# ERGONOMIC DESIGN OF TEXTILE ORTHOSES FOR PATIENTS WITH HALLUX VALGUS

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# Ergonomic Design of Textile Orthoses for Patients with Hallux Valgus

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## Abstract

Hallux valgus, a common foot deformity affecting around 23% of adults, is characterized by the deviation of the first metatarsal ray, leading to subluxation and pain in the first metatarsophalangeal joint. Hallux valgus can cause a range of problems such as foot pain, swelling, blisters, decreased mobility, poor balance, and even walking disability. Hallux valgus can have a significant impact on the quality of life and self-esteem of patients. Severe cases sometimes require surgical intervention. In the United States, more than 200,000 people undergo hallux valgus surgery each year, but the recurrence rate after surgery is relatively high at around 16%.

A non-surgical approach to alleviating symptoms is the use of hallux valgus orthoses. However, current orthotic designs made of rigid, semi-rigid, or neoprene foam materials have several issues related to comfort, fit, and functionality. Their bulky and rigid design makes them difficult and uncomfortable to wear with shoes, leading to poor compliance and reduced treatment efficacy. Given the increasing prevalence of hallux valgus and its associated complications, there is an urgent need for improved orthotic design.

A systematic review and meta-analysis were conducted to evaluate the effectiveness of orthoses in treating hallux valgus. The study focused on interventional research that examined the design of hallux valgus orthoses and their outcomes. The results indicated that orthoses with toe separators were the most effective in reducing the hallux valgus angle (SMD: 0.50, 95% CI: 0.189 to 0.803) and relieving foot pain (SMD: 1.13, 95% CI: 0.319 to 1.887). They allow the foot to form the correct anatomical alignment.

Whereas pooled estimates of dynamic orthoses showed a small effect on hallux valgus angle reduction (SMD: 0.27, 95% CI: -0.211 to 0.751). Additionally, prefabricated full-length orthoses with arch support could significantly reduce plantar pressure by 16.8 kPa (SMD: 0.65, 95% CI: -0.090 to 1.354). Adequate arch support plays a role in restoring the proper alignment of the foot.

An experimental study was also conducted to investigate the direct effects of soft and semi-rigid hallux valgus orthoses on balance, plantar pressure, hallux valgus angle, and subjective sensation. The study involved ten female subjects with healthy feet and six with hallux valgus. The results demonstrated that wearing orthotics can reduce the hallux valgus angle in patients (semi-rigid orthosis: 2.5°, soft orthosis: 2.6°). However, the angle reduction with a semi-rigid orthosis is negatively correlated with pressure reduction of the forefoot during walking ($r = -0.889$, $p = 0.018$). The comparison between the two types of orthoses revealed that the orthosis made of soft and thin material was more effective in reducing the angle, providing greater comfort, and reducing plantar pressure on the hallux. These findings offer insights into the design of hallux valgus orthoses and provide practical guidance for selecting orthoses that balance performance and comfort.

The longitudinal arch of the foot is an intrinsic factor associated with the lateral deviation of the hallux. This study quantitatively examined the improvement of the first metatarsal and arch conditions through arch support. The study measured the footprints of seventy-six female subjects to investigate the effect of arch support on arch elevation and correction of hallux valgus pathology. The results showed that arch support significantly improved the curvature of the foot arch. Subjects with both hallux valgus and flatfoot had a 0.063 reduction in foot type index ($p = 0.013$). Whereas a slight hallux

angle reduction could be found (1.536°, $p = 0.086$). Among the arch parameters, arch breadth and foot type index ($r = 0.960$, $p < 0.001$) were identified as key indicators for characterizing foot shape and arch condition. The developed numerical model further shows that the use of arch support can effectively redistribute pressure and load from the forefoot to the midfoot region. Soft materials are found to be more effective at achieving optimal plantar pressure distribution, while hard materials are more effective at providing arch lift while standing. Wear trial results obtained from twenty-two female subjects showed that the soft silicone arch support provided better balance and significantly reduced plantar pressure in the forefoot ($p = 0.049$).

Given the paucity of studies on the design of hallux valgus orthoses, this study employed a scientific approach based on foot anthropometry and biomechanics. It utilized suitable textile materials, three-dimensional scanning and printing technologies to produce an in-shoe hallux valgus orthosis with the appropriate amount of corrective force, and improved fit and comfort. To optimize the design, a biomechanical model was created to simulate the effect on the mechanical properties of corrective bands made with materials of different hardness and structures. The results showed that more than 6 Newtons of force were required to reduce the hallux valgus angle from mild to normal. The results suggested the use of Shore A 30 silicone band with an auxetic structure.

A total of twenty-two females with mild to moderate hallux valgus and shoe sizes EU 37 to EU 39 were recruited to evaluate the immediate and short-term effects of the proposed orthosis on angle reduction, plantar pressure, balance, and subjective perception through wear trials. In a one-hour wear trial, the new orthotic design significantly corrected the hallux valgus angle (3.5°, $p < 0.001$), reduced plantar

pressure in the lateral toe region ($p = 0.026$), and had a positive effect on comfort. After fourteen days of wear, the hallux valgus angle was reduced to 5.47° ($p < 0.001$), which was greater than the reduction observed in the one-hour trial. This suggests that the duration of orthosis wear may influence the effect of hallux valgus angle reduction. These results provide valuable information for designing ergonomic hallux valgus orthoses.

## Publications arising from the thesis

### Journal Papers

**Kwan, M. Y.**, Yick, K. L., Yip, J., & Tse, C. Y. (2021). Hallux valgus orthosis characteristics and effectiveness: a systematic review with meta-analysis. *BMJ open, 11*(8), e047273. https://doi.org/10.1136/bmjopen-2020-047273

**Kwan, M. Y**., Yick, K. L., Yip, J., & Tse, C. Y. (2021). The Immediate Effects of Hallux Valgus Orthoses: A Comparison of Orthosis Designs. *Gait & Posture., 90,* 283–288. https://doi.org/10.1016/j.gaitpost.2021.09.174

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### Conference Papers

**Kwan, M.**, Yick, K., Yip, J., Tse, C. (2022). Intervention of arch support: A quantitative study. In: Ravindra S. Goonetilleke and Shuping Xiong (eds) Physical Ergonomics and Human Factors. *AHFE (2022) International Conference*. AHFE Open Access, vol 63. AHFE International, USA. http://doi.org/10.54941/ahfe1002593 **[AHFE 2022 Best Student Paper]**

**Kwan, M.**, Yick, K., Yip, J., Tse, C. (2023). Ergonomic Design of Hallux Valgus Orthosis Developed Using 3D Scanning And 3D Printing. *PRSC 2023*, 8-9 May 2023, Hong Kong. **[PRSC 2023 Best Presentation Award]**

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**List of abbreviations**

| | |
|---|---|
| ANOVA | One-way analysis of variance |
| AOFAS | American Orthopedic Foot and Ankle Score |
| CIs | Confidence intervals |
| COP | Center of pressure |
| COPx | Center of pressure in the medial-lateral direction |
| COPy | Center of pressure in the anterior-posterior direction |
| EAI | Epidemiological Appraisal Instrument |
| FAOS | Foot and Ankle Outcome Score |
| FEA | Finite element analysis |
| FEM | Finite element model |
| GRF | Ground reaction forces |
| HV | Hallux valgus |
| HVA | Hallux valgus angle |
| 3D | Three-dimensional |
| 2D | Two-dimensional |
| BMI | Body mass index |

| | |
|---|---|
| ICC | Interclass correlation |
| IMA | First intermetatarsal angle |
| MTP1 | First metatarsal |
| MTPJ1 | First metatarsophalangeal joint |
| PLA | Polylactic acid |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analysis |
| rANOVA | Repeated-measures analysis of variance |
| ROM | Range of motion |
| SDs | Standard deviations |
| SMDs | Standardized mean differences |
| VAS | Visual Analogue Scale |
| WVT | Water vapor transmission |

# Chapter 1 Introduction

## 1.1 Background

Hallux valgus (HV) or bunions are the progressive deformity of the hallux. It is characterized by the deviation of the first metatarsal ray, which eventually leads to subluxation and pain of the first metatarsophalangeal joint (MTPJ1) (Fournier et al., 2019). HV can cause foot pain, swelling, blisters, poor balance, and even walking disability which will seriously affect the daily life of patients. Coughlin and Jones (2007) found that there is a significant incidence of metatarsalgia in 48% of the HV patients in their study. HV is one of the most common foot complaints received by foot specialists, affecting nearly one in every four adults (Wong et al., 2020), and on average, 23% of adults between the ages of 18 and 65 (Vanore et al., 2003; Nix et al., 2010). Patients with severe HV often require surgical intervention, but the recurrence rate is as high as 16% (Caminear et al., 2012). Surgical operations such as osteotomies (surgery on bone or removal of bone) reduce the subsequent mobility of the hallux, and the impact on athletes and dancers can be devastating. Complications associated with the surgical correction of HV may also occur, such as nerve damage. While HV orthoses can be used as a low-risk non-surgical alternative to prevent deterioration of the foot, however, its efficacy remains controversial. There are few scientific studies that point to the ability of orthoses for HV to provide consistent levels of corrective forces and amount of pressure distribution. There is also inherent ambiguity because the hallux and foot are both complex structures, and there are corresponding changes during locomotion from changes in body weight and balance. Also, the bulky design and rigid fabrication of current orthoses for HV make them difficult and uncomfortable to wear in shoes,

thus resulting in poor compliance. Therefore, there is an urgent need to improve orthosis designs for HV. This issue is addressed in this study. A scientific approach based on foot anthropometry and biomechanics will be developed for an optimally fitting in-shoe orthosis for HV with suitable textile materials that provide appropriate corrective forces, wear comfort, and patient satisfaction, and can be used in all sorts of daily activities.

### 1.2 Problem statement

Current HV orthoses, which are less invasive than surgery, are generally made of rigid, semi-rigid and/or neoprene foams. However, there are various problems associated with the comfort, fit and functionality of the current HV braces available in the market. These are listed as follows.

1) Poor in-shoe fit of current HV orthoses

   HV orthoses are available in many designs and suitable for many end-uses. Rigid and stiff materials generally align the foot by exerting corrective forces onto designated regions, whilst soft and flexible materials offer comfort during wear and protect the soft tissues from stress and alleviate pain. They may come in various lengths and be made of different materials, and they may or may not include a toe separator. Unfortunately, most orthotic products can only be worn at night due to their bulky and stiff design and cannot be worn in shoes. The level of patient compliance with the continuous use of HV braces has been unsatisfactory. Bulky orthoses may induce excessive dorsal pressure on the toe, which could increase irritation and pain to the dorsomedial cutaneous nerves. To obtain the required amount of corrective forces, rigid materials are commonly used, but most rigid

orthoses are uncomfortable when worn in hot and humid climates, which contribute to overheating and even severe itchiness. Moreover, the human foot has a complex form with many variations. An in-shoe HV brace that has an anatomically engineered design and good fit to accommodate the complex features of a deformed foot remains elusive. Human body dynamics significantly impact body measurements as foot measurement changes with movement would inevitably affect the in-shoe fit. Foot measurements taken from a static quiet standing posture may not provide accurate foot anthropometric data for dynamic postures, particularly at the metatarsophalangeal joints.

Yet few investigations have been carried out on the requirements and foot anthropometry of HV patients when designing footwear and HV orthoses for them. To enhance treatment compliance, consideration should be given to the fit and design of current HV orthoses. Precise three-dimensional (3D) foot scanning can be incorporated as part of the research design of HV orthoses to obtain a good understanding of the needs and foot morphology of HV patients. Foot dimensions and features can be extracted efficiently and safely.

2) Adequate functionality of current HV orthoses

The design of HV orthoses is multifactorial, however, previous related studies have merely focused on evaluating their effectiveness. There has been very little work that systematically analyses the biomechanical parameters for the design of HV orthoses. The effects of different orthosis design features and material properties on functionality have not been fully reported in the field.

To date, the clinical choice is subjective and usually a compromise between comfort

and functional performance. Therefore, in this study, the biomechanical principle behind HV orthoses will be systematically investigated. The impact of design features and fabrication materials regarding the absorption of external forces and reduction of deformity by inducing internal corrective forces during natural movement will be analysed.

### 1.3 Aims and objectives

The specific research objectives of the proposed project are as follows:

1. To establish a thorough scientific basis for understanding the prevalence, pathogenesis, and diagnosis of HV, and related current therapeutic practices.
2. To examine the biomechanical behavior of feet induced by various orthosis designs on the basis of gait and plantar pressure analyses, and to investigate the features and material properties of the orthosis in relation to angle correction, thus improving the orthosis designs.
3. To formulate a biomechanical model that simulates the corrective forces in relation to the mechanical and stress-strain properties of the fabrication materials, geometry of the anatomic sites and orthosis designs.
4. To design and develop an optimally fitting in-shoe orthosis for HV based on anthropometry, biomechanics, additive manufacturing technologies and textile science analyses.
5. To undertake laboratory wear trials that will validate the analysis of the finite element model (FEM) and evaluate whether the intended objectives of the orthosis can control the progression of HV and determine the effectiveness and

practical use of the orthosis.

### 1.4 Significance of the study

HV is a common foot deformity that can seriously affect the quality of life of patients. Each year, more than 200,000 patients undergo HV surgery in the United States (American College of Foot and Ankle Surgeons, 2018), placing a burden on healthcare resource utilization. The use of an orthosis is a common non-surgical way to alleviate the symptoms of HV. However, scientific knowledge of the corrective forces and pressure distribution associated with such orthoses during human locomotion is greatly lacking. Thus, a scientific approach based on foot anthropometry and biomechanics will be used in this study to develop an in-shoe orthosis for HV with suitable textile materials that provide the appropriate amount of corrective forces and optimize the fit and comfort of the orthosis.

Current HV orthoses are generally made of rigid, semi-rigid and/or neoprene foams. Due to their bulky and stiff design, few patients fully comply with their use as a treatment method, which adversely affects treatment efficacy. Doty et al. (2015) also suggested that a large orthosis may be uncomfortable to wear because it increases the dorsal pressure at the toe, which could increase irritation and cause pain to the dorsomedial cutaneous nerves. However, with the increasing prevalence of HV, the high risk of progressive deformity and the sequelae of this condition, there is an urgent need to enhance orthotic designs for patients with HV.

Given the limited research on the design of HV orthoses, a scientific approach

based on foot anthropometry and biomechanics will be used here to develop an in-shoe orthosis for HV based on suitable textile materials, 3D scanning and 3D printing technologies to provide the proper amount of corrective forces and optimize the fit and comfort of the orthosis. Biomechanical models will also be designed to simulate the mechanical and stress-strain properties of the applied materials to optimize the HV orthosis design. The FEM is used to evaluate the biomechanical foot-orthotic interaction, and the parametric effects of different orthotic designs and material properties on comfort and corrective forces can be studied. The results of this study will provide valuable information for designing ergonomic HV orthoses.

### 1.5 Outline of report

This thesis consists of nine chapters. Chapter 1 introduces the study, including its background, concepts, and objectives. Chapter 2 is a literature review focusing on HV, including its formation, available treatments and orthoses, and interface pressure between orthoses and the foot. Chapter 3 explores the use of foot orthoses as a treatment for HV deformities, highlighting the positive correlation between reduction in hallux valgus angle (HVA) and pain levels with orthoses that include toe separators. Additionally, the importance of using full-length orthoses or dynamic orthoses to maintain the anatomy of the hallux is emphasized. Chapter 4 examines the performance of different orthotic materials, finding that while semi-rigid orthoses may cause discomfort and increase center of pressure (COP), soft orthotics provide greater HVA correction, improved comfort, and reduced plantar pressure on the hallux. The recommendation for future orthosis design is to utilize soft, thin, and smooth flexible

materials. Chapter 5 presents the results of an arch support intervention study, demonstrating the significant improvement of foot arch with the use of hard arch support. The chapter also explores alternative methods for predicting foot type index, with arch breadth being identified as the most suitable measurement. Chapter 6 analyzes the effectiveness of arch support by using a numerical model, predicting plantar pressure distribution during standing. Soft materials are found to be more effective in achieving optimal pressure distribution, while hard materials provide better arch lift. The study also reveals that wearing soft arch supports leads to improved balance and lower plantar pressure in HV patients. Chapter 7 discusses the key design elements and fabrication processes involved in developing ergonomic HV orthoses. Design criteria, 3D scanning, 3D printing technologies, and pressure distribution comparisons with commercially available orthoses are explored, providing valuable insights into HV orthosis development. Numerical models were applied to the design of the orthosis. Chapter 8 evaluates the immediate and short-term effects of a new orthosis through wear trials, assessing angle reduction, plantar pressure, balance, and subjective ratings. The chapter also demonstrates a novel method for analyzing dynamic HVA during walking. Participant feedback contributes to improving orthosis design and effectiveness. Chapter 9 concludes the thesis and provides recommendations for future research in the field.

# Chapter 2 Literature Review

## 2.1 Introduction

Nix et al. (2010) found that among the 496,957 participants in 78 studies on HV, approximately 23% of the adults and 35.7% of the elderly have HV, and Crevoisier et al. (2016) found that females are more prone to the condition. In Europe, the male to female ratio of patients with HV is 1:8, while data from North District Hospital of Hong Kong show that the male to female ratio of HV patients is 3:7 (Kwong, 2016). This study focuses the effects of HV on female population to provide a more accurate representation of the typical HV patient population. There are different causes of HV, Wong et al. (2020) proposed that the intrinsic cause of HV development is ligamentous laxity. HV is commonly associated with foot pain, which inhibits the mobility and physical activity level of those who suffer from the deformity (Fournier et al., 2019; Nix & Smith et al., 2012). Bryant et al. (2000) found that the peak pressure in the lesser toes of the participants in their study who suffer from HV is significantly increased.

Foot orthoses have emerged as a significant non-surgical approach in the management of foot deformities and the alleviation of foot pain, as noted by Hawke et al. (2008). Charrette (2009) proposed that HV orthoses can provide biomechanical support by reducing pressure on the first metatarsal (MTP1), thus preventing further deterioration of mobility. Additionally, Moulodi et al. (2019) found that foot orthoses can correct the HVA, while simultaneously reducing plantar pressure, relieving associated pain, and providing a greater range of motion (ROM).

There is a wide variety of HV orthoses available, and they can be found with different design features and materials. However, there is currently a lack of comprehensive

research on the effects of HV orthosis design. The pathologies of HV may also affect the design of the orthoses. To optimally design a HV orthosis, a thorough scientific basis for understanding the prevalence, pathogenesis and related therapeutic practices is necessary.

## 2.2 Pathology of HV

HV is a highly complex forefoot deformity (Baščarević et al., 2011). The condition can be found almost exclusively in shoe-wearing societies (Nguyen et al., 2010). It is also prevalent. Coughlin and Thompson (1995) estimated that more than 200,000 patients have HV surgery in the United States each year, which would increase to an estimated 300,000 patients by 2013. There is a higher prevalence of HV in females; in fact, data from the North District Hospital of Hong Kong showed that the ratio of males to females with HV is 3:7 (Kwong, 2016), and in Europe, the male to female ratio is 1:8 (Crevoisier et al., 2016).

There are several patho-mechanical factors that are responsible for HV (Frowen et al., 2010; Perera et al., 2011; Uchiyama et al., 2005). Restricting footwear and foot type which is hereditary are the two main contributors to the initiation of HV (Coughlin & Jones, 2007; Easley & Trnka, 2007; Perera et al., 2011; Piqué-Vidal et al., 2007). Piqué-Vidal et al. (2007) found that ill-fitting shoes affect 24% of the adult patients in their study of 350 participants. Women often wear shoes that crowd their toes such as high heels or shoes with a tight toe box (American College of Foot and Ankle Surgeons, 2018). These ill-fitting shoes shift the load to the medial side of the forefoot, cause overload of the distal forefoot, and produce valgus

moments (Corrigan et al., 1993). In addition, tibialis posterior dysfunction which causes foot pronation, and a lower longitudinal arch is an intrinsic factor closely related to HV formation. The intrinsic and extrinsic risks of HV are summarized as follows.

***Intrinsic risk factor 1. Flatfoot and rearfoot pronation***

Flatfoot and rearfoot pronation are both related to the development of HV. As Richie (2021a) explained, in flatfoot, the foot is pronated and the arch collapses under the weight of the body. It may lead to change in the alignment of the first ray axis, whilst the pronation of the rearfoot may induce excessive loading of the forefoot and followed by supination. Literature also indicated that the pronation of flatfoot and rearfoot has been associated with lateral drift of the hallux or medial deviation of the MTP1 (Richie, 2021a).

***Intrinsic risk factor 2. Muscle imbalance***

The weakness of the abductor hallucis muscle in the foot is also an intrinsic risk factor for HV which allows lateral drift of the hallux. Studies have shown decreased bioelectric activity of the abductor hallucis in HV patients compared to healthy controls (Incel et al., 2003; Mortka et al., 2018). The abductor hallucis muscle of HV patients also has reduced dorsoplantar thickness, medial-lateral width, and cross-sectional area (Stewart et al., 2013). The muscle changes are consistent among those with mild, moderate, and severe HV thus suggesting that the abductor hallucis might have been

abnormal before the deformity developed.

### *Intrinsic risk factor 3. Heredity*

Heredity is another risk factor for HV (Munteanu et al., 2017). Piqué-Vidal et al. (2007) found that 90% of the HV patients in their study have a family history of the disease. Nix et al. (2010) found that the pooled estimate of HV incidence in female is 30% and is 13% in male, revealing a twofold prevalence of female having HV. As female have two X chromosomes, while male have only one, the traits governed by genes thus show sex-related inheritance. Monteanu et al. (2017) pointed out that genetic factors influence the development of HV. A high proportion of the genetic determinants of HV is gender-specific (Hsu et al., 2015). Ligament laxity has also been determined to be more common in HV patients and the female population (Ferrari et al., 2004).

### *Extrinsic risk factor 1. Improper fitted footwear*

The most common extrinsic factor that causes HV is improper fitted footwear. Lateral drift of the hallux can be induced by wearing constrictive footwear (Richie, 2021a)**.** A number of studies have also shown that there is a clear relationship between HV and wearing shoes with elevated heels and/or constrictive toe boxes (Dawson et al., 2002; Frey, 2000; Nix et al., 2012). Not only are improper fitted shoes a contributor to HV but wearing shoes itself can also cause HV. For example, Shine (1965) found that the risk of developing HV increases almost linearly with each year of wearing shoes. HV deformity was found in only 2% of the unshod population, whereas among those who

had worn shoes for over 60 years, the prevalence was significantly higher, with 16% among men and 48% among women.

***Extrinsic risk factor 2. Prolonged periods of athletic training***

Prolonged periods of athletic training along with the use of improper footwear are the main contributors to HV. Previous studies discovered that 9.3% of Muay Thai kickboxers suffer from HV (Hunt et al., 2010; Vaseenon, et al., 2015; Schöffl & Küpper., 2013). Additionally, tight climbing shoes exert high pressure on the forefoot, affecting 53% of long-term high-level climbers (Killian et al., 1998). Another study focusing on the prevalence of HV among dancers discovered that former ballet dancers aged between 50 and 70 exhibit a significantly higher rate of HV (73.7%) compared to the controls (2.6%) within the same age group (Kitaoka et al., 2002). However, surgical operation may negatively affect the subsequent mobility of the hallux, which is especially detrimental to athletes. Consequently, studies (Hunt et al., 2010) have emphasized the importance of employing conservative treatment for HV in athletes. Therefore, HV orthoses have become a viable and popular option for correcting the deformity and relieving foot pain (du Plessis et al., 2010; Farzadi et al., 2015).

## 2.3 Formation of HV

The formation of HV is shown in Figure 2.1. As explained by Richie (2021a), the lateral rotation of the hallux and the dorsiflexion and inversion of MTP1 firstly induce tensile loads on the collateral and sesame ligaments. The connection between the ligaments of

MTP1 declines, leading to a weakening and loss of stability of the MTPJ1. Second, the progressive transverse plane adduction of the first ray occurs, which leads to attenuation of the MTPJ1. The flexor hallucis longus muscle continues to produce medial force in MTP1, and the magnitude of the medial force is proportional to the severity of HVA. Then, the articular cartilage of MTP1 erodes and forms medial protrusion of bone overgrowth. With the development of HV, the deep transverse metatarsal ligament is not directly attached to MTP1, which leads to hypermobility of the first ray. Muscle imbalance can also propagate HV malformations. The lateral and dorsal displacement of the sesamoids relative to the MTP1 is described as the "pronation deformity" of the MTP1 in the HV malformation.

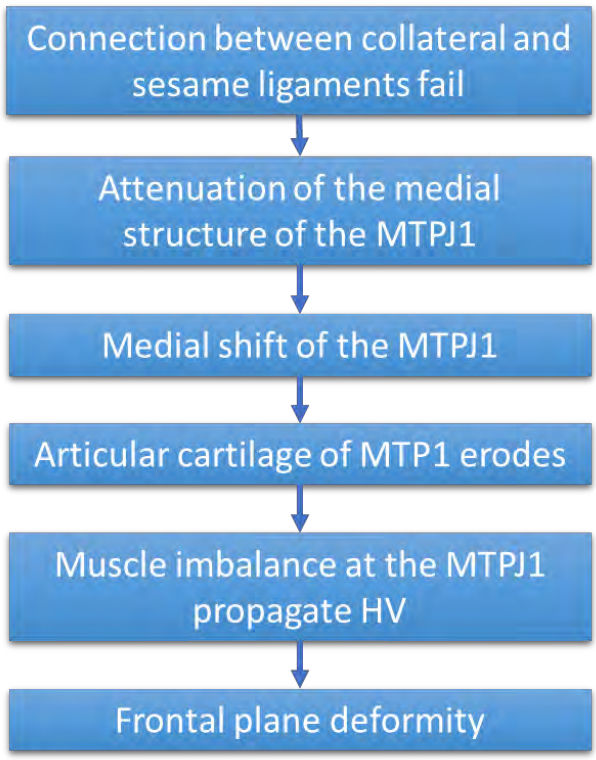



Figure 2.1: Development of HV

## 2.4 Diagnosis of HV

Hypermobility of the first ray is commonly found in HV patients. Investigators who have reported pronation deformity in HV patients are describing an eversion deformity of either the MTP1, the sesamoid complex, or both (Kim et al., 2015; Dayton et al., 2015**)**. HV is commonly evaluated through a radiographic examination. The HVA is used as an indicator for objectively measuring the level of deformity, which is the angle between the axis of the MTP1 and that of the proximal phalanx of the hallux (Hardy & Clapham, 1951). In the weight-bearing anterior/posterior view, HV is diagnosed when the HVA exceeds 15 degrees (Richie, 2021a)**.** An analysis by Piqué-Vidal and Vila (2009) indicated that HVA and the first intermetatarsal angle (IMA) are angle measurements that need to be taken into consideration to categorize the severity of HV (Table 2.1 and Figure 2.2).

While radiographic examination is commonly used to diagnose HV, footprint analysis by using podographs is also a viable, cost-effective, and readily available option (Queen et al., 2007). These have also been widely used in footwear design. Lo (2014) measured the HVA by both radiography and footprint and found that there is a significant correlation between their measured HVA ($p < 0.001$). Moreover, the interclass correlation (ICC) is higher than 90%, concluded that footprint is a reliable method for measuring the HVA.

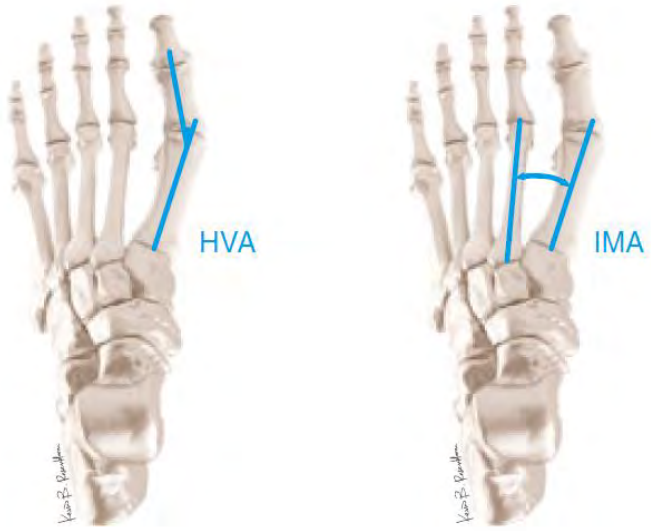



Figure 2.2: Measurements of HVA and IMA to determine HV severity (Richie, 2021a)

Table 2.1: Categorization of HV severity

| Level of Severity | HVA | IMA |
|---|---|---|
| **Normal** | <15° | <9° |
| **Mild** | 15-20° | 9-11° |
| **Moderate** | 21-39° | 12-17° |
| **Severe** | ≥40° | ≥18° |

## 2.5 Adverse effects of HV

HV has different adverse effects on the quality of life (Karabicak et al., 2015). Pain caused by friction from shoes is the most common complaint from patients with HV, which can inhibit exercise level (Abhishek et al., 2010; Cho et al., 2009; Menz et al., 2010; Roddy et al., 2008). The medial translation of the MTP1 results in a prominent metatarsal head. The metatarsal head rubs against the shoe while walking, thus creating feelings of pain (Dayton, 2017; Wülker & Mittag, 2012). Moreover, HV has been known to increase plantar pressure which results in feet pain, discomfort and swelling (Menz & Morris, 2005). This deformity can also result in functional disabilities, including poor balance (Menz & Lord, 2001), unstable gait pattern (Menz & Lord, 2005) and an increased risk of falls in older adults (Tinetti et al., 1988). These findings highlight the significant and negative effects of HV on gait patterns, leading to instability and an increased risk of falls, especially among the older adults. It is important to note that falls are the leading cause of accidental deaths in this population (Fuller, 2000). Menz et al. (2011) reported that as the severity of HV increases, the quality of life in terms of health generally declines. The serious sequelae of HV means that there is an urgent need to develop an effective yet easy to wear orthosis for HV.

## 2.6 Treatment options

Treatment options for HV include surgical and nonsurgical. The most common type of HV surgery is osteotomy, in which the joint of the hallux is cut and realigned (Gallentine et al., 2007). However, surgery is often risky. Complications associated with the surgical correction of HV include recurrence of deformity, avascular

necrosis, and malunion of metatarsal osteotomies (Lehman, 2003; Sammarco & Idusuyi, 2001). Surgery, while effective in some cases, can reduce the mobility of the hallux, which can have devastating consequences for athletes (Fournier et al., 2019). Therefore, research findings suggest that a conservative approach should be adopted among athletes. Non-surgical conservative treatments, such as the use of foot orthoses, have become a feasible and popular choice for HV patients to correct the deformity and alleviate foot pain (du Plessis et al., 2010; Farzadi et al., 2015). Compared to surgery, conservative treatments are lower in risk. HV orthoses can be prescribed to conform to the foot shape in all respects for the correction of the intrinsic and/or extrinsic deformity and relief of foot pain. HV orthoses act as biomechanical supports, reducing stress on the MTPJ1 to prevent further degeneration (Charrette, 2009).

HV orthoses are available in a diverse range of designs and materials, offering both ready-made and custom-made options. Ready-made or prefabricated orthoses are made by using standard patterns (Jahss, 1991). They can be made of soft or semi-rigid materials, such as polyamide and polyurethane gel. Custom-made orthoses are formed by using footprints or foot molds and manufactured in accordance with the specifications of clinicians (Farzadi et al., 2015). Kim and Won (2019) found that orthoses made of soft material, such as elastic band, can realign the foot as effectively as semi-rigid material, and offer higher wear comfort. In terms of characteristics, HV orthoses can be divided into static or dynamic. Most static daily use HV orthoses are equipped with a toe separator and/or insoles of different lengths, while most daily dynamic HV orthoses correct the HVA by pulling out the hallux. They provide cushioning and support and allow a flexible range of motion.

Although many factors are involved in the design of HV orthoses, previous studies on HV orthoses have merely focused on their effectiveness. There are few studies systematically analyzing the biomechanical parameters of HV orthosis design. The effects of the design features and material properties on foot support and control performance have not been fully reported in the field. A systematic review and meta-analysis therefore need to be carried out in a timely manner to determine the strength of the existing evidence on the outcomes of this conservative treatment which practitioners can gain insights into how design decisions affect the performance of HV orthoses. This research work is a systematic study that investigates the relationship between the characteristics and effectiveness of these orthoses, and quantitatively synthesizes the results based on the best available evidence. The results serve as a valuable reference for clinical decision-making and offer insights into potential advancements in orthotic design, with the aim of enhancing treatment effects.

## 2.7 Current designs of HV orthoses

HV orthoses are available in a variety of designs and materials. They can be with or without toe separators. They also come in different lengths and can be made from different materials. Commercial examples listed in Figure 2.3 include orthoses made of polyester, nylon, and medical-grade materials, some of which contain gel or foam padding to relieve pressure and are adjustable through Velcro straps or elastic bands. Some have aluminum stay and splints, and some have flexible hinge to allow a greater range of motion for the hallux. Studies have shown that dynamic and static orthoses with toe separator can effectively reduce the HVA in HV patients by 2.1° to 5.79°

(Chadchavalpanichaya et al., 2018; Moulodi et al., 2019). In addition to HVA correction, Tehraninasr et al. (2008) has demonstrated that an orthosis with toe separator can significantly alleviate pain levels. The dynamic orthosis in Moulodi et al. (2019) also showed positive effects on pain relief and significant improvements in ROM. Moreover, Doty et al. (2015) pointed out that the use of full-length or 3/4-length orthoses has been found to significantly reduce plantar pressure, with values of 11.82 kPa and 10.37 kPa, respectively.

According to Glasoe et al. (2010), individuals with HV commonly exhibit excessive arch laxity and extreme pronation of the medial arch joint. In the treatment of early-stage HV, it is recommended to utilize orthoses or arch supports instead of pursuing surgical correction. As a result, foot orthoses with medial arch support are frequently employed by HV patients to alleviate pain by reducing pressure on the forefoot. These orthoses play a role in transferring loads from the medial forefoot to the midfoot region (Chen et al., 2012; Norouzi et al., 2023; Yamamoto et al., 2016).

Furthermore, foot orthotics with medial arch supports contribute to reorienting the first metatarsal axis from a vertical to a transverse orientation. This realignment helps prevent hypermobility of the first ray and contributes to the improvement of hallux deviation. Studies have shown the effectiveness of such orthotics in achieving these outcomes (Landsman et al., 2009; Munuera et al., 2006).

Previous studies provide insights into the optimal design of HV orthoses. There is a consensus that dynamic or static orthoses with toe separators are effective in reducing HVA. On the other hand, full-length orthoses and orthoses with medial arch support can reduce the plantar pressure to prevent further degeneration of mobility.

Figure 2.3: Examples of current HV orthoses

## 2.8 Gait analysis after HV orthosis intervention

The gait cycle is a repetitive pattern of limb movement that involves the stance and the swing phases of each leg (Wheeless, 2012). Figure 2.4 shows that stance phase begins with a heel-strike and ends with a toe-off, while the swing phase starts with a toe-off and ends with a heel-strike. Gait analysis involves the assessment of the 3D kinematics, kinetics, and temporal parameters of gait, including cadence, step length and time, and speed (Karol & Jeans, 2011). Researchers have been able to quantify the movement of the lower limbs of patients, forces during gait, and plantar pressure through gait analyses. Karol and Jeans (2011) used Vicon analysis software to assess the gait outcomes of patients with idiopathic clubfoot and concluded that gait analysis is a valid measure of joint movement, joint power and plantar pressure which can be used to ascertain the effect of nonoperative treatments and the changes following surgical intervention. Chien, Lu and Liu (2013) investigated the effect of the heel base and heel height on body motion during high-heeled gait. Jafarnezhadgero et al. (2017) studied the effects of foot orthoses on the ankles, knees, and hip joints

during strides in children with flexible flat feet. Bishop, Hutchison, Uden, and Scharfbillig (2013) investigated the kinetic effects of both footwear and foot orthoses during running on subjects with pronated feet by using a 12-camera motion capture system and the ground reaction forces (GRF) were measured with two force platforms. They found that stability shoe can reduce the peak knee internal rotation throughout the stance phase of jogging. Although gait analysis is widely used, there has been little research focus on the gait pattern of those with HV. In this study, the HVA will be analyzed for its impact on gait and its relationship with the design features of an orthosis will be investigated. Understanding the gait kinematics associated with orthosis design can provide insight into improving the efficacy of the orthosis design.

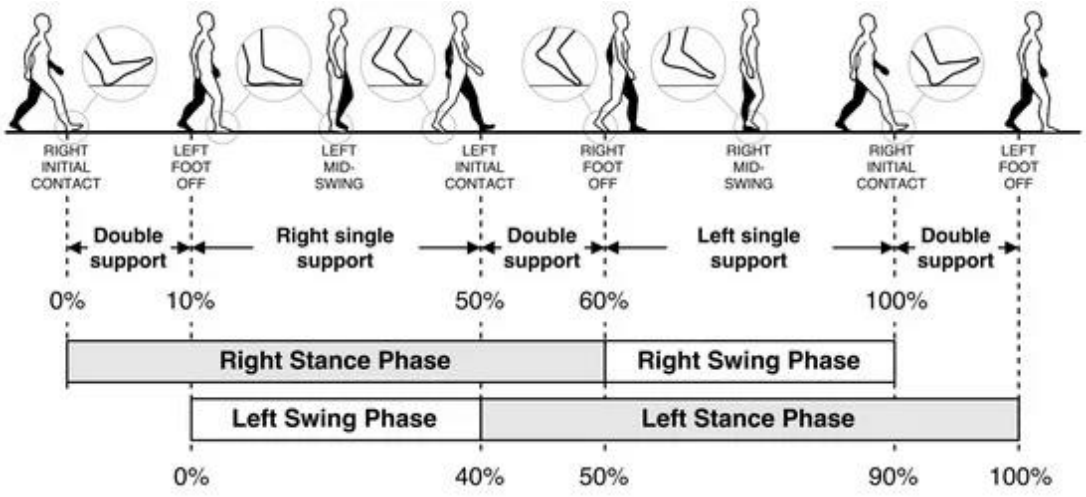



Figure 2.4: A gait cycle (Tunca et al., 2017)

## 2.9 Changes in plantar pressure with HV orthosis intervention

During the gait cycle, plantar pressure serves as an important measure of foot function. It has been observed that the hallux bears more than twice the load carried by all the other toes combined. Only the first and second metatarsals experience a higher load than the hallux (Mueller et al., 1996). Research has demonstrated that individuals with HV exhibit significantly higher peak pressure in the hallux region when walking barefoot, compared to those without HV. This increase in pressure is attributed to the deviation in the angle of the first ray, leading to foot pain and adaptive changes in gait characteristics (Gu et al., 2014; Martínez-Nova et al., 2010). Generalized ligament laxity has been identified as a contributing factor in the progression of HV, as it impairs the load-bearing capacity of the MTP1, leading to increased deforming forces and malalignment (Wong et al., 2020). Galica et al. (2013) found a shift of load away from the hallux to the lateral digits in HV patients. They showed intact pressure under the hallux, loss of pressure under the MTP1 and transfer of load to the central metatarsals during walking. Loss of weight bearing under the hallux with dysfunction of the windlass mechanism is one cause of this lateral shift. Higher forces exerted through the lateral digits of HV patients were also found in the Framingham foot study in Galica et al. (2013). They compared the plantar pressure of 1123 HV patients, 641 patients with HV and other foot disorders, and 3707 healthy controls. Subjects with HV exhibited notable findings in comparison to subjects without HV, including a higher peak pressure in the medial rearfoot region, a smaller COP excursion index, and a lower arch profile. The findings link HV to a pronated rearfoot alignment during gait. Furthermore, the subjects with HV demonstrated reduced loading of the hallux along with increased loading of the lesser digits.

The variations in the findings of plantar pressure studies of HV patients might be due to the compensated gait patterns cause by foot pain. More importantly, there are very few studies that have analyzed the effect of wearing an HV orthosis on plantar pressure, and its relationship with other functions of orthoses, such as angle correction. The Novel Pedar System is the most widely applied system for accurate measurements of pressure distribution between the foot and the shoe (Putti et al., 2007). In this study, 99 Pedar sensors will be placed under the orthosis to measure the plantar pressure distribution precisely and accurately after the subject donned the orthosis (Figure 2.5). The effects of different orthotic designs for HV on foot pressure and the corresponding distribution amongst the foot regions can thus be compared.

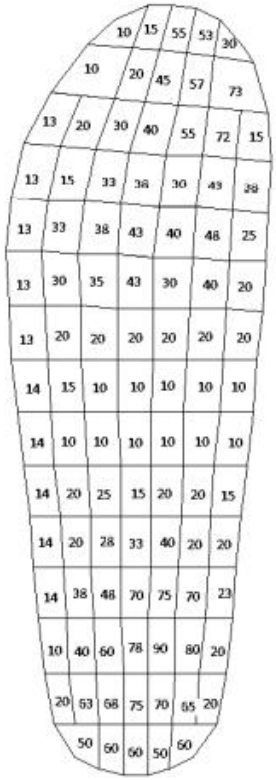



Figure 2.5: Pressure system with 99 sensors (Lo, 2014)

## 2.10 Finite element analysis of foot orthoses

Finite element analysis (FEA) is a numerical method employed to simulate and analyze various physical phenomena. The method allows the testing of many virtual designs and has been widely used in foot biomechanics research. Antunes et al. (2008) and Hsu et al. (2008) developed an anatomically detailed ankle model to conduct an FEA of the biomechanical behavior and support performance of the feet. FEM has been utilized to study the biomechanical behavior and performance of foot orthoses by incorporating the geometrical properties of both bony and soft tissue components (Cheung & Zhang, 2008; Zhang et al., 2007; Qian et al., 2010). Budhabhatti et al. (2007) carried out an FEA to predict the plantar pressure distribution underneath the first ray, surgical arthrodesis, and footwear intervention during the push-off phase of walking (Figure 2.6). Franciosa et al. (2013) examined the impacts of the geometry of the shoe sole and its material design on the comfort of the wearer through an FEA simulation. Zhang et al. (2020) developed a model to predict the stress between the foot and sock and pressure distribution with different sock materials. Additionally, FEM has been employed to investigate the relationship between pressure and displacement of socks (Dan et al., 2011). Luo et al. (2011) computed the stress, strain and strain energy density produced in the pedal tissues to design optimal insoles for the reduction of pedal tissue trauma and concluded that changing insole design and using different materials can significantly redistribute the stress/strain inside the heel pad as well as on the skin surface.

