郵：_____

日期：_____

~ 完 ~

謝謝你寶貴的意見！

Appendix VI. Questionnaire for the evaluation of the proposed splint in the second week of intervention

香 港 大 學
THE UNIVERSITY OF HONG KONG

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

狹窄性腱鞘炎手架研究

手架穿戴第二週 – 跟進問題

1. 平均每日穿戴治療手架的時間為 _____ 小時
2. 穿戴手架時有沒有不舒服? 有 □, _____ 無 □
3. 手架有沒有損壞的地方? 有 □, _____ 無 □

		非常不同意	不同意	並非同意或不同意	同意	非常同意
4.	治療手架能夠有效地醫治狹窄性腱鞘炎	1	2	3	4	5
5.	治療手架能夠有效地舒緩手腕痛楚	1	2	3	4	5

6. 其他意見:_____

- 謝謝 -

Appendix VII. Data sheet for the evaluation of hand condition in clinical study

香 港 大 學
THE UNIVERSITY OF HONG KONG

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

Project title: Development of Functional Splint for De Quervain's Disease Treatment

1.	Finkelstein's test	Positive ☐	Negative ☐

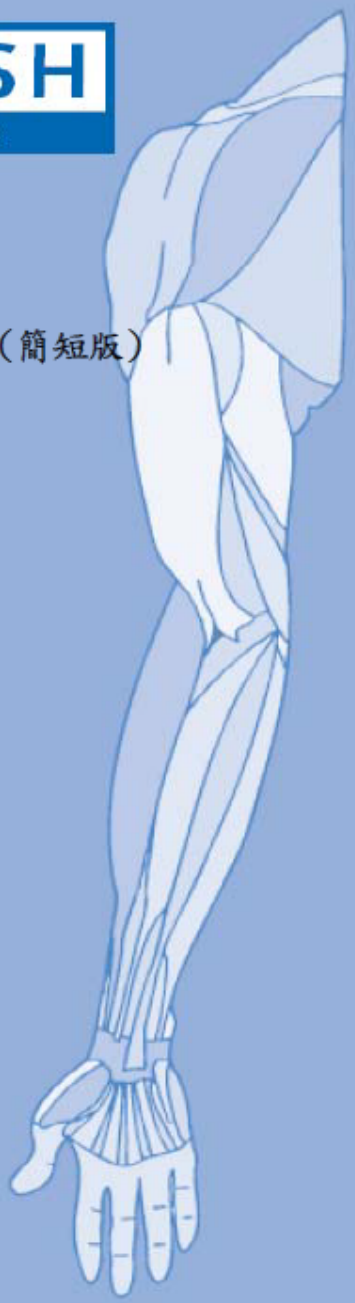
Please circle the best answer.

		NONE ☺		MILD		MODERATE		SEVERE		EXTREME ☹	
2.	Thumb and fingers extension	1	2	3	4	5	6	7	8	9	10
3.	Opposition	1	2	3	4	5	6	7	8	9	10
4.	Daily Activity 1:	1	2	3	4	5	6	7	8	9	10
5.	Daily Activity 2:	1	2	3	4	5	6	7	8	9	10
6.	Daily Activity 3:	1	2	3	4	5	6	7	8	9	10
7.	Grip strength	Right hand:_____ Affected hand ☐						Left hand:_____ Affected hand ☐			
8.	Pinch strength	Right hand:_____ Affected hand ☐						Left hand:_____ Affected hand ☐			

Appendix VIII. *Quick*DASH Questionnaire

上肢功能受損程度問卷（簡短版）
Chinese *Quick*DASH

THE QuickDASH OUTCOME MEASURE



上肢功能受損程度問卷（簡短版）

說明：

本問卷的內容會問及有關你的病癥，以及你進行某些活動的能力。

請根據你過去一星期內的情況，就下列每一條問題，圈出最適合的數字作答。

如果你過去一星期內，沒有機會進行該項活動，請估計你進行該項活動的能力，並選取最適合的答案。

你只需要考慮你進行該項活動的能力去選取答案，而不必理會你是用那一隻手或手臂去進行。

CHINESE QUICK DASH (QMH, HK, Version)

Chinese (QMH, Hong Kong Version) translation courtesy of Rebecca K Y Chan, Occupational Therapy Dept., Queen Mary Hospital, Hong Kong.

上肢功能受損程度問卷（簡短版）
Chinese *Quick*DASH

第一部份：活動能力

請評估你過去一星期內，進行下列活動的能力，並圈出最適合的數字作答。

	沒有困難	少許困難	中度困難	非常困難	不能做到
1. 扭開緊或新的瓶蓋	1	2	3	4	5
2. 做消耗大量體力的家務(例如：抹窗或洗擦地板)	1	2	3	4	5
3. 攜帶購物袋或公事包	1	2	3	4	5
4. 清洗背部	1	2	3	4	5
5. 用刀切食物	1	2	3	4	5
6. 進行一些需要上肢（包括肩膊、手臂或手部）發力或承受衝力的餘閒活動（例如：打高爾夫球、打排球、打網球、錘擊等）	1	2	3	4	5

	完全沒有	少許	中度	相當大程度	極度
7. 過去一星期內，因為你肩膊、手臂或手部的問題而影響你和家人、朋友、鄰居或團體的正常社交活動，其程度有多大？	1	2	3	4	5

	完全沒有限制	少許限制	中度限制	非常受限制	不能做到
8. 過去一星期內，你的工作或其他日常活動，有沒有因你肩膊、手臂或手部的問題而受到限制？	1	2	3	4	5

第二部份：病癥嚴重程度

請根據你過去一星期內，以下病癥的嚴重程度，圈出最適合的數字作答。

	沒有	輕微	中度	嚴重	極度
9. 肩膊、手臂或手部感到痛楚	1	2	3	4	5
10. 肩膊、手臂或手部有被針刺的感覺	1	2	3	4	5

	沒有困難	少許困難	中度困難	非常困難	困難至不能入睡
11. 過去一星期內，由於你肩膊、手臂或手部的痛楚而引致睡眠困難，其程度有多大？	1	2	3	4	5

*Quick*DASH Disability/ Symptom score= $\left(\frac{(\text{sum of n responses})}{n}-1\right) \times 25$

(May not be calculated if there is greater than 1 missing item)

Sum of responses from Part I and II : _____

No. of responses (n) from Part I and II : _____

上肢功能受損程度問卷（簡短版）
Chinese *Quick*DASH

第三部份(選擇部份):工作能力

以下問題會問及你肩膊、手臂或手部的問題對你工作能力的影響
(如你的主要職責是做家務，請包括在內)。 請註明你的職業：_____

☐ 我一向沒有工作（可略過以下部份）

過去一星期內，在下列情況，你有沒有遇到困難？ 請圈出最能形容你的能力的數字。

	沒有困難	少許困難	中度困難	非常困難	不能做到
1. 以慣常的技巧和方法工作，困難有多大？	1	2	3	4	5
2. 由於肩膊、手臂或手部痛楚，做日常工作時的困難有多大？	1	2	3	4	5
3. 工作時，要達致你想做到的一樣，困難有多大？	1	2	3	4	5
4. 用你平常所需要的時間去完成工作，困難有多大？	1	2	3	4	5

第四部份(選擇部份)：高技巧的體育活動或音樂彈奏

以下內容會問及關於你肩膊、手臂或手部的問題，對你彈奏樂器或/及進行體育活動的影響。
如你彈奏的樂器或參與的體育活動多於一項，請選擇你覺得**最重要的活動**作答。
請註明你覺得最重要的運動或樂器：_____

☐ 我一向沒有參加體育活動或彈奏樂器（可略過以下部份）

過去一星期內，在下列情況，你有沒有遇到困難？ 請圈出最能形容你的能力的數字。

	沒有困難	少許困難	中度困難	非常困難	不能做到
1. 以慣常的技巧彈奏樂器或進行體育活動，困難有多大？	1	2	3	4	5
2. 彈奏慣用的樂器或進行慣常的體育活動時，因為肩膊、手臂或手部痛楚，而引致的困難有多大？	1	2	3	4	5
3. 彈奏慣用的樂器或進行慣常的體育活動時，要達致你想做到的一樣，困難有多大？	1	2	3	4	5
4. 用你平常所需要的時間去練習樂器或進行體育活動，困難有多大？	1	2	3	4	5

Scoring the optional modules: $\left(\left(\frac{\text{sum of responses}}{4}\right)-1\right) \times 25$

(Optional module score may not be calculated if there is any missing item)

Optional Modules:

Sum of responses from Part III : _____

Sum of responses from Part IV : _____

Appendix IX. Proposed Splint Evaluation Questionnaire

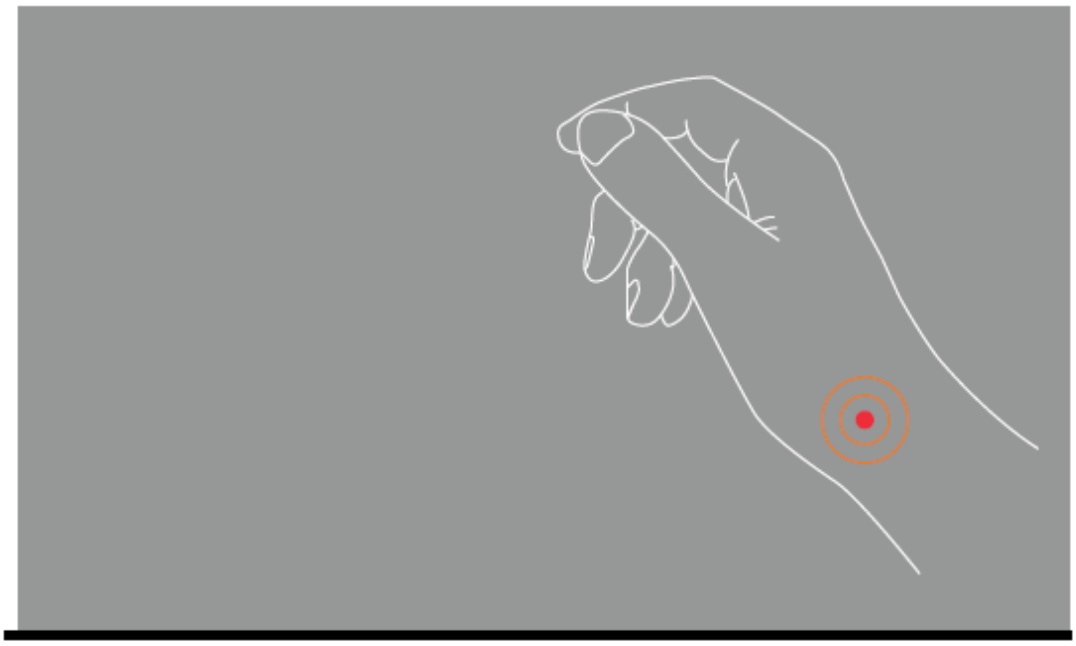
香 港 大 學
THE UNIVERSITY OF HONG KONG

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

狹窄性腱鞘炎手架研究問卷

你好。感謝您撥空填這份問卷，您寶貴的意見，將作為狹窄性腱鞘炎手架研究之參考。是次研究項目的主要目的是研發及設計新的狹窄性腱鞘炎治療手架。

本問卷的內容會問及有關你使用治療手架的情況及對治療手架的意見。



第一部份：使用治療手架的情況

請在你認為最合適答案的格子內打勾☑。

1.	平均每日穿戴治療手架的時間為 _____小時				
2.	穿戴時間為	上午 ☐	下午 ☐	晚上 ☐	睡眠時 ☐
3.	有沒有一些動作或活動讓你不能夠穿戴治療手架 (除洗澡和洗手外，例如: 上班工作，做家務，抱嬰孩或小童)？			有 ☐	無 ☐
	如有，以上動作或活動是 _____				
	不能夠穿戴治療手架的原因是 (可選多於一項)	不方便 ☐	局促 ☐	布料引至不舒適 ☐	其他 ☐: _____