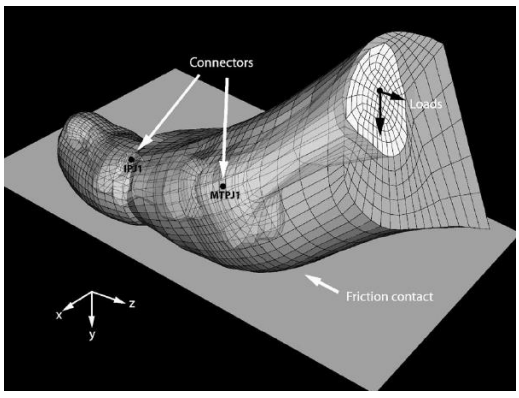
More recently, Wong et al. (2020) focused on the intrinsic risk factor of HV and evaluated the isolated influence of generalized ligament laxity on deterioration of HV with the use of FEA (Figure 2.7). They constructed a FEM of the foot of a patient with

HV and performed gait analysis simulating walking. The findings showed that generalized ligament laxity deteriorates HV. The validation was completed when a linear relationship was found between FE prediction and experimental measurement of the plantar pressure. FEA is also widely utilized in the design of functional wear, such as sailing apparel, tennis clothing, and climber pants (Bye & Hakala, 2005; Chae & Evenson, 2014; Jin & Black, 2012; Michaelson et al., 2018). To formulate the FEM, a complete outline and surface of the foot should be first aquired by using 3D scanning technology along with the relevant software program (Zhang et al., 2020; Lo, 2014). 3D scanner can accurately capture body shape (Kwan et al., 2021; Stewart et al., 2017; Wan et al., 2017; Yu et al., 2016). Li (2019) indicated that the 3D foot shape can be quickly and reproducibly captured by using various laser scanning systems and their applicable software programs within a few seconds. The 3D scanning method performed by using a full-color Artec Eva handheld 3D scanner (Artec 3D, Luxembourg) has proven to be reliable, accurate and repeatable (Seminati et al., 2017; Modabber et al., 2016; Verhulst et al., 2018). 3D resolution is up to 0.2 mm.

Although some studies have been conducted to evaluate foot dimensions and footwear design, to the best of my knowledge, the parametric effects of the orthotic geometry and material properties on corrective functions remain unaddressed. The relationship between angle correction and orthosis design has not been reported. Therefore, an ergonomic evaluation of the biomechanical behavior is required. As stated in Section 2.7, previous studies have shown that dynamic and static orthoses with a toe separator are effective in reducing the HVA. However, the use of a toe separator will enlarge the volume of the toe box, so when wearing shoes, the forefoot will be squeezed, thereby increasing the severity of the HV. Thin dynamic orthoses might be a better option for daily use. The goal of this study is to construct a thin dynamic textile orthosis that can

effectively reduce the HVA. With an FEA, it can be anticipated that the influence of different design factors, such as fabric properties and pulling force, on the angle correction of the hallux can be systematically simulated. Their relative interaction will also be examined.

The Oxford Foot Model as shown in Figure 2.8 is considered the most widely used biomechanical model in the clinical setting, focusing on foot pathology (Bishop et al., 2012; Deschamps et al., 2011; Kothari et al., 2016; Levinger et al., 2010; Reay et al., 2022). The description of the markers is shown in Table 2.2. The model can be used to study the complex dynamics of the foot, providing a comprehensive understanding of foot biomechanics. It contains a multi-segment representation of the foot. Each part is modeled as a rigid body articulated to simulate foot movement and interaction with the ground.

(a) 

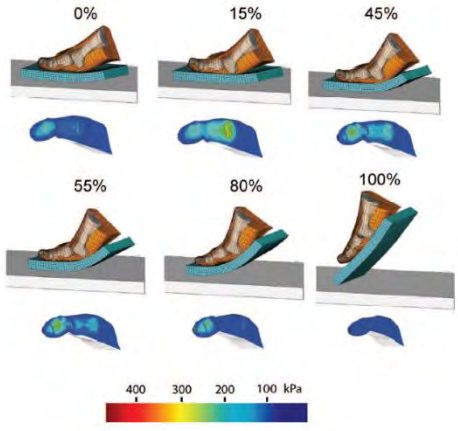
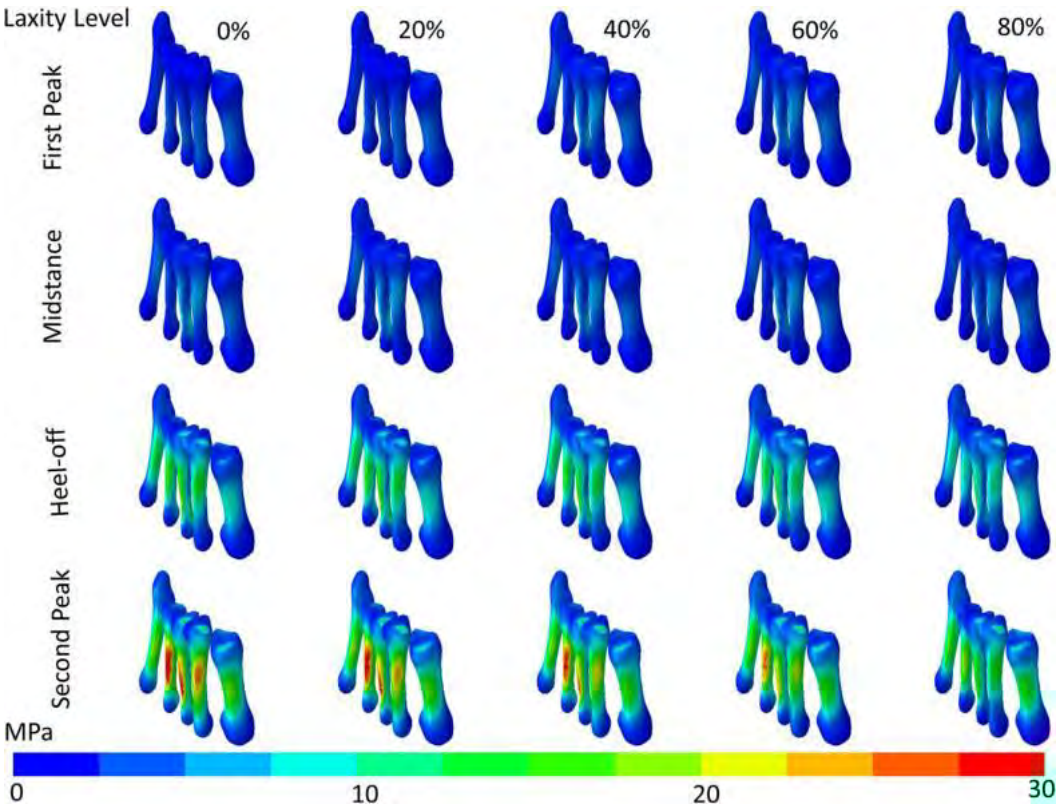
(b) 


Figure 2.6: (a) FEM of the first ray, and (b) late-stance simulation results for footwear intervention (Budhabhatti et al., 2007)

(a)




(b)

| Part | Material property | References |
|---|---|---|
| Bone | $E$ = 10 GPa, ν = 0.3 | Chen et al., 2003 |
| Encapsulated soft tissue | Hyperelastic (second-order polynomial strain energy potential equation, $C_{10}$ = 0.08556 $Nmm^{-2}$, $C_{01}$ = −0.05841 $Nmm^{-2}$, $C_{20}$ = 0.03900 $Nmm^{-2}$, $C_{11}$ = −0.02319 $Nmm^{-2}$, $C_{02}$ = 0.00851 $Nmm^{-2}$, $D_1$ = 3.65273 $mm^2N^{-1}$, $D_2$ = 0.0000 $mm^2N^{-1}$) | Lemmon et al., 1997 |
| Ground plate (deformable layer) | $E$ = 10,000 GPa, ν = 0.1 | |
| Ligament | $E$ = 260 MPa, ν = 0.4, Cx-A = 18.4 $mm^2$ | Siegler et al., 1988 |
| Plantar fascia | $k$ = 203.3 $Nmm^{-1}$ (1st column) $k$ = 232.5 $Nmm^{-1}$ (2–4th column) $k$ = 182.2 $Nmm^{-1}$ (5th column) | Kitaoka et al., 1994 |
| Skin | Hyperelastic (first-order Ogden model, μ = 0.122 MPa, α = 18), $T$ = 2.0 mm | Gu et al., 2010 |

*Cx-A: Cross-sectional area; E: Young's modulus; k: elastic stiffness; T: Thickness; v: Poisson's ratio.*

Figure 2.7: (a) Stress distribution of the metatarsal shafts at different laxity levels in different stances, and (b) material properties of different parts of foot (Wong et al., 2020)

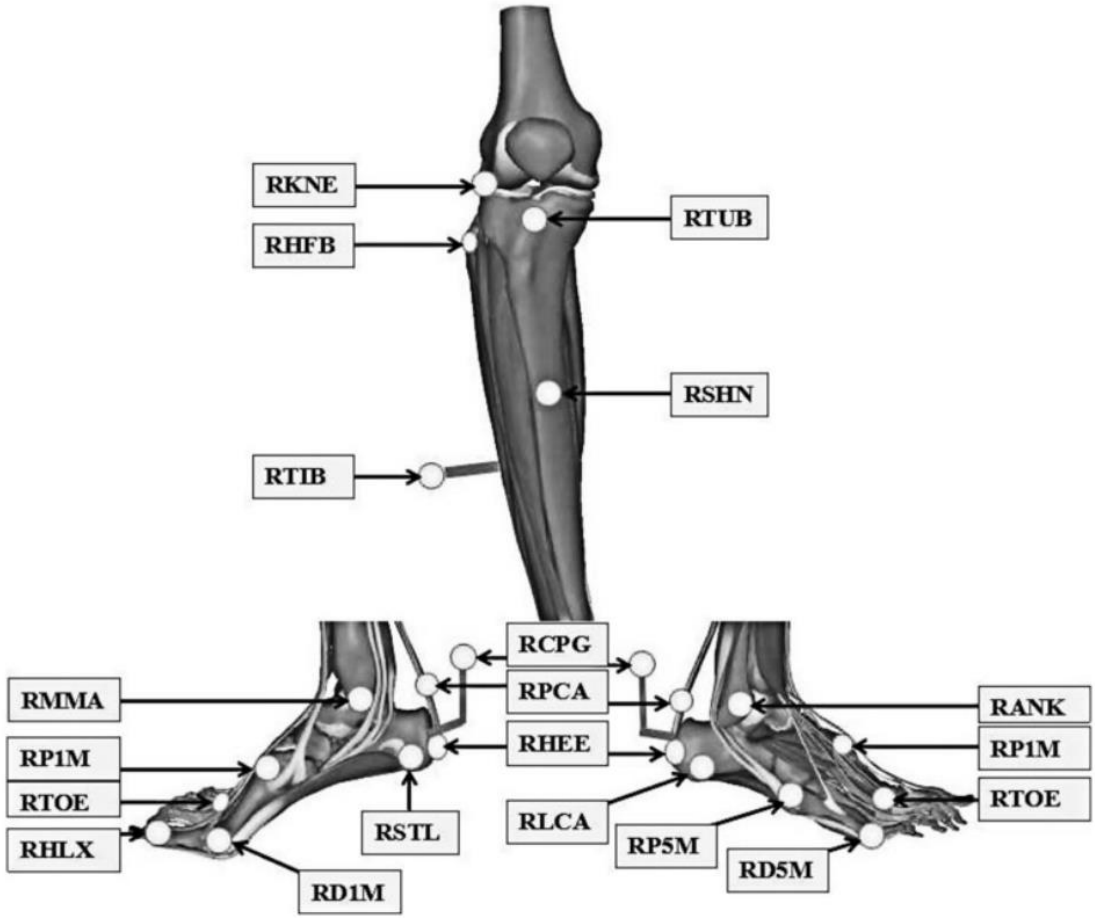



Figure 2.8: The Oxford Foot Model marker placement (Yu et al., 2019)

Table 2.2: Description of Oxford Foot Model marker placement (Nexus Model Documentation, 2012)

| Marker | Description | Marker | Description |
|---|---|---|---|
| RKNE | Standard lateral knee | RHEE | Heel |
| RTIB | Tibial marker | RLCA | Lateral calcaneus |
| RHFB | Lateral head of fibula | RSTL | Sustaniculum Tali |
| RTUB | Tibial tuberosity | RP1M | 1st metatarsal, proximal dorsal |
| RSHN | Anterior aspect of the shin | RD1M | 1st metatarsal, distal medial |
| RANK | Ankle | RP5M | 5th metatarsal, proximal lateral |
| RMMA | Medial Malleoli | RD5M | 5th metatarsal, distal lateral |
| RCPG | Posterior end of calcaneus | RTOE | Toe |
| RPCA | Posterior calcaneus proximal | RHLX | Hallux |

## 2.11 Design framework and model

To develop an in-shoe HV orthosis, two design models for functional wear were referenced with the aim of developing a smooth and efficient prototyping and production process. Clarkson et al. (2007) emphasized that functional products need to provide suitable functions to meet the needs of target users. Figure 2.9 shows the design model proposed by Clarkson et al. (2007). The key stages of the design and development process were discussed which include discovering needs, translating the needs of users into requirements, creating design concepts, and developing solutions. To meet the requirements and expectations of users, their actual needs and the problems should be understood from the beginning, so that the real underlying challenges can be understood without any implicit bias towards a particular solution. Designer must also

understand what makes a product functional, desirable, profitable, and usable and how these needs conflict with each other. Subsequently, the requirements are defined. Prototypes should be created, and feedback should be obtained from key stakeholders. Prototypes can also be evaluated against design requirements using expert appraisal and user testing. Evaluations are conducted continuously throughout the design process to assess the success of the product. A good product is often built on understanding the real needs of users and the success of a product can be measured by its functionality, usability, desirability, and feasibility.

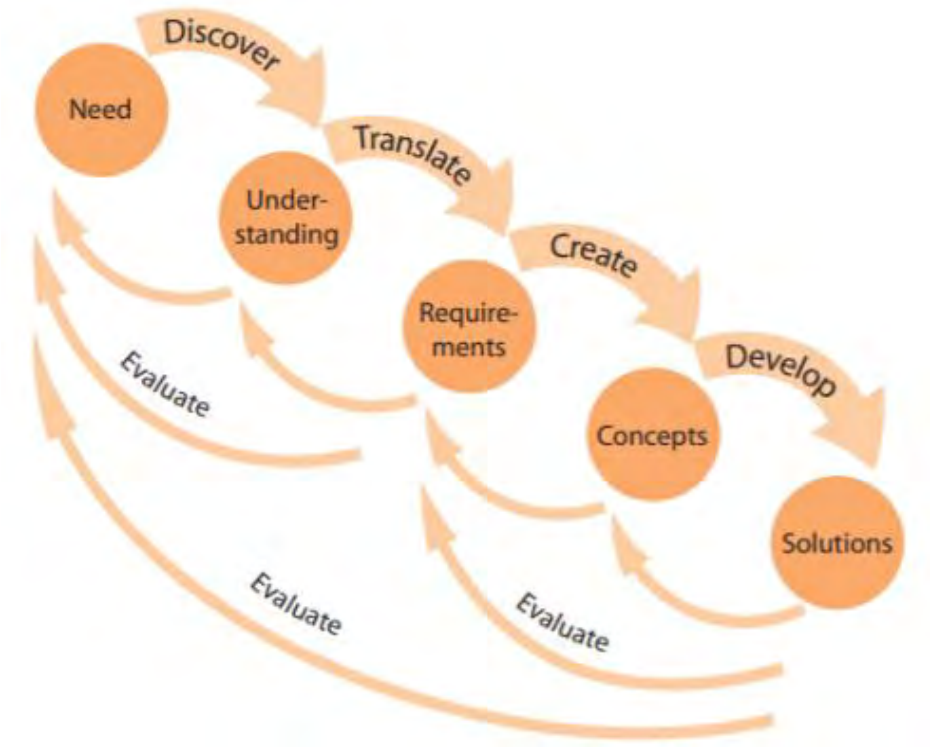



Figure 2.9: Design model I (Clarkson et al., 2007)

Another design model proposed by Gupta (2011) is shown in Figure 2.10. This model also emphasizes the ability of functional clothing to meet the needs of users. The model classifies user requirements into physiological, biomechanical, ergonomic, and psychological. Specifically, the designer should consider the shape, size, feel and design of the garment, the materials chosen, the kinematics of human movement, dynamics and behavioral analysis, human mobility, fit, degrees of freedom, and the pressure and friction exerted by the garment on the body.

The model suggests that user requirements can be identified through surveys. After understanding the primary needs of users regarding functionality and their expectations, the design processes can be carried out, including garment design, assembly, testing and analysis (Figure 2.10). The importance of testing and analyzing clothing performance was also emphasized by Carroll and Kincade (2007). Textile stress, strain, and breathability are examples of properties that need to be considered when selecting materials to enhance user comfort and safety. Standard material test methods can be used. In addition, since the interaction between clothing and the human body is involved, functional clothing also needs to be tested by humans to determine the relevant performance. Statistical considerations related to the comparison of different datasets and the ethical issues of conducting tests on humans must also be addressed.

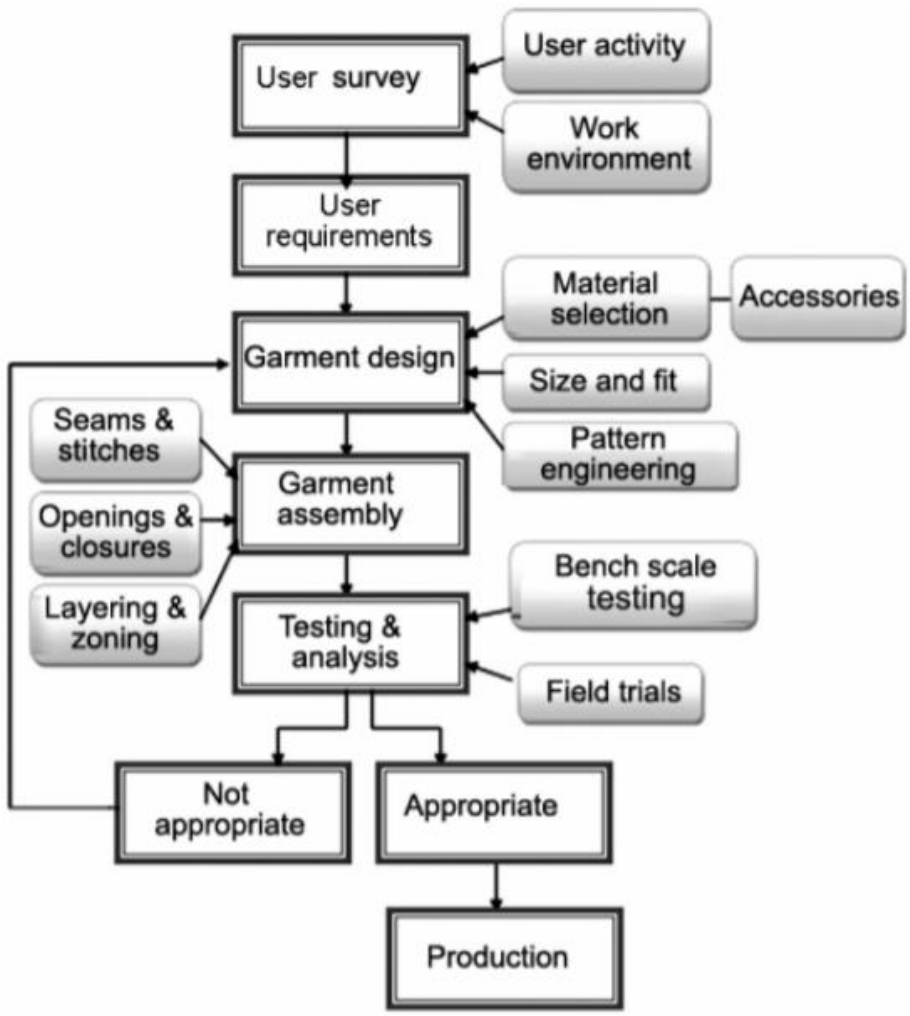



Figure 2.10: Design model II (Gupta, 2011)

## 2.12 Fabrication of foot orthoses

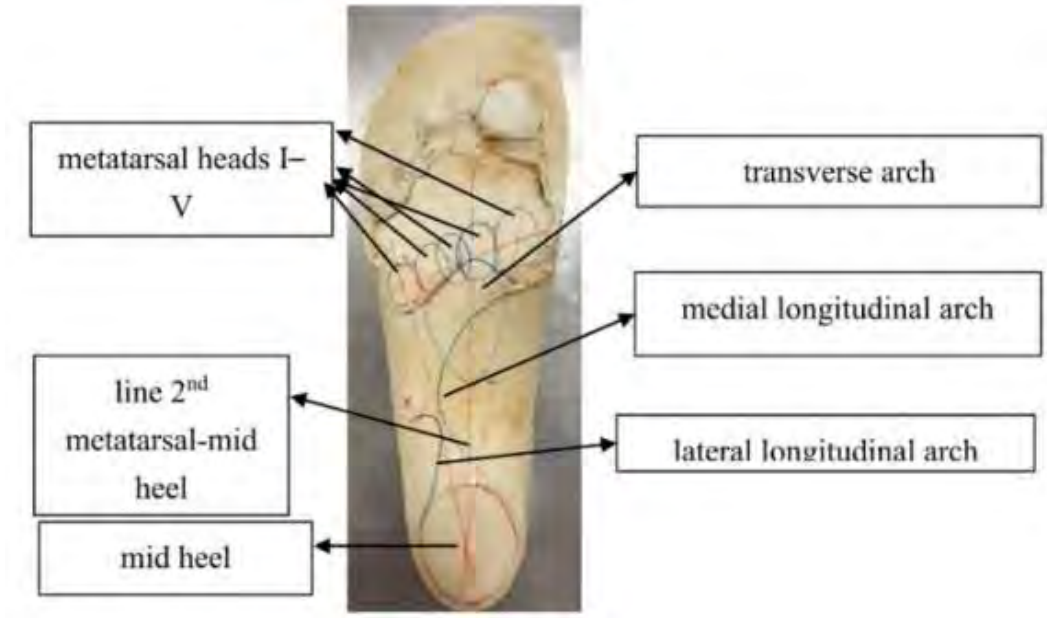
Orthoses for HV patients have traditionally been produced through specific procedures by skilled technicians in commercial orthotic laboratories (Lee et al., 2022). Alternatively, a foot assessment is performed by an evaluating podiatrist to examine the severity and characteristics of the HV deformity and determine specific requirements for orthotics, followed by digital scans of the foot and plaster casts (Ho et al., 2022;

Redmond et al., 2008). The fabrication of customized foot orthotics is also often performed by experienced prosthetists (Chen et al., 2022).

According to Chen et al. (2022), to fabricate a customized foot orthosis, foot molds were made using foam-box foot impression. This impression was taken with the patient sitting in a non-weight-bearing position with the knees bent at a 90-degree angle. The subtalar joint is kept in a neutral position and no downward pressure is applied. The negative mold obtained from the impression is then filled with liquid plaster to form the positive mold. This positive mold served as the foundation for making the foot orthosis. To achieve the desired properties, such as support and alignment, the transverse, medial and lateral arches are contoured on the positive mold. These contours determine the shape and structure of the orthosis, providing the corrective properties necessary to address HV (Figure 2.11).

The orthosis is typically made from materials such as semi-rigid polypropylene, thermoplastic, carbon fiber or polyester, that can shape the contours of the foot, provide support, cushioning, and corrective properties.

(a)




(b)

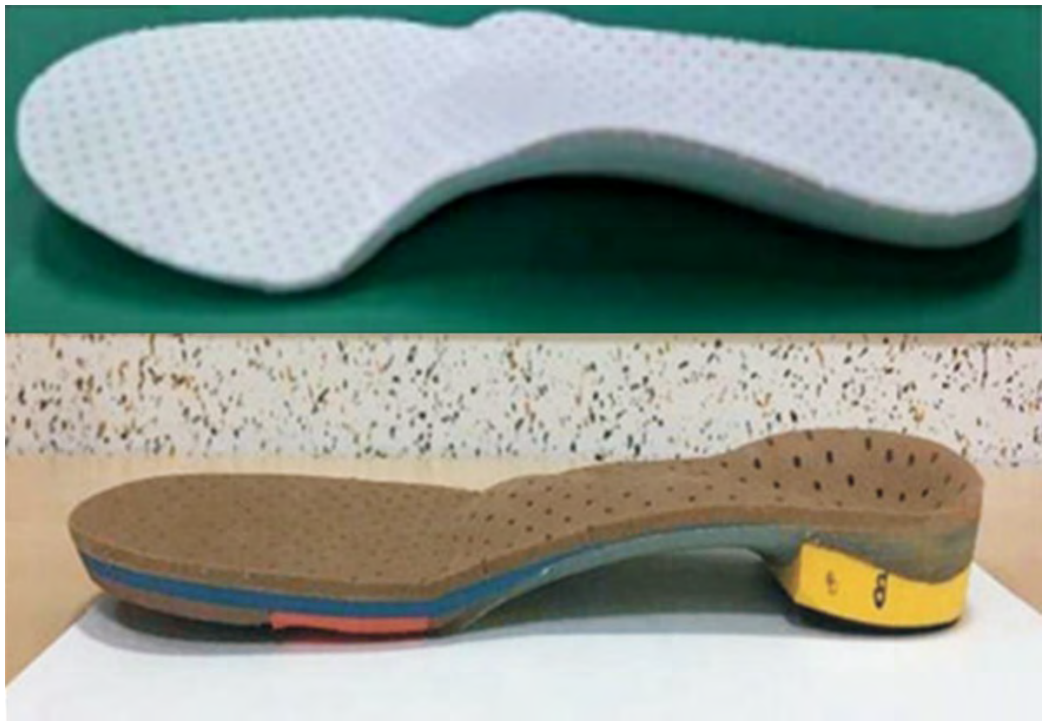


Figure 2.11: (a) Positive foot mold for making customized foot orthosis, and (b) examples of customized foot orthoses (Chen et al., 2022; Lee et al., 2022)

The traditional process of orthosis production has several limitations, including limited design options, high costs, labor-intensive procedures, and long wait times (Wojciechowski et al., 2019). To address these challenges, many orthotic laboratories have adopted 3D printing technology to manufacture custom-made foot orthoses, aiming to reduce production time, decrease reliance on labor, and minimize long-term costs (Ho et al., 2022). This trend of utilizing 3D printing for the commercial production of custom-made orthoses has gained traction.

Recently, Grimmelsmann, Meissner and Ehrmann (2016) reported a new potential means of modifying the mechanical properties of textiles through 3D printing. 3D printing or additive manufacturing has been widely adopted in the medical field for fabricating implants, orthoses, and prostheses over the past decade. Figure 2.12 shows a typical 3D printing workflow. The initial input for the production process is a digital 3D mesh model, which can be produced by using software, or converted from a 3D scanned image through reverse engineering. The image must be converted to STL format, and pre-processing operations including slicing it to the desired layer thickness need to be completed. The sliced file will then be transferred to a 3D printer for production. After building the model, post processing will be undertaken, such as removal of support structure to enhance the mechanical properties of the printed components. 3D printing can produce complex geometric shapes with different properties, such as customized orthoses with porous property. It can overcome the design limitations that are commonly found in traditional manufacturing techniques. In this research work, 3D printing is used to produce precise printed components for the orthosis.

Additionally, research conducted by Wojciechowski et al. (2019) demonstrated that

their 3D printed ankle-foot orthoses were comparable to traditional custom-made and prefabricated orthoses in terms of temporal-spatial parameters, biomechanical effects, mechanical stiffness, and energy dissipation.

Sun et al. (2021) employed 3D printing technology to develop a HV orthosis and investigate its effects. The results demonstrated that the 3D printed HV orthosis effectively corrected the HV angle during static standing and dynamic walking, particularly during the push-off phase of gait. Thus, it is a viable option for individuals with HV. 3D printed foot orthoses are also as effective as traditionally manufactured orthoses in providing arch support (Dombroski et al., 2014). However, it should be noted that 3D-printed orthoses may have weaknesses between layers, potentially affecting their longevity and stiffness.

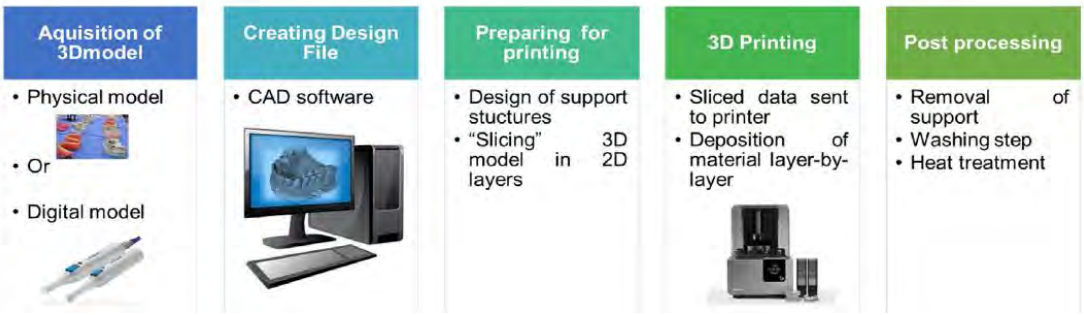



Figure 2.12: Basic workflow of 3D printing (Galante et. al. 2019)

## 2.13 Chapter summary

Using foot orthoses has been an increasingly popular means of preventing the HV progression. While the selection of materials for constructing orthoses is crucial for achieving effective treatment outcomes, there remains a lack of comprehensive reporting on the functional performance of the design and fabrication of HV orthoses. It is essential to understand the biomechanical behavior of feet with HV, its relationship with foot orthoses, and the material properties of different orthoses to optimize the design and materials used. Though there are studies that describe the construction of biomechanical models of the human foot for medical applications, few studies in the literature have combined the body model with orthoses and investigated the influence of the different orthotic components on the corrective effect.

# Chapter 3 Hallux Valgus Orthosis Characteristics and Effectiveness: A Systematic Review with Meta-analysis

Very few studies have systematically analyzed the biomechanical parameters of HV orthoses. The effect of orthotic design features and material properties on support and control performance have not been fully reported. This part of the study aims to determine the available evidence for the effectiveness of this conservative treatment, and the practitioner can gain insight into how design decisions affect the performance of HV orthoses, in order to establish a solid scientific basis for improving treatment results.

## 3.1 Methods

### 3.1.1 Search methods for identification of studies

A systematic search was conducted on PubMed, Scopus, Cinahl, and Medline databases, covering all available years up to February 2020, to identify relevant peer-reviewed journal articles that described the construction of HV orthoses and/or assessed their effectiveness. Table 3.1a presents the PICO questions that were formulated based on the study selection criteria. A highly sensitive search strategy was implemented, as shown in Table 3.1b, using specific keywords including “hallux valgus”, “orthosis”, “design”, “fabrication”, “construction”, “pressure”, “gait”, “alignment”, “pain”, and “walking speed”.

Table 3.1: (a) PICO question, and (b) a list of search strategy

| PICO question | | |
|---|---|---|
| P | Population or Problem | Studies that included people with HV, and people without HV at baseline were included |
| I | Intervention | Randomized controlled trial, uncontrolled intervention study and quasi-experimental of the use of HV orthoses |
| C | Comparison or Control | The comparison could be no HV orthotic treatment, or with other orthotic designs |
| O | Outcome | Any effect of HV orthotic treatment |

(a)

| Search strategy |
|---|
| 1. (“Hallux Valgus” AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement) |
| 2. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction)) NOT (Implant OR Replacement) |
| 3. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND Pressure) NOT (Implant OR Replacement) |
| 4. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND Gait) NOT (Implant OR Replacement) |
| 5. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND Alignment) NOT (Implant OR Replacement) |
| 6. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND Pain) NOT (Implant OR Replacement) |
| 7. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND “Walking speed”) NOT (Implant OR Replacement) |
| 8. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pressure) NOT (Implant OR Replacement) |
| 9. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Gait) NOT (Implant OR Replacement) |
| 10. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Alignment) NOT (Implant OR Replacement) |
| 11. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND Pain) NOT (Implant OR Replacement) |
| 12. (“Hallux Valgus” AND (Orthoses OR Orthosis) AND (Design OR Fabrication OR Construction) AND “Walking speed”) NOT (Implant OR Replacement) |

(b)

### 3.1.2 Inclusion and exclusion criteria

The titles and abstracts of the identified articles were reviewed by two investigators. Subsequently, full-text articles examining HV orthosis design or assessing outcomes related to HV orthosis effectiveness were selected for detailed evaluation. A two-stage selection process was applied, which involved assessing the titles, abstracts, and full texts of the retrieved items. The assessment of study eligibility was conducted by one investigator.

### 3.1.3 Statistical analysis

3.1.2.1 Quality assessment and risk of bias

The methodological quality of the included papers was assessed by using the Epidemiological Appraisal Instrument (EAI), which has been validated for the assessment of observational studies and comprised thirty-one items (Faraone, 2008; Genaidy, 2004; Genaidy & LeMasters, 2006; Genaidy et al., 2007). Items not applicable to cross-sectional studies, such as those related to interventions, randomization, follow-up period, or loss to follow-up, were excluded from the assessment. Each item was assigned a score based on the following categories: 'No' or 'Unable to determine' (score=0), 'Partial' (score=1), 'Yes' (score=2), 'Not Applicable' (item excluded from the scoring process). The average score across all items was calculated for each study, and the risk of bias was evaluated by using Cochrane Collaboration tools.

3.1.2.2 Data management

One investigator recorded the publication details (author, year, country, and study aim), sample characteristics (number of HV cases, number of control subjects, age, and sex), study methodology (device, associated factors investigated and orthosis wearing details), and results for each included paper. Standardized mean differences (SMDs) and 95% confidence intervals (CIs) were also calculated. To calculate the SMDs, the means and standard deviations (SDs) of pre-intervention and post-intervention (Durlak, 2009), as well as the mean and SDs of the control and treatment groups were recorded (McGough & Faraone, 2009). The mean difference was divided by the pooled SD (Deeks et al., 2008). The SMDs are calculated with the following formulas:

Equation 3.1:

$$SMDs_{\ intervention} = \frac{\mu\_pre - \mu\_post}{\sigma\_pooled}$$

Equation 3.2:

$$SMDs_{\ group} = \frac{\mu\_treatment - \mu\_control}{\sigma\_pooled}$$

In Equation 3.1, μ_pre represents the mean of the pre-intervention measurements, μ_post is the mean of the post-intervention measurements, and σ_pooled is the pooled standard deviation for the entire population. In Equation 3.2, μ_treatment represents the mean of the treatment group, and μ_control is the mean of the control group.

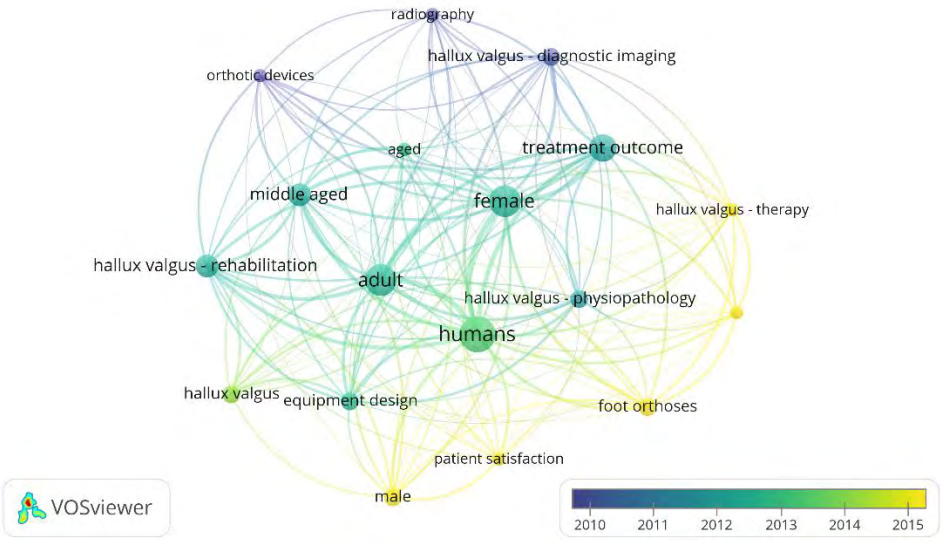
The interpretation of the SMDs was based on guidelines in previous studies: small effect ≥ 0.2, medium effect ≥ 0.5, and large effect ≥ 0.8 (Cohen, 2013; Faraone, 2008; McGough & Faraone, 2009). An SMD of "0" indicates that there is no difference in effect between the treatment and control groups. SMDs that are "> 0" or "< 0" indicate that one group exhibits greater efficacy compared to the other, and vice versa. SMDs are usually accompanied by 95% CIs to assess the reliability of the comparison. (Faraone, 2003; Faraone, 2008; McGough & Faraone, 2009). The total variation observed across studies that is due to heterogeneity is denoted as $I^{2,}$ where values of 0%–40% indicated low heterogeneity, 30%–60% indicated moderate heterogeneity, 50%–90% indicated substantial heterogeneity, and 75%–100% indicated considerable heterogeneity.

## 3.2 Results

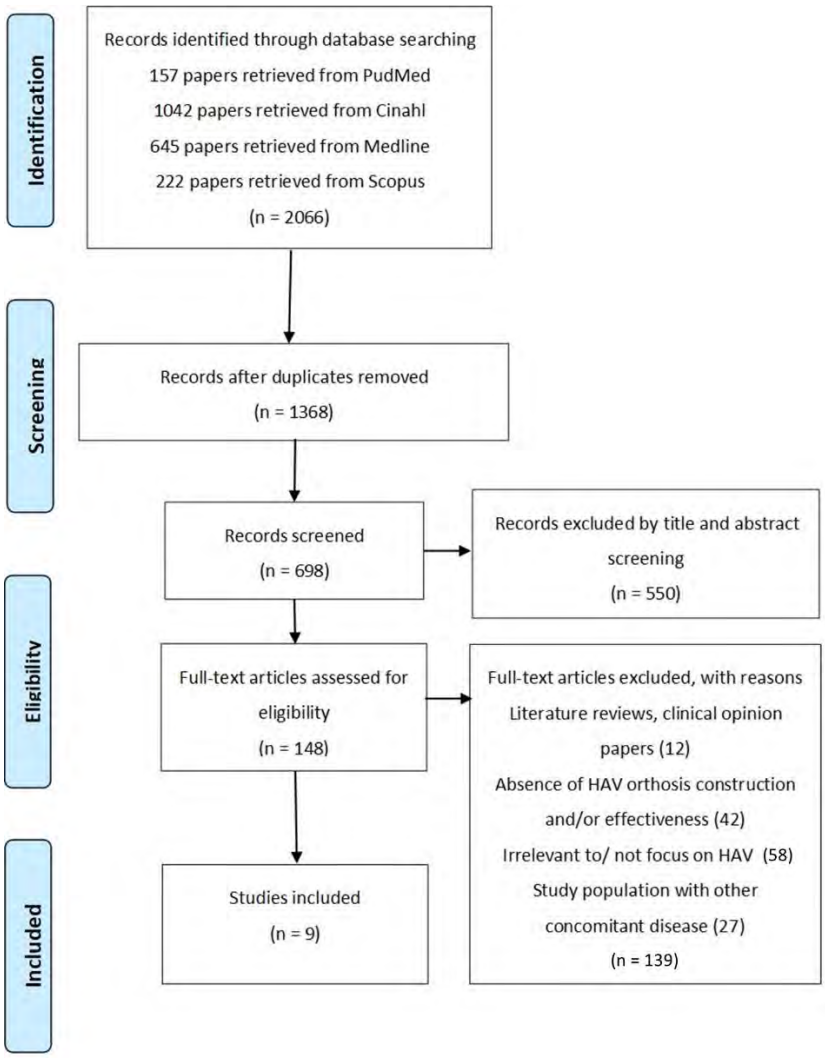
### 3.2.1 Search results and study characteristics

This review follows the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement and has a registered protocol (PROSPERO registration number: CRD42021260403). The initial search strategy yielded a total of 2066 articles from the PubMed, Scopus, Cinahl, and Medline databases. After removing 1368 duplicate articles, the titles and abstracts of the remaining 698 articles were screened against the research objective. Consequently, 550 papers were excluded as they did not meet the study design requirements. The remaining 148 articles underwent a full-text assessment against the inclusion and exclusion criteria and imported into the VOSviewer (version 1.6.13) to examine the trend of results. Keywords with fewer than three occurrences were excluded, and general terms were filtered to focus on more specific, informative terms (Van & Waltman, 2010). Figure 3.1a to visualizes the results that amongst the 148 remaining articles, 18 keywords meet the threshold, in which “male”, “patient satisfaction”, “foot orthoses” and “hallux valgus-therapy” are the latest research terms. The total link strength ranged from 26 to 71, with larger label denoting a higher total link strength. On average, the publication years of the articles ranged from 2002 to 2020. After the assessment, another 89 articles were removed. Nine studies were included in this systematic review. Figure 3.1b presents a PRISMA flow chart illustrating the article selection process. The selected studies evaluated the effects of eleven different types of HV orthoses on angle correction (IMA and HVA), plantar pressure, ROM, pain [measured by the Visual Analogue Scale (VAS) and Foot and Ankle Outcome Score (FAOS) -pain], function during daily activities [measured by the American Orthopedic

Foot and Ankle Score (AOFAS), FAOS -function and quality of life, and health-related quality of life index] (Table 3.2). The number of subjects with HV ranged from 16 to 69, exhibiting mild to moderate HV. Four of the studies involved control groups with 23 to 69 participants. Overall, the majority of the subjects are female.