請圈出最適合的數字作答。

		非常不同意	不同意	並非同意或不同意	同意	非常同意
4.	治療手架能夠有效地醫治狹窄性腱鞘炎	1	2	3	4	5
5.	治療手架能夠有效地舒緩手腕痛楚	1	2	3	4	5
6.	治療手架能夠提醒我注意或避免某些手部動作或活動	1	2	3	4	5
7.	治療手架能夠讓我手部放鬆	1	2	3	4	5
8.	穿戴治療手架時會讓我感到困擾	1	2	3	4	5
9.	穿戴治療手架時會讓我感到擔憂	1	2	3	4	5
10.	穿戴治療手架時會令我自信心下降	1	2	3	4	5
11.	睡眠時穿戴治療手架會影響及令我的睡眠質素下降	1	2	3	4	5
	如選擇同意或非常同意，睡眠質素被影響或下降的原因是 (可選多於一項)	不方便 ☐	局促 ☐	布料引至不舒適 ☐	其他 ☐: _____	

第二部份：對治療手架意見

請在你認為最合適答案的格子內打勾☑。

1. 穿戴治療手架時，手部有沒有感到不舒適的地方？ 有 □ 無 □

如有，請在以下圖中圈出在穿戴治療手架時，手部不舒適的地方

手掌

手背

側面（拇指）

側面（尾指）

2. 你對手架設計中各方面的滿意程度

		非常不滿意	不滿意	頗滿意	滿意	非常滿意
1.	外觀	1	2	3	4	5
2.	功能性	1	2	3	4	5
3.	舒適度 (如: 透氣、散熱)	1	2	3	4	5
4.	手架輕型度 (包括重量)	1	2	3	4	5
5.	耐用性	1	2	3	4	5
6.	清洗方面	1	2	3	4	5
7.	穿戴方面	1	2	3	4	5

個人資料及背景

姓名：_____ 性別：_____

年齡： 36 – 45 歲 □ 46 – 55 歲 □ 56 – 65 歲 □ 65 或以上 □

手腕感到痛楚時間 (如 3 個月、1 年 8 個月等)：_____

電話號碼：_____ 電郵：_____

日期：_____

~完~

謝謝你寶貴的意見！

Appendix X. Medical Outcomes Study 12-Item Short-Form Health Survey version 2

標準十二題簡明健康狀況調查表-第二版

說明：這項調查是詢問您對自己健康狀況的了解。此項資料記錄您的自我感覺和日常生活的情況。

請在一個方格內填上 X 號來回答每個問題。如果您不肯定怎樣回答，請按照您的理解選擇最合適的答案。

1. 總括來說，您認為您的健康狀況是：

極好	很好	好	一般	差
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. 下列問題是關於您日常生活中可能進行的活動。以您目前的健康狀況，您在進行這些活動時，有沒有受到限制？如果有的話，程度如何？

	有很大限制	有一點限制	沒有任何限制
a. 中等強度的活動，比如搬桌子，使用吸塵器清潔地面，玩保齡球或打太極拳	☐ 1	☐ 2	☐ 3
b. 上幾層樓梯	☐ 1	☐ 2	☐ 3

3. 在過去四個星期裏，您在工作或其它日常活動中，有多少時間會因為身體健康的原因而遇到下列的問題？

	常常如此	大部分時間	有時	偶爾	從來沒有
a. 實際做完的比想做的要少	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. 工作或其它活動的種類受到限制	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. 在過去的四個星期裏，您在工作或其它日常活動中，有多少時間由於情緒方面的原因（比如感到沮喪或焦慮）遇到下列的問題？

	常常如此	大部分時間	有時	偶爾	從來沒有
a. 實際做完的比想做的要少	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. 工作時或從事其它活動時不如往常細心了	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. 在過去四個星期裏，您身體上的疼痛對您的日常工作（包括上班和家務）有多大影響？

毫無影響	有很少影響	有一些影響	有較大影響	有極大影響
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. 下列問題是有關您在過去四個星期裏您覺得怎樣和您其它的情況。針對每一個問題，請選擇一個最接近您的感覺的答案。在過去四個星期裏有多少時間：

	常常如此	大部分時間	有時	偶爾	從來沒有
a. 您感到心平氣和？	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. 您感到精力充足？	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. 您覺得心情不好，悶悶不樂？	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. 在過去四個星期裏，有多少時間由於您的身體健康或情緒問題妨礙了您的社交活動 (比如探親、訪友等）？

常常有妨礙	大部分時間有妨礙	有時有妨礙	偶爾有妨礙	完全沒有妨礙
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

多謝您參與研究！

----------完----------

References

3M (Producer). (2022). FUTURO™ Thumb deluxe stabilizer. Retrieved from https://www.futuro-usa.com/3M/en_US/futuro-us/products/~/FUTURO-Thumb-Deluxe-Stabilizer/?N=4318+3294505497+3294529207&preselect=5583512+8757824+3293786499&rt=rud

Adachi, S., Yamamoto, A., Kobayashi, T., Tajika, T., Kaneko, T., Shibusawa, K., & Takagishi, K. (2011). Prevalence of de Quervain's disease in the general population and risk factors. *The Kitakanto Medical Journal, 61*(4), 479-482. doi:10.2974/kmj.61.479

Agrawal, K., & Chauhan, N. (2012). Pressure ulcers: Back to the basics. *Indian J Plast Surg, 45*(2), 244-254. doi:10.4103/0970-0358.101287

Alexander, R. D., Catalano, L. W., Barron, O. A., & Glickel, S. Z. (2002). The extensor pollicis brevis entrapment test in the treatment of de Quervain's disease. *Journal of Hand Surgery-American Volume, 27*(5), 813-816. doi:10.1053/jhsu.2002.35309

Amazon (Producer). (2022). VELPEAU Wrist brace with thumb spica splint support. Retrieved from https://www.amazon.com/Velpeau-Quervains-Scaphoid-Fracture-Recovery/dp/B06XBJKBVF/ref=sr_1_2_sspa?currency=USD&keywords=Splint%2Bfor%2BDequervains&language=en_US&qid=1555739569&s=gateway&sr=8-2-spons&th=1

Antoniadou, E. (2018). 35 - Upper limb pain and dysfunction. In *Braddom's rehabilitation care: A clinical handbook* (pp. 244-247.e246). Philadelphia, PA: Elsevier.

Artec 3D (Producer). (2022). Artec Eva. Retrieved from https://www.artec3d.com/portable-3d-scanners/artec-eva-v2

Association of Hong Kong Gloves Traders Ltd. (2002). *Information handbook on gloves manufacture and trading*. Hong Kong: The Association of Hong Kong Gloves Traders Ltd.

Astifidis, R. P. (2016). Chapter 33 - Wrist and hand tendinopathies. In *Hand and upper extremity rehabilitation: A practical guide* (4th ed., pp. 319-327). Saint Louis, Missouri: Elsevier.

Baack, B. R., & Brown, R. E. (1991). Atypical mycobacterium soft-tissue infection of the dorsal radial wrist: A possible complication of steroid injection for de Quervain's disease. *Annals of Plastic Surgery, 27*(1), 73-76. doi:10.1097/00000637-199107000-00012

Barakat, M. J., Field, J., & Taylor, J. (2013). The range of movement of the thumb. *HAND, 8*(2), 179-182. doi:10.1007/s11552-013-9492-y

Bergman, D. R. (2018). *Computational acoustics: Theory and implementation*. Hoboken, NJ: John Wiley & Sons, Inc.

Bookman, A. A. M., von Schroeder, H. P., & Fam, A. G. (2010). The wrist and hand. In *Fam's Musculoskeletal Examination and Joint Injection Techniques* (Second ed., pp. 29-43).

BraceAbility (Producer). (2022). Thumb & wrist splint: Tendonitis hand spica brace for de Quervain's tenosynovitis. Retrieved from https://www.braceability.com/products/thumb-spica-splint

BRACOO (Producer). (2022). BRACOO TP31 Thumb & wrist brace. Retrieved from https://bracoo.com/products/bracoo-tp31-thumb-wrist-brace

Brunelli, G. (2003). Finkelstein's versus Brunelli's test in de Quervain tenosynovitis. *Chirurgie de la Main, 22*(1), 43.

Bui, H. P., Tomar, S., & Bordas, S. P. A. (2019). Corotational cut finite element method for real-time surgical simulation: Application to needle insertion simulation.

Computer Methods in Applied Mechanics and Engineering, 345, 183-211. doi:10.1016/j.cma.2018.10.023

Cassidy, T., & Goswami, P. (2018). *Textile and clothing design technology* (1st ed.). Milton: CRC Press.

Cavaleri, R. B. M. B., Schabrun, S. M. P., Te, M. B. M. B., & Chipchase, L. S. P. (2016). Hand therapy versus corticosteroid injections in the treatment of de Quervain's disease: A systematic review and meta-analysis. *Journal of Hand Therapy, 29*(1), 3-11. doi:10.1016/j.jht.2015.10.004

Cazon, A., Kelly, S., Paterson, A. M., Bibb, R. J., & Campbell, R. I. (2017). Analysis and comparison of wrist splint designs using the finite element method: Multi-material three-dimensional printing compared to typical existing practice with thermoplastics. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 231*(9), 881-897. doi:10.1177/0954411917718221

Chan, K. Y. R., Leung, Y. C., Leung, K. L. F., Fang, X. S. C., Cheung, K. P. A., Lau, K. C. T., & Fung, K. M. J. K. (2019). Reliability and validity of the Chinese (Queen Mary Hospital, Hong Kong version) of the Disabilities of the Arm, Shoulder and Hand on patients with upper extremity musculoskeletal disorders in Hong Kong. *Hong Kong journal of occupational therapy, 32*(1), 62-68. doi:10.1177/1569186119849502

Chen, C.-K. (2018). 11 - Upper limb orthoses. In *Braddom's rehabilitation care : A clinical handbook* (pp. 66-74.e62). Philadelphia, PA: Elsevier.

Cherven, K. (2015). *Mastering Gephi network visualization*. Birmingham: Packt Publishing.

Chow, K. K. C. (2009). Splint for de Quervain disease: A new design. *Hong Kong journal of occupational therapy, 19*(1), 31-32. doi:10.1016/S1569186109700427

Clarke, M. T., Lyall, H. A., Grant, J. W., & Matthewson, M. H. (1998). The histopathology of de Quervain's disease. *Journal of Hand Surgery-British And European Volume, 23*(6), 732-734. doi:10.1016/S0266-7681(98)80085-5

Coldea, A., & Vlad, D. (2011). Research regarding air permeability of knitted fabric. *Annals of the University of Oradea: Fascicle of Textiles, Leatherwork, XII*(2), 54-57.