**(a)**




**(b)**

Figure 3.1: (a) Visualization of main keywords from 148 papers, and (b) flowchart of study selection procedure

Table 3.2: Selected characteristics of studies included in analysis (9 unique studies)

| Study ID | Country | Study aim | Method | Device | N HV/ control | N males/ females | Age (Mean ± SD) | Orthosis | Orthosis material/wearing duration | Associated factors investigated | Result |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Chadchavalpanichaya 2018 | Thailand | To investigate the effect of using a custom-mold room temperature vulcanizing silicone toe separator to decrease HV angle and hallux pain | Prospective randomized trial | Radiographic measurements and clinical assessment | 45/45 | 5/85 | HV group: 60.3 ± 9.4<br>Control group: 60.8 ± 10.8 | Custom-mold room temperature vulcanizing toe separator | Silicone/12 months | HVA angle | Both groups had significant differences in mean HVA angle with a decrease of 3.3° ± 2.4° for the study group and increase of 1.9° ± 1.9° for the control group. Hallux pain was decreased in the study group. |
| Doty 2015 | Tennessee | To compare the HV deformity pressure parameters seen in standard footwear and in the same footwear with 3 different length orthoses | Case-control | Tactilus Free Form® Sensor System | 25/0 | 2/23 | mean: 57 | The full-length orthosis<br>The sulcus-length orthosis<br>The 3/4-length orthosis | NR/immediate | Plantar pressure | No significant changes in medial pressure with the addition of any orthosis compared with standard footwear alone |
| Farzadi 2015 | Iran | To investigate the effect of a foot orthosis with medial arch support on pressure distribution | Quasi-experimental | Pedar-X® in-shoe system | 16/0 | 0/16 | 26.1 ± 5.7 | Prefabricated arch support foot orthosis | 5 mm thick polypropylene/1 month | Plantar pressure | The use of the foot orthosis led to a decrease in peak pressure and maximum force |
| Moulodi 2019 | Iran | To compare the HV angle, ROM, and patient satisfaction after the use of the orthosis | Case-control; clinical examination | Goniometer | 24/0 | 12/12 | 22.79 ± 1.44 | Static HV splint with toe separator<br>Dynamic HV splint | A bar and a single strap/1 month<br>Firm plastic, straps and a free joint/1 month | HVA angle, ROM, Pain, function in daily activities, FAOS score | Both static and dynamic orthoses can reduce HVA angle up to 2–3°; significant difference in ROM by using dynamic orthosis |
| Plaass 2020 | Germany | To analyze the effect of a dynamic HV splint | Prospective randomized trial | Radiographic measurements and clinical assessment | 36/34 | 4/66 | HV group:: 53.2 ± 14.0<br>Control group: 48.5 ± 12.9 | Dynamic HV splint | NR/3 months | IMA and HVA angles, AOFAS score, FAOS score | Dynamic HV splint can provide some pain relief in patients with a symptomatic HV but showed no effect on HVA angle |
| Reina 2013 | Spain | To determine if the use of custom-made foot orthotics prevented the advancement of HV | Prospective trial using a repeated-measures design | Radiographic measurements | 23/23 | 0/54 | HV group: 30.31 ± 9.27<br>Control group: 30.94 ± 14.06 | Custom-made foot orthoses | 3 mm thick polypropylene sheet and 3 mm thick polyethylene foam sheet/12 months | IMA and HVA angles | Custom-made orthoses appear to have no effect |
| Tang 2002 | Taiwan | To assess the effects of a new foot-toe orthosis on painful HV | Uncontrolled intervention study | Radiographic measurements and clinical assessment | 17/0 | 0/17 | 42.59 ± 16.52 | Total contact insole with toe separator | Plastazote poron, microcell pull, plastazote no. 3 and mineral oil–based polymer gel toe separator/3 months | HVA angle | The new total contact insole with fixed toe separator improved the HVA angle |
| Tehraninasr 2008 | Iran | To compare the effects of wearing an insole with toe separator and night splint on HV, intermetatarsal angles and on the intensity of pain in patients suffering from painful HV deformity | Case control; x-ray examination | Radiographic measurements | 30/0 | 0/30 | 27 ± 8.91 | Insole with toe separator<br>Night splint | Polyfoam, polyethylene, plastazote toe separator/3 months<br>Polyfoam and a rigid polyethylene bar/3 months | IMA and HVA angles; Foot pain Visual Analogue Scale | IMA and HVA angles decreased in both groups; however, the reduction was not significant; the insole with toe separator significantly decreased the pain intensity |
| Torkki 2003 | Finland | To compare the effectiveness of surgical and orthotic treatment with no treatment in patients with HV | Randomized controlled trial | NR | 69/69 | 8/61 | HV group: 49 ± 10<br>Control group: 47 ± 9 | NR | NR/12 months | Foot pain Visual Analogue Scale, Health-related quality of life index | Orthoses provide short-term symptomatic relief |

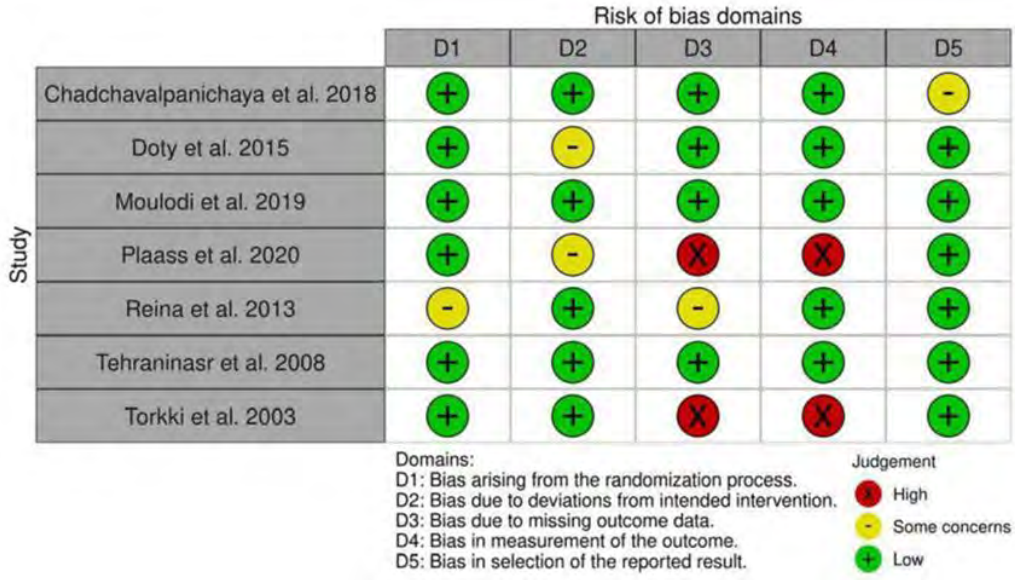
### 3.2.2 Quality assessment and risk of bias

The inter-rater agreement on the EAI is 95%, with 14 disagreements out of 279 quality assessment items rated, across all included studies (Table 3.3). All studies defined the associated factors investigated and reported the sampling frame and statistical methods (9/9, 100%). The majority of studies clearly stated their aims and study design (8/9, 89%). More than half of the studies reported inclusion criteria, sample characteristics, sample size calculations, and statistical parameters (7/9, 78%; 6/9, 67%; 7/9, 78%; and 7/9, 78%, respectively). However, only a few studies attempted to blind the assessors regarding the group allocation (1/4, 25%).

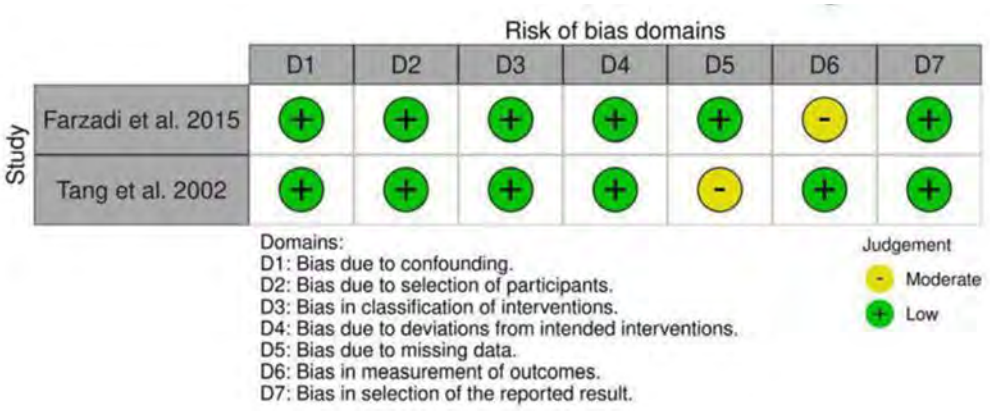
No study fully considered confounding factors such as age and sex by using statistical adjustment techniques or comparing the case and control groups. The reliability and validity assessments were performed separately for both HV assessment and the measurement of associated factors. Only a small proportion of the studies (2/9; 22%) provided a clear definition of HV by reporting angle values. Likewise, a similar proportion of studies (2/9; 22%) reported the reliability of the HVA assessment, and only 11% (1/9) reported the validity of the HV assessment. The risk of bias in the included studies is summarized in Figure 3.2, with the main sources of potential bias being missing outcome data and errors in outcome measurement.

Table 3.3: Results of quality assessment of all included papers (9 unique studies)

| Author(s) | Chadchavalpanichaya *et al* 2018 | Doty *et al* 2015 | Farzadi *et al* 2015 | Moulodi *et al* 2019 | Plaass *et al* 2020 | Reina *et al* 2013 | Tang *et al* 2002 | Tehraninasr *et al* 2008 | Torkki *et al* 2003 | Studies scoring 'yes' (%) |
|---|---|---|---|---|---|---|---|---|---|---|
| Reference no. | 36 | 37 | 22 | 38 | 39 | 40 | 43 | 41 | 42 | |
| Q1. Reported study aim/objective clearly | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 89 |
| Q2. Associated factors clearly defined | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 100 |
| Q3. HV clearly defined | 1 | 2 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 22 |
| Q4. Reported study design | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 89 |
| Q5. Reported sampling frame | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 100 |
| Q6. Reported inclusion criteria | 2 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 78 |
| Q7. Reported participation rate | 2 | 0 | 0 | 2 | 1 | 2 | 1 | 0 | 2 | 44 |
| Q8. Reported sample characteristics | 2 | 2 | 1 | 1 | 2 | 2 | 2 | 1 | 2 | 67 |
| Q9. Reported statistical methods | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 100 |
| Q10. Reported all basic data | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 11 |
| Q11. Reported variability in data | 2 | 0 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 78 |
| Q12. Reported statistical parameters | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 2 | 78 |
| Q13. Sample size calculations | 2 | 1 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 78 |
| Q14. Comparability of case/control groups | 2 | – | – | – | 2 | 2 | – | – | 2 | 100 |
| Q15. Adequate participation rate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 100 |
| Q16. Recruitment period for case/control groups | 2 | – | – | – | 2 | 2 | – | – | 0 | 75 |
| Q17. Non-responder characteristics described | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Q18. Reliability of all associated factors | 2 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 22 |
| Q19. Validity of all associated factors | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 11 |
| Q20. Standardised assessment of associated factors | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 100 |
| Q21. Blinding of assessors | 2 | – | – | – | 1 | 0 | – | – | 0 | 25 |
| Q22. Reliability of HV assessment | 2 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 22 |
| Q23. Validity of HV assessment | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 11 |
| Q24. Standardised assessment of HV | 2 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 0 | 56 |
| Q25. Assessment period for case/control groups | 2 | – | – | – | 2 | 2 | – | – | 2 | 100 |
| Q26. Collected data on HV severity/symptoms | 2 | 0 | 0 | 0 | 2 | 1 | 1 | 1 | 1 | 22 |
| Q27. Adjusted for covariates | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Q28. Reported data for ≥3 levels of associated factors | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 |
| Q29. Reported data for subgroups of subjects | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Q30. Generalisability of results to study population | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Q31. Generalisability of results to other populations | 2 | 0 | 0 | 0 | 2 | 0 | 0 | 2 | 2 | 44 |
| Overall quality score | 1.45 | 0.89 | 0.93 | 1.22 | 1.23 | 1.13 | 0.96 | 1.07 | 1.06 | |




(a)




(b)

Figure 3.2: Risk of bias in included studies (a) risk of bias for randomized studies, and (b) risk of bias for non-randomized studies

### 3.2.3 Overview of results from meta-analyses

The SMDs were calculated for each individual study, comparing eight measurement factors before and after intervention within the HV group. The results were shown in Table 3.4, which SMDs ≥ 0.2 or ≤ −0.2 are highlighted in yellow; SMDs ≥ 0.5 or ≤ −0.5 in orange, and SMDs ≥ 0.8 or ≤ −0.8 in green.

The primary function of HV orthosis is to correct the HVA, and a total of six studies investigated the effect of orthosis on the HVA correction. A small effect for HV orthosis in correcting HVA was found (SMD: 0.31, 95% CI: 0.075 to 0.547) with $I^2$ 28.28%. According to Tang et al. (2002), their full-length orthosis with a toe separator demonstrated a significant and positive reduction in HVA of 5.79° in the HV group (SMD: 0.85, 95% CI: 0.121 to 1.546). This orthosis exhibited the highest corrective effect among all the recorded orthoses. Similarly, Moulodi et al. (2019) found that the static orthosis with a toe separator resulted in a significant and positive reduction in HVA of 2.67° (SMD: 0.75, 95% CI: 0.143 to 1.325). Chadchavalpanichaya et al. (2018) developed a custom-molded room temperature vulcanizing toe separator, which reduced the HVA by 2.1° in the HV group (SMD: 0.41, 95% CI: -0.012 to 0.827). The pooled estimation for orthoses with a toe separator was further investigated that the effect is medium (SMD: 0.50, 95% CI: 0.189 to 0.803) with $I^2$ 14.52%. The dynamic orthosis tested also showed a significantly positive reduction of the HVA of 2.13° (SMD: 0.55, 95% CI: -0.038 to 1.127). The pooled estimation for dynamic orthoses showed small effect in HVA correction (SMD: 0.27, 95% CI: -0.211 to 0.751) with $I^2$ 42.29%. Furthermore, Plaass et al. (2020) and Reina et al. (2013), investigated the impact of the orthosis in terms of the IMA, but neither showed any significant results.

In addition to HVA correction, three of the studies examined the pain scores by using two different types of rating scales. Tehraninasr et al. (2008) demonstrated that their orthosis with a toe separator effectively reduces the pain level (SMD: 1.13, 95% CI: 0.319 to 1.887). With the use of the VAS, Torkki et al. (2003) also found that their orthosis can help to reduce pain (SMD: 0.38, 95% CI: 0.043 to 0.719), however, they did not provide a description of the orthosis. The dynamic orthosis in Moulodi et al. (2019) also showed a positive impact on releasing pain (SMD: -0.27, 95% CI: -0.837

to 0.311). The FAOS for pain is reduced by 4.28. The level of physical functioning before and after the application of an orthosis have also been compared. A small effect (SMD: -0.30, 95% CI: -0.700 to 0.102) was achieved. Two other studies investigated the impact of the foot orthosis on plantar pressure. Small effect for HV orthosis in plantar pressure reduction was found (SMD: 0.41, 95% CI: 0.118 to 0.700) with $I^2$ 0.00%. It was found that the prefabricated full-length orthosis with an arch support can significantly reduce the plantar pressure by 16.8 kPa (SMD: 0.65, 95% CI: -0.090 to 1.354). Moreover, Doty et al. (2015) pointed out that in their study, the use of a full-length orthosis and a 3/4-length orthosis result in a significant reduction of the plantar pressure of 11.82 kPa and 10.37 kPa among HV patients, respectively (full-length orthosis: SMD: 0.47, 95% CI: -0.104 to 1.031; 3/4-length orthosis: SMD: 0.45, 95% CI: -0.122 to 1.012).

Comparisons of physical functioning levels before and after the application of an orthosis have also been undertaken. The static orthosis with a toe separator and the dynamic orthosis tested by Moulodi et al. (2019) showed a significantly positive FAOS for function with an increase of 6.25 and 4.51 points, respectively (static orthosis: SMD: -0.36, 95% CI: -0.934 to 0.218; dynamic orthosis: SMD: -0.25, 95% CI: -0.814 to 0.333). The effects of foot orthoses on changes in the ROM have also been examined in the studies of concern. The dynamic orthosis in Moulodi et al. (2019) showed a significant improvement of the ROM by 9.77° (SMD: - 0.52, 95% CI: -1.091 to 0.072).

Table 3.4: Comparison of observations



| Parameter | Author(s) | Orthosis type | Pre-intervention Mean | Pre-intervention SD | Post-intervention Mean | Post-intervention SD | Pooled SD | Mean Difference | SMDs | 95% CIs |
|---|---|---|---|---|---|---|---|---|---|---|
| HVA | Chatchavalpanichaya et al. 2018 | Custom-molded RTV toe separator | 32.50 | 4.80 | 30.40 | 5.40 | 5.11 | -2.10 | -0.41 | -0.012 to 0.827 |
| | Moulodi et al. 2019 | Static orthosis with toe separator | 18.21 | 3.41 | 15.54 | 3.74 | 3.58 | -2.67 | -0.75 | 0.143 to 1.325 |
| | Moulodi et al. 2019 | Dynamic orthosis | 17.96 | 3.75 | 15.83 | 3.94 | 3.85 | -2.13 | -0.55 | -0.038 to 1.127 |
| | Plaass et al. 2020 | Dynamic orthosis | 35.40 | 8.60 | 34.90 | 9.20 | 8.91 | -0.50 | -0.06 | -0.410 to 0.521 |
| | Reina et al. 2013 | Custom-made foot orthoses | 20.55 | 5.10 | 21.02 | 5.14 | 5.12 | 0.47 | 0.09 | -0.675 to 0.494 |
| | Tang et al. 2002 | Full-length orthosis with toe separator | 31.04 | 6.40 | 25.25 | 7.14 | 6.78 | -5.79 | -0.85 | 0.121 to 1.546 |
| | Tehraninasr et al. 2008 | Orthosis with toe separator | 25.46 | 3.68 | 25.36 | 3.68 | 3.68 | -0.10 | -0.03 | -0.701 to 0.754 |
| | Tehraninasr et al. 2008 | Nighttime orthosis | 24.13 | 2.05 | 24.16 | 2.09 | 2.07 | 0.03 | 0.01 | -0.742 to 0.714 |
| | | | | | | | | Overall: | 0.31 | 0.075 to 0.547 |
| | | | | | | | | Heterogeneity: $I^2$=28.28% | | |
| IMA | Plaass et al. 2020 | Dynamic orthosis | 15.40 | 3.00 | 15.20 | 3.10 | 3.05 | -0.20 | -0.07 | -0.400 to 0.530 |
| | Reina et al. 2013 | Custom-made foot orthoses | 10.86 | 2.33 | 11.10 | 2.34 | 2.34 | 0.24 | 0.10 | -0.686 to 0.483 |
| | | | | | | | | Overall: | -0.00 | -0.360 to 0.360 |
| | | | | | | | | Heterogeneity: $I^2$=0.00% | | |
| FAOS-pain | Moulodi et al. 2019 | Static orthosis with toe separator | 85.28 | 12.24 | 87.49 | 12.29 | 12.27 | 2.21 | 0.18 | -0.750 to 0.395 |
| | Moulodi et al. 2019 | Dynamic orthosis | 81.61 | 17.41 | 85.89 | 14.50 | 16.02 | 4.28 | 0.27 | -0.837 to 0.311 |
| | | | | | | | | Overall: | -0.22 | -0.620 to 0.180 |
| | | | | | | | | Heterogeneity: $I^2$=0.00% | | |
| Foot pain VAS | Tehraninasr et al. 2008 | Orthosis with toe separator | 4.26 | 1.48 | 2.66 | 1.34 | 1.41 | 1.60 | 1.13 | 0.319 to 1.887 |
| | Tehraninasr et al. 2008 | Nighttime orthosis | 4.13 | 1.78 | 4.00 | 1.13 | 1.49 | 0.13 | 0.087 | -0.643 to 0.813 |
| | Tarkki et al. 2003 | NR | 5.00 | 2.40 | 4.10 | 2.30 | 2.35 | 0.90 | 0.38 | 0.043 to 0.719 |
| | | | | | | | | Overall: | 0.48 | 0.000 to 0.958 |
| | | | | | | | | Heterogeneity: $I^2$=51.39% | | |
| FAOS-Quality of life | Moulodi et al. 2019 | Static orthosis with toe separator | 66.14 | 16.68 | 67.44 | 16.48 | 16.58 | 1.30 | 0.08 | -0.649 to 0.495 |
| | Moulodi et al. 2019 | Dynamic orthosis | 65.10 | 16.78 | 65.88 | 15.63 | 16.22 | 0.78 | 0.05 | -0.619 to 0.524 |
| | | | | | | | | Overall: | -0.06 | -0.461 to 0.337 |
| | | | | | | | | Heterogeneity: $I^2$=0.00% | | |
| FAOS-Function | Moulodi et al. 2019 | Static orthosis with toe separator | 78.47 | 18.70 | 84.72 | 15.47 | 17.16 | 6.25 | 0.36 | -0.934 to 0.218 |
| | Moulodi et al. 2019 | Dynamic orthosis | 80.55 | 19.91 | 85.06 | 16.84 | 18.44 | 4.51 | 0.25 | -0.814 to 0.333 |
| | | | | | | | | Overall: | -0.30 | -0.700 to 0.102 |
| | | | | | | | | Heterogeneity: $I^2$=0.00% | | |
| ROM | Moulodi et al. 2019 | Static orthosis with toe separator | 120.00 | 18.32 | 121.40 | 19.72 | 18.99 | 1.35 | 0.07 | -0.644 to 0.499 |
| | Moulodi et al. 2019 | Dynamic orthosis | 117.50 | 19.62 | 127.30 | 17.97 | 18.92 | 9.77 | 0.52 | -1.091 to 0.072 |
| | | | | | | | | Overall: | -0.29 | -0.722 to 0.146 |
| | | | | | | | | Heterogeneity: $I^2$=14.12% | | |
| Plantar pressure | Doty et al. 2015 | Full-length orthosis | 47.58 | 21.59 | 35.76 | 28.20 | 25.11 | 11.82 | 0.47 | -0.104 to 1.031 |
| | Doty et al. 2015 | Sulcus-length orthosis | 47.58 | 21.59 | 43.15 | 26.20 | 24.01 | 4.43 | 0.18 | -0.379 to 0.743 |
| | Doty et al. 2015 | 3/4-length orthosis | 47.58 | 21.59 | 37.21 | 24.20 | 22.93 | 10.37 | 0.45 | -0.122 to 1.012 |
| | Farzadi et al. 2015 | Prefabricated full-length foot orthosis with arch support | 123.90 | 25.30 | 107.10 | 26.50 | 25.91 | 16.80 | 0.65 | -0.090 to 1.354 |
| | | | | | | | | Overall: | 0.41 | 0.118 to 0.700 |
| | | | | | | | | Heterogeneity: $I^2$=0.00% | | |

### 3.2.4 Observation of key design features

#### 3.2.4.1 Customized vs. prefabricated

Among the orthoses evaluated for their effectiveness in reducing HVA in patients with HV, the custom-made orthoses developed by Chadchavalpanichaya et al. (2018) and Tang et al. (2002) showed significant reductions. Prefabricated orthoses in studies by Moulodi et al. (2019), Tehraninasr et al. (2008), Torkki et al. (2003), Doty et al. (2015), and Farzadi et al. (2015) also showed notable HVA reduction. When comparing the treatment and control groups, the orthoses discussed by Chadchavalpanichaya et al. (2018) and Reina et al. (2013) are custom-made, while the orthosis in Plaass et al. (2020) is prefabricated. These findings suggest that the ability of an orthosis to reduce HV severity or its treatment effectiveness may not be solely dependent on customization versus prefabrication. However, proper adjustment and fitting remain crucial factors, and patients are instructed to adjust the prefabricated orthosis to the best fitting position (Plaass et al., 2020).

#### 3.2.4.2 Static vs. dynamic

When comparing the treatment group and the control group, the use of both static and dynamic orthoses showed significant reductions of HV symptoms, and all the static orthoses have a toe separator (Chadchavalpanichaya et al., 2018; Plaass et al., 2020). Regarding the reduction of HVA, the results consistently show positive treatment effects in HV patients before and after the intervention. Both static and dynamic orthoses exhibit positive treatment effects, with all static orthoses that help reduce HVA incorporating a toe separator. Therefore, the toe separator in static orthoses is likely a

key factor in correcting the HVA.

3.2.4.3 Considerations around orthosis length and arch support

In terms of orthosis length, the study by Tang et al. (2002) highlights the exceptional corrective effect of full-length orthoses on HV. The full-length orthoses in Farzadi et al. (2015) and Doty et al. (2015) can significantly reduce the plantar pressure. These findings indicate that full-length orthoses are preferred when considering the length of the orthosis for HV patients. Among these orthoses, only the orthosis tested by Farzadi et al. (2015) provides arch support. It is anticipated that arch support may not be a mandatory design feature to achieve therapeutic effects.

## 3.3 Discussion

This is the first study to systematically evaluate and synthesize results from the extensive pool of literature that investigates the characteristics of HV orthoses and their effects on different factors. The results suggest that dynamic orthoses and static orthoses with toe separator help to reduce the HVA in patients with HV by 2.1° to 5.79° (Chadchavalpanichaya et al., 2018; Moulodi et al., 2019; Tang et al., 2002). It is worth noting that orthoses with toe separators have a greater treatment effect on HVA correction compared to dynamic orthoses.

Dynamic orthoses can reduce MTPJ1 contracture and better align the hallux with low torque and prolonged stretching (Chadchavalpanichaya et al., 2018; John, 2009; Nicholas, 1996). In dynamic orthoses, the freedom of joint movement does not limit the ROM of the hallux, but rather helps to maintain joint mobility and prevent stiffness, ,

which appears to be beneficial in the treatment of HV (Moulodi et al., 2019).

The results of this study show that both dynamic and static orthoses have a positive effect, and all static orthoses that help to reduce the HVA have a toe separator. According to Tang et al. (2002) and Tehraninasr et al. (2008), the toe separator can effectively reduce pain by improving the alignment of the hallux and relieving the strain on collateral ligaments and bone subluxation. In general, users tend to express higher satisfaction with dynamic orthoses compared to static orthoses, citing reasons such as ease of use, better fit, and improved appearance (Moulodi et al., 2019).

The full-length orthosis developed by Tang et al. (2002) has a significant and exceptional corrective effect on HVA in the HV group. The full-length orthoses tested by Farzadi et al. (2015) and Doty et al. (2015) significantly reduce plantar pressure by 11.82 kPa to 16.8 kPa. Therefore, it can be suggested that forefoot pain has an evident relationship with plantar pressure in the metatarsalgia region (Arias-Martín et al., 2018; Kelly & Winson, 1998; Postema et al., 1998). The foot orthoses with an arch support developed by Farzadi et al. (2015) reduces forefoot pain, and potentially improve body load distribution by relieving excessive pressure on the forefoot through metatarsal unloading. The finding indicates that when considering the length of the orthosis for HV patients, full-length is optimal. By maximizing the total contact area of the foot with a full-length orthosis, peak plantar pressure can be reduced by 30% to 40% (Kitaoka et al., 2002; Nouman et al., 2017). In addition, adequate arch support can restore proper anatomical alignment of the foot (Tehraninasr et al., 2008)

Both custom-made and prefabricated orthoses have demonstrated significant effectiveness in reducing HV symptoms. A study by Ring and Otter (2014) compared the clinical efficacy of casted and prefabricated foot orthoses for the treatment of plantar

heel pain in 67 patients. The results showed no significant difference in the effectiveness of custom or prefabricated orthoses. Additionally, prefabricated orthotics cost 38% less per patient than custom-made devices. The authors concluded that prefabricated orthoses could offer similar benefits to casted foot orthoses while significantly reducing costs. As shown in Table 3.2, the material properties, thickness, and rigidity of the three orthoses studied remain unknown. Thus, no conclusions can be made on the best material for HVA reduction. However, Chadchavalpanichaya et al. (2018) found that a room temperature vulcanizing silicone toe separator for HV is comfortable to wear and has a higher treatment compliance compared to nighttime HV straps. Additionally, using a toe separator made of room temperature vulcanizing silicone, which costs only one-tenth of medical-grade silicone, can be considered as a clinical and cost-effective option (Chadchavalpanichaya et al., 2018).

Previous studies provide insights into the optimal design of HV orthoses. The consensus among studies is that dynamic or static orthoses with a toe separator are effective in reducing HVA. On the other hand, full-length orthoses can reduce the plantar pressure to prevent further degeneration of mobility.

### 3.4 Chapter summary

Foot orthoses have been identified as a viable treatment option for reducing HV deformities. Systematic studies have established a positive correlation between the reduction of HVA and the degree of pain when orthoses with toe separators are utilized. It is recommended to incorporate a full-length orthosis with a fixed toe separator or a dynamic orthosis to preserve the hallux anatomy in individuals with HV. This systematic review highlights the significance of including toe separators in the

conservative treatment of HV deformity and in the future development of HV orthoses. The findings of this study provide valuable insights for patients, practitioners, and physicians, enabling them to better comprehend the characteristics and effectiveness of different HV orthoses in addressing HV deformity and informing treatment decisions.

# Chapter 4 The Immediate Effects of Hallux Valgus Orthoses: A Comparison of Orthosis Designs

HV orthoses are available in a wide variety of designs and materials, but the effect of their design on functional performance has not been fully investigated. Although orthotic materials are important for effective treatment, the effectiveness and functional characteristics of the design and materials for making HV orthoses have not been fully reported. This part of the study aims to comprehensively analyze biomechanical behavior of the foot caused by soft and semi-rigid HV orthoses on balance, plantar pressure, HVA and subjective sensations. The results can provide valuable insights into the design of HV orthoses and serve as a practical guide for the selection of HV orthoses.

## 4.1 Methods

### 4.1.1 Participants

The study involved a total of sixteen female participants, with ten individuals having no HV or significant lower-limb problems during the 12 months that preceded the study, and six participants exhibiting mild to moderate HV. The former was used as the control. The selected participants were between the ages of 20 and 30 years, with shoe sizes ranging from EU 35 to 39. They had no history of foot surgery and possessed a normal foot type (foot type index between 0.3 and 0.4). The inclusion and exclusion criteria were highly rigorous to specifically isolate the effects of HV from other foot conditions. Individuals with other forefoot pathologies or experienced foot pain in the past month were excluded from the study. The demographic information is listed in Table 4.1. Only data from the dominant foot were analyzed. The study received approval from the

Human Subjects Ethics Sub-Committee at the Hong Kong Polytechnic University (reference number: HSEARS20190924004), and all participants provided written consent.

Table 4.1: Participant demographics

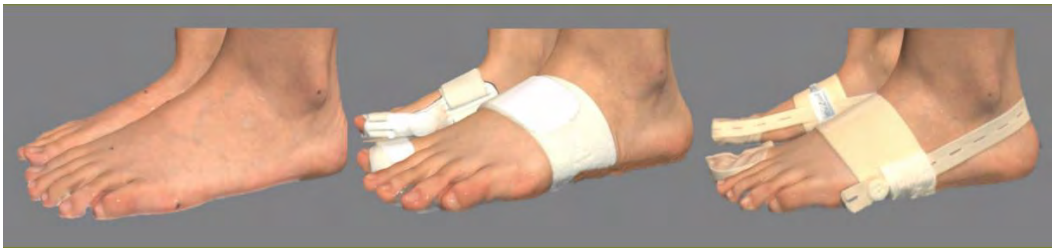
| | Subjects without HV (N = 10) | | HV subjects (N = 6) | |
|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. |
| Age | 24.72 | 4.46 | 24.17 | 3.98 |
| BMI | 20.20 | 1.40 | 20.28 | 1.57 |
| Shoe size | 37.42 | 1.23 | 36.83 | 1.34 |
| HVA | 11.30 | 3.35 | 17.83 | 1.34 |
| Foot length | 22.10 | 0.69 | 21.42 | 1.33 |
| Foot width | 8.66 | 0.44 | 8.70 | 0.51 |
| Arch width | 3.06 | 0.47 | 3.15 | 0.30 |
| Foot type index | 0.35 | 0.04 | 0.36 | 0.03 |
| Hallux dorsiflexion | 47.30 | 10.93 | 52.00 | 16.31 |
| Hallux plantarflexion | 25.10 | 10.23 | 34.00 | 15.94 |

### 4.1.2 Orthosis features and materials

Two commercially available HV orthoses were obtained for evaluation: a semi-rigid orthosis (Sample A) and a soft day-use orthosis (Sample B). Sample A is constructed with polyamide velour, has a polyurethane gel cushion which offers suitable cushioning and support (Healy et al., 2010), and a splint with a solid polyamide hinge with reversal slits.

The primary function of these orthoses is to correct the angle of the HV by realigning the position of the hallux. Sample A employs a hinged splint that allows controlled movement of the hallux, while Sample B is a soft orthosis featuring a powernet toe cover, elastic band, and webbing for realignment. Powernet is a warp knitted fabric structure commonly used for pressure therapy garments and/or orthoses in clinical applications (Yu et al., 2013). The size was selected to accommodate the participants. Both orthoses cover similar regions of the foot, including the hallux and arch, but differ in terms of materials and design. The type of orthosis material is critical as it can affect gait characteristics and plantar pressure (Gerrard et al., 2020; Hajizadeh et al., 2020). Therefore, comprehensive tests were done on the material properties of the two orthoses. The experimental conditions and construction of the two orthoses are shown in Figures 4.1a and 4.1b. Air permeability was determined by using the ASTM D737-96 standard, thermal conductivity was evaluated by using the KES-FB Thermo Labo according to the JIS L 1927 standard, tensile extension was measured according to the ISO 20932 standard, and surface properties such as friction and roughness were analyzed by using the Kawabata evaluation system of fabric (Apurba & Alagirusamy, 2010).

(a)



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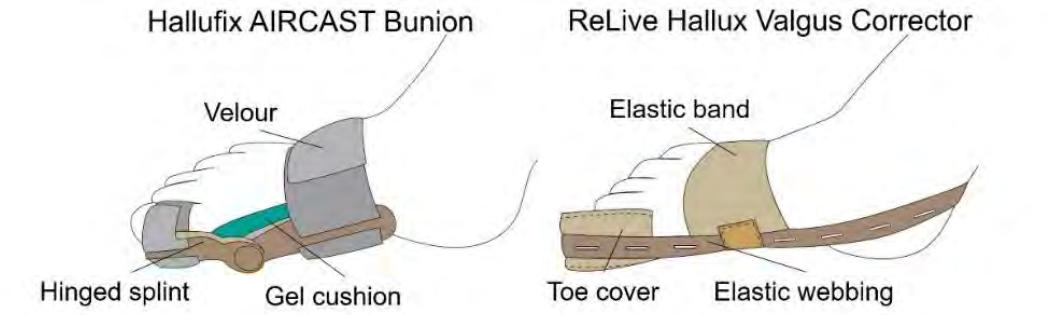


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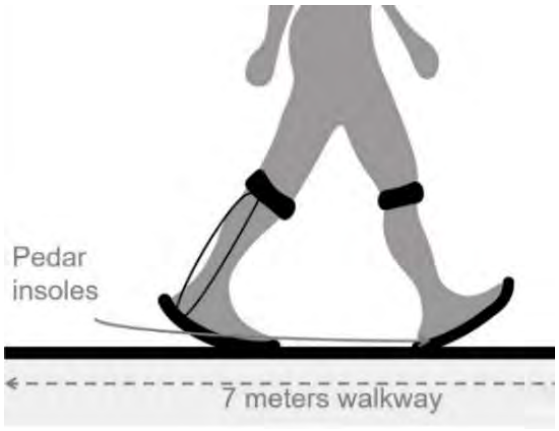


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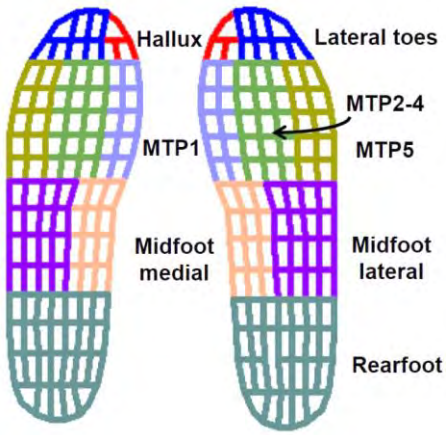



(e)

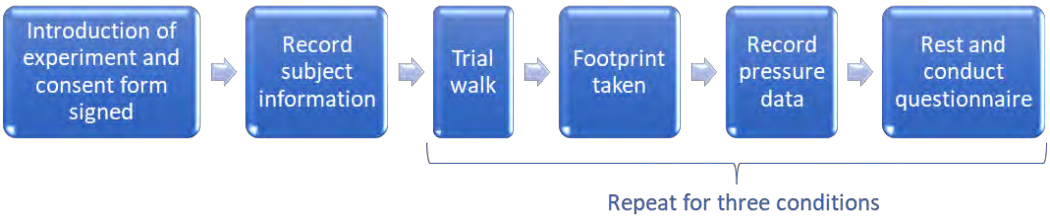



Figure 4.1: (a) Experimental conditions including barefoot, and wearing Samples A and B, (b) design features and materials, (c) schematic of experimental set-up, (d) regions of plantar pressure analysis, and (e) flow of experiment

### 4.1.3 Experimental procedures

Each subject conducted a trial walk for each experimental condition for acclimatization purposes, as depicted in Figure 4.1e. Subsequently, two-dimensional (2D) footprints were obtained in a weight-bearing standing posture by using a podograph. Measurements of the foot length, width and angle were made. After that, subjects were asked to stand and walk on the floor with a flat surface to measure their level of plantar pressure. A straight line of seven meters of tape was adhered to the floor as the reference line (Hurst et al., 2017). The experimental procedures took place within a controlled indoor environment, maintaining a temperature of 23°C and a humidity level of 65%. Figure 4.1c illustrates the schematic representation of the experimental set-up. To ensure consistency of the data, each subject completed three successful trials.

To measure the forefoot pressure and COP uniformly and accurately, the Pedar-X1 analysis program (Novel GmbH, Munich, Germany) and a pair of Pedar® insole sensors (EU 36/37) were used (Quesada et al., 1997). The Pedar system can provide accurate and reliable measurement results as compared with force plate, with advantage that it can be masked to pay specific attention to the forefoot region (Biomech et al., 2000; Forghany et al., 2018). Pedar® insoles were calibrated by using standard protocols prior to experiment and adhered to the foot with thin double-sided adhesive tape. Measurements were recorded at a frequency of 50 Hz.

The study examined peak pressure in eight regions of the foot, namely the hallux, lateral toes, MTP1, MTP2-4, MTP5, medial and lateral midfoot and rearfoot, as shown in Figure 4.1d. The location of the COP was recorded as X–Y coordinates, relative to the origin, which was the most medial and posterior points of the insole (Debbi et al., 2012). To prevent muscle fatigue, the subjects were given breaks after each test condition, as

suggested by Yung-Hui and Wei-Hsien (2005). During the rest, subjects were asked to complete a survey regarding their subjective feeling of the orthoses. The survey assessed factors include the degree of permeability, thinness, ease of wear, comfort, fit, receptivity, and satisfaction. A simplified 10-point VAS that ranged from level 1 ‘Not comfortable at all’ to level 10 ‘Most comfortable imaginable’ was used (Mündermann et al., 2002). Additionally, the participants ranked the importance of price, durability, function, comfort, and appearance. The experiment was 1.5 hours long.

### 4.1.4 Statistical analysis

Measurements during both walking and standing were taken. The upper and lower outliers were identified and excluded from the result. The pressure distribution on the plantar side of the foot was analyzed, and the maximum peak pressure was recorded for each of the eight regions. To eliminate the influence of acceleration and deceleration during the initiation and termination of each walking trial, the first and last two steps were excluded from the analysis (Arts et al., 2011). A statistical analysis was performed with SPSS v.24 (IBM Corp., Armonk, New York). A repeated-measures analysis of variance (rANOVA) was utilized to compare the mean differences between wearing orthoses and being in a barefoot condition, aiming to examine the effects of the two types of orthoses. The Bonferroni test adjust the probability for multiple comparisons. Sidak pairwise comparisons were performed to compare the mean difference between (1) barefoot and sample A, and (2) barefoot and sample B. Independent-samples t tests were performed to compare the differences between the subject groups under each condition. The alpha level was set to 0.05.

## 4.2 Results

### 4.2.1 Material properties

The material test results are presented in Table 4.2. Sample A components are thicker and heavier compared to Sample B, resulting in Sample A having twice the total weight of Sample B. The thickness of the side of the MTP1 in Sample B, which incorporates elastic webbing, measures only 0.98 mm, while Sample A, with a gel cushion and hinge splint, has a thickness of 4.99 mm. Sample A requires wearing loose fitting shoes which might cause injury. Sample A is secured with velour, whereas Sample B utilizes an elastic band, which exhibits high air resistance (12.33 kPa·s/m) and consequently lacks adequate air permeability. It is tightly woven, and air cannot easily pass-through during wear. The powernet toe cover (0.04 W/mk) and the elastic band (0.05 W/mk) in Sample B have higher thermal conductivity, leading to enhanced heat conduction. In contrast, the polyamide velour (0.02 W/mk) in Sample A offers good thermal comfort and a cool sensation due to its relatively low thermal conductivity, as heat is not being trapped against wearers' skin. This can contribute to overall thermal comfort. Under a maximum load, the fabric extension of velour is comparatively low (48.86 mm), indicating lesser elasticity and stretchability. Conversely, the elastic band (99.86 mm) and elastic webbing (100.04 mm) in Sample B provide better flexibility and fit of the orthosis. Lastly, the toe cover and elastic band material in Sample B exhibit higher surface friction and roughness compared to the velour in Sample A, both in the warp and weft directions, which contributes to a poor hand feel and rough contact with the skin.