Colicchia, C., Creazza, A., & Strozzi, F. (2018). Citation network analysis for supporting continuous improvement in higher education. *Studies in Higher Education, 43*(9), 1637-1653. doi:10.1080/03075079.2016.1276550

Cook, R. D., Malkus, D. S., Plesha, M. E., & Witt, R. J. (2002). *Concepts and applications of finite element analysis* (4th ed.). New York, NY: Wiley.

Coppard, B. M., & Lohman, H. (2014). *Introduction to orthotics: A clinical reasoning and problem-solving approach* (4th ed.). St Louis: Elsevier.

Copper Compression (Producer). (2022). Copper compression recovery thumb brace. Retrieved from https://www.coppercompression.com/products/copper-compression-recovery-thumb-brace/

Cox, T. R., & Erler, J. T. (2011). Remodeling and homeostasis of the extracellular matrix: Implications for fibrotic diseases and cancer. *Disease Models & Mechanisms, 4*(2), 165-178. doi:10.1242/dmm.004077

Dawson, C. M. D., & Mudgal, C. S. M. D. (2010). Staged description of the Finkelstein test. *Journal of Hand Surgery-American Volume, 35*(9), 1513-1515. doi:10.1016/j.jhsa.2010.05.022

Desmet, P., & Hekkert, P. (2007). Framework of product experience. *International Journal of Design, 1*(1), 57-66.

Dhatt, G., Touzot, G., & Lefrançois, E. (2012). *Finite element method*. London: Hoboken, N.J.: Wiley.

DJO Global (Producer). (2022). PROCARE® Quick-fit™ W.T.O. Retrieved from https://www.djoglobal.com/products/procare/quick-fit-wto

Dorsch, T. E., Vierimaa, M., & Plucinik, J. M. (2019). A citation network analysis of research on parent−child interactions in youth sport. *Sport, Exercise, and Performance Psychology, 8*(2), 145-162. doi:10.1037/spy0000140

Draghi, F. (2014). *Ultrasonography of the upper extremity : hand and wrist*. Cham: Springer.

Drake, R. L. (2015). *Gray's atlas of anatomy* (2nd ed.). Philadelphia, PA: Churchill Livingstone/Elsevier.

Dutton, M. (2005). *Orthopaedic examination, evaluation, & intervention: A pocket handbook*. New York: McGraw-Hill.

Earp, B. E. M. D., Han, C. H. B. A., Floyd, W. E. B. A., Rozental, T. D. M. D., & Blazar, P. E. M. D. (2015). De Quervain tendinopathy: Survivorship and prognostic indicators of recurrence following a single corticosteroid injection. *Journal of Hand Surgery-American Volume, 40*(6), 1161-1165. doi:10.1016/j.jhsa.2014.12.027

Emlyn-Jones, G. (1974). *Make your own gloves*. London: G. Bell.

Evans, R. C. (2009). *Instant access to orthopedic physical assessment* (2nd ed.). St. Louis: Mosby Elsevier.

Fernandez-Vicente, M., Escario Chust, A., & Conejero, A. (2017). Low cost digital fabrication approach for thumb orthoses. *Rapid Prototyping Journal, 23*(6), 1020-1031. doi:10.1108/RPJ-12-2015-0187

France, A. K., & Ebrary, I. (2014). *Make: 3D printing* (1st ed.). Sebastopol, Calif.: Maker Media, Inc.

Gerhardt, J. J., Cocchiarella, L., & Lea, R. D. (2002). *The practical guide to range of motion assessment* (1st ed.). Chicago, Ill.: American Medical Association.

Goel, R., & Abzug, J. M. (2015). De Quervain's tenosynovitis: A review of the rehabilitative options. *HAND, 10*(1), 1-5. doi:10.1007/s11552-014-9649-3

Goubau, J. F., Goubau, L., Van Tongel, A., Van Hoonacker, P., Kerckhove, D., & Berghs, B. (2014). The wrist hyperflexion and abduction of the thumb (WHAT) test: A more specific and sensitive test to diagnose de Quervain tenosynovitis than the Eichhoff's test. *Journal of Hand Surgery-European Volume, 39*(3), 286-292. doi:10.1177/1753193412475043

Graham, J. B., Hulkower, S. D., Bosworth, M., White, E. L., & Gauer, R. (2007). Are steroid injections effective for tenosynovitis of the hand? *Journal of Family Practice, 56*(12), 1045-1047.

Green, J. B., Deveikas, C., Ranger, H. E., Draghetti, J. G., Groat, L. C., Schumer, E. D., & Leslie, B. M. (2016). Chapter 10 - Hand, wrist, and digit injuries. In *Pathology and intervention in musculoskeletal rehabilitation* (2nd ed., pp. 344-435). Saint Louis, Missouri: Elsevier.

Greene, W. B., & Netter, F. H. (2006). *Netter's orthopaedics* (1st ed.). Philadelphia, Pa.: Saunders Elsevier.

Gummesson, C., Ward, M. M., & Atroshi, I. (2006). The shortened disabilities of the arm, shoulder and hand questionnaire (QuickDASH): Validity and reliability based on responses within the full-length DASH. *BMC Musculoskeletal Disorders, 7*(1), 44-44. doi:10.1186/1471-2474-7-44

Hajder, E., de Jonge, M. C., van der Horst, C. M. A. M., & Obdeijn, M. C. (2013). The role of ultrasound-guided triamcinolone injection in the treatment of de Quervain's disease: Treatment and a diagnostic tool? *Chirurgie de la Main, 32*(6), 403-407. doi:10.1016/j.main.2013.09.002

Hamilton, N., Weimar, W., & Luttgens, K. (2012). *Kinesiology : scientific basis of human motion* (12th ed.). New York: McGraw-Hill.

Hart, R. G., Kleinert, H. E., & Lyons, K. (2005). A modified thumb spica splint for thumb injuries in the ED. *American Journal of Emergency Medicine, 23*(6), 777-781. doi:10.1016/j.ajem.2005.03.004

Hirt, B., Seyhan, H., & Wagner, M. (2017). *Hand and wrist anatomy and biomechanics: A comprehensive guide*. Stuttgart: Thieme.

Howell, E. R. (2012). Conservative care of de Quervain's tenosynovitis/ tendinopathy in a warehouse worker and recreational cyclist: A case report. *Journal of the Canadian Chiropractic Association, 56*(2), 121-127.

Hua, Z., Wang, J.-W., Lu, Z.-F., Ma, J.-W., & Yin, H. (2018). The biomechanical analysis of three-dimensional distal radius fracture model with different fixed splints. *Technology and Health Care, 26*(2), 329-341. doi:10.3233/THC-171050

Huang, T.-H., Feng, C.-K., Gung, Y.-W., Tsai, M.-W., Chen, C.-S., & Liu, C.-L. (2006). Optimization design of thumbspica splint using finite element method. *Medical & Biological Engineering & Computing, 44*(12), 1105-1111. doi:10.1007/s11517-006-0131-4

Hummon, N. P., & Dereian, P. (1989). Connectivity in a citation network: The development of DNA theory. *Social Networks, 11*(1), 39-63. doi:10.1016/0378-8733(89)90017-8

Ilyas, A. M., Ast, M., Schaffer, A. A., & Thoder, J. (2007). De Quervain tenosynovitis of the wrist. *Journal of the American Academy of Orthopaedic Surgeons, 15*(12), 757-764. doi:10.5435/00124635-200712000-00009

Information Resources Management Association USA. (2017). *3D printing: Breakthroughs in research and practice*. Hershey, PA: Engineering Science Reference.

Jabran, A., Peach, C., Zou, Z., & Ren, L. (2019). Parametric design optimisation of proximal humerus plates based on finite element method. *Annals of Biomedical Engineering, 47*(2), 601-614. doi:10.1007/s10439-018-02160-6

Jirarattanaphochai, K., Saengnipanthkul, S., Vipulakorn, K., Jianmongkol, S., Chatuparisute, P., & Jung, S. (2004). Treatment of de Quervain disease with triamcinolone injection with or without nimesulide: A randomized, double-blind, placebo-controlled trial. *Journal of Bone And Joint Surgery-American Volume, 86*(12), 2700-2706. doi:10.2106/00004623-200412000-00017

Jongprasitkul, H., Suputtitada, A., Kitisomprayoonkul, W., & Pintawiruj, K. (2011). Elastic bandage vs. neoprene thumb stabilizer splint in acute de Quervain's tenosynovitis. *Asian Biomedicine, 5*(2), 263-267. doi:10.5372/1905-7415.0502.035

Joseph, C. (2006). *Pocket anatomy: A complete guide to the human body, for artists and students* (1st ed.). Hauppauge, N.Y.: Barron's Educational Series, Inc.

Júnior, P., Pires, P., Andrade, M., & Lima, G. (2016). Surgical and anatomical studies on de Quervain's tenosynovitis syndrome: Variations in the first extensor compartment. *Hand and Microsurgery, 5*(2), 50-55. doi:10.5455/handmicrosurg.204925

Kapandji, A. (1986). Clinical test of apposition and counter-apposition of the thumb. *Annales de Chirurgie de la Main: Organe Officiel des Sociétés de Chirurgie de la Main, 5*(1), 67.

KATO TECH CO. LTD. (Producer). (2007). KES-F7. Retrieved from https://www.keskato.co.jp/archives/products/kes-f7

Khokhar, D. (2015). *Gephi cookbook*. Birmingham: Packt Publishing.

Kimmel, A. J. (2015). *People and products: Consumer behavior and product design*. London: Routledge.

Koban, K. C., Cotofana, S., Frank, K., Green, J. B., Etzel, L., Li, Z., . . . Schenck, T. L. (2019). Precision in 3-dimensional surface imaging of the face: A handheld scanner comparison performed in a cadaveric model. *Aesthetic Surgery Journal, 39*(4), 36-44. doi:10.1093/asj/sjy242

Lai, Y.-S., Chen, W.-C., Huang, C.-H., Cheng, C.-K., Chan, K.-K., & Chang, T.-K. (2015). The effect of graft strength on knee laxity and graft in-situ forces after posterior cruciate ligament reconstruction. *PLoS One, 10*(5), e0127293-e0127293. doi:10.1371/journal.pone.0127293

Lam, C., Wong, C., Lam, E. T. P., Lo, Y. Y. C., & Huang, W. W. (2010). Population norm of Chinese (HK) SF-12 health survey-version 2 of Chinese adults in Hong Kong. *Hong Kong Practitioner, 32*, 77-86.

Lam, C. L. K., Tse, E. Y. Y., & Gandek, B. (2005). Is the Standard SF-12 Health Survey Valid and Equivalent for a Chinese Population? *Qual Life Res, 14*(2), 539-547. doi:10.1007/s11136-004-0704-3

Lam, E. T. P., Lam, C. L. K., Fong, D. Y. T., & Huang, W. W. (2013). Is the SF-12 version 2 Health Survey a valid and equivalent substitute for the SF-36 version 2 Health Survey for the Chinese? *J Eval Clin Pract, 19*(1), 200-208. doi:10.1111/j.1365-2753.2011.01800.x

Lane, L. B., Boretz, R. S., & Stuchin, S. A. (2001). Treatment of de Quervain's disease: Role of conservative management. *Journal of Hand Surgery-British And European Volume, 26*(3), 258-260. doi:10.1054/jhsb.2001.0568

Larson, C. O. (2002). Use of the SF-12 Instrument for Measuring the Health of Homeless Persons. *Health Serv Res, 37*(3), 733-750. doi:10.1111/1475-6773.00046

Lin, H.-T., Kuo, L.-C., Liu, H.-Y., Wu, W.-L., & Su, F.-C. (2010). The three-dimensional analysis of three thumb joints coordination in activities of daily

living. *Clinical Biomechanics, 26*(4), 371-376. doi:10.1016/j.clinbiomech.2010.11.009

Liu, G. R., & Quek, S. S. (2013). *The finite element method a practical course* (2nd ed.). Oxford: Butterworth-Heinemann.