Table 4.2: Experimental Parameters

| | Sample A | Sample B |
|---|---|---|
| Place of origin | Germany | Hong Kong |
| Size | EU 36-45 | Free size |
| Components & materials | Polyamide velour,<br>Polyurethane gel cushion,<br>Polyamide hinged splint with reversal slits | Powernet toe cover,<br>Elastic band,<br>Button-hole elastic webbing |
| Design features | Combination of soft-hard materials | Soft material |
| Mechanism | Align hallux by adjusting the velour | Align hallux by adjusting the webbing |
| Usage | Day Use,<br>Suitable for mild and moderate HV | Day Use,<br>Suitable for mild HV |
| Thickness (mm) | Velour: 3.10<br>Gel cushion: 2.54<br>Hinged splint: 2.45 | Toe cover: 0.41<br>Elastic band: 2.35<br>Elastic webbing: 0.98 |
| Weight (g) | 31.59 | 14.17 |
| Air resistance (kPa·s/m) | Velour: 3.10 | Toe cover: 0.06<br>Elastic band: 12.33 |
| Thermal conductivity (W/mk) | Velour: 0.02 | Toe cover: 0.04<br>Elastic band: 0.05 |
| Tensile extension at Maximum Load (mm) | Velour: 48.86 | Elastic band: 99.86<br>Elastic webbing: 100.04 |
| Surface friction (MIU) | Velour (weft/warp): 0.26/ 0.37 | Toe cover (weft/warp): 0.34/ 0.46<br>Elastic band (weft/warp): 0.37/ 0.34 |
| Surface roughness (SMD) | Velour (weft/warp): 4.14/ 0.75 | Toe cover (weft/warp): 16.35/ 1.03<br>Elastic band (weft/warp): 9.10/ 8.01 |

### 4.2.2 COP and plantar pressure

The range of the COPx (center of pressure in the medial-lateral direction) and COPy (center of pressure in the anterior-posterior direction) values were calculated and are shown in Table 4.3 and Appendix III. In barefoot, the COPx range of the HV subjects is larger than that of subjects without HV during walking and standing. A larger range of the COPy is also found with the HV subjects. When walking in Sample B, compared to the barefoot condition, there is a significant increase in the range of COPx among HV subjects ($p = 0.002$).

The analysis of peak plantar pressures in both groups, during walking and standing, revealed interesting findings. HV subjects wearing sample B exhibited lower pressure in the hallux when in a standing position. However, when walking with both sample A and sample B, the pressure in the lateral midfoot was significantly higher ($p = 0.013$ and $p = 0.031$, respectively). In contrast, when subjects without HV walked with sample A, there is a significant pressure increase in the hallux ($p = 0.004$). When they stood, the pressure in the MTP2-4 region decreased significantly ($p = 0.005$). The HV subjects wearing sample A had significantly higher pressure on the rearfoot then subjects without HV ($p = 0.029$).

Table 4.3: Comparison of COP between subjects without HV and HV subjects

| | | Static Standing Test | | Dynamic Walking Test | |
|---|---|---|---|---|---|
| | | Subjects without HV (N = 10) | HV subject (N = 6) | Subjects without HV (N = 10) | HV subject (N = 6) |
| Range of COPx (mm) | Barefoot | 1.58 | 3.74 | 17.05 | 23.45 |
| | Sample A | 1.66 | 2.21 | 15.77 | 18.38 |
| | Sample B | 2.07 | 2.00 | 18.48 | 29.96 |
| Range of COPy (mm) | Barefoot | 13.40 | 24.76 | 103.45 | 132.40 |
| | Sample A | 17.47 | 20.39 | 105.97 | 127.11 |
| | Sample B | 16.72 | 16.03 | 108.03 | 129.37 |

### 4.2.3 Changes in HVA

Compared to the barefoot condition, the HVA of the subjects without HV reduced 1.2 degrees with Sample A and significantly reduced 2.7 degrees with Sample B ($p = 0.005$) (Appendix III). The HVA of the HV subjects reduced 2.5 degrees with Sample A and 2.6 degrees with Sample B (Appendix III). Comparing the HVA of the two subject groups, it was found that the HVA after wearing Sample A ($p = 0.014$) and Sample B ($p = 0.005$) were significantly different (Appendix I).

In addition, the correction of the angle with Sample A is negatively correlated with pressure reduction of MTP2-4 during walking for HV subjects ($r = -0.889$, $p = 0.018$). The corresponding foot realignment with major corrections in the HVA might inhibit a reduction of the plantar pressure of MTP2-4. Among the subjects without HV, the angle correction with Sample B is positively correlated with reduced pressure at MTP1 during standing ($r = 0.501$, $p = 0.024$). Increased correction of the HVA is correlated with less

pressure at MTP1.

### 4.2.4 Subjective evaluation of orthoses

The average scores for ease of wear, comfort, fit, receptivity, and satisfaction were 6.49 (sample A) and 7.18 (sample B), respectively. Sample B excels Sample A in terms of comfort, which can be attributed to the utilization of soft and lightweight materials. In addition to the rating, participants provided negative feedback on the design and material fabrication of the orthoses. Issues raised included poor fit of Sample A, inflexible joint design, rough texture, and the use of non-breathable materials, all of which negatively impacted the overall comfort, receptiveness, and satisfaction of the orthoses. It is also noted that the toe cover of sample B increases the friction between the hallux and the second toe, itchiness of the foot arch, and difficulties in donning the contraption. When prescribing HV orthoses, function, comfort, and price are considered as the most important factors to take into account.

The subjective ratings showed satisfaction with the ease of using Sample A which is receptive with a mean score that exceeds 7. Sample B excels Sample A in comfort and is lighter in weight. In addition to the rating, 56% of the subjects without HV and 67% of the HV participants provided negative feedback about Sample B, which includes pain in the gap between the hallux and second toe, itchiness of the foot arch, and difficulties in donning the contraption. Moreover, 39% of the subjects without HV and 67% of the HV participants stated that Sample A causes discomfort in the gap between the hallux and second toe, is bulky, with inflexible joints, and the material of the arch is too airtight with a rough feel.

## 4.3 Discussion

### 4.3.1 Orthosis designs and materials

Traditionally, rigid orthotic materials provide enhanced support but also lower tolerance during wear, while soft and flexible materials do not effectively address underlying foot problems. Nevertheless, our findings demonstrate that orthoses made of soft, thin, and light-weight materials are more effective in reducing HVA compared to semi-rigid materials during short-term wear.

Elastic bands also accommodate various foot sizes and shapes. Nevertheless, as an HV orthosis is generally worn inside footwear, the materials should dissipate heat and wick moisture away from the skin. Elastic tapes with a loosely woven structure would more likely facilitate heat transfer and wear comfort. Considering the prolonged use of an orthosis and its intimate contact with the skin, soft and smooth textile materials can minimize the friction between the orthosis and the foot, hence enhancing wear comfort.

### 4.3.2 Physical balance and body loading

Balance control is crucial for daily activities. Research showed that the risk of falls is related to COPx measurements (Machado et al., 2015). A large COPy range may also lead to imbalance. Inability to maintain one's center of gravity within a certain range result in falls (Roman-Liu, 2018). Here, larger ranges of COPx and COPy values are found in the HV subjects while standing and walking and exceed those of the subjects without HV. This finding aligns with Shima et al. (2020) who found that HV patients have impaired balance and overcompensate with more intensive corrective movements to maintain balance. The range of COPx exhibited an increase when wearing orthosis

B, negatively impacting the postural balance of the subjects. This increase in COPx may be attributed to the displacement of the orthosis during walking. Consequently, the foot becomes more unstable and exerts greater effort to "correct" the COP back to a neutral position, leading to an increase in plantar pressure in the lateral region of the midfoot.

Plantar pressure serves as an indicator of foot function during gait. Previous studies have demonstrated that individuals with HV exhibit significantly higher peak pressure in the hallux region when walking barefoot, compared to individuals without HV (Gu et al., 2014; Martínez-Nova et al., 2010). This increased pressure is caused by the deviation of the first ray angle, which results in foot pain and adaptive changes in gait (Martínez-Nova et al., 2010). In this study, both orthoses exhibited poor performance in relieving peak pressure during walking (Figure 4.2). Their lack of additional support in the arch region reducing the contact area between the foot and orthosis and failing to alleviate excessive pressure in the forefoot region (Farzadi et al., 2015).

A full-length insole with arch support can effectively distribute plantar pressure (Yu et al., 2013). When the subjects used the orthoses, lateral component slip to the plantar side of MTP1 and hallux. Extra plantar pressure may be exerted. This problem is more obvious with Sample A, which has a thicker and cumbersome design. Thinner materials should be therefore used.

### 4.3.3 Angle correction and comfort

The use of orthotics resulted in a reduction of the HVA in both groups by more than 2 degrees. The findings for Sample A are consistent with Moulodi et al. (2019), who

reported a reduction of 2 to 3 degrees in the HVA after one month of continuous orthotic use. Notably, Sample B demonstrated a significantly more noticeable correction. Previous studies have indicated that softer materials provide less mechanical constraint compared to semi-rigid materials (Hadadi et al., 2010; Kim & Won, 2019). Kim and Won (2019) conducted a study comparing a conventional ankle-foot orthosis with an elastic band-type orthosis and found that the latter can effectively realign the foot and achieve similar range of motion for the ankle and knee joints during gait. In the subjective assessment conducted in this study, functionality and comfort were prioritized. Similar findings were reported by Kim and Won (2019), where the soft orthosis was found to offer higher wear comfort.

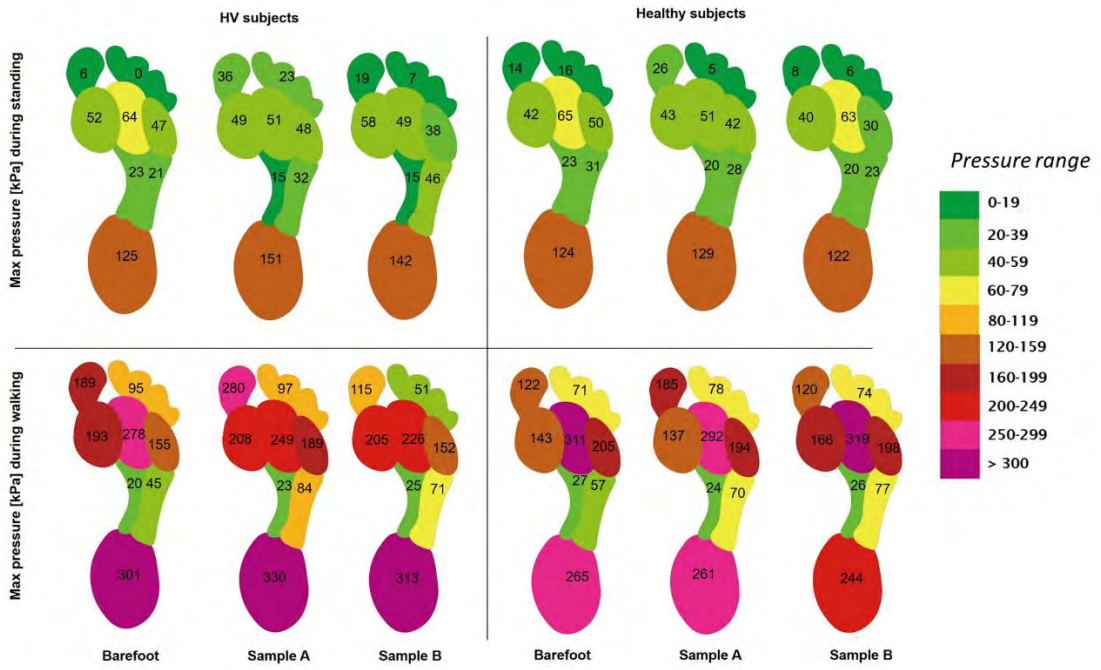



Figure 4.2: Plantar pressure distribution during standing and walking.

## 4.4 Chapter summary

Our research indicates that during short-term wear, semi-rigid orthoses can lead to discomfort during wear and an increase in COP. On the other hand, soft orthotics offer superior correction of HVA, enhanced wearing comfort, and reduced plantar pressure on the hallux. As a result, future orthosis designs should prioritize the use of soft, thin, and smooth flexible materials. These findings not only serve as a guide for selecting HV orthoses but also highlight the design limitations of current orthotics and provide recommendations for future advanced designs.

# Chapter 5 Ergonomic Design of Arch Support for HV and Flatfoot

## 5.1 Introduction

HV is a foot deformity commonly associated with foot pain, which inhibits the mobility and physical activity level of those who suffer from the deformity (Nix et al., 2012). Richie Jr (2021a) proposed that flatfoot is an intrinsic risk factor related to the development of HV. In flatfoot, the foot is pronated and the arch collapses under the weight of the body. It may lead to a change in the alignment of the first ray axis and is associated with lateral drift of the hallux or medial deviation of the MTP1. Custom-made arch support can be an effective means for pain relief and the alignment of the first ray axis for patients with flat foot and/or HV. Studies showed that wearing an arch-support insole provides the generation of propulsion force while walking and improve joint kinetics (Huang et al., 2020, Wang et al., 2020). In this study, an insole embedded with a rigid arch support made of carbon fiber was designed and developed for a two-month wear trial. The first aim of the present study was to evaluate the effect of our arch support intervention by footprint. We expect significant improvement in pathology in patients with flatfoot. The pathology of HV patients can also be alleviated accordingly.

It is important to diagnose HV and flatfoot scientifically to prevent further deterioration. Compared with ultrasonography, 2D static footprint analysis by podograph is a cost-effective and reliable method (Queen et al., 2007). There is a significant correlation between their measurement ($p < 0.001$) (Lo, 2014). In terms of arch measurements, researchers developed the foot type index as a highly sensitive and reliable indicator for the diagnosis of flatfoot (Pita-Fernández et al., 2015). Foot type index > 0.45 is the cut-off point for the diagnosis of flatfoot (Pita-Fernández et al., 2015). However,

traditionally collected footprints without clear outlines that data may be lost due to the inability to measure (Queen et al., 2007). In this study, multiple foot parameters including foot length, foot breadth, heel breadth, arch angle, arch breadth, and plantar arch index were compared against foot type index to obtain the desired measurements. This can help clinicians in choosing a better alternative to the foot type index and measuring the missing data. Thus, the second part of this study is to investigate the relationship between the foot type index and selected arch measurements which can contribute to the ergonomic design of HV orthosis.

## 5.2 Methods

### 5.2.1 Participants

Seventy-six females volunteered for the study, with an average height of 151 centimeters (cm), an average weight of 54 kilograms, and an average BMI of 24. The participants lived in elderly centers and were older retirees with more of their daily activities at the center, their activity levels were expected to be lower. Participants were divided into four groups, namely (1) subject with HV, (2) subject with flatfoot, (3) subject with both HV and flatfoot and (4) healthy control. Of the seventy-six participants, twenty-eight (36.84%) have HV and thirty (39.47%) have flatfoot, of which fifteen (19.74%) have both HV and flatfoot. Thirty-three (43.42%) subjects without HV or flatfoot will serve as the control group. They were asked to wear an arch support intervention for two months, from June to August, with at least 20 hours per week. The arch support made of carbon fiber was shown in Figure 5.1. Carbon fiber is lightweight with excellent bending stiffness, usually used in athletic footwear to minimize energy loss and help wearers perform better in sports (Gregory et al., 2018;

Ko et al., 2023. 2D footprints were collected from each volunteer by using podograph before and after the wear trial. Written consent was obtained from all participants before study commencement, and the study procedures were approved by the Human Subjects Ethics Sub-Committee at the Hong Kong Polytechnic University (reference number: HSEARS20190924004), following all policies regarding the use of human participants.

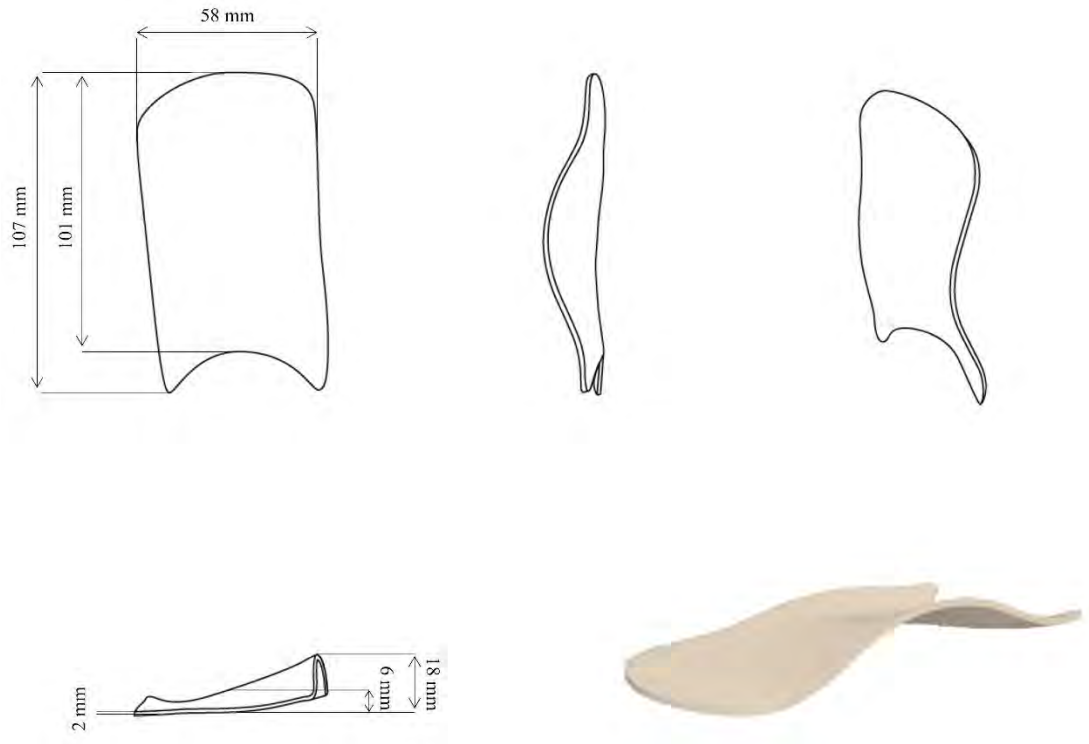



Figure 5.1: Schematic diagram of the carbon fiber arch support

### 5.2.2 Measurements

2D footprints were collected from each volunteer in a barefoot weight-bearing standing position by using a podograph. During the test of footprints, the subjects should stand naturally with feet shoulder-width apart. The length, breadth and angle measurements

of the dominant foot were suggested in Figure 5.2. The foot type index was calculated as arch breadth divided by foot breadth (Equation 5.1). A lower index suggests adequate arch support (Pita-Fernández et al., 2015). The plantar arch index establishes a relationship between the central and posterior regions of the footprint. It was calculated as arch breadth divided by heel breadth (Equation 5.2). A lower index value means a higher arch.

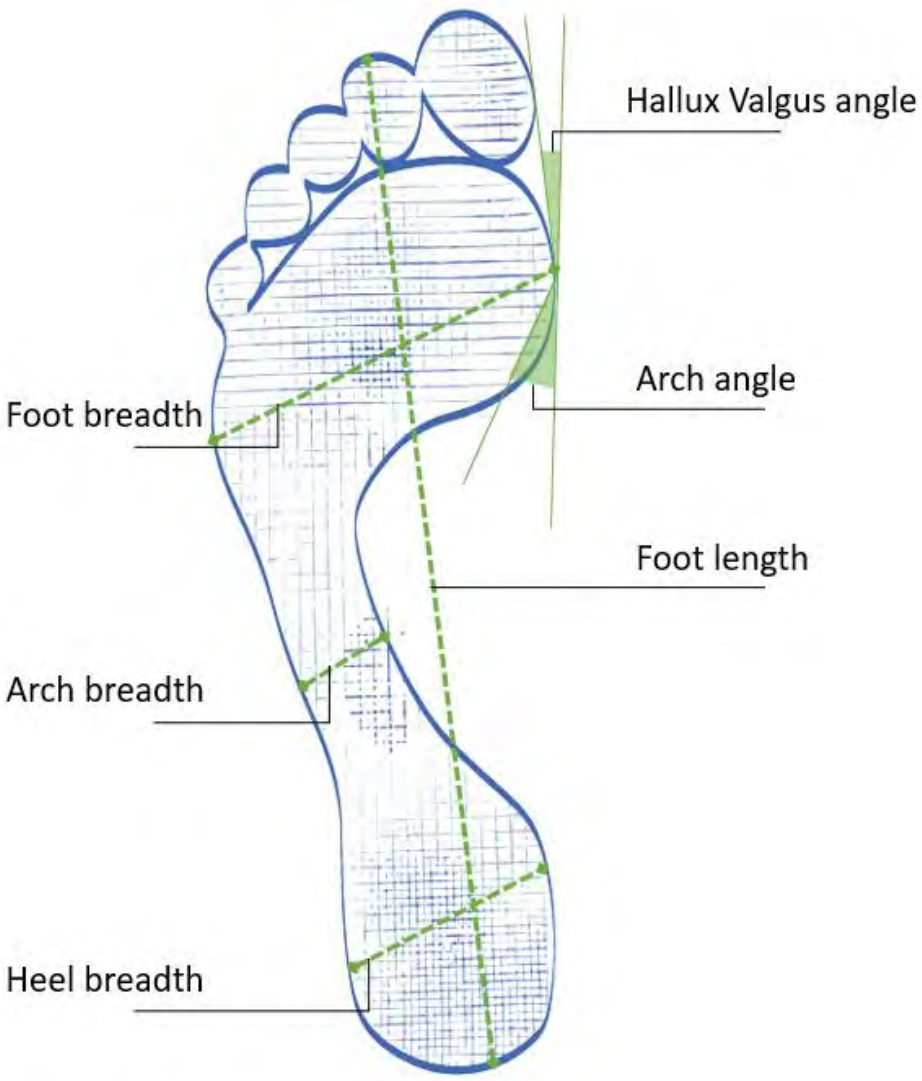



Figure 5.2: Foot anthropometric measurements

Equation 5.1:

$$FTI = \frac{AB}{FB}$$

Equation 5.2:

$$PAI = \frac{AB}{HB}$$

In Equation 5.1 and 5.2, PAI represents Plantar Arch Index, and FTI is the Foot Type Index. AB, HB, and FB represent arch breadth, heel breadth, and foot breadth, respectively.

### 5.2.3 Statistical analysis

Data on the footprint of the subjects will be assessed. The R project for statistical computing was used to analyze the data. The normality assumption will be checked by the normal QQ plot. Linear regression and Pearson's correlations were adopted to analyze the association between foot type index and other foot measurements. Statistical differences were calculated with paired samples t-test. The significance level for statistical analysis was set at 0.05.

## 5.3 Results and discussion

Paired samples t-tests have been carried out to evaluate the changes in foot parameters measured before and after the wear trial (Table 5.1). The data were normally distributed.

After the wear trial, there are significant changes in all the arch measurements. It suggested that all the four groups of subjects showed statistically significant improvements in arch angle, arch breadth, plantar arch index, and foot type index after the wear trial. Using the arch support design shows greater improvements on foot deformations in subjects with pathology compared to controls. The arch support plays a greater effect on the target patient. This conclusion matches our hypothesis. The phenomenon was particularly evident in subjects with both HV and flatfoot, who had a 7.933-degree improvement in arch angle ($p = 0.002$), 0.149 reduction in plantar arch index ($p < 0.001$), 0.657 cm reduction in arch breadth ($p = 0.003$), and 0.063 reduction in foot type index ($p = 0.013$).

The result suggests that long-term wearing of arch support can help improve flatfoot. Previous research has shown that arch support intervention increases the contact area of the midfoot, providing support for the medial arch. Arch support, which is composed of harder materials, can also provide better support, resulting in shorter stance time in level walking (Perry et al., 2007). The shorter stance time could reflect the patient is gradually changed from a pathological gait to a normal gait and may increase gait speed while walking (Guo et al., 2017, Studenski et al., 2011). In this study, a rigid carbon fiber arch support was used, which effectively supports the midfoot.

In terms of HVA, no significant changes were found in any group, but a slight improvement could be found in subjects with HV, with a 1.536-degree reduction in HVA ($p = 0.086$). In addition to HV subjects, a 0.933-degree reduction in HVA could be found in subjects with both HV and flatfoot ($p = 0.334$). The use of arch support to lift the arch may contribute to HV correction. We believe that adequate arch support can restore proper anatomical alignment of the foot (Farzadi et al., 2015, Kwan et al.,

2021, Tehraninasr et al., 2008). However, the results of the two-month wear trial showed that the HVA correction could not catch up with the improvement of the arch index, while control of further deformation may be achieved with long treatment period.

Linear Regression was further computed to analyze the relationship between foot type index and other foot measurements and their interactions. Results were shown in Figure 5.3. Significantly negative relationship with foot type index and arch angle ($r^2 = 0.545$, $p < 0.001$), and significantly positive relationship between foot type index and plantar arch index ($r^2 = 0.878$, $p < 0.001$), and arch breadth ($r^2 = 0.928$, $p < 0.001$) can be found. The coefficient of determination is the highest in arch breadth, followed by plantar arch index, and then arch angle. The improvements in the foot type index resulted in increased arch angle, with reduced arch breadth, plantar arch index, heel breadth, and HVA. A significant positive relationship between foot type index and heel breadth ($r^2 = 0.036$, $p = 0.019$), and HVA ($r^2 = 0.037$, $p = 0.017$) were also found.

Correlations between foot type index and other foot arch related measurements were also analyzed. Arch angle, arch breadth, and plantar arch index were strongly correlated with foot type index. Among them, the correlation between foot type index and arch breadth was the strongest ($r = 0.960$, $p < 0.001$). The presented results suggest that all the arch indices studied are suitable for diagnosing flatfoot, while arch breadth is the most suitable measurement to substitute foot type index when necessary. If foot type index is not available, arch breadth, plantar arch index or arch angle provide useful foot information at the time of diagnosis. An arch breadth $\geq 4$ cm, a plantar arch index $\geq 0.8$, or an arch angle $\leq 29$ degrees are considered as flatfoot, using a foot type index $> 0.45$ as an indicator.

Table 5.1: Two-month effect of the wear trial

| Parameters | | Subject with HV (N = 28) | Subject with flatfoot (N = 30) | Subject with both HV and flatfoot (N = 15) | Control (N = 33) |
|---|---|---|---|---|---|
| Arch angle (degree) | Mean of differences | 6.000 | 5.950 | 7.933 | 2.833 |
| | p-value | < .001*** | < .001*** | 0.002** | 0.002** |
| Plantar arch index | Mean of differences | -0.108 | -0.092 | -0.149 | -0.021 |
| | p-value | < .001*** | < .001*** | < .001*** | < .001*** |
| Arch breadth (cm) | Mean of differences | -0.511 | -0.448 | -0.657 | -0.105 |
| | p-value | < .001*** | < .001*** | 0.003** | 0.003** |
| Foot type index | Mean of differences | -0.056 | -0.046 | -0.063 | -0.010 |
| | p-value | < .001*** | 0.004** | 0.013* | 0.013* |
| HV angle (degree) | Mean of differences | -1.536 | 1.033 | -0.933 | 1.455 |
| | p-value | 0.086 | 0.190 | 0.334 | 0.334 |
| Foot length (cm) | Mean of differences | 0.205 | 0.152 | 0.257 | 0.265 |
| | p-value | 0.014* | 0.023* | 0.009** | 0.009** |
| Heel breadth (cm) | Mean of differences | 0.048 | 0.037 | 0.150 | 0.018 |
| | p-value | 0.502 | 0.545 | 0.163 | 0.163 |
| Foot breadth (cm) | Mean of differences | -0.043 | -0.097 | -0.210 | -0.062 |
| | p-value | 0.712 | 0.302 | 0.193 | 0.193 |

Note. * p < .05, ** p < .01, *** p < .001

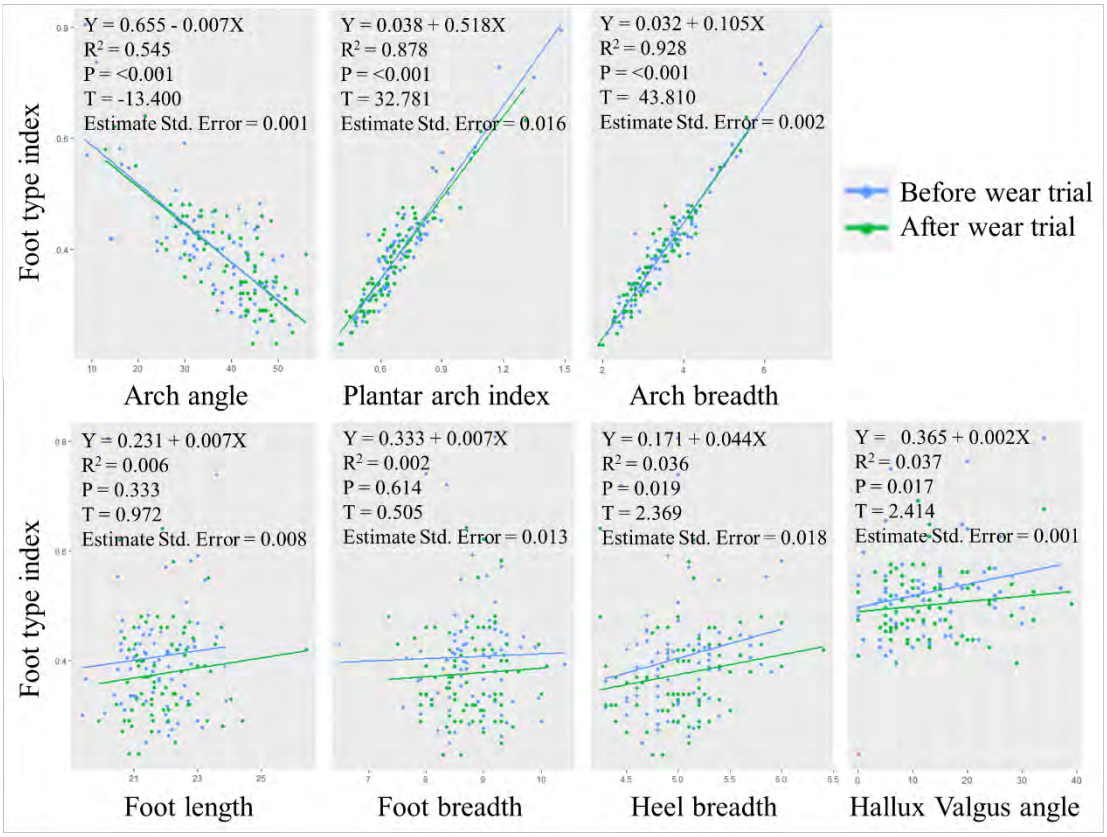



Figure 5.3: Relationship between foot type index and other foot measurements (N = 76)

## 5.4 Chapter summary

It may be concluded that our arch support intervention, with the use of hard arch support, can significantly improve the foot arch after a two-month wear trial. However, the effect on plantar pressure distribution remains unknown. This issue will be discussed in next chapter. Foot type index, as an indicator of 2D static footprint analysis, has been used worldwide. Since the contour of the footprint is not clear, it is important to find another reliable method to replace or predict the foot type index. The presented results suggest that all the arch indices studied have strong correlations with foot type index, while among the measurements, arch breadth is the best predictor of the foot type index, it can be regarded as the most suitable measurement to substitute foot type index in research studies or when making a clinical diagnosis.

# Chapter 6 Evaluation of Arch Support with Biomechanical Simulation Model

## 6.1 Introduction

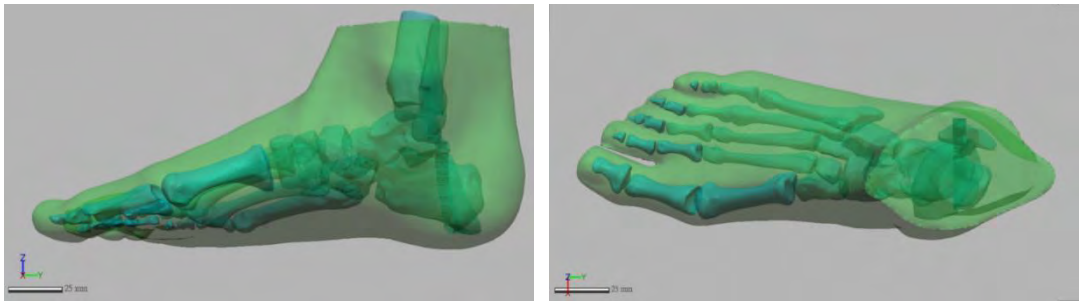
With the advancement of computer technology, FEA has emerged as a widely used method in simulation analysis. Its applications extend beyond engineering and physics, encompassing the design of medical devices, orthopedic devices, and brace designs. FEA facilitates the direct visualization of experiments, enabling researchers to gain valuable insights.

In addition to arch lifting and HV angle correction, plantar pressure is also an indicator of foot function during gait. Previous studies have demonstrated that patients with HV exhibit significantly higher peak pressure in the hallux, which can be attributed to the deviation of the first ray angle. This increased pressure often leads to foot pain and causes adaptive changes in gait (Gu et al., 2014; Martínez-Nova et al., 2010). To address this issue, additional support in the arch region is necessary to achieve better distribution of the body load and alleviate excessive pressure at the forefoot (Farzadi et al., 2015).

In this study, simulations of plantar pressure distribution upon standing were conducted to analyze the distribution of plantar pressure while standing using arch supports made of different materials, including carbon fiber, urethane foam, and silicone. Silicone and urethane foam are widely recognized for their superior energy absorption characteristics and are commonly utilized in the production of arch supports or insoles for pressure reduction (Jasper & Tong, 2010; Mei, 2021).

## 6.2 FEM construction

The dominant foot MR images of a female subject with a normal BMI who has an 18-degree HV angle was taken in a neutral unloaded position to construct the FEM. The geometry of the foot was taken from the model subject by using a structured light handheld 3D scanner (Artec Eva, Luxembourg) with a 3D resolution up to 0.2 mm. The foot was put in a neutral and non-weight-bearing condition during scanning. The scanned data was registered using Artec Studio 13 and then processed with 3D modeling software (3ds Max, Autodesk). The foot model was shown in Figure 6.1. The mesh size of the solid elements ranged from 3 mm to 10 mm. Tetrahedral elements were chosen as mesh elements due to their geometric versatility for meshing complex shapes (Table 6.1).



(a) (b)

Figure 6.1: The simplified bone and ligament structure: (a) lateral view, and (b) anterior-posterior view

To enhance the fit, a new arch support was designed using modified reverse engineering techniques based on the scanned arch shape of the foot. Figure 6.2 illustrates the incorporation of a honeycomb structure into the design. Honeycomb structures have gained popularity due to their favorable characteristics such as high stiffness-to-weight ratio, low mass–volume ratio, and excellent energy absorption capacity (Chandrashekhar et al., 2021). This design choice ensures optimal support while keeping the weight low and allowing air permeability for improved comfort.

The effect of the original and new arch support designs on plantar pressure was simulated using FEM. The designs were processed using 3D modeling software (3ds Max, Autodesk), with a mesh size of 3 mm for the arch support. The bones, arch support, and foot were constructed using FE analysis software (MSC Marc/Mentat) as depicted in Figure 6.3. The material properties utilized are outlined in Table 6.1.

The FEM would be used to simulate balanced standing. The foot and arch support models were initially aligned such that they would touch each other when one of them moves towards the other. The floor was constrained to move solely in an upward direction. A point force equivalent to half the body weight (225 Newtons) of the subject was applied to the floor to represent the load.

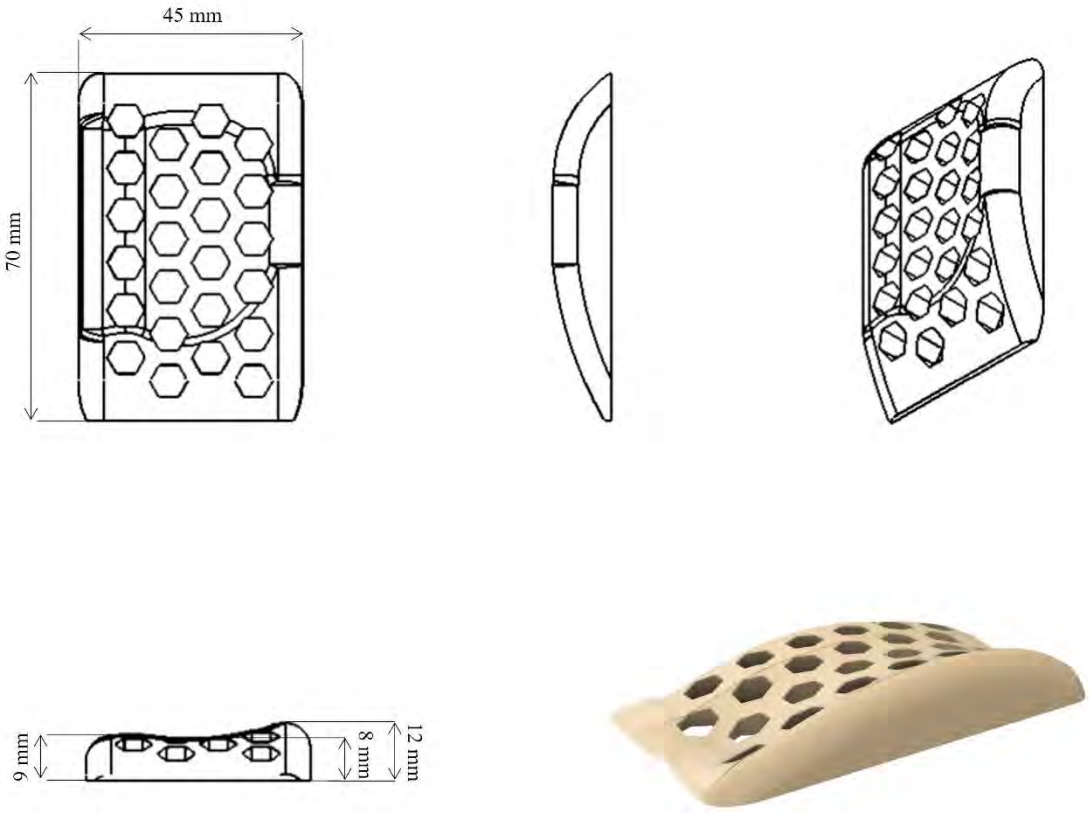



Figure 6.2: Schematic diagram of the new arch support design

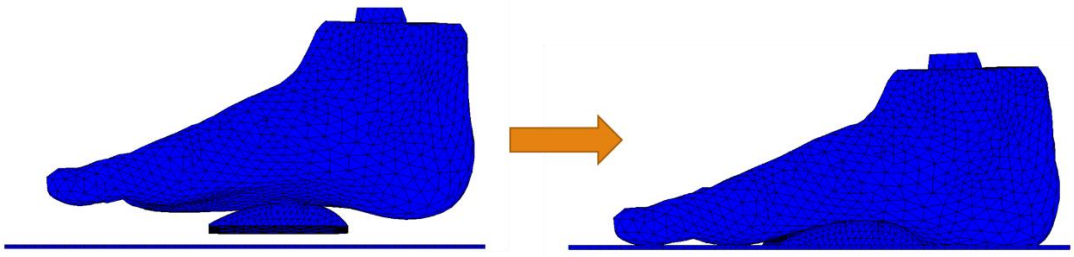


Figure 6.3: The FEM of arch support and sub-model of foot with HV

Table 6.1: Material parameters of the FEM

| Components | Young's Modulus (MPa) | Poisson's ratio | Element type | Material type | References |
|---|---|---|---|---|---|
| Ground | 30000 | 0.3 | Solid | | (Wong et al., 2014) |
| Bone | 7300 | 0.3 | Solid | | (Nakamura et al., 1981) |
| Ligament | 260 | 0.4 | Truss | | (Siegler et al., 1988) |
| Soft tissue | 0.15 | 0.49 | Solid | Elastic-plastic isotropic | (Lemmon et al., 1997) |
| Carbon fiber | 80000 | 0.3 | Solid | | (Chung, 1994) |
| Urethane foam | 1 | 0.35 | Solid | | (Larson, 2019) |
| Shore A 10 silicone | 0.4 | 0.47 | Solid | | (Larson, 2019) |
| Shore A 5 silicone | 0.3 | 0.47 | Solid | | (Larson, 2019) |

## 6.3 FEM validation

Through the FEA, the pressure distribution on the foot was systematically evaluated upon the arch support intervention. The accuracy of the FE contact model was also validated. The experimentally obtained from the Novel Pedar® system and simulated interface are compared in Figure 6.4. The foot was divided into three regions (forefoot, midfoot, and rearfoot) for the simulation. The differences observed among these three regions were within 10%, which is considered an acceptable margin of error for predicting pressure (Rahman et al., 2019; Safarin, 2015).

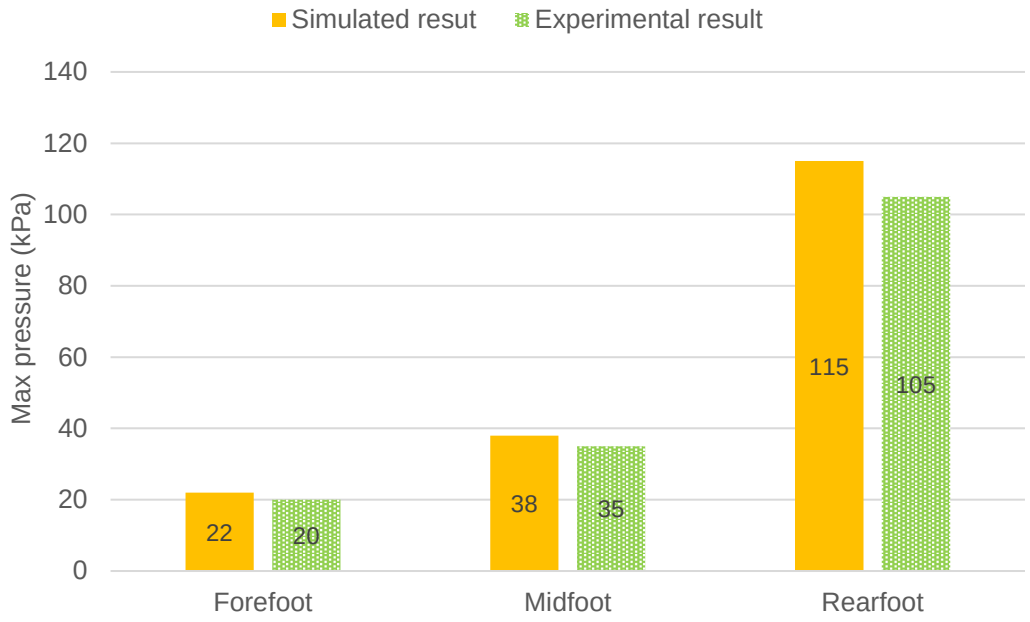



Figure 6.4: Comparison of experimental and simulated results in plantar pressure distribution upon barefoot standing

### 6.4 Results and discussion of FEA

By FE simulation with material properties of carbon fiber, the new arch support design featuring a honeycomb structure achieves improved plantar pressure distribution, as shown in Figure 6.5 and 6.6, with the transfer of pressure from the forefoot and rearfoot regions to the arch region. The results of the new arch support design, considering different material properties, are illustrated in Figure 6.7. Previous research by Anderson et al. (2020) defined that the most desirable insole design exhibited lower pressures under the hallux and MTPJ1, while demonstrating greater pressures and contact area under the medial midfoot. The results indicate that the arch support can effectively redistribute plantar pressure from the MTPJ1 to the midfoot region, potentially alleviating forefoot pain experienced by individuals with HV. Reducing pain

in the lower extremities can contribute to improved walking stability (Chen et al., 2003; Mulford et al., 2008). Moreover, Goonetilleke (2012) suggested that adequate support in the midfoot region can help prevent plantar fasciitis.