Liu, Y., Wang, L., Di, Y., Liu, J., & Zhou, H. (2013). The effects of clothing thermal resistance and operative temperature on human skin temperature. *Journal of Thermal Biology, 38*(5), 233-239. doi:10.1016/j.jtherbio.2013.03.001

Lusardi, M. M., Jorge, M., & Nielsen, C. C. (2012). *Orthotics & prosthetics in rehabilitation* (3rd ed.). St. Louis, Mo.: Elsevier Saunders.

Magee, D. J. (2014). *Orthopedic physical assessment* (6th ed.). St. Louis, Missouri: Elsevier Saunders.

Mahle, A., & Ward, A. (2018). *Adult physical conditions: Intervention strategies for occupational therapy assistants* (1st ed.). Philadelphia: F. A. Davis Company.

Mallick, S. K., Jha, D. K., Majumdar, A., & Mahapatra, S. (2018). A comparative study between splinting versus corticosteroid injection in de-quervain's disease. *International Journal of Orthopaedics Sciences, 4*(3.1), 22-26. doi:10.22271/ortho.2018.v4.i3a.05

Mardani-Kivi, M. M. D., Karimi Mobarakeh, M. M. D., Bahrami, F. M. D., Hashemi-Motlagh, K. M. D., Saheb-Ekhtiari, K. M. D., & Akhoondzadeh, N. M. D. (2014). Corticosteroid injection with or without thumb spica cast for de Quervain tenosynovitis. *Journal of Hand Surgery-American Volume, 39*(1), 37-41. doi:10.1016/j.jhsa.2013.10.013

Marketsandmarkets. (2013). *3D printing market (2013-2020) by technology, materials, application & geography*. Magarpatta, India: Marketsandmarkets.

Mars Med Supply (Producer). (2022). Mars Wellness New 8" universal wrist and thumb splint. Retrieved from https://marsmedsupply.com/new-8-universal-wrist-and-thumb-splint-universal-size/

Mathiowetz, V., Weber, K., Volland, G., & Kashman, N. (1984). Reliability and validity of grip and pinch strength evaluations. *Journal of Hand Surgery-American Volume, 9*(2), 222-226. doi:10.1016/S0363-5023(84)80146-X

McDermott, J. D., Ilyas, A. M., Nazarian, L. N., & Leinberry, C. F. (2012). Ultrasound-guided injections for de Quervain's tenosynovitis. *Clinical Orthopaedics and Related Research, 470*(7), 1925-1931. doi:10.1007/s11999-012-2369-5

McKee, P., & Morgan, L. (1998). *Orthotics in rehabilitation: Splinting the hand and body*. Philadelphia, PA: F.A. Davis.

Medex® (Producer). (2022). W05 – De Quervain's thumb splint. Retrieved from https://www.medexbrace.com/de-quervains-thumb-splint

Mehdinasab, S. A., & Alemohammad, S. A. (2010). Methylprednisolone acetate injection plus casting versus casting alone for the treatment of de Quervain's tenosynovitis. *Archives of Iranian Medicine, 13*(4), 270-274.

Mital, A. (2008). *Product development a structured approach to consumer product development, design, and manufacture*. Amsterdam: Elsevier.

Mueller (Producer). (2022). Adjust-To-Fit® Thumb stabilizer. Retrieved from https://www.muellersportsmed.com/b2c-us/en/Open-Catalog/By-Body-Part/Hand-Support-&-Thumb-Stabilizer-Braces/ADJUST-TO-FIT-THUMB-STABILIZER-OSFM/p/6237

Nemati, Z., Javanshir, M. A., Saeedi, H., Farmani, F., & Aghajani Fesharaki, S. (2017). The effect of new dynamic splint in pinch strength in de Quervain syndrome: A comparative study. *Disability and Rehabilitation: Assistive Technology, 12*(5), 457-461. doi:10.3109/17483107.2016.1139635

Newman, M. E. J., & Girvan, M. (2004). Finding and evaluating community structure in networks. *Physical Review E, 69*(2). doi:10.1103/PhysRevE.69.026113

Nisa, Z., Umer, B., & Hassan, T. (2016). Prevalence of de Quervain's syndrome among young mobile phone users. *Journal of Riphah College of Rehabilitation Sciences, 4*(1), 22-24.

Norkin, C. C., & White, D. J. (2016). *Measurement of joint motion: A guide to goniometry* (5th ed.). Philadelphia, PA: F A Davis.

Össur (Producer). (2022). Formfit® Thumb. Retrieved from https://www.ossur.com/en-ca/bracing-and-supports/upper-extremity/formfit-thumb

Pagonis, T., Ditsios, K., Toli, P., Givissis, P., & Christodoulou, A. (2011). Improved corticosteroid treatment of recalcitrant de Quervain tenosynovitis with a novel 4-point injection technique. *American Journal of Sports Medicine, 39*(2), 398-403. doi:10.1177/0363546510382858

Palastanga, N., Soames, R., & Palastanga, D. (2008). *Anatomy and human movement pocketbook*. Edinburgh: Churchill Livingstone.

Patel, K. R., Tadisina, K. K., & Gonzalez, M. H. (2013). De Quervain's disease. *Eplasty, 13*, 52.