In terms of material properties, it is observed that Shore A 5 silicone achieves a more even distribution of plantar pressure, with the lowest pressure recorded in the forefoot region and moderate pressure distributed to the midfoot region. This material demonstrated a greater ability to effectively distribute pressure compared to harder materials. Other studies have also found that softer materials are more effective in reducing plantar pressure as they conform better to the geometrical shape of the foot, resulting in increased contact area across the foot (Che et al., 1994; Luximon et al., 2014; Melia et al., 2021; Pan et al., 2021; Sprigle et al., 1990). Additionally, softer materials are associated with greater comfort (Finestone et al., 2004; Hennig et al., 1996). The findings of this study further support the notion that soft materials can effectively reduce plantar pressure, particularly in the forefoot region during balanced standing.

Furthermore, the arch height was measured by determining the vertical distance from the arch to the rigid ground in the FEM analysis. The results in Table 6.2 demonstrate that the arch support effectively lifted the arch, with the arch being lifted to a greater height when harder materials were used. Among the examined materials, the arch support with carbon fiber exhibited the highest arch lift. This finding may provide an explanation for the effective arch lifting observed in the wear trial discussed in Chapter 5. These results offer valuable insights for the selection of materials for arch support designs.

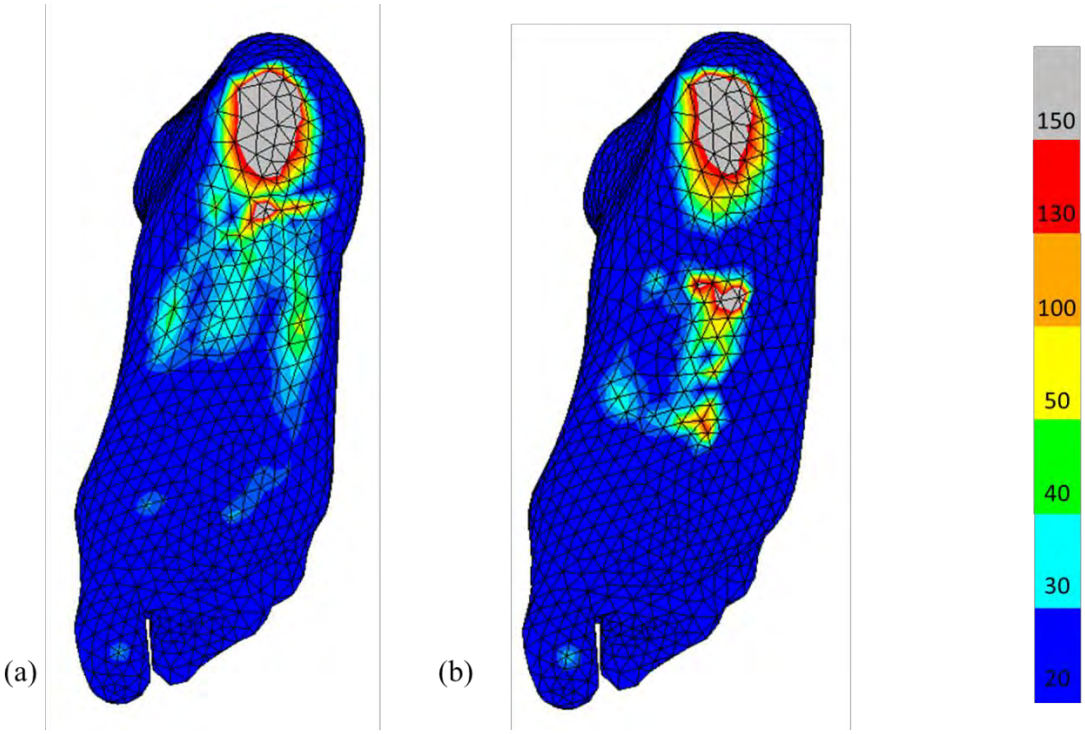



Figure 6.5: Visualization of the stimulated plantar pressure distribution of different arch support designs in carbon fiber: (a) original design, and (b) new design

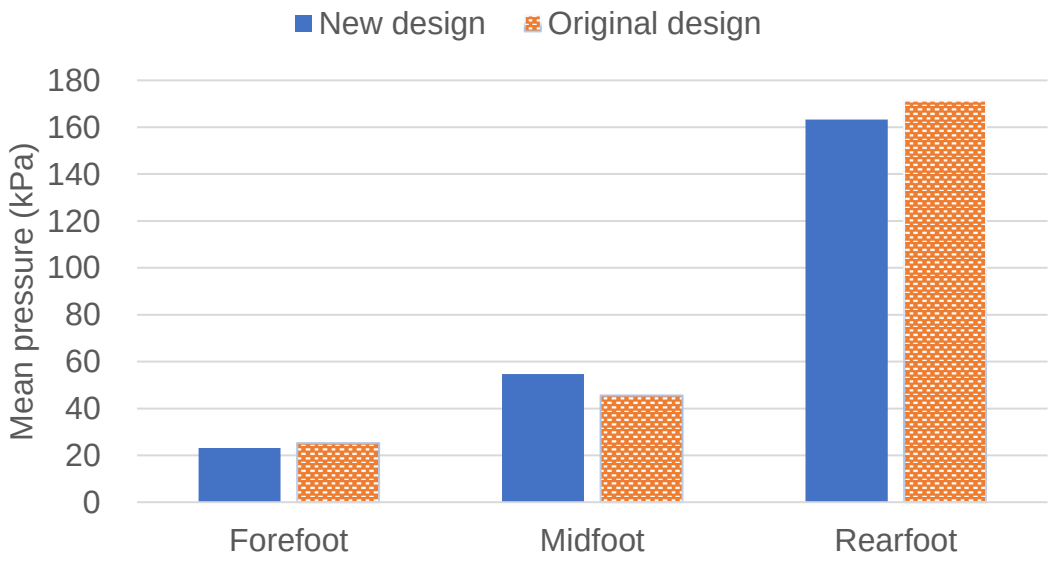



Figure 6.6: Stimulated plantar pressure distribution of different arch support designs

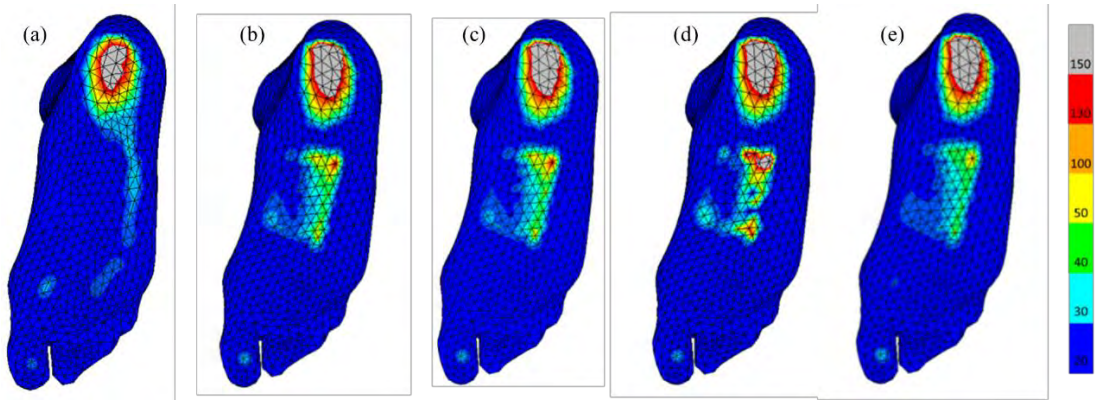



Figure 6.7: Visualization of the stimulated plantar pressure distribution of different arch support materials: (a) barefoot, (b) with urethane foam arch support, (c) with Shore A 10 silicone arch support, (d) with carbon fiber arch support, and (e) with Shore A 5 silicone arch support

Table 6.2: Arch height measured in FEM

| | Arch height (mm) |
|---|---|
| Barefoot | 6.44 |
| Shore A 5 silicone | 6.95 |
| Shore A 10 silicone | 7.10 |
| Urethane foam | 7.35 |
| Carbon fiber | 7.60 |

## 6.5 Evaluation of FEA by wear trial

### 6.5.1 Methods

The FEA confirmed that the use of hard carbon fiber is not as effective as soft silicone or urethane foam in achieving improved plantar pressure distribution. To further analyze the pressure distribution in detail, a wear trial was conducted involving participants with mild to moderate HV and had a shoe size ranging from EU 37 to EU 39. The participants underwent a trial walk for each experimental condition to familiarize themselves with the orthosis. Subsequently, they were instructed to walk in a straight line on a flat surface at a self-selected speed while their COP and average peak pressure were measured using the Novel Pedar pressure system and Pedar® insole sensors. This allowed for the evaluation of how the arch support influenced balance control and pressure distribution. Each participant successfully completed three trials to ensure data consistency. The regions used for analysis align with those stated in Chapter 4 (Figure 4.1d). A paired samples t-test was conducted to examine the effect of the arch support on plantar pressure distribution.

### 6.5.2 Results and discussion

Body balance is often evaluated through the measurement of COP displacement. Table 6.3 provides a summary of the COP measurements. The results indicate that the range of COPx is significantly higher after using the urethane foam ($p = 0.028$). This suggests that one of the challenges associated with using urethane foam is poor balance control in the medial-lateral direction during walking. Difficulty in maintaining the center of

gravity within a specific range can increase the risk of falls (Roman-Liu, 2018).

Table 6.3: Range of COP during walking (N = 22)

| | Barefoot | | Silicone | | Urethane foam | | Barefoot vs Silicone | Barefoot vs Urethane foam |
|---|---|---|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | Mean | S.D. | p | p |
| COPx | 48.40 | 7.20 | 49.60 | 10.08 | 52.70 | 5.67 | 0.256 | 0.028* |
| COPy | 176.60 | 14.22 | 181.30 | 37.59 | 187.00 | 28.89 | 0.566 | 0.235 |

Note. * p < .05, ** p < .01, *** p < .001

The results of pressure distribution are presented in Table 6.4. It is observed that the use of arch support made of either silicone or urethane foam leads to a significant increase in midfoot pressure. However, when silicone arch support is employed, there is a significant reduction in plantar pressure in the MTP2-4 and rearfoot regions (p = 0.049 and p < .001, respectively). These findings suggest that silicone is more effective in redistributing plantar pressure during walking compared to urethane foam.

Table 6.4: Plantar pressure distribution during walking (N = 22)

| | Barefoot | | Silicone | | Urethane foam | | Barefoot vs Silicone | Barefoot vs Urethane foam |
|---|---|---|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | Mean | S.D. | p | p |
| Hallux | 198 | 138 | 191 | 183 | 195 | 164 | 0.748 | 0.893 |
| Lateral toes | 100 | 108 | 105 | 112 | 112 | 113 | 0.945 | 0.430 |
| MTP1 | 158 | 88 | 182 | 107 | 185 | 94 | 0.444 | 0.113 |
| MTP2-4 | 300 | 104 | 263 | 112 | 281 | 85 | 0.049* | 0.689 |
| MTP5 | 173 | 100 | 162 | 143 | 156 | 124 | 0.814 | 0.189 |
| Midfoot medial | 38 | 83 | 101 | 62 | 77 | 78 | < .001*** | < .001*** |
| Midfoot lateral | 73 | 59 | 120 | 30 | 71 | 37 | < .001*** | 0.890 |
| Rearfoot | 272 | 65 | 236 | 66 | 256 | 77 | < .001*** | 0.776 |

Note. * $p < .05$, ** $p < .01$, *** $p < .001$

## 6.6 Chapter summary

This chapter analyzes the effectiveness of arch support. The developed numerical model successfully predicts the performance of arch supports of different materials in terms of plantar pressure distribution during standing. The results demonstrated that the use of arch support can effectively redistribute the pressure and load from the forefoot to the midfoot region. Soft materials are found to be more effective at achieving optimal plantar pressure distribution, while hard materials are more effective at providing arch lift. Additionally, the chapter investigated the peak plantar pressures of participants wearing soft arch supports during walking. Results of the study showed that HV patients who used silicone arch supports had better balance and significantly lower plantar pressure under the MTP region compared to urethane foam arch support.

# Chapter 7 Ergonomic Design of New HV Orthosis

## 7.1 Introduction

HV is a deformity where the hallux deviates laterally towards the other toes and joints, and the MTP1 deviates medially, which result in a valgus angle at the MTPJ1 (Lee et al., 2012). HV is an inflammatory joint disease that mainly affects females, as 90% of HV patients are female (Walther & Szeimies, 2012). Conservative measures, such as the use of HV orthoses, can help to reduce the symptoms of HV (Kwan et al., 2021; Moulodi et al., 2019). However, the bulky design of currently available orthoses made of rigid materials inevitably cause wear discomfort which also do not fit in daily use footwear, thus adversely affecting treatment compliance. To address these issues and meet user requirements, this study proposes a functional, sock-like HV orthosis by using 3D foot scanning and 3D printing technologies to apply corrective forces onto the hallux and the MTPJ1 to preserve wear comfort and improve treatment compliance. The key design elements and fabrication processes are presented in this chapter.

## 7.2 Design criteria and design idea

The design model for functional wear discussed in Chapter 2 shows that it is important to identify user needs. Thus, feedback and comments from orthopedists and users of commercially available orthoses were sought through interviews and questionnaires.

A common theme among the feedback is the importance of a good fit. Users emphasized that a well-fitted orthosis could reduce the likelihood of discomfort. Orthopedists

echoed this sentiment, noting that a good fit is crucial for the orthosis to function effectively. Additionally, both orthopedists and users highlighted the need for sufficient corrective force in an HV orthosis to effectively reduce the HVA. They pointed out that an orthosis that can generate adequate force can help in realigning the hallux to its natural position, thereby alleviating the symptoms of HV. Therefore, good fit and sufficient force are considered the ideal qualities of an HV orthosis.

Previous literatures have also shown that fit, function, wear comfort, and ease of donning and doffing are the primary considerations, while aesthetics and expressive considerations are less crucial for functional wear (Booradya, 2011; Faust & Carrier, 2014; Michaelson et al., 2018). An improper fit of functional garments can adversely affect their effectiveness and potentially lead to injuries (Michaelson et al., 2018). Wear comfort is influenced by factors such as the materials used, fit, and pressure against the body.

After understanding the needs of the users, their needs were translated into design concepts, the essential design elements were defined, and design process was implemented (Carroll & Kincade, 2007; Clarkson et al., 2007; Gupta, 2011). With reference to previous design models for functional wear, this study designs an HV orthosis following the design framework shown in Figure 7.1, which addresses current design deficiencies while considering practical user requirements in daily life activities. To complete the design, material testing and selection, pattern drafting, and a finite element analysis (FEA) are done. Finally, an evaluation is conducted, and any necessary changes to the design are made based on feedback. This final step will be discussed in the next chapter.

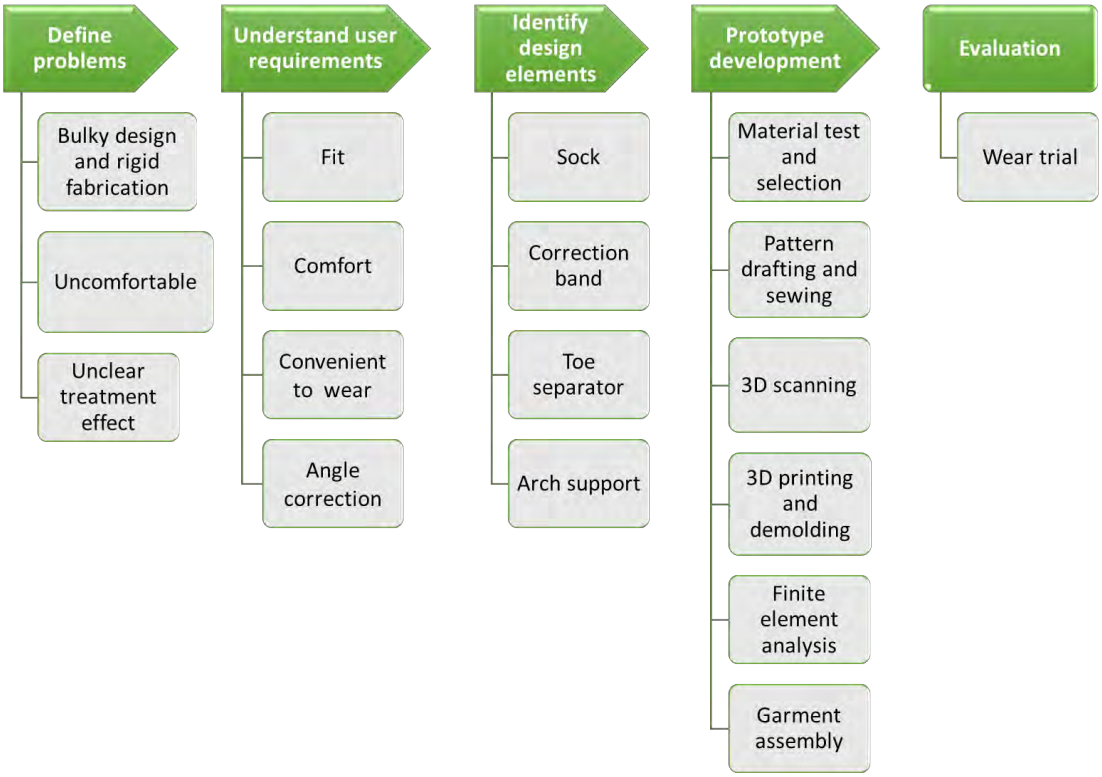



Figure 7.1: Design framework of HV orthosis

## 7.3 Design and prototype

### 7.3.1 Sock wear design and development

#### 7.3.1.1 Pattern construction

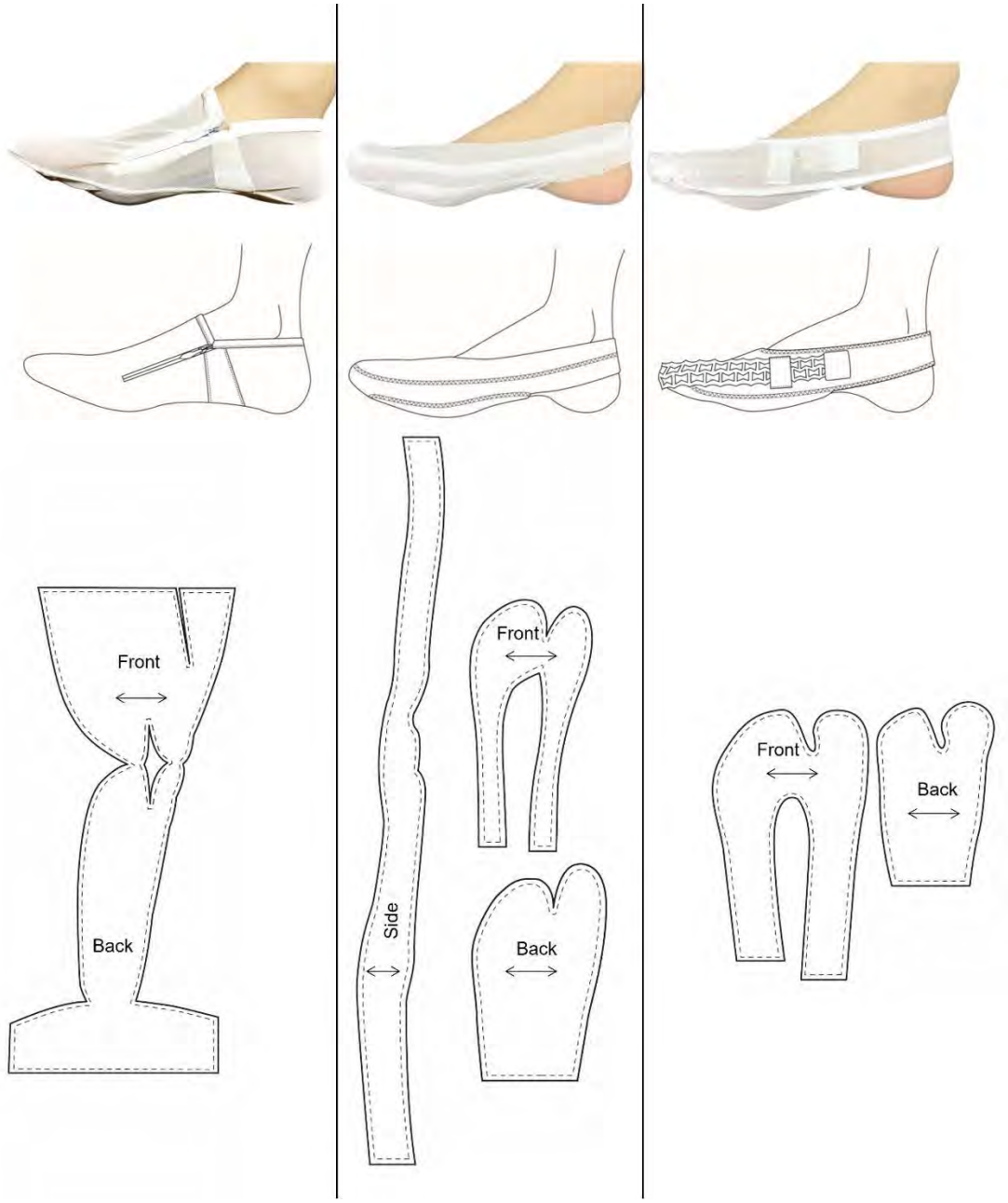
The use of orthoses is generally considered to be less intrusive than HV surgery. Their use is a conservative approach that aims to correct the angle of the hallux, alleviate pain, and prevent further deformation of the MTPJ1. As indicated in the evaluation of orthosis designs in Chapter 4, current orthoses designed for HV treatment are generally bulky and do not fit well, so a sock-like orthosis is proposed in this study. This functional sock provides a more convenient means to use an HV orthosis and is more comfortable to wear, which help to improve patient compliance. To design a sock-like HV orthosis with optimal fit, a sock pattern was developed through draping. A total of three prototypes were created which are shown in Figure 7.2.

The first pattern is a one piece to minimize the seams that may cause discomfort to the skin (Figure 7.2a). The pattern separates the toes to relieve discomfort and to facilitate the intervention of correction devices. An invisible zipper was placed at the narrow part of the foot. However, this design does not offer a good fit, and creates extra space inside the sock. Although the zipper is invisible, it causes discomfort when worn with women's shoes.

To solve the problems of the first prototype, a second pattern was developed (Figure 7.2b) with a 3D pattern, which was divided into front, back, and side panels to ensure a good fit. The zipper was eliminated to maintain wear comfort. Moreover, the second

prototype is an open-back style so that the sock will not be evident, thus increasing the aesthetics of the treatment.

To further enhance the productivity and improve wear comfort, a third pattern was developed (Figure 7.2c). The second pattern was reduced to two pieces, which would require fewer seams. The lesser toe box was enlarged to provide better wear comfort and allow flexible movement of the toes. A curved edge in the webspace replaced the sharper edge for a better fit and to facilitate ease of sewing. A 0.5 mm seam allowance was added.




(a) (b) (c)

Figure 7.2: Design pattern and fabrication of the proposed sock-like orthosis (a) first prototype, (b) second prototype, and (c) final prototype

#### 7.3.1.2 Material and structure

Conventional HV orthoses are typically constructed with bulky and rigid materials, which can result in low treatment compliance and reduced wear comfort. In this study, the proposed HV orthosis is constructed as a sock, which is much less rigid than conventional orthoses and has the potential to enhance wear comfort. Material selection plays an important role in optimizing the design, with a focus on materials that are low in thickness, breathable, and lightweight. By using the right type of materials, the proposed orthosis could provide a close fit, breathability, and effective correction for the wearer.

Powernet was identified as a suitable material for constructing the HV orthosis due to its versatile properties, particularly for fabricating close-fitting garments that require elasticity and a certain level of tension. Powernet has been widely used in activewear and orthopedic products as it provides support and wear comfort while allowing ease of movement. Five types of powernet fabrics were sourced and are listed in Table 7.1. Their properties in terms of thickness, fabric weight, air permeability, thermal conductivity, water vapor transmission (WVT) rate and surface roughness were subsequently compared.

Table 7.1: Fabric specifications

| Fabric | Fibre Content | Thickness (mm) | Weight ($g/m^2$) |
|---|---|---|---|
| A | 83% Polyamide SD, 17% Elastane | 0.45 | 180 |
| B | 77% Polyamide 23% Spandex | 0.44 | 169 |
| C | 59% Polyamide FD, 41% Elastane | 0.43 | 195 |
| D | 62% Polyamide RB, 38% Elastane | 0.44 | 195 |
| E | 83% Polyamide SD, 17% Elastane | 0.40 | 165 |

The air permeability of the fabrics was measured by using the Kawabata Evaluation System, a KES-F8-AP1 tester, and the ASTM D737 standard test method. The fabrics that allow more air to pass through are considered breathable and more comfortable to wear. The thermal conductivity of each fabric was evaluated by using the KES-F7 Thermo Labo II tester. The fabric sample was placed between a water box (20°C) and a heat plate (30°C) that simulates the temperature of the human body. The heat loss through the fabric sample was then recorded.

The WVT rate is used to evaluate the ability of a fabric to transfer moisture, which is also important for wear comfort. The ASTM E96 standard test method was used. The test simulates the transfer of water vapor from the skin to the environment. Lastly, the hand feel of the fabrics was objectively tested by using the KES-FB4-AUTO-A Automatic Surface Tester. Both the right and wrong sides of the fabrics in the warp and weft directions were measured, and the surface roughness was recorded.

The test result is presented in Table 7.2. Fabrics B and E are comparatively lighter in weight. All the tested fabrics have a similar thickness and air permeability value. They can therefore be considered as breathable with a net-like structure, which allows air to pass through the small holes. The fabric also has a similar and moderate thermal conductivity value, which may be due to their similar thickness, density, and yarn conductivity. Fabric with a higher thermal conductivity value can better transfer heat (Yip et al., 2002).

The WVT rate of the fabric samples is related to the transfer of moisture or sweat. Fabrics with a high WVT rate can greatly increase wear comfort by readily transferring moisture and wicking sweat away. Powernet has a comparatively high WVT rate compared to other fabrics such as simplex fabrics due to their thinness and low yarn density (Wong, 2020). Table 6.2 shows that Fabric B has the highest WVT rate (58.82 g/hr· $m^2$).

The surface properties of the fabric samples were also assessed to provide wearers with a comfortable orthosis that has a good hand feel. Fabric B has the lowest surface roughness value (1.20) in the wale direction. A lower surface roughness value means the fabric has a smooth and slippery feeling, which may be affected by the evenness of the fabric surface. In the proposed prototype, Fabric B is selected as the preferred option because it is lightweight and has a good WVT rate that may help to prevent sweat and odors, and a comparatively smooth hand feel.

The selection of a suitable seam is also crucial for ensuring wear comfort in a close-fitting apparel product such as an orthosis. Suitable types of seams and seam structures can create a clean and neat appearance, as well as link different pieces with durability. A seam that is stretchable, strong, and flat is needed to prevent irritation and exert high

pressure onto the skin, particularly in the sensitive toe region. A stretchable zigzag lockstitch is therefore considered. It is widely used in close-fitting elastic garments such as activewear. As shown in Table 7.3, the zigzag lockstitch provides the highest degree of extension, which is compatible with the properties of the fabric, compared to the regular plain seam and the stretchable three thread overedge chainstitch. Sufficient elasticity also allows the sock to fit comfortably against the foot without creating excessive pressure. The stitching is also durable enough to withstand normal wear and tear, and can prevent fraying of the raw edges, thus providing a neat appearance for the orthosis. Its smooth and flat structure is less likely to cause irritation or discomfort.

Table 7.2: Results of fabric properties

| Fabric | Air permeability (kPa· s/m) | Thermal conductivity (w/Mk) | WVT (g/hr· m²) | Surface roughness (SMD) | |
|---|---|---|---|---|---|
| | | | | Wale | Course |
| A | 0.01 | 0.06 | 57.21 | 3.24 | 19.13 |
| B | 0.01 | 0.06 | 58.82 | 1.20 | 16.87 |
| C | 0.00 | 0.06 | 52.40 | 1.36 | 15.06 |
| D | 0.00 | 0.07 | 53.87 | 2.38 | 16.90 |
| E | 0.01 | 0.06 | 56.54 | 19.26 | 17.17 |

Table 7.3: Results of seam properties

| | Maximum Load (N) | Extension at Maximum Load (%) |
|---|---|---|
| Plain seam | 169.26 | 180% |
| Zig zag lockstitch | 151.67 | 354% |
| Three thread overedge chainstitch | 153.02 | 215% |

### 7.3.2 Toe separator

The use of a toe separator is recommended for separating the hallux from the lesser toes, preventing the hallux from continuing to bend inward, and effectively facilitating the reduction of the HVA, (Kwan et al., 2021). The toe separator is also effective in reducing plantar pressure in patients with HV during walking (Dissaneewate et al., 2022). In this study, a soft and skin-friendly silicone toe separator has been developed by using 3D printing and demolding technologies (Figure 7.3a). The geometry of the toe separator is based on the 3D scanned data of a subject with mild HV, thus ensuring a secure fit in the webspace as required by patients.

Figure 7.3b shows a commercially available toe separator, which has a cylindrical shape. However, the webspace between the hallux and lesser toes is neither symmetrical nor regular. Therefore, the geometry of the toe separator was modified to better fit the webspace, as shown in Figure 7.3c. A structured light handheld 3D scanner (Artec Eva, Luxembourg) with a 3D resolution up to 0.2 mm was used to capture the 3D geometry of the webspace. The 3D scanned data were then transformed into a mold by using 3D

modeling software (Autodesk Fusion 360, USA) and printed by using an extrusion-based fused deposition modeling (FDM) 3D printer (Raise3D E2, USA) with polylactic acid (PLA) filaments. FDM is widely used and provides excellent dimensional accuracy (Jurgenson, 2022; Varga et al., 2017). It is suitable for producing small-sized prototypes at a low production cost. The toe separator was then produced by demolding silicone (Smooth-On, USA) from a 3D printed mold. Soft silicone can simulate human skin, and the hardness of the material was confirmed to be Shore A 10, with reference to the commercially available toe separator. To make it more skin-friendly, the sharp edges were further modified to be round edges (Figure 7.3d). The effect of the toe separator will be further discussed in Chapter 8.

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

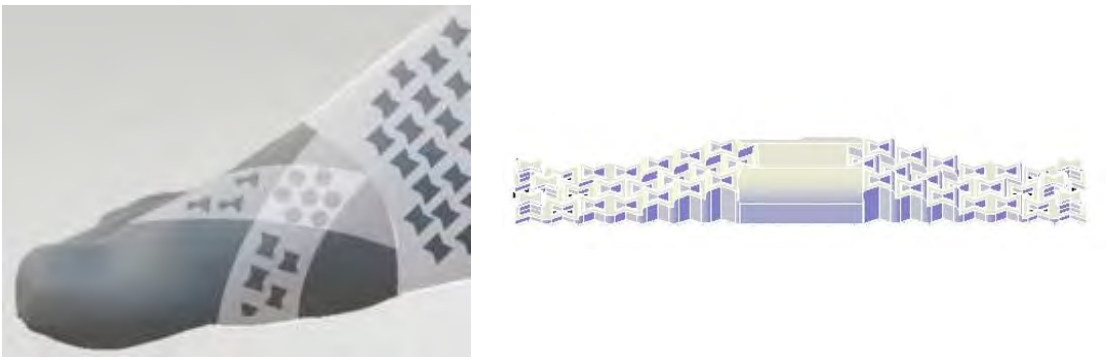
Figure 7.3: Design of toe separator (a) placement, (b) typical geometry, (c) modified geometry by using 3d scanned data, and (d) final prototype

### 7.3.3 Application of corrective forces

#### 7.3.3.1 Development of corrective band

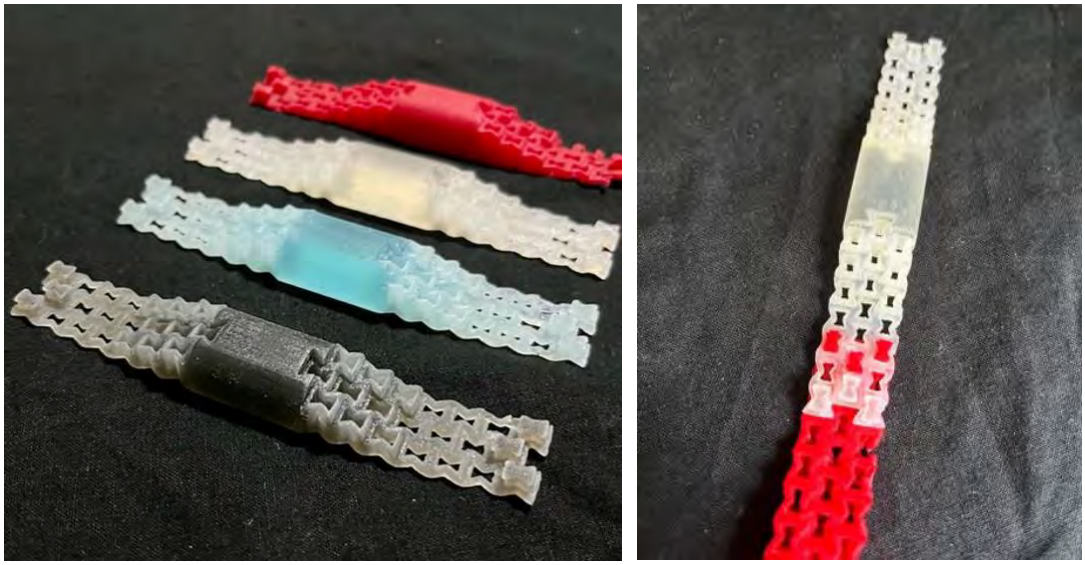
To correct the HVA, a stretchable silicone band with an auxetic structure was designed and strategically applied in the proposed HV orthosis, which underwent two stages of prototyping. The first prototype was created directly by using a 3D printer. It is designed to wrap around the hallux and connect to the medial arch side of the foot for stretching. The rounded edges were specifically designed to avoid friction on the skin, which can lead to discomfort. The middle part was made thicker and acted as the toe separator, which is a crucial component for reducing the HVA (Dissaneewate et al., 2022). The conceptual idea and the 3D model are shown in Figure 7.4. The Stratasys J750™ Polyjet 3D printer was used to construct this prototype. The dimensional accuracy of Polyjet 3D printing has been confirmed in Murugesan et al. (2012) and Varga et al. (2017). This technology can provide a product with a uniformly smooth surface and adequate surface details (Murugesan et al., 2012). As such, a skin-friendly corrective band that does not cause itchiness can be manufactured. The printer is capable of printing soft resin, which aligns with the goal of producing a soft in-shoe orthosis. Resin rubber, widely used in footwear, is a synthetic material introduced around 1950 and manufactured by using a combination of synthetic rubber and plastic. This uniform material that can be used in the sheet form or as a molded unit (Miller, 1976). The printed resin band samples are shown in Figure 7.5, with a Shore hardness of A 10, 30, 50, and 70, respectively. However, currently 3D printed resin is fragile and not stretchable, regardless of its hardness. Soft stretchable silicone was therefore considered for its excellent resilience, durability, and skin-friendly properties (Chow, 2020; Hearle, 2008). Studies have shown that silicone can withstand repeated

functional loads without dimensional changes, thus preventing loss of force due to repeated stretching. In this study, a commercially available skin-safe silicone, Dragon Skin (Smooth-On, USA), is used, which has excellent mechanical properties and is widely used in soft robotics and stretchable energy storage devices (Park et al., 2018). The stretch and recovery ability of elastic materials is a factor that affects biomechanics (Xiong & Tao, 2018). In this study, the recovery of the elastic materials that influence the corrective effect is tested by using an Instron 4411 tensile strength tester. Figure 7.6 shows the recovery capabilities of silicone samples with different hardness and those of four types of commercially available elastic bands. The results show that all the tested elastic materials have a recovery rate of more than 80. This can prevent deformation and fatigue during use and maintain the tensile force, while Shore A 30 silicone has the highest recovery rate (92.60%) after loading.



(a) (b)

Figure 7.4: Initial concept of corrective band design (a) conceptual idea, and (b) 3D model of the first prototype of corrective band



(a) (b)

Figure 7.5: Corrective band printed with 3D printer (a) 3D printed resin band, and (b) combination of two corrective bands

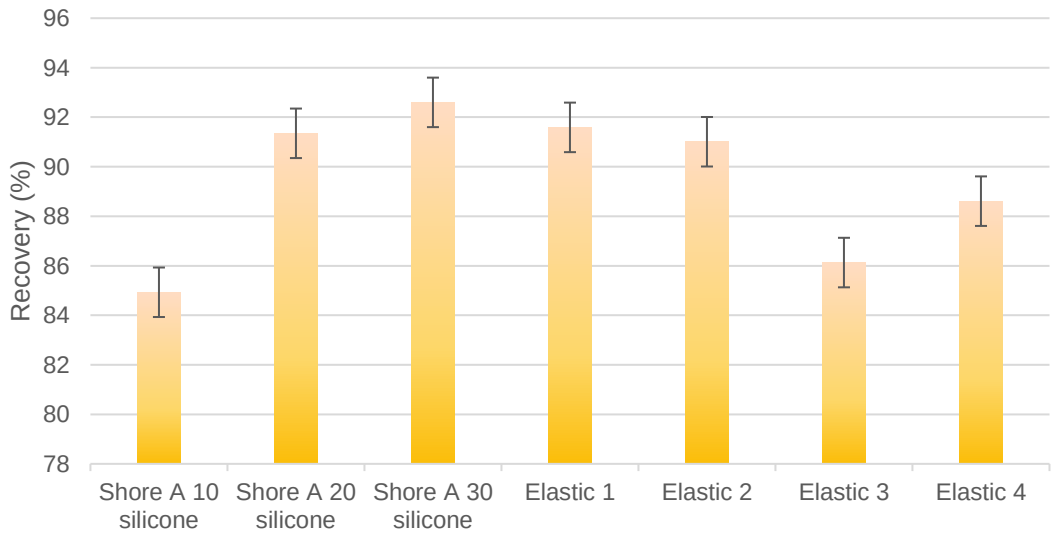



Figure 7.6: Recovery of elastic materials

In the second prototype, the band was designed to apply force from the medial side of the distal phalanges and passed along the lateral side of the hallux, then attached to the most concave area of the foot (connection between the talus and calcaneus) by using a soft hook and loop fastener. This area was chosen to minimize the prominence of the orthosis and ensure comfort while wearing the orthosis in shoes. Five types of hook and loop fasteners were sourced, and the thinnest one is adopted (1.5 mm). The dimensions of the corrective band are 106 mm x 17 mm x 2 mm, with a thickness of only 2 mm. This band is much thinner than the commercially available orthoses mentioned in Chapter 4, which helps to minimize the prominence of the orthosis, especially on the painful and deformed MTPJ1. The corrective band also helps to guide the bones back to their correct position. The band was constructed by demolding a 3D printed PLA mold by using FDM, which offers excellent dimensional accuracy and is low in production cost (Jurgenson, 2022; Varga et al., 2017). The Raise3D E2 printer (USA) was used to produce the mold. The 3D model was sliced by using IdeaMaker software. A trial with the 3D printed mold and the associate silicone band is shown in Figure 7.7.

The re-entrant auxetic structure is used to improve the fit of the corrective band, as shown in Figure 7.8. Auxetic materials are characterized by a negative Poisson's ratio, which means that they expand laterally when stretched and contract laterally when compressed in the longitudinal direction (Hu & Zulifqar, 2016). This unique property allows the auxetic structure to expand and shrink in the transverse direction above and below the neutral plane during bending (Chow, 2022). This contributes to synclastic curvature, which enables the creation of a dome shape and increases the shape adaptability (Chow, 2022; Wang & Hu, 2014). The special structural change of auxetic materials enhances their ability to conform to curved shapes, which is particularly useful for fitting the band to the foot.

In addition to improving the fit, auxetic materials also demonstrate superior energy absorption properties (Liu & Hu, 2010). This can help to absorb the impact of shoes on the foot when the corrective band is used as the cushioning medium to provide effective support and protect the foot. The silicone band placed around the hallux cushions the metatarsals and prevents the joint from rubbing against the shoe, which can cause redness and soreness. This is especially important as HV forces the MTPJ1 to protrude, which makes it more prone to friction and irritation.

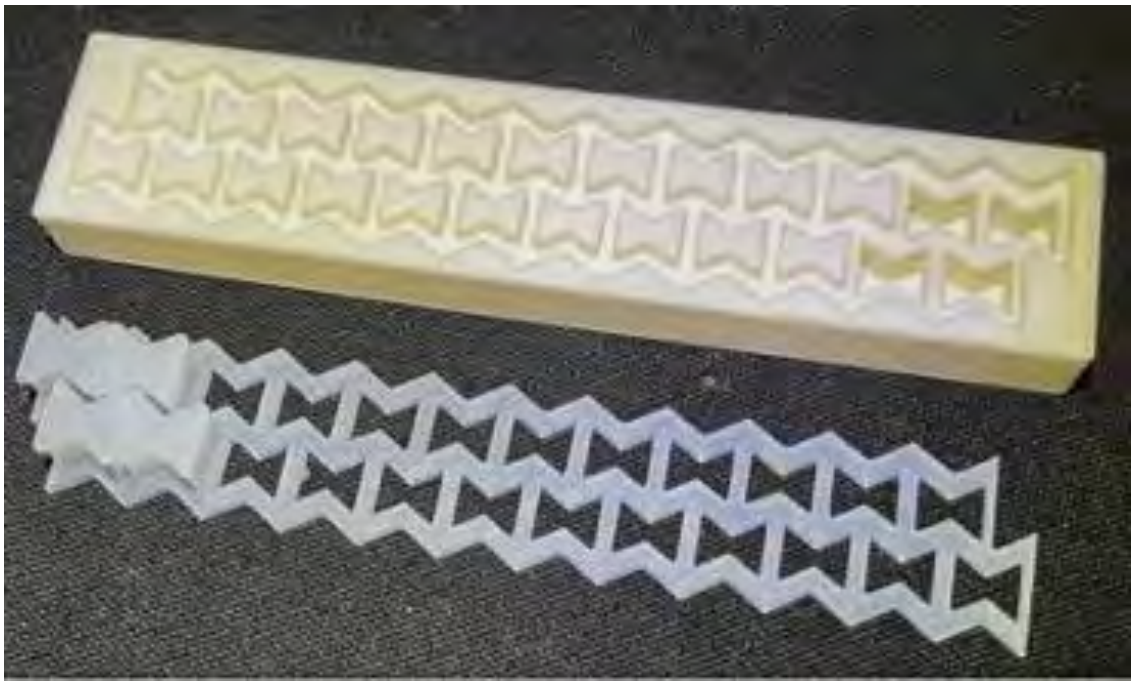


Figure 7.7: Trial of PLA mold and associated silicone band

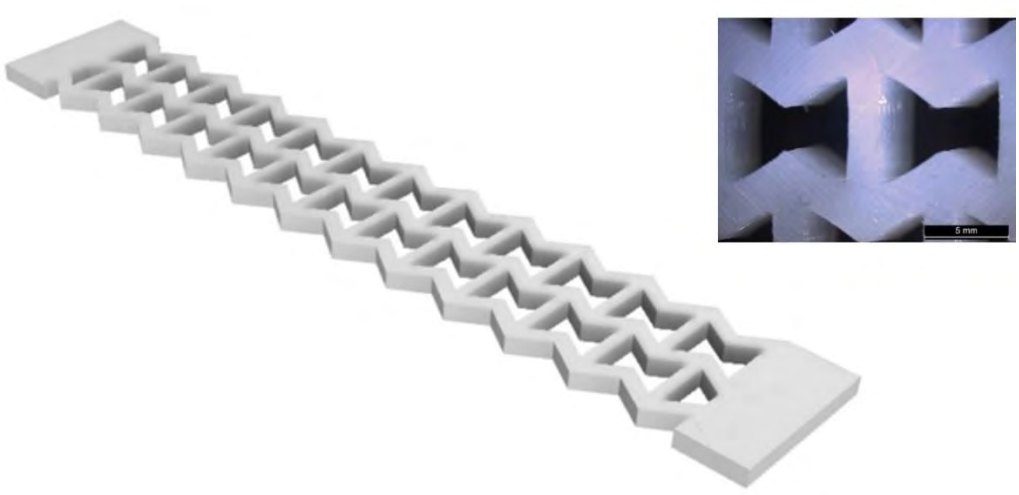



Figure 7.8: Final prototype of silicone corrective band with auxetic structure

7.3.3.2 Numerical simulation of corrective forces

FEA is a powerful tool for studying biomechanics and pressure distribution in the human body. By inputting the geometry, material properties, and boundary conditions, an FEA can then estimate the corrective forces, displacement, and pressure distribution. In this study, the dominant foot of a female subject with mild HV is used to construct the FEM. The geometry of the foot was obtained by using a handheld 3D scanner and processed with 3D modeling software. The study was approved by the Human Subjects Ethics Sub-Committee at the Hong Kong Polytechnic University (reference number: HSEARS20190924004). The FEA provides a wide range of simulations for product development, thus reducing the need for prototyping, minimizing waste, and facilitating decision-making. Additionally, an FEA allows observation of structural changes that may not be easily achievable in experiments. However, it is important to note that an FEA is an approximation and idealization of the actual situation.

In developing the HV orthosis, an FEA was used to optimize the design of the orthosis

for effective treatment while maintaining wear comfort. The geometry and material properties of the proposed silicone corrective band, with different hardness and structures, were inputted to predict their effect on reducing the HVA. The corrective effect of the auxetic band of different hardness and structures on the foot model was then analyzed. The corrective bands were prepared with dimensions of 106 mm (length) x 17 mm (width) x 2 mm (thickness) so that their volume was 2087 $mm^3$ and 2037 $mm^3$ for the auxetic and honeycomb structures, respectively. The material properties were obtained from the tensile test, and the details of the material and mesh properties are provided in Table 7.4. The 3D models were meshed by using MSC Apex and then imported into MSC Marc Mentat to build the FEM. The mesh size of the corrective band is 1 mm.

Table 7.4: Material properties of silicone

| Component | Young's modulus (MPa) | Poisson's ratio | Element type | Type of material |
|---|---|---|---|---|
| Shore A 10 silicone | 0.4 | 0.47 | Solid | Elastic-plastic isotropic |
| Shore A 20 silicone | 0.7 | 0.47 | | |
| Shore A 30 silicone | 1.1 | 0.47 | | |

The effect of applying silicone with different hardness and structures was simulated to identify the optimal silicone band. The force required to stretch the band to the desired position, which is on the medial arch side, was also analyzed. Fastening the band on the medial arch side makes the orthosis fit better.

The hallux of the FEM was stretched by using a silicone band (Figure 7.9). The results are shown in Figure 7.10 and 7.11. To reduce the HVA from 18 degrees to the normal 15 degrees, approximately 6 Newtons of force are required. To further correct the angle to within the normal 15 degrees, a larger force is necessary. The conventional honeycomb structure can exert a higher force and lead to more correction. However, this structure also results in higher contact stress (Figure 7.12), which may cause discomfort. Moreover, its shape adaptability and energy absorption properties may not be as good as the sample with an auxetic structure (Chow, 2022; Liu & Hu, 2010; Wang & Hu, 2014). The auxetic structure is well-known for its synclastic curvature during bending (Donoghue, 2009; Evans & Alderson, 2000), and is applicable, but not limited to, biomedical materials and fashion textiles (Konaković, 2016).

To achieve a significant reduction of the HVA to less than 15 degrees, with a better fit and less stress on the skin, a Shore A 30 silicone band with an auxetic structure was chosen as the corrective component of the orthosis for the wear trial. The wear trial details will be discussed in Chapter 8. The accuracy of the FE contact model was also validated. The HVA before and after the application of the Shore A 30 silicone band with an auxetic structure was compared. The experimental results were obtained from a footprint, and the simulated interface was determined with the FEM. The results are compared in Figure 7.13, and the difference is around 1%, which is an acceptable margin of error for prediction purposes.

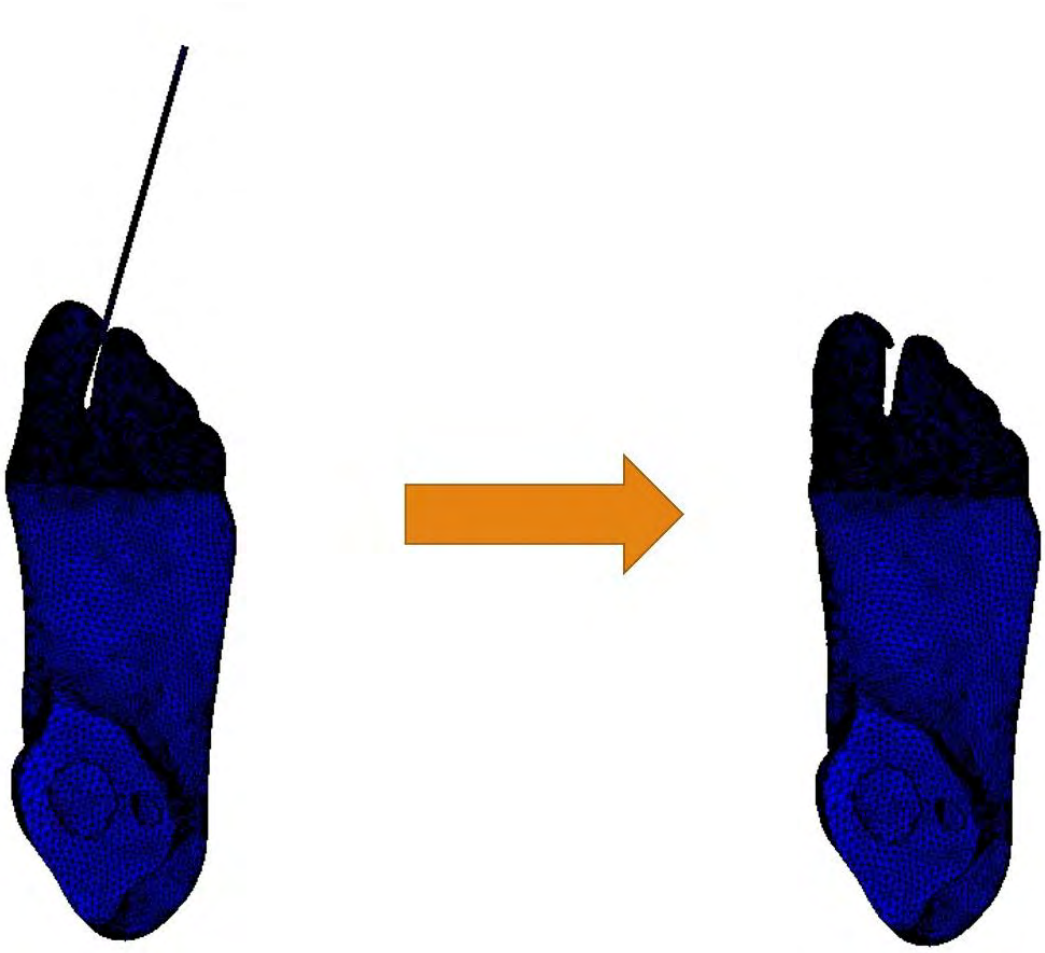
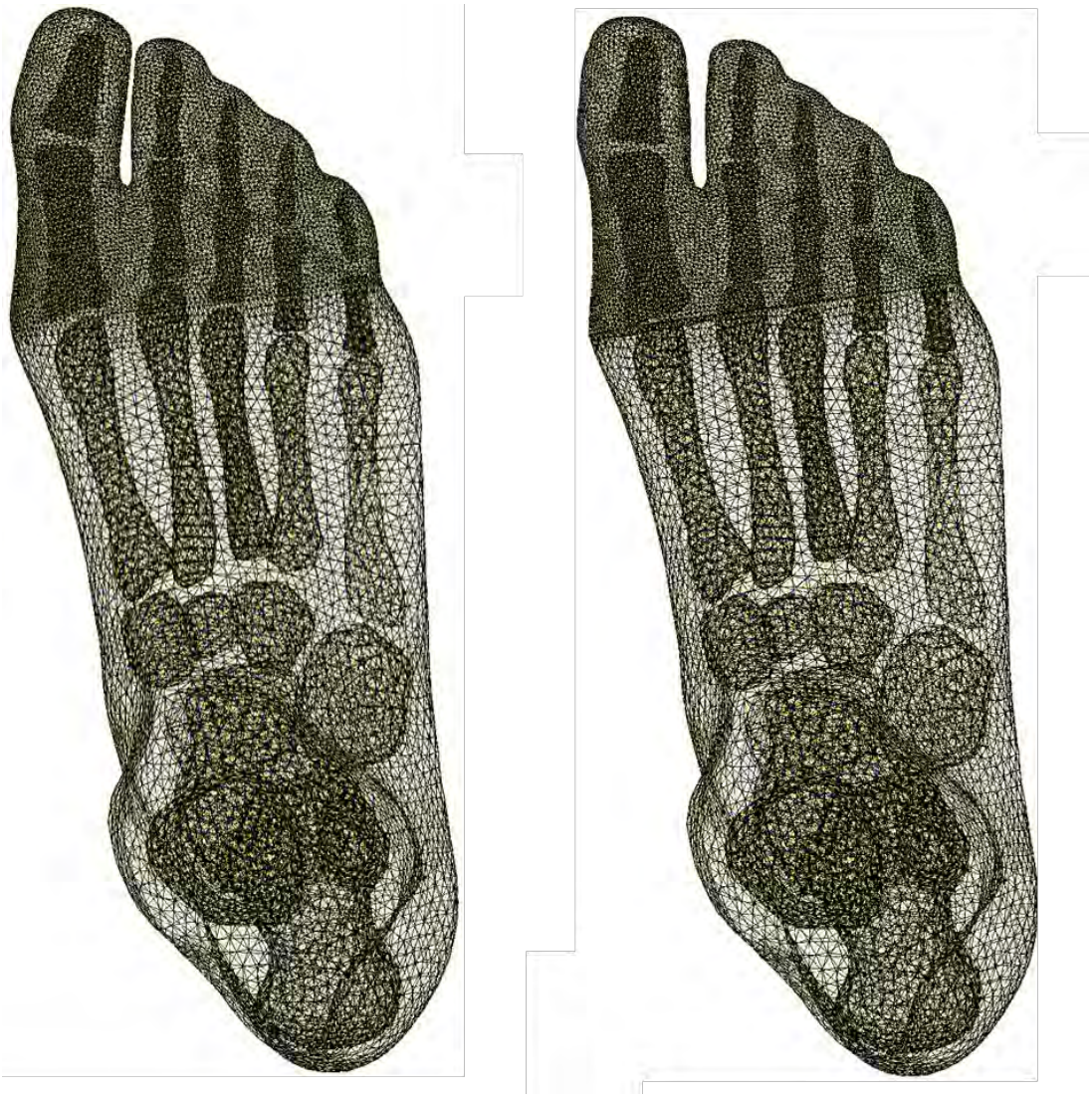


Figure 7.9: FEM of corrective band on sub-model of foot with HV



(a) (b)

Figure 7.10: Effect visualization (a) without corrective band intervention, and (b) after intervention

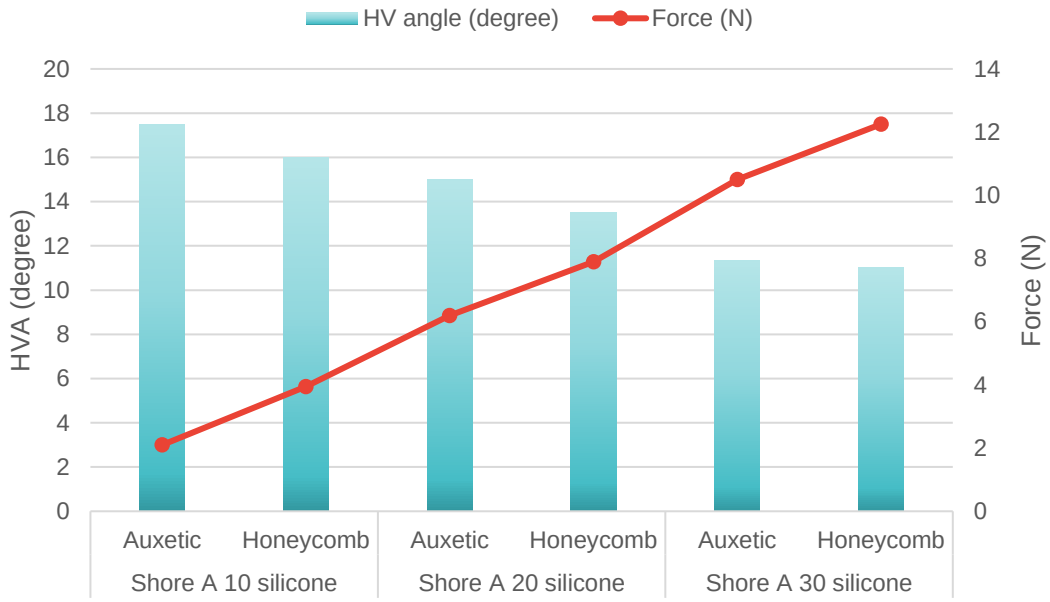



Figure 7.11: HVA correction and the required corrective forces in FEA

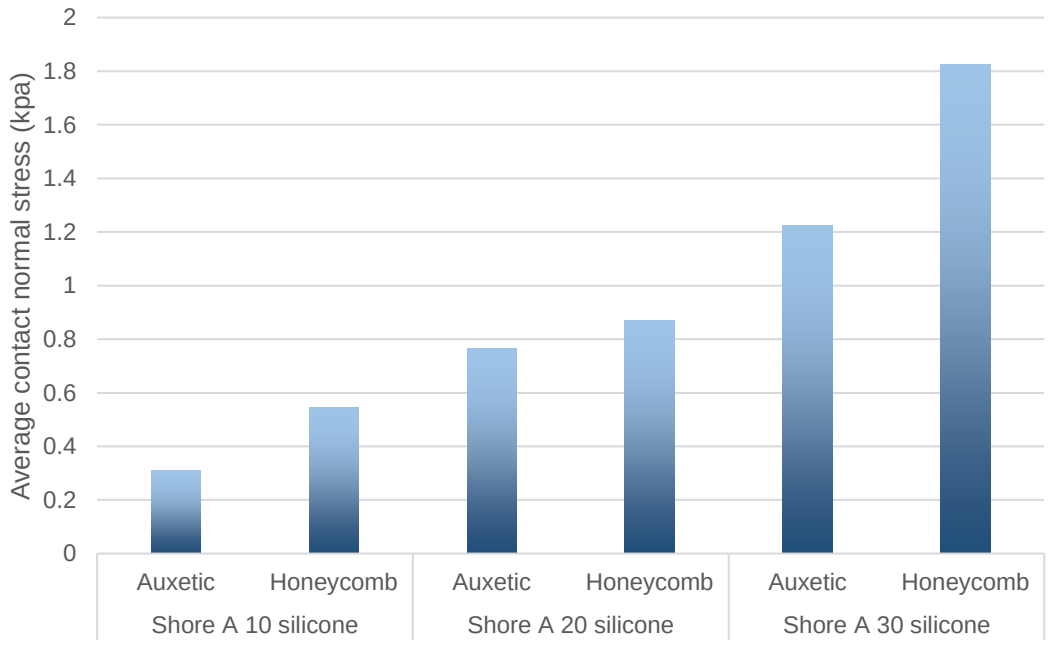



Figure 7.12: Contact stress induced by corrective band

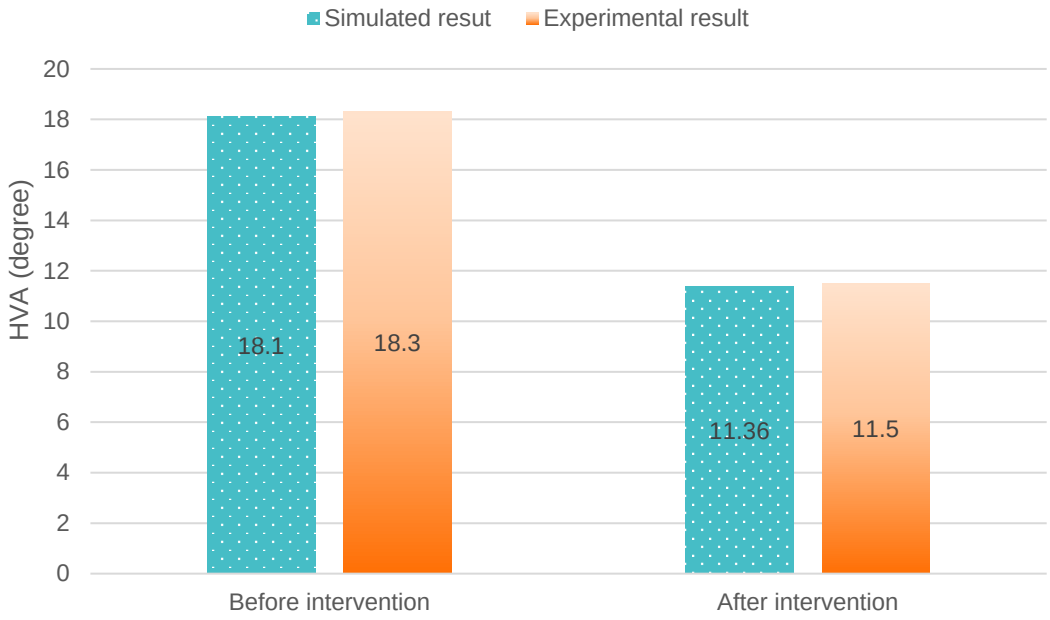



Figure 7.13: Comparison of experimental and simulated results of HVA

### 7.3.4 Sample prototyping

The main function of the HV orthosis is to reduce the HVA, so effective design elements for design optimization were identified to develop an HV orthosis that meets this requirement. It is anticipated that the small and soft design components will help patients feel comfortable about the long-term use of the orthosis. To achieve a comfortable fit with the shoe design, the ergonomic design of orthosis can be summarized into three parts, as shown in Figure 7.14, which include a split toe sock with an open-back style, a toe separator that “fits into the web space" and a soft stretchable silicone corrective band with an auxetic structure. Their effect on reducing the HVA is then assessed. The production process can be summarized into seven steps: (1) material testing and selection, (2) pattern drafting and sewing: producing socks using elastic powernet fabric, using a stretchable zigzag lockstitch, with a split toe and low-cut design to separate the hallux from the lesser toes, (3) 3D scanning: obtaining

an accurate geometry of the foot of the patient by using a structured light handheld 3D scanner (Artec Eva, Luxembourg), (4) processing the 3D scanned data: importing scanned data into 3D model processing software, (5) 3D modelling: developing the 3D models of the toe separator mold that corresponds to the web space of the hallux and lesser toe, as well as the 3D mold of the auxetic band, (6) 3D printing: using an extrusion-based 3D printer to print the molds with PLA filaments, 7) silicone molding: using soft silicone that mimics human skin, i.e. Shore A 30 for the auxetic band and Shore A 10 for the toe separator (Smooth-On, Pennsylvania), (8) an FEA of the design components, and (9) garment assembly: attaching the silicone parts to the sock.

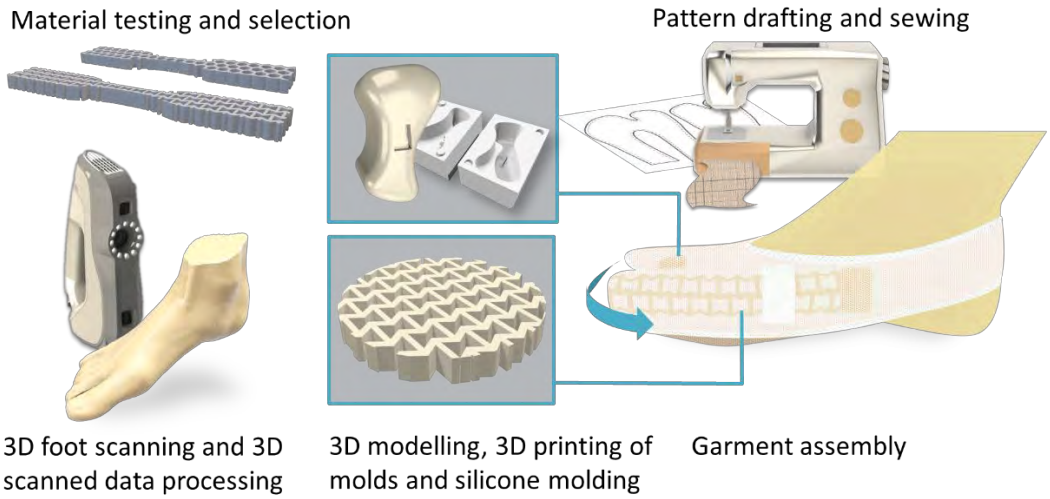



Figure 7.14: Design of in-shoe HV orthosis

### 7.3.5 Preliminary prototype evaluation

In the wear trial of the commercially available HV orthoses discussed in Chapter 4, 56% of the subjects who do not have HV and 67% of the HV participants provided negative feedback on the commercially available soft Sample B. Meanwhile, 39% of the subjects

without HV and 67% of the HV participants provided negative feedback on the semi-rigid Sample A. Among the negative feedback, 57% of the negative comments that target the commercially available soft orthosis and 50% that target the semi-rigid orthosis are related to the discomfort around the arch, as well as the gap between the hallux and second toe. This discomfort may be caused by the toe cover that lacks a good fit, and the use of rough fabric, thus resulting in high friction and pressure on the skin. Therefore, it is crucial to find a more suitable type of fabric as well as enhance the fit of the orthosis.

Pressure can be used to quantify the wear comfort of the sock. In this study, five female subjects between 20 to 34 years old with mild HV (average HVA: 18.4°) were invited to wear the proposed orthosis and to compare the pressure of four commercially available orthoses on the skin, including two commercially available soft orthoses, and two commercially available semi-rigid orthoses. The commercially available soft orthoses are made of soft and stretchable textile materials including polyurethane and powernet, while the semi-rigid orthoses contain splint made of polyamide or titanium, as well as soft textile materials.

Pressure measurements were conducted by using the Pliance® system with single sensors. The system has been evaluated and validated for accuracy by Lai and Li-Tsang (2009) and Wiseman et al. (2018). Sixteen pressure points on the dorsal, medial, lateral, and plantar areas where the orthoses came into contact with the foot were measured (Figure 7.15).

The results presented in Table 7.5 show that, on average, the commercially available semi-rigid orthosis II had the highest pressure, followed by the commercially available semi-rigid orthosis I. The soft orthoses generally exerts less pressure, and the proposed

soft sock-like orthosis has the lowest average pressure (3.39 kPa). This suggests that there may be a reduction in pressure and associated discomfort when wearing the proposed orthosis due to the improved fit and proper choice of fabric, seam and fastener. The highest pressure point of the proposed orthosis is on the hallux, which is the point of correction, thus indicating that the force has been precisely applied to the region for corrective purposes. In contrast, the highest pressure point of the commercially available soft orthosis I is on the plantar region, where the button for adjusting the length of the band is located, thus leading to high pressure when standing. This may be one of the reasons for the complaints regarding discomfort around the arch that were raised by the subjects and documented in section 4.2.4 of this project.

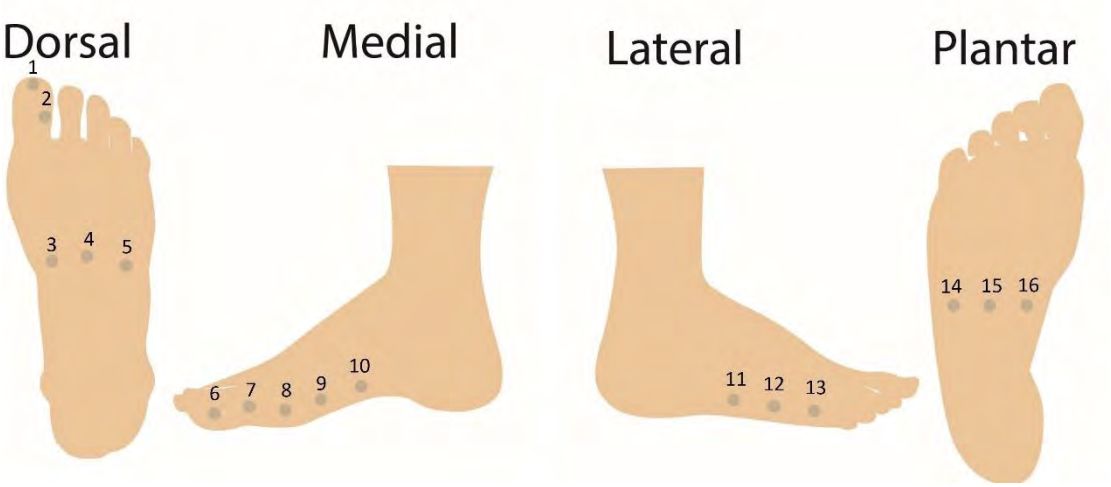



Figure 7.15: Pressure measurement points on foot

Table 7.5: Pressure measurement (kPa) of HV orthoses

| | Point | Proposed soft orthosis | Commercially available soft orthosis I | Commercially available soft orthosis II | Commercially available semi-rigid orthosis I | Commercially available semi-rigid orthosis II |
|---|---|---|---|---|---|---|
| | |  |  |  |  |  |
| | 1 | 10.63 | 5.13 | 13.58 | 0.00 | 0.00 |
| | 2 | 4.73 | 0.00 | 5.75 | 9.69 | 15.42 |
| Dorsal | 3 | 0.00 | 5.29 | 0.00 | 10.63 | 2.42 |
| | 4 | 2.25 | 4.44 | 0.00 | 7.75 | 5.75 |
| | 5 | 7.63 | 3.21 | 0.00 | 2.04 | 0.00 |
| | 6 | 3.25 | 2.69 | 6.42 | 14.06 | 8.17 |
| | 7 | 2.04 | 3.42 | 4.75 | 2.71 | 12.50 |
| Medial | 8 | 7.13 | 3.00 | 3.83 | 10.00 | 2.67 |
| | 9 | 3.29 | 4.97 | 2.25 | 3.15 | 6.33 |
| | 10 | 2.04 | 2.63 | 0.00 | 2.04 | 13.25 |
| | 11 | 0.00 | 7.94 | 4.58 | 3.42 | 7.17 |
| Lateral | 12 | 0.00 | 7.04 | 6.33 | 3.19 | 5.00 |
| | 13 | 2.50 | 3.71 | 5.42 | 3.08 | 10.25 |
| | 14 | 0.00 | 10.63 | 2.92 | 0.00 | 0.00 |
| Plantar | 15 | 2.04 | 2.04 | 2.50 | 0.00 | 0.00 |
| | 16 | 6.63 | 0.00 | 3.33 | 4.00 | 2.00 |
| Average pressure | | 3.39 | 4.13 | 3.85 | 4.74 | 5.68 |

## 7.4 Chapter summary

This chapter discusses the key design elements and fabrication processes involved in the development of HV orthoses with an ergonomic design. The chapter begins by describing the design criteria associated with the design of HV orthoses, which need to be properly fitted, convenient to wear in shoes, and effective in correcting the deformity. Next, the chapter provides a detailed overview of the design process for HV orthoses, including the utilization of 3D scanning and 3D printing technologies. Finally, the chapter examines the benefits of an ergonomic design for HV orthoses by comparing the pressure distribution with that of commercially available orthoses. Overall, this chapter offers valuable insights into the development of HV orthoses.

# Chapter 8 Effects of Newly Developed HV Orthosis

## 8.1 Introduction

In this study, a functional sock-like HV orthosis has been developed with reference to the experimental findings, as well as the clinical opinions of prosthetists and orthotists. The goal was to create an orthosis that would effectively correct the HVA while ensuring wearing comfort for better treatment compliance. To evaluate the performance of this orthoses, various aspects of biomechanical behavior of the foot were analyzed, including balance, plantar pressure, HVA, and subjective sensations. These analyses aim to provide a comprehensive understanding of how the proposed orthoses affect foot mechanics, and insight into the design of HV orthoses and therefore serve as a practical guide for the selection of HV orthoses.

## 8.2 Methods

### 8.2.1 Participants

Twenty-two females with mild to moderate HV participated in the study. The selected subjects are between 18 and 50 years old, had a shoe size ranging from EU 37 to EU 39, have no history of foot surgery, significant lower-limb problems, and sprains in the past six months. Additionally, the participants have a normal body mass index (BMI) within the range of 18.5 to 22.9. Table 8.1 provides an overview of the demographic characteristics and foot measurements of the sample population. As 91% of the participants are right foot dominant, the data analysis focused on the right foot. The

study received ethical approval from the Human Subjects Ethics Sub-Committee at the Hong Kong Polytechnic University (reference number: HSEARS20190924004), and all participants provided written consent.

Table 8.1: Participant demographics (N = 22)

| | Range | Mean | S.D. |
|---|---|---|---|
| Age | 18 - 50 | 29.82 | 8.18 |
| Shoe size (EU) | 37 - 39 | 37.77 | 0.78 |
| BMI | 18.44 - 22.51 | 20.36 | 1.17 |
| HVA (degree) | 15.50 - 24.50 | 17.23 | 2.28 |
| Foot width (cm) | 7.80 - 9.30 | 8.56 | 0.42 |

### 8.2.2 Experimental procedures

To investigate the effects of the proposed orthosis, wear trials were conducted to comprehensively analyze its impact on balance, plantar pressure, HVA, subjective sensation, and gait. The wear trial consisted of two stages, as illustrated in Figure 8.1.

In Stage One, referring to the experimental protocol for the evaluation of commercially available HV orthoses in Chapter 4, each participant was required to provide 2D footprints in a weight-bearing standing posture on a podograph. The HVA was then

measured, which was done by measuring the angle between two lines: (1) a line from the medial width of the heel to the widest point of the bone of MTP1, extending beyond the foot, and (2) a line between the widest point of the bone of MTP1 and the outer edge of the hallux. The participants took part in a walking trial for each experimental condition to acclimate themselves. After that, they were instructed to stand and walk on a flat surface while their COP and average peak pressure were measured by using the Novel Pedar pressure system and Pedar® insole sensors. This allowed for the examination of how the orthosis design affects balance control and pressure distribution. The Pedar® insoles were calibrated before the experiment. The participants were instructed to walk straight at a self-selected speed, focusing on a target point in the middle. Motion capture was also conducted with five of the subjects to preliminary test the possibility to detect dynamic HVA and analyze the gait pattern after wearing the new orthosis. The testing conditions are shown in Figure 8.2. Conditions were tested randomly, and each participant completed three successful trials to ensure data consistency. Data were analyzed by using statistical analysis software (SPSS v.24).

The participants were also asked to complete a survey on their subjective feelings about the orthoses. A simplified 10-point VAS and a modified Foot Health Status Questionnaire (FHSQ) were used. Additionally, participants were asked to rank the importance of different potential factors when choosing an orthosis to gain insights into their expectations.

All recruited participants were invited to participate in Stage Two of the stud, where they were provided with the proposed HV orthosis to wear for a period of fourteen days, as depicted in Figure 8.3. During this intervention period, no other treatments were allowed to avoid interference with the effects of the proposed orthosis. The participants

were instructed to wear the orthosis for at least 6 hours each day. They were allowed to withdraw from the study at any time. To optimize the effectiveness of the orthosis, the participants were advised to wear the device with wide-toe shoes that have flat heels, such as sports shoes, as high heels or shoes with tight toe boxes can induce valgus moments (American College of Foot and Ankle Surgeons, 2018; Corrigan et al., 1993). After fourteen days, the participants were interviewed, and their footprints were taken again. A paired samples t-test and one-way analysis of variance (ANOVA) were performed to analyze the effects of the orthosis. A Pearson's correlation analysis was also conducted to examine the relationships between different factors. The level of statistical significance was set at 0.05.

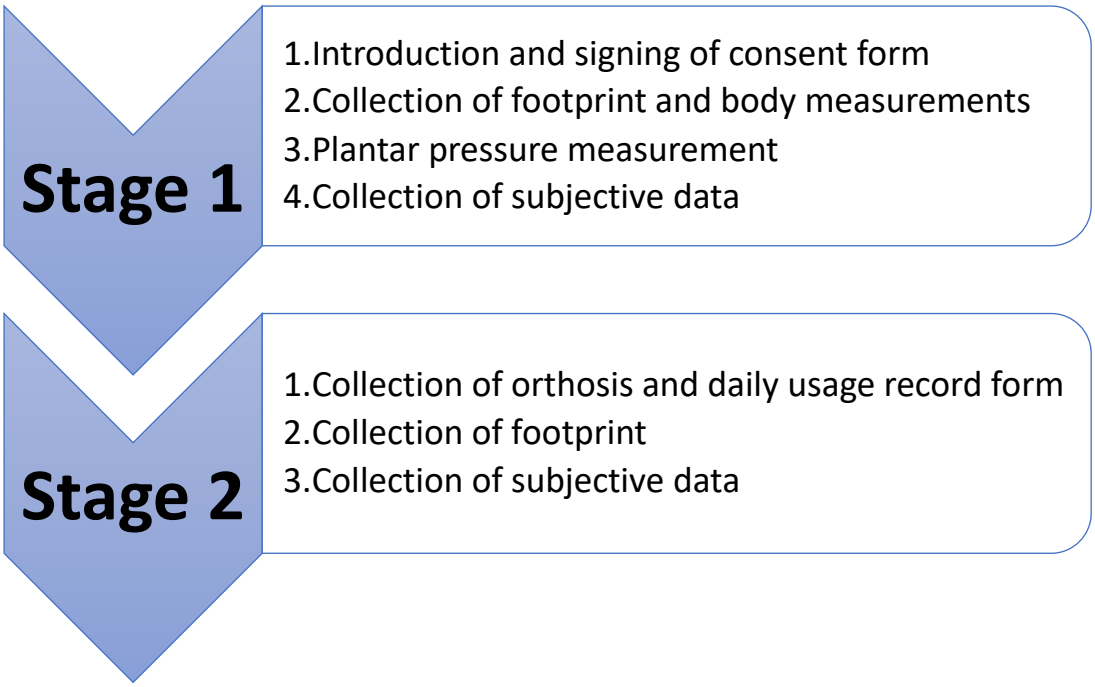
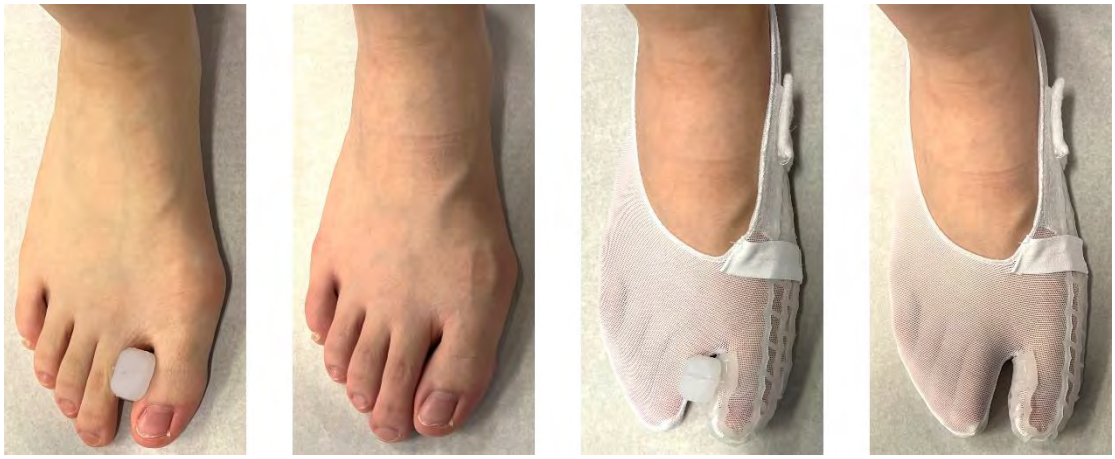



Figure 8.1: Experimental flow



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

Figure 8.2: Foot conditions tested for one-hour wear trial (a) with toe separator only, (b) barefoot, (c) with toe separator and corrective band, and (d) with corrective band only

Figure 8.3: Orthosis of fourteen-day wear trial

## 8.3 Results and discussion

### 8.3.1 Effect of one-hour trial

#### 8.3.1.1 Effect on plantar pressure distribution

Plantar pressure is an important indicator of foot function during gait. Previous studies have demonstrated that individuals with HV exhibit significantly higher peak pressures in the hallux region when walking barefoot compared to individuals without HV (Gu et al., 2014; Martínez-Nova et al., 2010). This increased pressure is attributed to the deviation of the first ray angle, which leads to foot pain and adaptive changes in gait (Martínez-Nova et al., 2010).

In this study, measurements of the plantar pressure were taken during both walking and standing while wearing the proposed orthosis. The pressure distribution and maximum peak pressure on the plantar side of the foot were examined. Specifically, the peak pressure in eight regions of the foot was analyzed, including the hallux, lateral toes, MTP1, MTP2-4, MTP5, medial and lateral midfoot, and rearfoot. This division of the regions aligns with that in Chapter 4 (Figure 4.1d). A paired samples t-test was performed to investigate the effect of the proposed orthosis on the plantar pressure distribution.

It is observed that when wearing semi-rigid commercially available orthoses, there is an increase in the pressure in the hallux (Figure 8.5). Additionally, when wearing either the semi-rigid or soft commercially available orthoses, there is a significant increase in pressure in the lateral region of the midfoot ($p = 0.013$ and $p = 0.031$, respectively). However, unlike the results reported in Chapter 4, there is no significant increase in

plantar pressure when walking with the proposed orthosis. Instead, there is a slight reduction in pressure in five of the eight regions (Table 8.2 and Figure 8.4). This indicates that after wearing the orthosis, there is a slight transfer of pressure to the hallux (9.30 kPa), MTP5 (14.80 kPa), and lateral midfoot (1.10 kPa), while no components shifted to the plantar region during walking, which would have caused an increase in pressure as observed with commercial orthoses. These findings suggest that the proposed orthosis fits well, and its design components are appropriately placed to effectively address the discomfort associated with orthotic interference. Furthermore, unnecessary shifting during walking is avoided with the proposed orthosis design.