Razbin, M., Jeddi, A. A. A., Semnani, D., & Ramzanpoor, M. (2020). A generalized method of measuring the Poisson's ratio of warp knitted fabrics under uniaxial loading based on image processing technique. *JOURNAL OF THE TEXTILE INSTITUTE*, 1-10. doi:10.1080/00405000.2020.1863568

Richie, I. C. A., & Briner, J. W. W. (2003). Corticosteroid injection for treatment of de Quervain's tenosynovitis: A pooled quantitative literature evaluation. *Journal of the American Board of Family Medicine, 16*(2), 102-106. doi:10.3122/jabfm.16.2.102

Rossi, C., Cellocco, P., Margaritondo, E., Bizzarri, F., & Costanzo, G. (2005). De Quervain disease in volleyball players. *American Journal of Sports Medicine, 33*(3), 424-427. doi:10.1177/0363546504268134

Rugarli, P. (2010). *Structural analysis with finite elements*. London: Thomas Telford.

Saghieh, S., Weinstein, S. L., & Hoballah, J. J. (2013). *Operative dictations in orthopedic surgery*. New York: Springer.

Satteson, E., & Tannan, S. C. (2020). De Quervain tenosynovitis. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK442005/

Sawaizumi, T., Nanno, M., & Ito, H. (2007). De Quervain's disease: Efficacy of intra-sheath triamcinolone injection. *International Orthopaedics, 31*(2), 265-268. doi:10.1007/s00264-006-0165-0

Schned, E. S. (1986). DeQuervain Tenosynovitis in Pregnant and Postpartum Women. *Obstetrics & Gynecology, 68*(3), 411-414. doi:10.1097/00006250-198609000-00025

Shurr, D. G., & Cook, T. M. (2002). *Prosthetics and orthotics* (2nd ed.). Upper Saddle River, N.J.: Prentice Hall.

Soh, S.-E., Morello, R., Ayton, D., Ahern, S., Scarborough, R., Zammit, C., . . . Zalcberg, J. (2021). Measurement properties of the 12-item Short Form Health Survey version 2 in Australians with lung cancer: a Rasch analysis. *Health and quality of life outcomes, 19*(1), 157-157. doi:10.1186/s12955-021-01794-w

Stahl, S., Vida, D., Meisner, C., Stahl, A. S., Schaller, H.-E., & Held, M. (2015). Work related etiology of de Quervain's tenosynovitis: A case-control study with prospectively collected data. *BMC Musculoskeletal Disorders, 16*(1), 126-126. doi:10.1186/s12891-015-0579-1

Ta, K. T., Eidelman, D., & Thomson, J. G. (1999). Patient satisfaction and outcomes of surgery for de Quervain's tenosynovitis. *Journal of Hand Surgery-American Volume, 24*(5), 1071-1077. doi:10.1053/jhsu.1999.1071

The Occupational Safety and Health Branch. (2017). *Occupational safety and health statistics bulletin*. Hong Kong: HKSAR Government Retrieved from https://www.labour.gov.hk/eng/osh/pdf/Bulletin2016.pdf

Turkay, R., Inci, E., Aydeniz, B., & Vural, M. (2017). Shear wave elastography findings of de Quervain tenosynovitis. *European Journal of Radiology, 95*, 192-196. doi:10.1016/j.ejrad.2017.08.011

Venes, D. (2013). *Taber's cyclopedic medical dictionary* (22nd ed.). Pennsylvania: F. A. Davis Company.

Walker-Bone, K., Palmer, K. T., Reading, I., Coggon, D., & Cooper, C. (2004). Prevalence and impact of musculoskeletal disorders of the upper limb in the general population. *Arthritis and Rheumatism, 51*(4), 642-651. doi:10.1002/art.20535

Ware, J., Kosinski, M., & Keller, S. (1995). *SF-12: How to Score the SF-12 Physical and Mental Health Summary Scales* (Second ed.). Boston, Massachusetts: The Health Institute, New England Medical Center.

Ware, J. E. (2002). *How to score version 2 of the SF-12 health survey (with a supplement documenting version 1)*. Lincoln, R.I. & Boston, Mass.: QualityMetric Inc. & New England Medical Center Hospital, Health Assessment Lab.

Ware, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-item short-form health survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care, 34*(3), 220-233. doi:10.1097/00005650-199603000-00003

Wheatley, B. B., Morrow, D. A., Odegard, G. M., Kaufman, K. R., & Haut Donahue, T. L. (2016). Skeletal muscle tensile strain dependence: Hyperviscoelastic

nonlinearity. *Journal of the Mechanical Behavior of Biomedical Materials, 53*, 445-454. doi:10.1016/j.jmbbm.2015.08.041

White, M. D., Bosio, C. M., Duplantis, B. N., & Nano, F. E. (2011). Human body temperature and new approaches to constructing temperature-sensitive bacterial vaccines. *Cellular and Molecular Life Sciences, 68*(18), 3019-3031. doi:10.1007/s00018-011-0734-2

Williams, N. (2014). DASH. *Occupational Medicine-Oxford, 64*(1), 67-68. doi:10.1093/occmed/kqt130

Wilton, J. (2014). *Hand splinting/orthotic intervention: Principles of design and fabrication*. Fremantle Western Australia: Vivid Publishing.

Wolf, J. M. M. D., Sturdivant, R. X. P., & Owens, B. D. M. D. (2009). Incidence of de Quervain's tenosynovitis in a young, active population. *Journal of Hand Surgery-American Volume, 34*(1), 112-115. doi:10.1016/j.jhsa.2008.08.020

Zingas, C., Failla, J. M., & Van Holsbeeck, M. (1998). Injection accuracy and clinical relief of de Quervain's tendinitis. *Journal of Hand Surgery-American Volume, 23*(1), 89-96. doi:10.1016/S0363-5023(98)80095-6