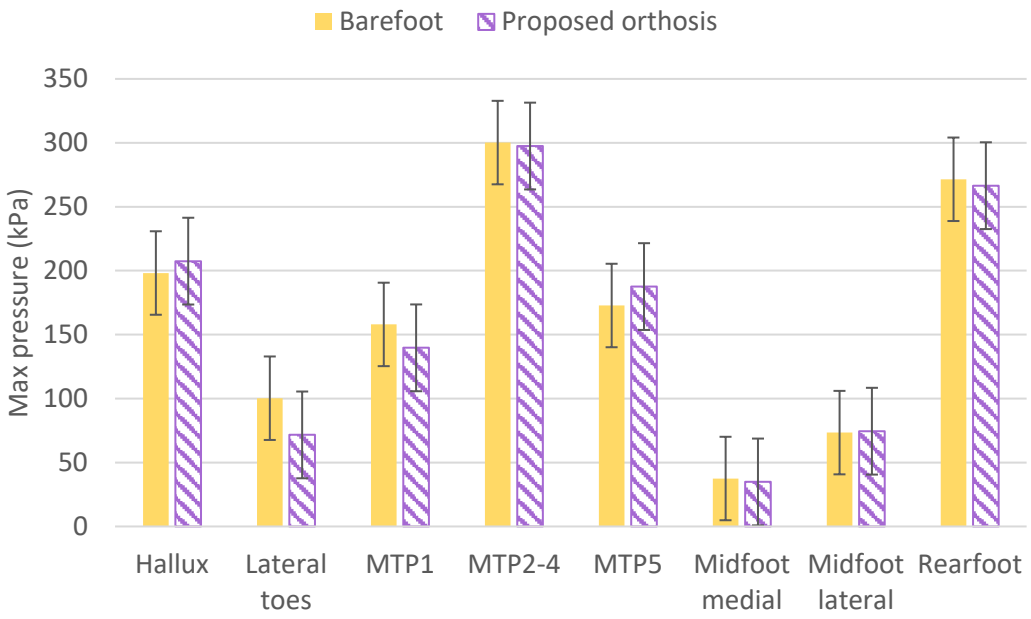



Figure 8.4: Max pressure (kPa) during walking

Table 8.2: Comparison of max pressure (kPa) during walking

| | Barefoot | | Proposed orthosis | | | |
|---|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | Difference | p |
| Hallux | 198.20 | 138.40 | 207.50 | 157.60 | 9.30 | 0.755 |
| Lateral toes | 100.30 | 108.30 | 71.60 | 55.80 | -28.70 | 0.212 |
| MTP1 | 158.00 | 87.70 | 139.70 | 76.90 | -18.30 | 0.342 |
| MTP2-4 | 300.20 | 104.30 | 297.50 | 120.40 | -2.70 | 0.599 |
| MTP5 | 172.80 | 100.30 | 187.60 | 113.50 | 14.80 | 0.585 |
| Midfoot medial | 37.50 | 83.20 | 34.80 | 68.70 | -2.70 | 0.694 |
| Midfoot lateral | 73.40 | 58.80 | 74.50 | 56.50 | 1.10 | 0.941 |
| Rearfoot | 271.50 | 64.90 | 266.50 | 68.30 | -5.00 | 0.473 |

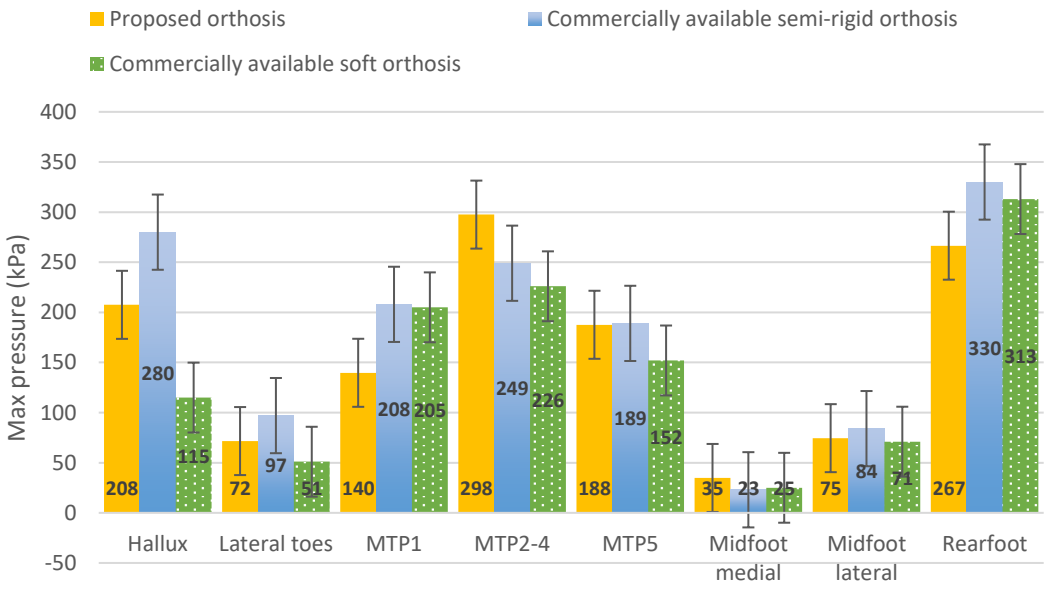



Figure 8.5: Comparison of max pressure (kPa) when walking with different orthoses

The study also examines the peak plantar pressures of participants during standing while wearing the orthosis. The results are presented in Figure 8.6 and Table 8.3. It can be observed that the subjects with HV who wore the orthosis experienced a significant reduction in plantar pressure under the lateral toe region ($p = 0.026$), and there are no significant increases observed in any other part of the foot. This suggests that the proposed orthosis effectively distributes plantar pressure, particularly reducing pressure in the lateral toe region during standing for HV subjects.

Since the pressures detected under barefoot conditions in this wear trial are not significantly different from those presented in Chapter 4, plantar pressures of the new orthosis were further compared with commercially available orthotics. As shown in Figure 8.7, when HV subjects wore the new orthosis, lower plantar pressure was detected across the foot than wearing commercially available orthoses.

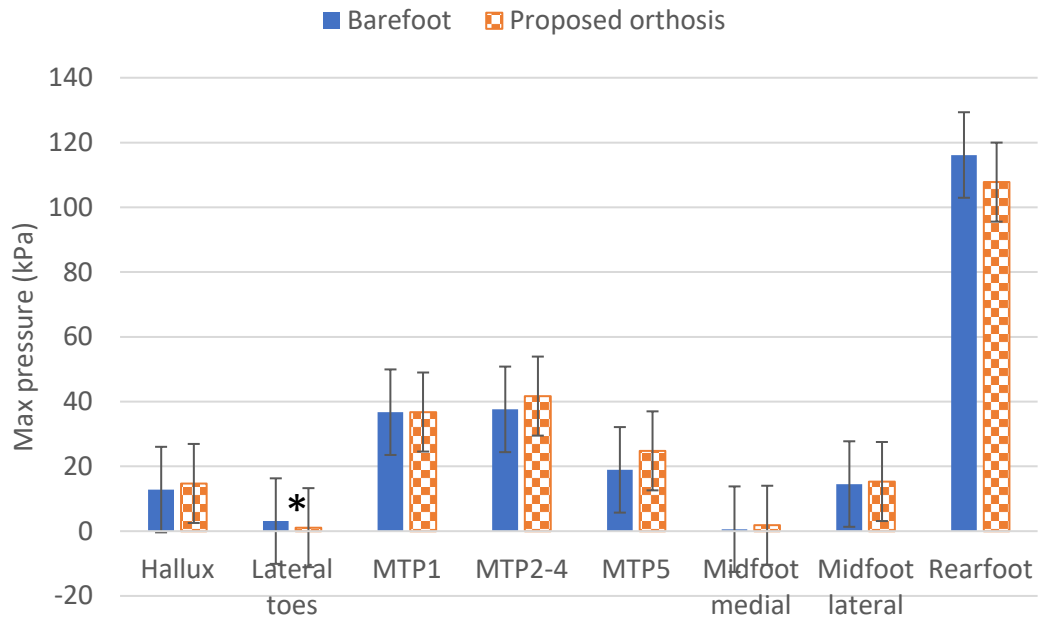



Figure 8.6: Max pressure (kPa) during standing

Table 8.3: Comparison of max pressure (kPa) during standing

| | Barefoot | | Proposed orthosis | | | |
|---|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | Difference | p |
| Hallux | 12.83 | 22.48 | 14.73 | 21.56 | 1.90 | 0.673 |
| Lateral toes | 3.11 | 7.63 | 1.08 | 4.58 | -2.03 | 0.026* |
| MTP1 | 36.73 | 31.78 | 36.78 | 33.58 | 0.05 | 0.480 |
| MTP2-4 | 37.61 | 29.43 | 41.70 | 32.21 | 4.09 | 0.858 |
| MTP5 | 18.93 | 19.83 | 24.80 | 23.90 | 5.87 | 0.421 |
| Midfoot medial | 0.61 | 3.48 | 1.82 | 6.31 | 1.22 | 0.290 |
| Midfoot lateral | 14.55 | 29.66 | 15.33 | 22.58 | 0.78 | 0.867 |
| Rearfoot | 116.14 | 37.73 | 107.77 | 45.61 | -8.37 | 0.322 |

Note. * p < .05, ** p < .01, *** p < .001

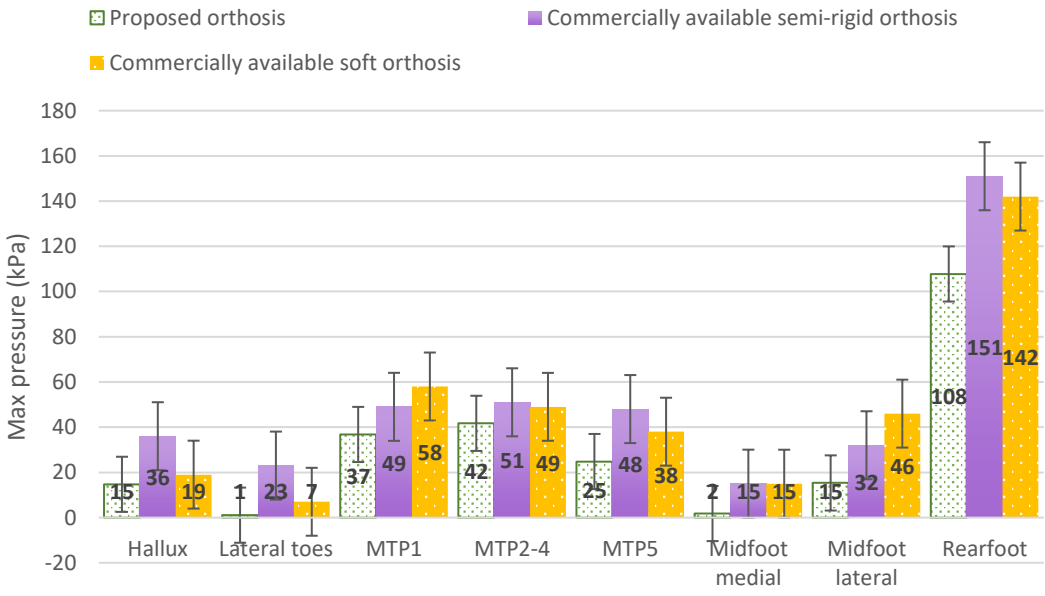



Figure 8.7: Comparison of max pressure (kPa) when standing with different orthoses

8.3.1.2 Effect of orthosis on HVA

The primary function of the HV orthosis is to prevent further deformation of the hallux and potentially reduce the HVA. In Chapter 4, the results demonstrated that compared to the barefoot condition, the HVA of individuals with HV was reduced by approximately 2.5° when using commercially available orthoses. However, when the HV subjects used the proposed orthosis, there is a more significant and pronounced correction of the HVA, as indicated in Table 8.4. The mean angular reduction ranges from 2.1° to 3.5° after the intervention of the new design components. Notably, the combination of the corrective band and toe separator in the orthosis results in the greatest angular correction (3.5°, $p < 0.001$), allowing the angle to be reduced so that the HVA is within a normal range.

Previous studies have demonstrated the effectiveness of orthoses with toe separators in reducing HVA, thus alleviating foot pain (Plaass et al., 2020; Tehraninasr et al., 2008). The toe separators in this study have shown positive outcomes in achieving relevant results. Additionally, the soft silicone auxetic band is effective in reducing the HVA. Silicone is commonly used in medical prosthetics due to its strength, stretchability, low intermolecular force, and high elasticity. The auxetic structure, characterized by a synclastic curvature during bending further enhances the properties of the silicone material (Donoghue et al., 2009; Evans & Alderson, 2000). This study demonstrates that the combined use of both the corrective band and toe separator in the orthosis yields better results. The correlation between the HVA and the intervention of the toe separator only and corrective band only shows highly significant positive associations with the HVA after wearing both components ($r = 0.858$, $p < 0.001$; $r = 0.897$, $p < 0.001$,

respectively).

Table 8.4: Effect of orthosis on HVA correction

| | Mean | Difference | p |
|---|---|---|---|
| With auxetic band only | 15.10 | -2.13 | < 0.001*** |
| With toe separator only | 15.00 | -2.23 | < 0.001*** |
| Proposed orthosis | 13.70 | -3.53 | < 0.001*** |

Note. * p < .05, ** p < .01, *** p < .001

8.3.1.3 Effect of orthosis on balance

COP displacement is commonly used to assess body balance. Foot insoles have been recognized as a valuable tool in clinical settings for measuring the COP and evaluating gait stability (Hof et al., 2007; Mehdizadeh et al., 2020; Vlutters et al., 2016). COP provides information on the distribution of the forces applied to the area where the foot comes into contact with the ground (Mehdizadeh et al., 2020).

Balance control is crucial for everyday activities and has significant clinical implications. Studies have shown that COPx measurements are related to the risk of falls in the elderly (Machado et al., 2015). Additionally, a large range of COPy values can contribute to imbalance. Inability to maintain the center of gravity within a certain range can result in falls (Roman-Liu, 2018). Individuals with HV typically exhibit larger ranges of COPx and COPy values while standing and walking as they tend to use more pronounced corrective movements to maintain balance (Kwan et al., 2021; Shima

et al., 2020).

This study also investigated the impact of wearing the orthosis on the balance of the participants. Table 8.5 and Figure 8.8 present the measurements and statistical analysis of the COP displacement during walking in both the barefoot condition and when wearing the proposed orthosis. Similar to commercially available orthoses (Table 4.3), the COP measurements after wearing the proposed orthosis are higher compared to the barefoot condition, with a significantly higher range of COPx values ($p = 0.006$). To address the wear comfort and breathability of the orthosis, the use of powernet as the main fabric of the sock may lead to a slightly slippery surface. Adding silicone dots to the bottom of the orthosis in future could help to enhance grip and stability.

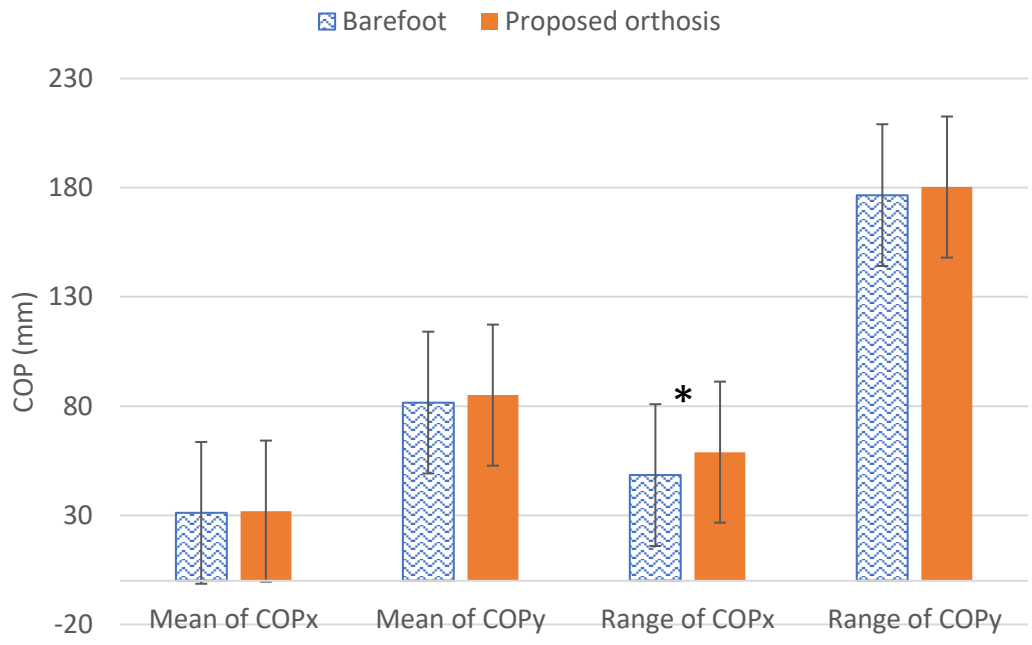



Figure 8.8: Measurement of COP during walking

Table 8.5: Measurement of COP (mm) during walking (N = 22)

| | | Barefoot | | Proposed orthosis | | | | 95% Confidence Interval | |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean | S.D. | Mean | S.D. | Mean difference | p | Lower | Upper |
| Mean | COPx | 31.10 | 7.84 | 31.90 | 6.67 | 0.80 | 0.400 | -2.67 | 1.14 |
| | COPy | 81.60 | 17.56 | 85.00 | 15.59 | 3.40 | 0.234 | -9.23 | 2.49 |
| Range | COPx | 48.40 | 7.20 | 58.90 | 6.37 | 10.50 | 0.006** | -17.48 | -3.59 |
| | COPy | 176.60 | 14.22 | 180.30 | 30.91 | 3.70 | 0.683 | -23.21 | 15.73 |

Note. * p < .05, ** p < .01, *** p < .001

8.3.1.4 Subjective evaluation of orthoses

This study also investigates the subjective experiences related to the ease of use, wear comfort, fit, receptivity, pain, and perceived corrective forces of the proposed orthosis, and compare the proposed orthosis with commercially available orthoses. A simplified 10-point VAS was utilized to gather subjective ratings (Mündermann et al., 2002). A one-way ANOVA was conducted, with the alpha level set at 0.05. The results, as presented in Figure 8.9 and Table 8.6, indicate that the proposed orthosis outperforms other orthoses in terms of ease of use, perceived wear comfort, fit, and receptiveness, with statistically significantly higher rankings. The participants also felt more corrective forces with the proposed orthosis compared to the other orthoses. However, it is worth noting that some patients experienced pain during the experiment.

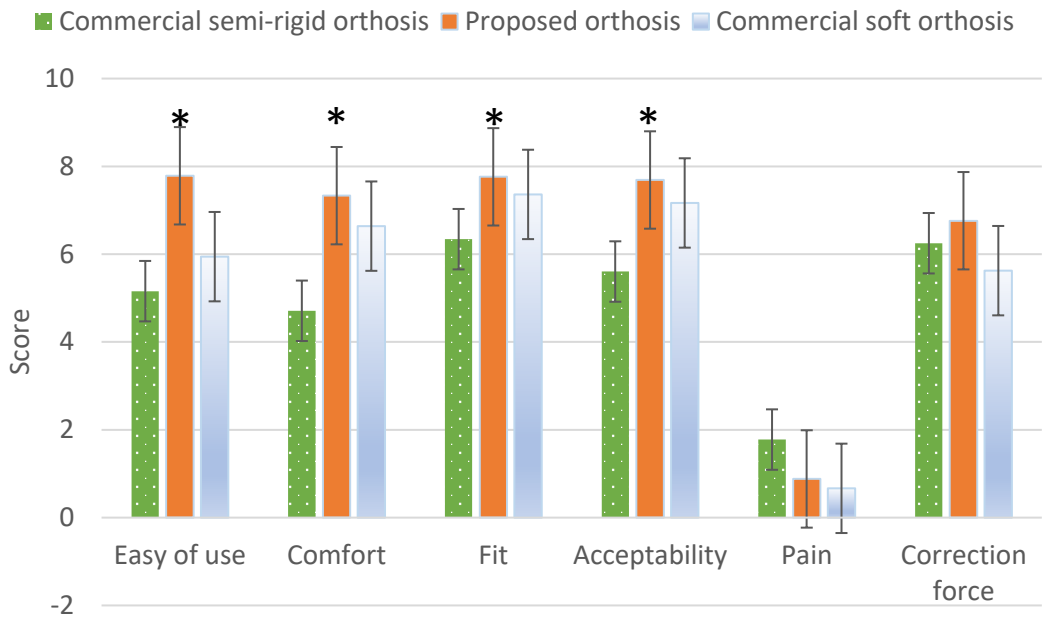



Figure 8.9: Subjective feelings while wearing HV orthosis

Table 8.6: Rated subjective feelings with use of HV orthoses (N = 22)

| | Commercially available semi-rigid orthosis | | Proposed orthosis | | Commercially available soft orthosis | | |
|---|---|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | Mean | S.D. | p |
| Ease of use | 5.16 | 2.01 | 7.79 | 1.42 | 5.94 | 1.92 | < .001*** |
| Comfort | 4.71 | 1.98 | 7.33 | 1.32 | 6.64 | 1.49 | < .001*** |
| Fit | 6.34 | 1.81 | 7.76 | 1.22 | 7.36 | 1.16 | 0.026* |
| Acceptability | 5.61 | 2.21 | 7.69 | 1.44 | 7.17 | 1.29 | 0.006** |
| Pain | 1.78 | 2.56 | 0.88 | 1.83 | 0.67 | 1.33 | 0.282 |
| Correction force | 6.25 | 1.83 | 6.76 | 1.61 | 5.63 | 2.20 | 0.417 |

Note. * $p < .05$, ** $p < .01$, *** $p < .001$

The Pearson's correlation coefficient was used to examine the relationships between different subjective factors. The results showed several significant correlations. There is a positive correlation between ease of use and receptiveness, with a correlation coefficient of 0.457 ($p = 0.037$). This suggests that if the orthosis is easier to use, the user is more receptive to the orthosis. Ease of use also has a positive influence on the ratings of wear comfort ($r = 0.668$, $p < 0.001$), perceived corrective forces ($r = 0.471$, $p = 0.031$), and fit ($r = 0.661$, $p = 0.001$). Similarly, the receptiveness to the orthosis is increased when wearers feel that it is more comfortable to use ($r = 0.559$, $p = 0.008$) and has a better fit ($r = 0.557$, $p = 0.009$). There is a statistically significant moderate positive correlation between fit and wear comfort ($r = 0.511$, $p = 0.018$). Wear comfort is negatively affected by perceived pain ($r = -0.511$, $p = 0.018$), thus indicating that when the participants experience pain, their score for the wear comfort is lower. In terms of fit, there is a highly significant positive correlation between perceived corrective forces and fit ($r = 0.770$, $p < 0.001$), thus suggesting that the wearer perceives more corrective forces with a better fit.

### 8.3.2 Effect of fourteen-day trial

#### 8.3.2.1 Effect of orthosis on HVA

During the fourteen-day trial, the participants were instructed to wear the orthosis for more than 6 hours a day and their foot measurements were collected after the trial period. The results showed that the HVA can be reduced up to 5.47° ($p < 0.001$), which is higher than the reduction observed in the one-hour trial. This suggests that the duration of

orthosis wear may impact the effectiveness of HVA reduction. In this study, hours of usage were recorded daily, and on average, the orthosis was donned 7.27 hours each day, with no withdrawals from the study. The correlation analysis revealed a slight positive correlation between the angle reduction and the wearing time ($r = 0.297$, $p = 0.203$).

#### 8.3.2.2 Subjective evaluation of orthoses

Subjective evaluations of the orthosis were also conducted in both Stages One and Two. A paired samples t-test was performed to compare the subjective ratings after wearing the orthosis in both stages. The results showed that after wearing the orthosis for a longer duration, the participants indicated a decline in the subjective feelings, although the change is not significant (Table 8.7). However, there is a significant increase in perceived pain ($p = 0.010$). A modified FHSQ was used to assess the intensity of the pain and any associated difficulties in daily life. The participants reported only a mild influence. Interviews were further conducted to gather additional information on the location and frequency of pain for future design modifications. Six of the twenty-two participants reported pain after wearing the orthosis for more than three hours daily, with one subject reporting pain after eight hours of use. The pain is specifically located at the hallux, MTPJ1, and the webspace between the hallux and the second toe, where participants felt stretching and intervention from the toe separator. To address this issue, future designs may consider adjusting the length of the corrective band to accommodate different foot sizes and reducing the hardness of the toe separator. The participants also suggested attaching the toe separator directly to the orthosis to facilitate more ease of wear. The willingness to continue the intervention received an average score of 6.87,

which indicates that the participants do not resist to wear the orthosis for treatment in the long-term.

Similar to Stage One, the ratings of ease of use, wear comfort, pain, receptivity, and fit were found to be intercorrelated in Stage Two. There is a significantly positive correlation between ease of use and wear comfort ($r = 0.615$, $p = 0.004$). Increased ease of use ($r = 0.843$, $p < 0.001$) and wear comfort ($r = 0.560$, $p = 0.01$) are also associated with higher receptivity. A better fitting orthosis is positively correlated with wear comfort ($r = 0.777$, $p < 0.001$), while perceived pain has a significantly negative effect on wear comfort ($r = -0.525$, $p = 0.025$) and receptivity ($r = -0.549$, $p = 0.018$).

Table 8.7: Subjective ratings

| | Stage 1 | | Stage 2 | | |
|---|---|---|---|---|---|
| | Mean | S.D. | Mean | S.D. | p |
| Ease of use | 7.79 | 1.42 | 6.95 | 1.67 | 0.959 |
| Comfort | 7.33 | 1.32 | 6.00 | 1.59 | 0.081 |
| Correction force | 6.76 | 1.61 | 6.58 | 1.76 | 0.516 |
| Fit | 7.76 | 1.22 | 6.35 | 2.30 | 0.101 |
| Acceptability | 7.69 | 1.44 | 6.98 | 1.63 | 0.289 |
| Pain | 0.88 | 1.83 | 2.94 | 2.90 | 0.010* |
| Pain while walk | / | / | 1.06 | 0.87 | / |
| Pain while stairs | / | / | 0.76 | 0.90 | / |
| Pain while sit | / | / | 0.39 | 0.61 | / |
| Pain while stand | / | / | 0.61 | 0.70 | / |
| Difficulties while walk | / | / | 0.21 | 0.54 | / |
| Difficulties while stairs | / | / | 0.17 | 0.38 | / |
| Difficulties while sit | / | / | 0.05 | 0.23 | / |
| Difficulties while stand | / | / | 0.11 | 0.32 | / |

Note. * $p < .05$, ** $p < .01$, *** $p < .001$

The importance of price, ease of use, corrective forces, wear comfort, fit, material usage, and appearance were ranked by the participants. The results, shown in Figure 8.10, indicate that the wear comfort is ranked as the most important factor, followed by fit and ease of use. Price and appearance are considered less important. This finding is consistent with other research that has identified wear comfort, fit, and ease of use as

the most important factors influencing orthotic compliance among patients. Okçu et al. (2022) referred to these factors as "device-related reasons." Their study also found that no patients discontinued the orthosis use due to aesthetic or cosmetic reasons. The compliance of patients with orthosis use can be influenced by factors such as disease duration, age, and the duration for which the orthosis is prescribed. They emphasized that patient awareness of the necessity of orthosis use may improve compliance. In this study, it is observed that these three factors (wear comfort, fit, and ease of use) are intercorrelated in terms of subjective ranking. Therefore, addressing any of these issues could potentially enhance patient compliance.

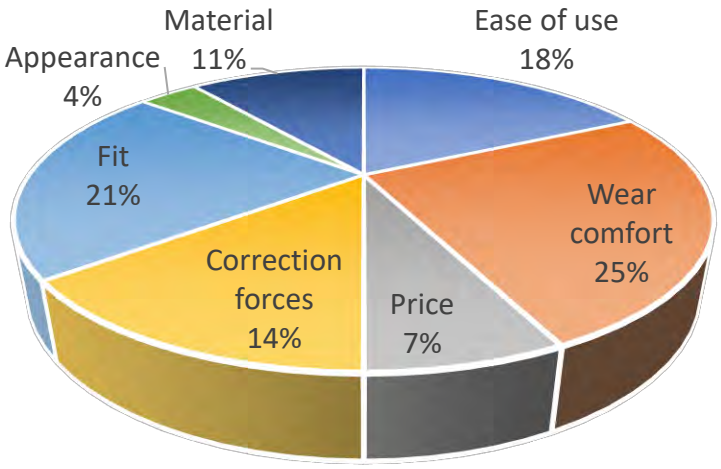



Figure 8.10: Ranking of important factors when choosing an HV orthosis (N = 22)

## 8.4 Preliminary study of dynamic HVA

In addition to studying the effect of the orthosis, a preliminary study was conducted to investigate the dynamic HVA by using the Vicon Motion System. This preliminary study aimed to provide a method to evaluate gait-related information of HV patients. Five female subjects with mild to moderate HV participated in the study, and their data also served as a reference for evaluating the performance of the orthoses. To capture the data, force plates and the Oxford foot model were utilized (Figure 8.12). The experimental setup is shown in Figure 8.11. Force plates are mechanical sensing systems that measure the moments involved in human motion and the GRF exerted by the ground on the body in contact with it (Popovic, 2019a; Popovic, 2019b). The stance phase, from heel strike to toe off, was identified and recorded. The subjects were instructed to walk in a straight line, focusing on the middle camera as a target point, at a self-selected speed for normal gait. Since the Vicon cameras capture the movement of the retroreflective markers, it is important for subjects to wear clothing that do not obstruct the markers used by the Vicon cameras. Any other reflective materials were not allowed in the capture volume. Close-fitting clothing such as leggings was used to minimize the noise captured by the motion capture system and ensure accurate determination of the underlying skeleton of the subjects. Each subject underwent three successful trials to ensure consistency of the data. Data from the dominant foot were analyzed by using SPSS v.24 (IBM Corp., Armonk, New York), and the alpha level was set to 0.05.

A new marker called "RHVA" was added on the hallux, on top of the Oxford foot model (Figure 2.8 and Table 2.2), to calculate the dynamic HVA (Figure 8.13). The HVA

measured by using the Vicon system was aligned through a clinical assessment. The angle was formed by intersecting the longitudinal axis A of the MTP1 (between RDLM and RHVA) and the longitudinal axis B of the proximal phalanx (between RDLM and RHVA). These angles were calculated based on the coordinate information extracted from the Vicon Motion System using a 2D approach, utilizing the coordinates in the x and y directions. Equations 8.1 to 8.4 are used to calculate the dynamic HVA during walking.

Equation 8.1:

$$A = \sqrt{(\mathrm{RSTLx} - \mathrm{RDLMx})^2 + (\mathrm{RSTLy} - \mathrm{RDLMy})^2}$$

Equation 8.2:

$$B = \sqrt{(\mathrm{RHVAx} - \mathrm{RDLMx})^2 + (\mathrm{RHVAy} - \mathrm{RDLMy})^2}$$

Equation 8.3:

$$\alpha = (RHVAx - RDLMx)(RSTLx - RDLMx) + (RHVAy - RDLMy)(RSTLy - RDLMy)$$

Equation 8.4:

$$HVA = 180 - \cos^{-1}\frac{\alpha}{AB}$$

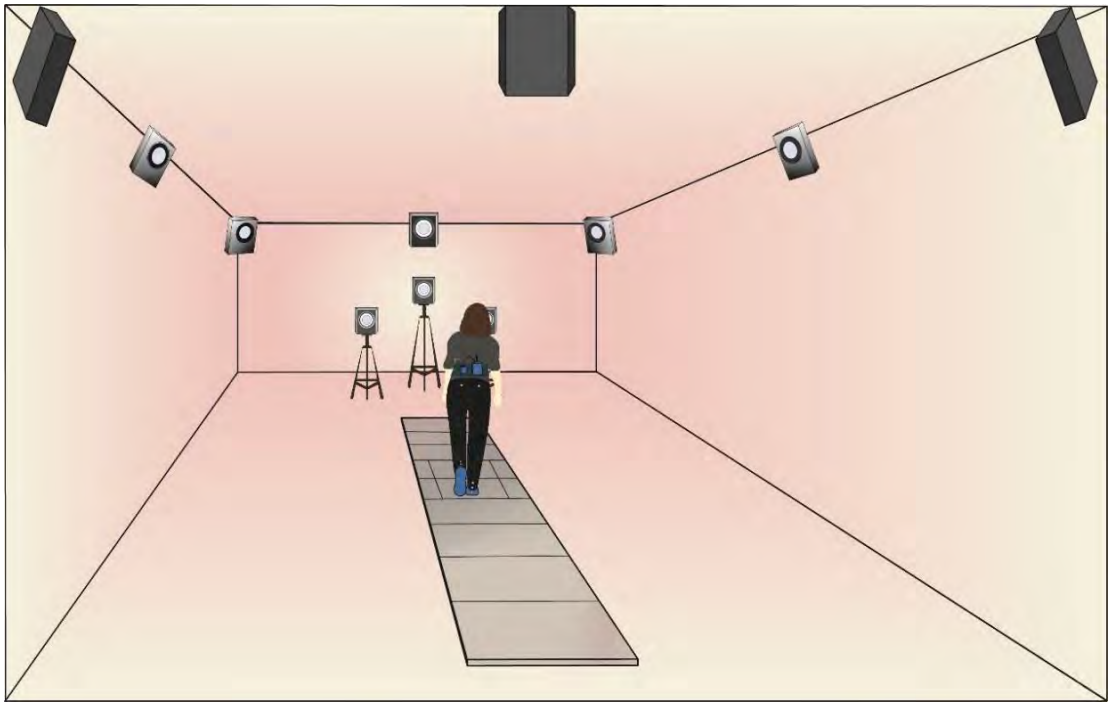


Figure 8.11: Experimental set-up, with the use of motion capture systems, and force plates

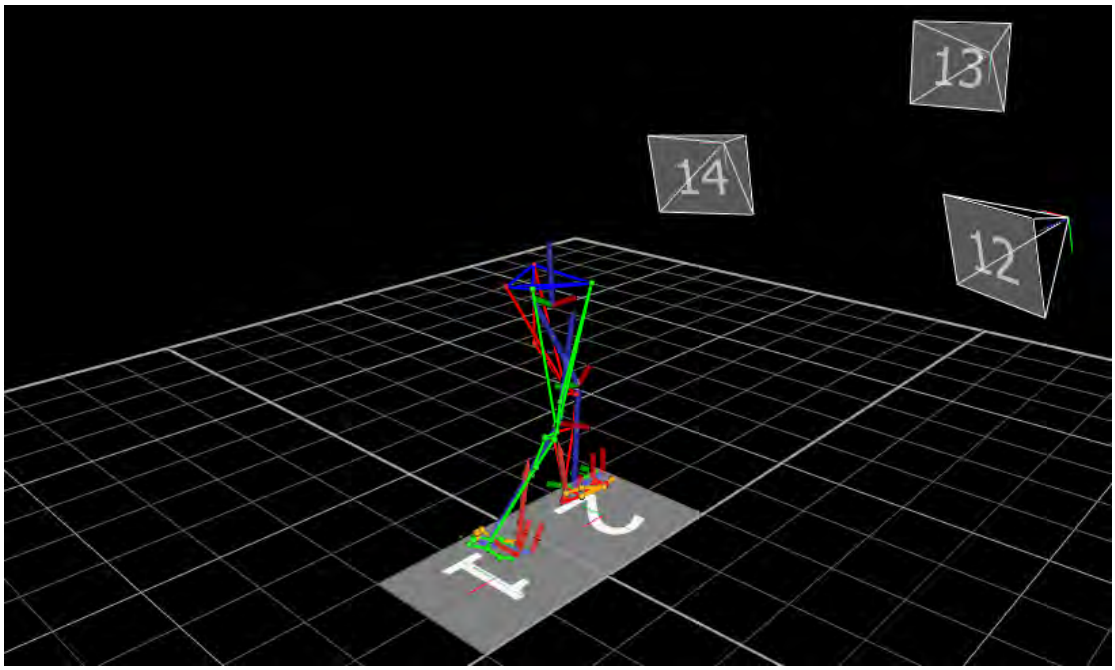



Figure 8.12: Motion capturing

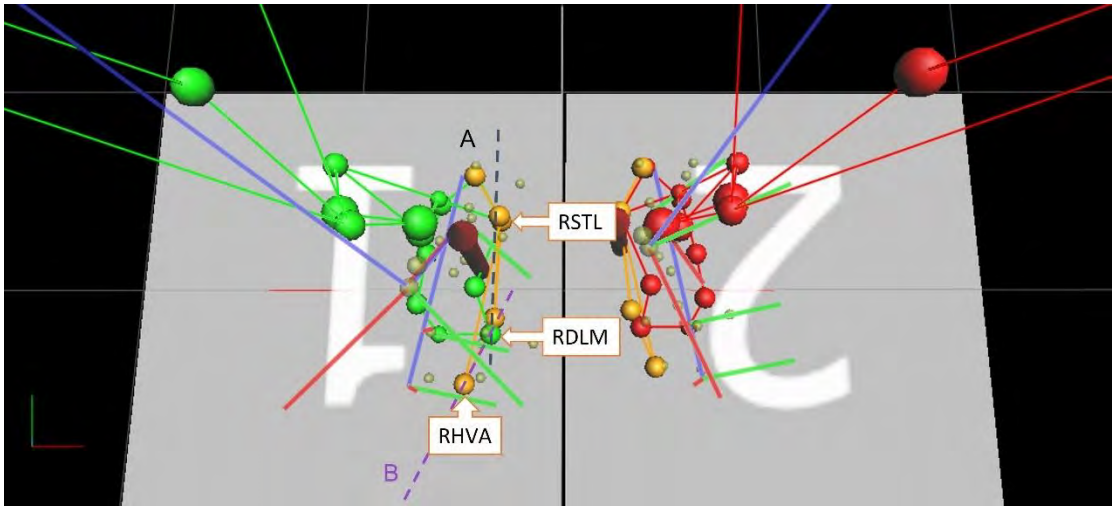



Figure 8.13: Markers on foot

The results of the paired samples t-test indicated that the HVA significantly differs between the barefoot condition and wearing the proposed orthosis while walking, with a mean difference of 5.45° ($p < .001$). Figure 8.14 shows that the angle varies during walking, but the variation is limited after wearing the orthosis. Alongside the HVA, GRF is an important factor to consider in orthosis design (Munro et al., 1987; Logan et al., 2010; Yu et al., 2021). The vertical GRF was recorded by using the force plate and normalized to the body weight of the subjects. The peak of the vertical GRF represents the maximum force exerted by the ground onto a person during movement, which occurs when the body comes into contact with the ground and pushes against it with the greatest force. There are typically two peaks: one during heel strike and another during toe off (Wannop et al., 2012; Mei et al., 2015). Previous research has shown that men tend to have equal peaks, while women tend to exhibit a higher second peak (Chao et al., 1983). In this study, Figure 8.14 shows that the vertical GRF differs between the two conditions, with a higher peak observed when wearing the proposed orthosis. A higher vertical GRF is believed to contribute to an increased risk of stress injuries to

the lower limbs (Mei et al., 2015). The use of the proposed orthosis design resulted in change of gait pattern and posture.

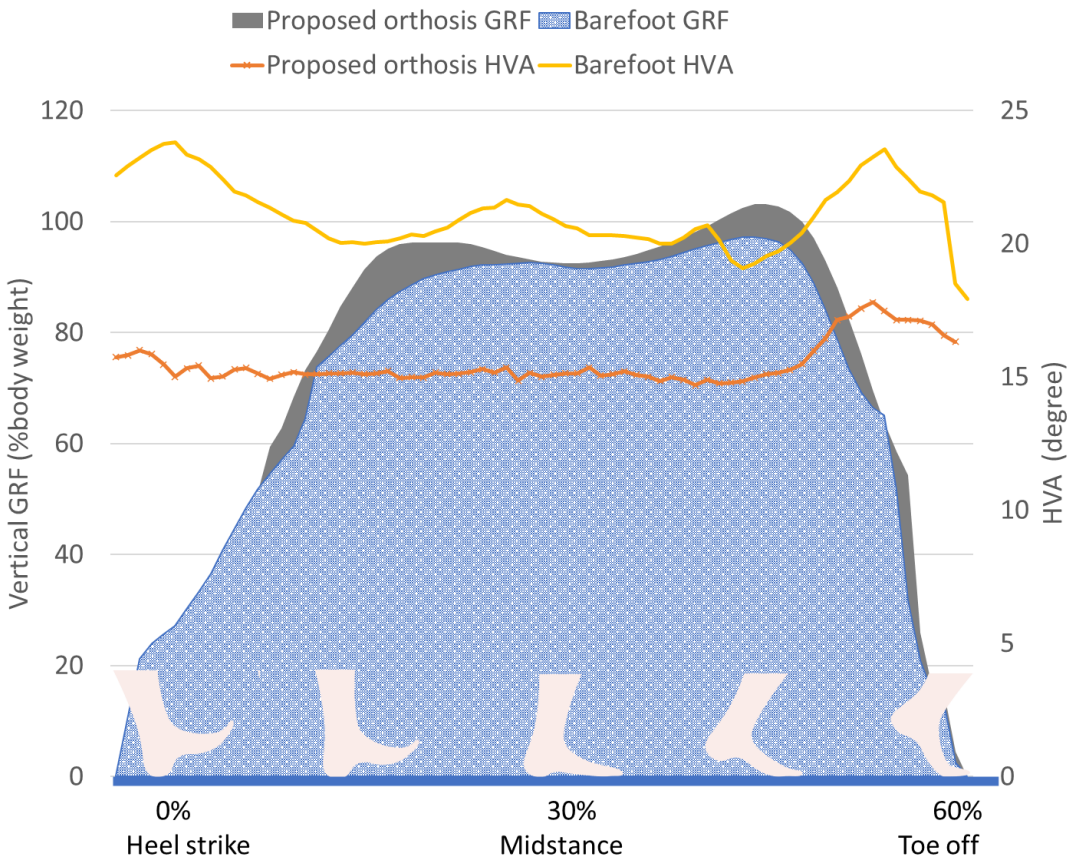



Figure 8.14: Effect of orthosis on HVA and GRF in stance phase

## 8.5 Chapter summary

This chapter evaluates the immediate and short-term effects of a proposed orthosis through wear trials. The evaluation focuses on several factors, including the angle reduction, plantar pressure, balance, and subjective ratings. Based on the findings, it can be concluded that the proposed orthosis can provide appropriate corrective forces

and can be effectively used during daily activities. During the wear trial, the participants provided valuable feedback on any issues or problems encountered while using the orthosis. These insights are crucial for improving the design and effectiveness of the orthosis in addressing HV. Additionally, a novel method for analyzing the dynamic HVA during walking has been discussed in this chapter. These results contribute to a better understanding of the effects of the proposed orthosis and have valuable implications for the prescription and development of orthotics, and follow-up of orthotic treatment.

# Chapter 9 Conclusions and Suggestions for Future Research

## 9.1 Conclusions

The main goal of this study was to design an orthosis that can be worn comfortably on a daily basis and prevent the progression of HV deformity with reference to experimental and numerical analysis and feedback from orthopedic surgeons. The project goals discussed in detail in Section 1.3 of Chapter 1 have been achieved, and the research results are summarized as follows:

1. A systematic literature review and meta-analysis were conducted to establish a comprehensive scientific basis for understanding the prevalence, pathogenesis, and diagnosis of HV, as well as current therapeutic practices. The meta-analysis revealed that a full-length orthosis with a toe separator is the most effective in correcting HVA and reducing foot pain. Foot orthoses, particularly those with a toe separator, are considered a viable treatment option for reducing HV deformity. Therefore, including this element in the conservative treatment of HV deformity and future development of HV orthoses is crucial. Understanding the biomechanical behavior of feet with HV, its relationship with foot orthoses, and the properties of different orthotic materials is crucial for optimizing design and achieving effective treatment outcomes.

2. A biomechanical study was conducted in this research, aimed to examine the effects of different HV orthosis designs on balance performance, plantar pressure, HVA correction, and subjective sensation. Sixteen female subjects participated in the study, including both HV and non-HV individuals. The immediate effects of soft

and semi-rigid HV orthoses were analyzed in comparison to barefoot condition. The results revealed that soft HV orthosis demonstrated superior HVA correction, greater wearing comfort, and reduced plantar pressure at the hallux. These findings suggest that future HV orthosis designs should incorporate soft, thin, durable, and smooth flexible materials. The results also serve as a practical reference for selecting HV orthoses.

3. This study develops a biomechanical model that simulates plantar pressure distribution and corrective forces in relation to the mechanical properties of fabrication materials, as well as the geometrical factors of anatomy and orthosis designs. The 3D foot scanning process provided valuable data for improving the fit and engineered design of HV orthoses. It also facilitated the establishment of FEM. The FEM allowed for the evaluation of corrective forces and the identification of design modifications supported by scientific evidence. The study systematically investigated the biomechanical effects of different design parameters and their interactions to optimize the wear comfort and corrective effect of orthopedic designs. The findings revealed that softer arch support materials can effectively reduce forefoot peak pressures, and to reduce the HVA from 18 degrees to the normal 15 degrees, approximately 6 Newtons of force are required. This research contributes to the advancement of orthosis design and provides valuable insights into the biomechanical aspects of HV treatment and foot arch support interventions.

4. An optimally fitting in-shoe orthosis for HV, by integrating anthropometry, biomechanics, additive manufacturing techniques, and textile science analysis, was developed. The new HV orthosis combines the use of fabric and silicone to provide adequate corrective forces, optimized in-shoe fit, ease of wear and comfort, thereby

improving patient compliance and the effectiveness of orthopedic treatments. It utilized 3D scanning, 3D printing and demolding technologies during the design process.

5. Laboratory tests and wear trials with the orthosis prototype were performed on the orthosis prototype to assess its immediate and short-term effectiveness and real-life suitability, as well as validate the accuracy of the FEM. The impact of the treatment, including angle reduction, plantar pressure, balance, and the subjective experiences of the wearers with the new prototype were assessed, and compared with commercially available orthoses. The findings indicate that the new orthosis provides appropriate corrective forces and can be effectively utilized during daily activities. Valuable feedback from participants during the wear trials contributed to improving the orthosis design and effectiveness in addressing HV. Additionally, a novel method for analyzing the dynamic HV angle during walking was demonstrated using the motion capture system, further enhancing our understanding of the orthotic effects.

## 9.2 Limitations and suggestions for future research

There are some limitations of this study, which are listed below, and suggestions for future work are made.

1. Apart from the simplifications of the structural and material properties of the foot in the FE computation, the FEM only simulated a balance standing posture and do not consider other dynamic activities such as walking, which could provide a more comprehensive evaluation. Future research can develop FEM that simulates

different loading conditions at various stages of the stance phase, such as heel strike and push-off, to predict the effects of design parameters on plantar pressure relief during gait.

2. The construction of the shoe is not included in the FE simulation, and the materials tested were also limited. It is recommended to incorporate shoes into the FEM to evaluate interfacial stresses on the foot within the shoe for a more comprehensive understanding and expand the range of materials for further exploration.

3. As with any systematic review or meta-analysis, the findings of this literature review are dependent on the quality of the included studies. Limitations of this study include the scarcity of relevant research, inconsistency in the study methods, variations in subjects' conditions, limited consideration of assessment reliability and validity, and a lack of randomized controlled trials and information on orthotic materials.

4. The generalizability of the results in this preliminary study may be limited by a relatively small sample size and the difference in the number of participants in each group. Only the maximum peak pressure and COP of the orthosis are examined while neglecting other measurements, such as contact area and force-time integral. More randomized controlled trials related to HV orthoses can be conducted to enhance the evidence base.

5. The new orthosis was originally designed to fit shoe sizes EU 37 to EU 39. This size range was chosen as a starting point to ensure compatibility with a commonly worn range of shoe sizes. However, it's important to note that the design of the orthotics can be extended to accommodate other sizes. By adjusting the dimensions of the orthosis, a wider range of options for individuals with varying

foot sizes can be provided.

6. When wearing the new orthosis, individuals may experience a higher range of COPx values. To enhance grip and stability while wearing the orthosis, silicone dots can be incorporated on the bottom surface. These dots act as small friction-enhancing elements, increasing the traction between the foot orthosis and the shoe sole. By improving grip, the silicone dots help to minimize slippage and provide a more secure and stable footing.

## Appendix I Supplementary materials (Immediate Effects of HV Orthoses)

Results of Independent-Samples T Test

| | N | p | Mean difference |
|---|---|---|---|
| Sample A - walking pressure - hallux | 16 | 0.110 | -95.47 |
| Sample A - walking pressure - lateral toe | 16 | 0.283 | -19.90 |
| Sample A - walking pressure - MTP 1 | 16 | 0.153 | -71.19 |
| Sample A - walking pressure - MTP 2-4 | 16 | 0.520 | 43.41 |
| Sample A - walking pressure - MTP 5 | 16 | 0.870 | 4.45 |
| Sample A - walking pressure - midfoot medial | 16 | 0.848 | -0.81 |
| Sample A - walking pressure - midfoot lateral | 16 | 0.875 | -14.43 |
| Sample A - walking pressure - rearfoot | 16 | 0.029* | -68.59 |
| Sample B - walking pressure - hallux | 16 | 0.600 | 5.28 |
| Sample B - walking pressure - lateral toe | 16 | 0.314 | 23.06 |
| Sample B - walking pressure - MTP 1 | 16 | 0.092 | -38.97 |
| Sample B - walking pressure - MTP 2-4 | 16 | 0.203 | 92.70 |
| Sample B - walking pressure - MTP 5 | 16 | 0.061 | 46.20 |
| Sample B - walking pressure - midfoot medial | 16 | 0.485 | 1.63 |
| Sample B - walking pressure - midfoot lateral | 16 | 0.481 | 6.21 |
| Sample B - walking pressure - rearfoot | 16 | 0.071 | -69.23 |
| Barefoot - walking pressure - hallux | 16 | 0.236 | -66.87 |
| Barefoot - walking pressure - lateral toe | 16 | 0.471 | -23.81 |
| Barefoot - walking pressure - MTP 1 | 16 | 0.414 | -50.56 |
| Barefoot - walking pressure - MTP 2-4 | 16 | 0.465 | 32.66 |
| Barefoot - walking pressure - MTP 5 | 16 | 0.109 | 50.38 |
| Barefoot - walking pressure - midfoot medial | 16 | 0.222 | 6.90 |
| Barefoot - walking pressure - midfoot lateral | 16 | 0.224 | 12.43 |
| Barefoot - walking pressure - rearfoot | 16 | 0.191 | -35.52 |
| Sample A - standing pressure - hallux | 16 | 0.516 | -10.33 |
| Sample A - standing pressure - lateral toe | 16 | 0.577 | -18.25 |
| Sample A - standing pressure - MTP 1 | 16 | 0.572 | -6.42 |
| Sample A - standing pressure - MTP 2-4 | 16 | 0.323 | -0.83 |
| Sample A - standing pressure - MTP 5 | 16 | 0.079 | -6.42 |
| Sample A - standing pressure - midfoot medial | 16 | 0.470 | 4.58 |
| Sample A - standing pressure - midfoot lateral | 16 | 0.337 | -4.08 |
| Sample A - standing pressure- rearfoot | 16 | 0.279 | -22.50 |
| Sample B - standing pressure - hallux | 16 | 0.760 | -10.75 |
| Sample B - standing pressure - lateral toe | 16 | 0.822 | -1.33 |
| Sample B - standing pressure - MTP 1 | 16 | 0.196 | -17.92 |
| Sample B - standing pressure - MTP 2-4 | 16 | 0.303 | 14.25 |
| Sample B - standing pressure - MTP 5 | 16 | 0.419 | -7.75 |
| Sample B - standing pressure - midfoot medial | 16 | 0.273 | 5.17 |
| Sample B - standing pressure - midfoot lateral | 16 | 0.191 | -23.25 |
| Sample B - standing pressure - rearfoot | 16 | 0.357 | -20.08 |
| Barefoot - standing pressure - hallux | 16 | 0.643 | 7.83 |
| Barefoot - standing pressure - lateral toe | 16 | 0.620 | 15.58 |
| Barefoot - standing pressure - MTP 1 | 16 | 0.258 | -10.58 |
| Barefoot - standing pressure - MTP 2-4 | 16 | 0.948 | 1.25 |
| Barefoot - standing pressure - MTP 5 | 16 | 0.706 | 3.17 |
| Barefoot - standing pressure - midfoot medial | 16 | 0.634 | 0.75 |
| Barefoot - standing pressure - midfoot lateral | 16 | 0.623 | 10.25 |
| Barefoot - standing pressure - rearfoot | 16 | 0.455 | -1.08 |
| Sample A - standing - COPx | 16 | 0.033 | -1.79 |
| Sample B - standing - COPx | 16 | 0.134 | -1.30 |
| Barefoot - standing - COPx | 16 | 0.384 | -0.22 |

| | | | |
|---|---|---|---|
| Sample A - standing - COPy | 16 | 0.289 | -2.92 |
| Sample B - standing - COPy | 16 | 0.005** | -7.15 |
| Barefoot - standing - COPy | 16 | 0.565 | 3.39 |
| Sample A - walking - COPx | 16 | 0.068 | -4.95 |
| Sample B - walking - COPx | 16 | 0.027* | -11.48 |
| Barefoot - walking - COPx | 16 | 0.097 | 1.54 |
| Sample A - walking - COPy | 16 | 0.469 | 14.79 |
| Sample B - walking - COPy | 16 | 0.186 | -21.34 |
| Barefoot - walking - COPy | 16 | 0.666 | 8.57 |
| Sample A HVA | 16 | 0.014* | -5.23 |
| Sample B HVA | 16 | 0.005** | -5.23 |

Note. * $p < .05$, ** $p < .01$, *** $p < .001$

## Appendix II Supplementary materials (Immediate Effects of HV Orthoses)

Results of rANOVA

| | HV subjects | | | Subjects without HV | | |
|---|---|---|---|---|---|---|
| | F | p | $\eta_p^2$ | F | p | $\eta_p^2$ |
| Walking pressure - hallux | 6.901 | 0.013* | 0.580 | 10.490 | 0.001** | 0.538 |
| Walking pressure - lateral toe | 2.660 | 0.119 | 0.347 | 0.182 | 0.721 | 0.020 |
| Walking pressure - MTP 1 | 2.988 | 0.096 | 0.374 | 1.130 | 0.345 | 0.112 |
| Walking pressure - MTP 2-4 | 0.907 | 0.435 | 0.153 | 1.328 | 0.290 | 0.129 |
| Walking pressure - MTP 5 | 3.436 | 0.073 | 0.407 | 0.502 | 0.613 | 0.053 |
| Walking pressure - midfoot medial | 0.178 | 0.840 | 0.034 | 0.976 | 0.396 | 0.098 |
| Walking pressure - midfoot lateral | 2.301 | 0.151 | 0.315 | 3.874 | 0.057 | 0.437 |
| Walking pressure - rearfoot | 2.688 | 0.116 | 0.350 | 0.141 | 0.869 | 0.015 |
| Standing pressure - hallux | 2.158 | 0.166 | 0.301 | 1.843 | 0.187 | 0.170 |
| Standing pressure - lateral toe | 1.816 | 0.212 | 0.266 | 1.255 | 0.314 | 0.201 |
| Standing pressure - MTP 1 | 1.063 | 0.381 | 0.175 | 0.279 | 0.759 | 0.030 |
| Standing pressure - MTP 2-4 | 1.086 | 0.374 | 0.178 | 6.504 | 0.007** | 0.420 |
| Standing pressure - MTP 5 | 2.657 | 0.119 | 0.347 | 3.046 | 0.107 | 0.253 |
| Standing pressure - midfoot medial | 0.798 | 0.477 | 0.138 | 0.253 | 0.779 | 0.027 |
| Standing pressure - midfoot lateral | 3.195 | 0.127 | 0.390 | 3.074 | 0.110 | 0.255 |
| Standing pressure - rearfoot | 0.298 | 0.749 | 0.056 | 0.174 | 0.841 | 0.019 |
| Standing - COPx | 0.888 | 0.397 | 0.151 | 17.045 | 0.001** | 0.773 |
| Standing - COPy | 1.289 | 0.309 | 0.205 | 2.335 | 0.147 | 0.318 |
| Walking - COPx | 12.622 | 0.002** | 0.716 | 0.783 | 0.465 | 0.080 |
| Walking - COPy | 1.493 | 0.271 | 0.230 | 0.106 | 0.853 | 0.012 |
| HVA | 3.621 | 0.066 | 0.420 | 3.270 | 0.061 | 0.267 |

Note. * $p < .05$, ** $p < .01$, *** $p < .001$

## Appendix III Supplementary materials (Immediate Effects of HV Orthoses)

Results of Pairwise Comparisons

| | HV subjects | | | Subjects without HV | | |
|---|---|---|---|---|---|---|
| | N | p | Mean difference | N | p | Mean difference |
| Sample A - walking pressure - hallux | 6 | 0.070 | 91.05 | 10 | 0.004** | 62.45 |
| Sample A - walking pressure - lateral toe | 6 | 0.910 | 2.30 | 10 | 0.432 | 7.18 |
| Sample A - walking pressure - MTP 1 | 6 | 0.508 | 14.99 | 10 | 0.306 | -5.64 |
| Sample A - walking pressure - MTP 2-4 | 6 | 0.691 | -28.57 | 10 | 0.256 | -18.82 |
| Sample A - walking pressure - MTP 5 | 6 | 0.313 | 34.38 | 10 | 0.351 | -11.53 |
| Sample A - walking pressure - midfoot medial | 6 | 0.352 | 2.97 | 10 | 0.183 | -2.74 |
| Sample A - walking pressure - midfoot lateral | 6 | 0.013* | 39.11 | 10 | 0.580 | 13.50 |
| Sample A - walking pressure - rearfoot | 6 | 0.117 | 28.52 | 10 | 0.746 | -3.55 |
| Sample B - walking pressure - hallux | 6 | 0.233 | -74.41 | 10 | 0.072 | -1.73 |
| Sample B - walking pressure - lateral toe | 6 | 0.129 | -44.49 | 10 | 0.770 | 3.19 |
| Sample B - walking pressure - MTP 1 | 6 | 0.126 | 12.48 | 10 | 0.855 | 23.07 |
| Sample B - walking pressure - MTP 2-4 | 6 | 0.350 | -52.13 | 10 | 0.641 | 7.92 |
| Sample B - walking pressure - MTP 5 | 6 | 0.352 | -2.80 | 10 | 0.456 | -6.98 |
| Sample B - walking pressure - midfoot medial | 6 | 0.819 | 4.83 | 10 | 0.441 | -1.28 |
| Sample B - walking pressure - midfoot lateral | 6 | 0.031* | 26.00 | 10 | 0.130 | 19.83 |
| Sample B - walking pressure - rearfoot | 6 | 0.659 | 12.21 | 10 | 0.623 | -20.51 |
| Sample A - standing pressure - hallux | 6 | 0.067 | 30.42 | 10 | 0.746 | 12.25 |
| Sample A - standing pressure - lateral toe | 6 | 0.326 | 22.83 | 10 | 0.822 | -11.00 |
| Sample A - standing pressure - MTP 1 | 6 | 0.493 | -2.92 | 10 | 0.585 | 1.25 |
| Sample A - standing pressure - MTP 2-4 | 6 | 0.827 | -13.08 | 10 | 0.005** | -14.00 |
| Sample A - standing pressure - MTP 5 | 6 | 0.104 | 0.83 | 10 | 0.083 | -7.75 |
| Sample A - standing pressure - midfoot medial | 6 | 0.248 | -8.08 | 10 | 0.181 | -3.10 |
| Sample A - standing pressure - midfoot lateral | 6 | 0.059 | 11.25 | 10 | 0.799 | -2.50 |
| Sample A - standing pressure - rearfoot | 6 | 0.890 | 26.08 | 10 | 0.648 | 4.50 |
| Sample B - standing pressure - hallux | 6 | 0.787 | 13.33 | 10 | 0.181 | -6.25 |
| Sample B - standing pressure - lateral toes | 6 | 1.000 | 7.00 | 10 | 0.623 | -10.24 |
| Sample B - standing pressure - MTP 1 | 6 | 0.471 | 5.83 | 10 | 0.901 | -1.50 |
| Sample B - standing pressure - MTP 2-4 | 6 | 0.235 | -15.00 | 10 | 0.644 | -2.00 |
| Sample B - standing pressure - MTP 5 | 6 | 0.321 | -9.58 | 10 | 0.107 | -20.00 |
| Sample B - standing pressure - midfoot medial | 6 | 0.371 | -7.75 | 10 | 0.181 | -3.07 |
| Sample B - standing pressure - midfoot lateral | 6 | 0.096 | 25.00 | 10 | 0.641 | -7.50 |
| Sample B - standing pressure - rearfoot | 6 | 0.555 | 17.25 | 10 | 0.721 | -1.75 |
| Sample A - standing - COPx | 6 | 0.229 | 1.20 | 10 | 0.736 | -0.36 |
| Sample B - standing - COPx | 6 | 0.982 | 1.12 | 10 | 0.010* | 0.04 |
| Sample A - standing - COPy | 6 | 1.000 | 6.05 | 10 | 1.000 | -0.26 |
| Sample B - standing - COPy | 6 | 0.431 | 9.53 | 10 | 0.206 | -1.01 |
| Sample A - walking - COPx | 6 | 0.312 | 5.21 | 10 | 1.000 | -1.28 |
| Sample B - walking - COPx | 6 | 0.002* | 14.46 | 10 | 1.000 | 1.43 |
| Sample A - walking - COPy | 6 | 1.000 | -3.69 | 10 | 1.000 | 2.52 |
| Sample B - walking - COPy | 6 | 0.562 | 34.49 | 10 | 1.000 | 4.57 |
| Sample A HVA | 6 | 0.140 | -2.50 | 10 | 0.343 | -1.20 |
| Sample B HVA | 6 | 0.076 | -2.60 | 10 | 0.005** | -2.70 |

Note. * $p < .05$, ** $p < .01$, *** $p < .001$

**Appendix IV Consent to participants**

The Hong Kong
POLYTECHNIC UNIVERSITY

**PARTICIPANT CONSENT FORM**

參與研究項目同意書

**Title of Project: Ergonomic Design of Textile Orthoses for Patients with Hallux Valgus**

研究主題**:**人體工學設計的拇指外翻矯形腳套

Name of Researchers: Dr. YICK Kit-lun, Mr. TSE Chi-yung and Dr. YIP Yiu-wan

1. I confirmed that I have read and understand the information sheet dated _ _ _ _ / _ _ _ _ / _ _ _ _ for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons, without my legal rights being affected.
3. The results will be published in referred journal. All information collected will be kept confidential.
4. I agree to take part in the above study.

研究員: 易潔倫博士, 謝志勇先生 及葉曉雲博士

1. 本人確定已詳細閱讀並了解於_ _ _ _ / _ _ _ _ / _ _ _ _ 提供之資料單張, 並已有足夠時間發問。

2. 本人明白是次參與為自願性質, 本人有權隨時退出而不必提出任何理由, 而本人的法律權利不會改變。

3. 研究結果將會發佈在醫學矯形和紡織設計刊物內, 其他資料一概保密。

4. 本人同意參與此項研究。

| | | |
|---|---|---|
| Name of participant<br>參加者姓名 | Date 日期 | Signature 簽名 |
| Name of researcher<br>研究員姓名 | Date 日期 | Signature 簽名 |
| Name of witness<br>見證人姓名(如適用) | Date 日期 | Signature 簽名 |

## Appendix V Information sheet for participant

The Hong Kong
POLYTECHNIC UNIVERSITY

### INFORMATION SHEET

### Ergonomic Design of Textile Orthoses for Patients with Hallux Valgus

### 研究主題:人體工學設計的拇指外翻矯形腳套

You are invited to participate on a postgraduate research study supervised by Dr. Kit-lun YICK, who is the staff member of the Institute of Textiles and Clothing, The Hong Kong Polytechnic University. 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 project aims to propose a scientific approach to develop an optimally fitting in-shoe orthosis for Hallux Valgus (HV) with suitable textile materials that provide appropriate corrective forces, wear comfort, and patient satisfaction, and can be used in all sorts of daily activities.

**Do you have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. The choice of participation in the study would not affect your legal rights. During the study, if you failed to turn up at appointments, your participation in this study will be immediately terminated without further notice.

**What will happen if you decide to take part?**

Participants of this study should be female aged between 18 and 65 and feet size from EU35 to 40 with diagnosed pathology of HV. Initial screening will be conducted and/or supported by a professional prosthetist-and-orthotist. Apart from recording personal information, body weight and height, foot scanning (at static, weight-bearing condition) and photos will be firstly taken. Health conditions of your feet and experiences in wearing high-heeled shoes and/or footwear style in daily activities will be logged.

Following the clinical diagnosis of HV, subjects will then be invited for X-ray scanning at clinic or medical center that HV angle (HVA) for the level of deformity will be measured. Subjects with HVA ranged between 15° and 39° will be invited to this study. An estimated 30 subjects will be recruited.

Foot scanning and measurements at different postures and weight bearing conditions will then be taken by using a handheld 3D laser scanner and/or a high-resolution 3D foot scanning system at The Hong Kong Polytechnic University (PolyU) and/or AiDesign Lab at Science Park (SP). When a Hallux Valgus brace (orthoses) is used, the changes of in-shoe microclimate, plantar pressure distribution, gait pattern and body balance during locomotion and foot shape geometry will also be recorded. The time taken is around 80-90 minutes. Once a new design is developed, wear trial would be arranged and the effects on gait pattern and distribution of plantar pressures will be reassessed. A simple questionnaire survey regarding the comfort and perception on the new design will also be conducted. No invasive test is necessary.

Upon the completion of foot measurement, evaluation of foot biomechanics and plantar pressure, and/or questionnaire survey, a HK$100 gift voucher will be given to participant.

**What is the Hallux Valgus orthoses being tested?**

Brace or orthoses are used extensively for patients receiving treatment for HV, together with soft leather shoes with extra width and depth of the toe box. Customized orthoses may be prescribed to conform to the foot shape in all respects for the correction of the intrinsic and/or extrinsic deformity and relief of foot pain. They are engineered to offer proper biomechanical support to reduce stress on the first metatarsal joint to prevent progression of deformity. As compared to surgery, non-operative treatment (HV orthoses) is less invasive, low in risk and a more conservative option for patients who suffer from HV.

HV orthoses are generally made of rigid, semi-rigid and/or neoprene foams. It is designed to restrict the position of the HV, absorb external forces and reduce deformity by inducing internal corrective forces during natural movement of walking.

**What are the disadvantages and risks of taking part?**

Foot anthropometry, motion and pressure measurements: no risk

HV orthoses: materials and design of the new HV textile orthoses are safe and comfortable. As compared with the orthoses presently being used, the induced corrective forces may probably cause discomfort. However, the new orthotic insoles have been tested in human subjects for short durations during its design and production periods.

**What are the benefits of taking part?**

Upon the completion of assessment, a gift voucher will be given to participant. The potential benefit is to have orthoses with better design, fitting and comfort for patients, and therefore enhance the effectiveness of foot orthotic treatments, thus prevent progressive deformity for HV surgery in which the toe joint is cut and realigned.

**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 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. The Research Ethics Committee and the regulatory authority(ies) will be granted direct access to the subject's study data for data verification. All information collected will be kept confidential.

**What will happen to the results of the research study?**

The results will be published in textiles/design referred journals.

**Who is organizing and funding the research?**

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

**Who has reviewed the study?**

The study has been reviewed and approved by Research Safety Sub-Committee of Human Subjects Ethics Office, 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. YICK Kit-lun at 2766 6551. Thank you very much in helping us to improve the patients' care.

Dr. Kit-lun YICK

Principle Investigator/Chief Supervisor

我們誠意邀請閣下參與一項研究，這項研究由香港理工大學紡織及製衣學系教職員易潔倫博士籌劃。請詳細閱讀以下資料，亦可與親友或醫護人員商量。 若需要更多資料，請向我們提出。

研究主旨

這項研究的目的是使用嶄新方法，用合適的紡織材料為拇外翻患者開發最合適的矯形腳套，以提供適當的矯正力，穿著舒適性和患者滿意度，並可用於各種日常活動。

你是否必定要參加？

這完全由你決定。如果你決定參加，請保留這資料篇，我們會給你們簽署一張同意書。你參與後有權隨時退出而不需要作任何解釋。

決定參加後,你需要做什麼？

參加者年齡需為十八至六十五歲, 鞋尺碼為 35-40 及有拇指外翻問題, 初步診斷由專業義肢及矯形師進行。除了一般的足部健康檢查，記錄參加者的個人資料，

身高體重，我們首先會使用立體素描方法及相片記錄足部狀況，並記錄參加者是否穿著高跟鞋及日常鞋履款式等。根據拇指外翻之診斷方法, 參加者將安排往 X 光造映, 準確量度拇指外翻角度, 此研究將招募三十名 15 至 39 度之參加者。我們會在香港理工大學或香港科學園進行足部立體素描, 量度你足部的尺碼和形狀，分析於不同負重時的足部變化。於使用一般矯形腳套時, 相關的溫濕度, 量度足底的壓力分佈，步姿平衡及腳型等改變。量度時間須約八十至九十分鐘。之後，當新設計的矯形腳套完成後，亦會裝上感應組件，再進行試用，測量步姿平衡等。我們亦會進行問卷調查，了解測試效果及行走時的舒適度。我們無使用任何侵入性測試。

為表謝意,每次完成足部詳細檢查,足底壓力分析後,我們會送上港幣一百元的現金購物券。

測試的「矯形腳套」究竟是怎樣的?

鞋具中加入矯形腳套的目的是改善拇指外翻問題, 預防患者持續變形,減低因痛楚而影響步姿及平衡力，甚至不良於行，其設計必須配合病者的足形，減少拇指外翻角度或與鞋履間之磨擦。矯形腳套較以手術切除變形之指骨安全及低風險。

現時的矯形腳套一般以硬性及半硬物料，或彈性乳膠製成，用以限制外翻拇指的變形位置, 減低行走時鞋履引起的壓迫力。

參與此研究有風險嗎?

量度足形，步姿及足底壓力的感應器材均無危險性。 因此,我們預期這項研究計劃並不會在受試者身上引起任何特別不適。個別受試者或有輕微皮膚敏感或因物料壓力造成足部不適，然而，於矯形腳套的設計及生產過程中，該物料已於人類中使用及研究了一段短時間。故與此研究有關的創傷均沒有任何意外賠償。

參加此研究有什麼實際益處?

為答謝參加者，在每次完成足部復康檢查及相關監測後，參加者可收取現金購物券。我們希望藉此可以發展一對令病人最貼身舒適的矯形腳套, 以改善足底壓力及矯形腳套的效用，並可減低患者痛楚及手術的可能。

參加此項研究，你有什麼補償?

本研究對受試者沒有提供補償安排。如果閣下對這項研究有任何不滿, 你可親身或以書面形式聯絡香港理工大學人事倫理委員會秘書 (地址：香港理工大學人力資源辦公室 M1303 室轉交) 。

我參與這研究資料是否保密?

凡有關閣下的資料均會保密，一切資料的編碼只有研究人員知道。其他的資料一概保密。

我們會怎樣處置研究結果?

我們會把結果發佈在醫學矯形和紡織設計刊物等。

是誰統籌和資助此研究?

是項研究是由香港理工大學紡織及製衣學系統籌，由大學研究基金資助。

誰審核過此研究?

香港理工大學研究委員會研究倫理委員會。

請保存這份資料和同意書作日後參考。如有疑問，請至電 27666551 易潔倫博士查詢。特此再次多謝你的參與，閣下的支持定能對將來改善醫院病人的服務有莫大的幫助。
易潔倫博士 (研究組組長)

## Appendix VI Questionnaire (Immediate Effects of HV Orthoses)

Subject No. Date □
Consent form signed □
Photo taken □

Name 姓名: _____
Height 身高 (mm): _____
Dominant leg 慣用腳: _____ Age 年齡: _____
Weight 體重(kg): _____ Shoe size 鞋碼 (EU): _____
Occupation/ Previous occupation (retirement age) 職業/以往職業(退休年齡):_____

| Name | Description | L | R |
|---|---|---|---|
| Full Leg Length | ASIS marker to medial malleolus, via the knee joint, whilestanding | _____mm | _____mm |
| Knee Width | Medio-lateral width of the knee across the line of the kneeaxis, while standing | _____mm | _____mm |
| Ankle Width | Medio-lateral distance across the malleoli, while standing | _____mm | _____mm |

| Conditions | Footprint | 3D scan | FLIR photo no. | Goniometer |
|---|---|---|---|---|
| Barefoot | | | | |
| Sample A | | | | |
| Sample B | | | | |

Other than hallux valgus, do you have any other foot problems or diseases?

_____

除了拇外翻，可有其他脚部問題或不適? 如有，請詳述

_____

Everyday shoes 日常穿著鞋款 :_____

Do you have the habit of exercising? 您有做運動的習慣嗎？

☐ No 沒有

☐ Exercising regularly, _____ times per week, _____per once, type of exercising: _____

有規律運動，每週運動___次，每次運動_____分鐘 運動類別：_____

☐ Exercising sometimes, how many times per week:__, how long per once:___, type of exercising: _____

偶爾運動，每週運動_____次，每次運動_____分鐘 運動類別：_____

Does hallux valgus affect your daily lives? Please state if it does:_____

_____

拇外翻是否對您的日常活動構成影響？如有，請詳述

_____

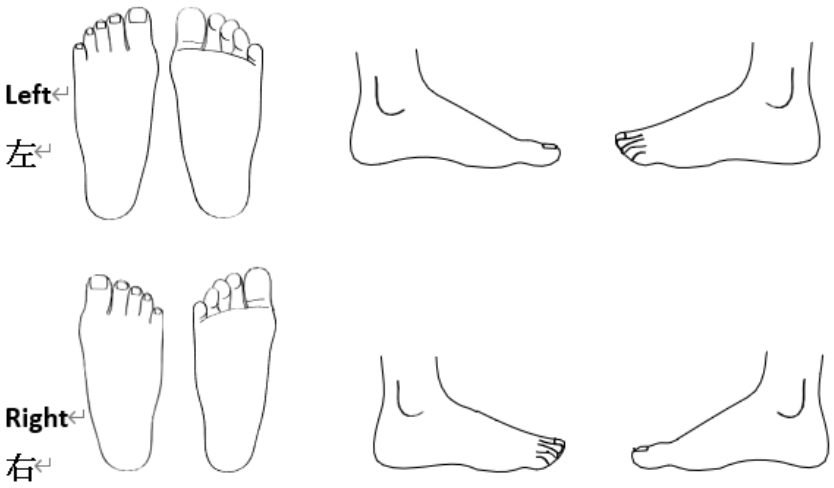
Did you seek for improvements? Please state if you did:_____

您有否尋求改善方法？如有，請詳述_____

**Condition 1: Barefoot**

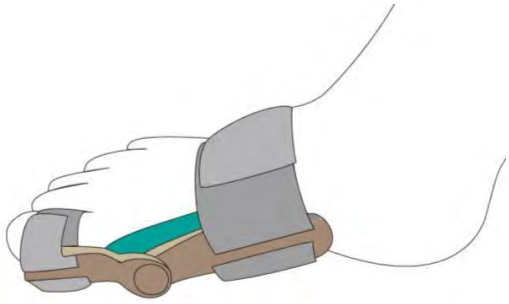
Please circle the area you felt uncomfortable during the experiment.

請圈出您於實驗中感到不適的地方 。

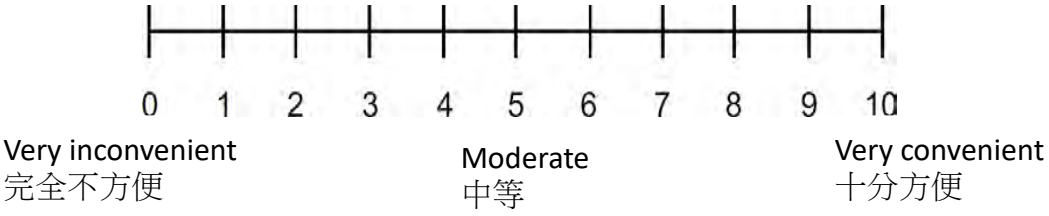


**Condition 2: Sample A**

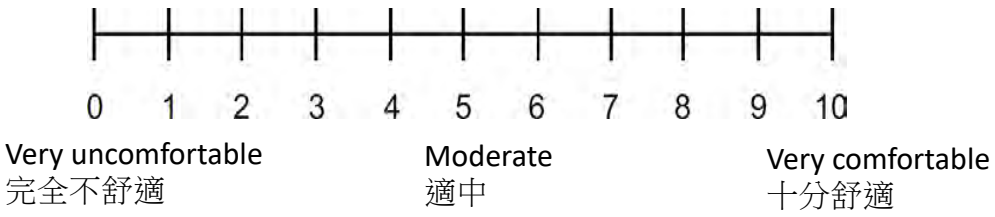
Please rate the following features by 1-10. 請以 1-10 的等級對以下特徵進行評分。



Ease of wear 穿著方便程度

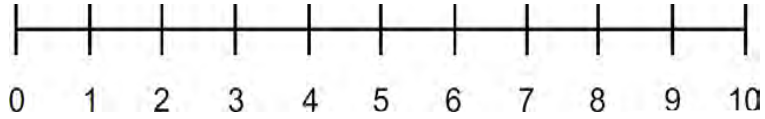



Overall wear comfort 整體設計的舒適度




Overall fit 整體設計的合腳程度

Receptiveness 設計的接受程度

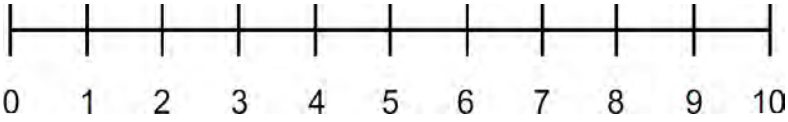



Very unacceptable
完全不能接受

Moderate
中等

Very acceptable
十分可接受

Weight 整體設計的重量

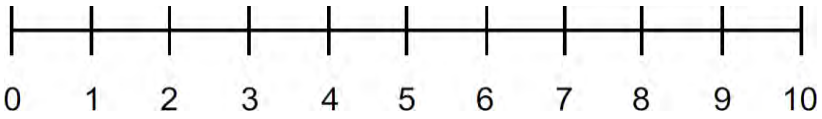



Very heavy
十分重

Moderate
中等

Very light
十分輕

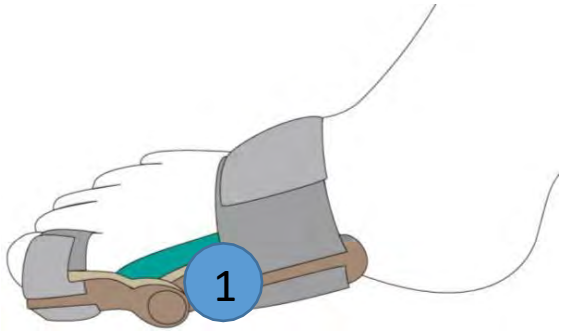
Satisfaction towards appearance 外觀的滿意度



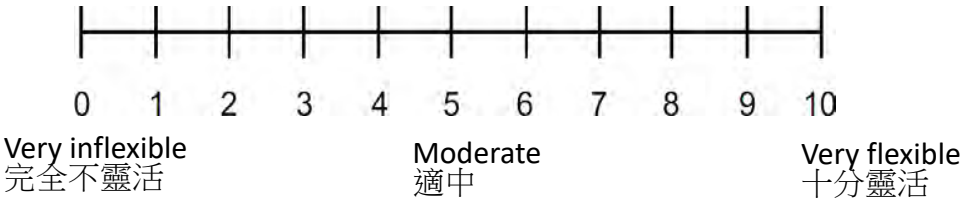

Very dissatisfied
十分不滿意

Moderate
中等

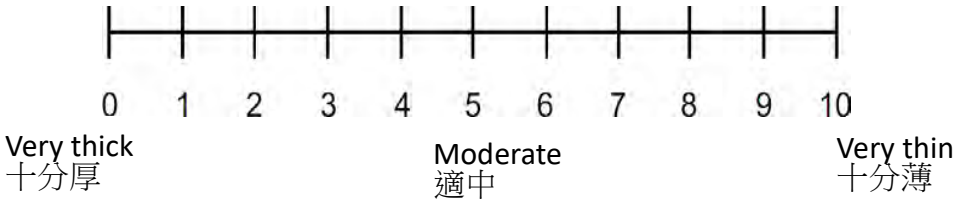
Very satisfied
十分滿意



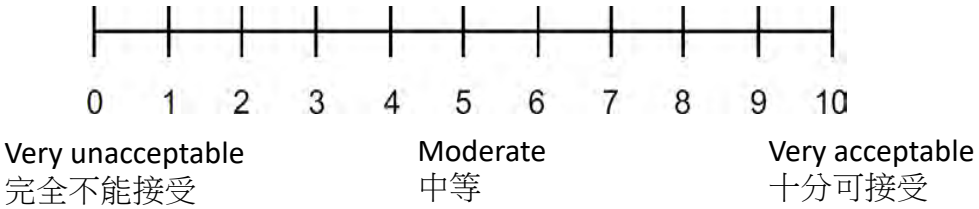

Flexibility 物料的靈活程度




Thickness 物料的厚度




Acceptance of material 物料的接受程度




Comfort 物料的舒適度

0 1 2 3 4 5 6 7 8 9 10

Very uncomfortable
完全不舒適

Moderate
適中

Very comfortable
十分舒適

Permeability 物料的透氣度

0 1 2 3 4 5 6 7 8 9 10

Very impermeable
完全不透氣

Moderate
適中

Very permeable
十分透氣

Thickness 物料的厚度

0 1 2 3 4 5 6 7 8 9 10

Very thick
十分厚

Moderate
適中

Very thin
十分薄

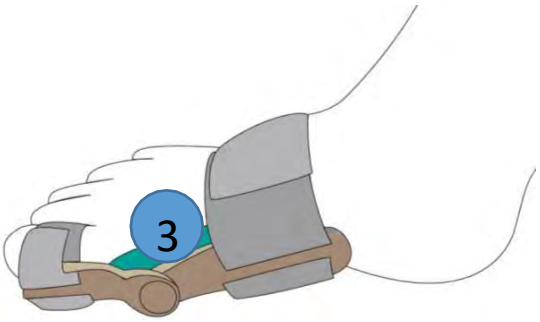
Acceptance of material 物料的接受程度

0 1 2 3 4 5 6 7 8 9 10

Very unacceptable
完全不能接受

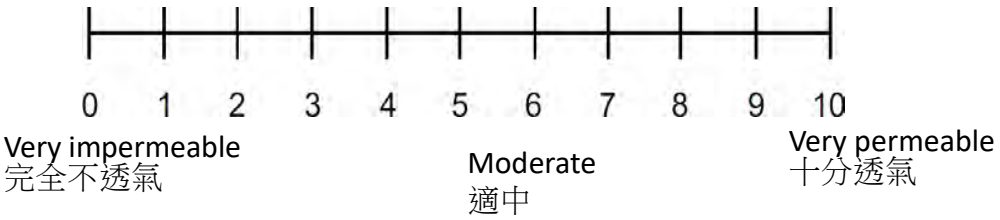
Moderate
中等

Very acceptable
十分可接受

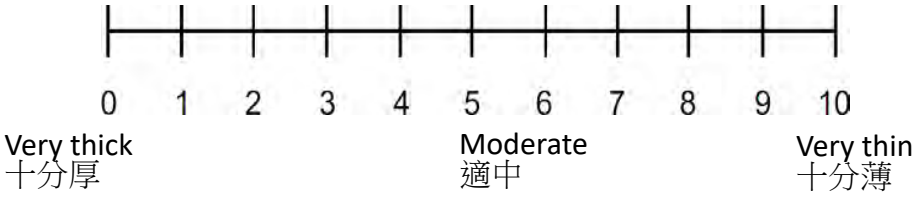



Comfort 物料的舒適度

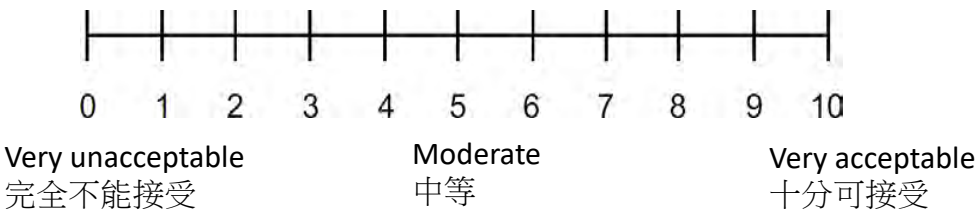

Permeability 物料的透氣度




Thickness 物料的厚度




Acceptance of material 物料的接受程度



Other opinion 其他意見:

---

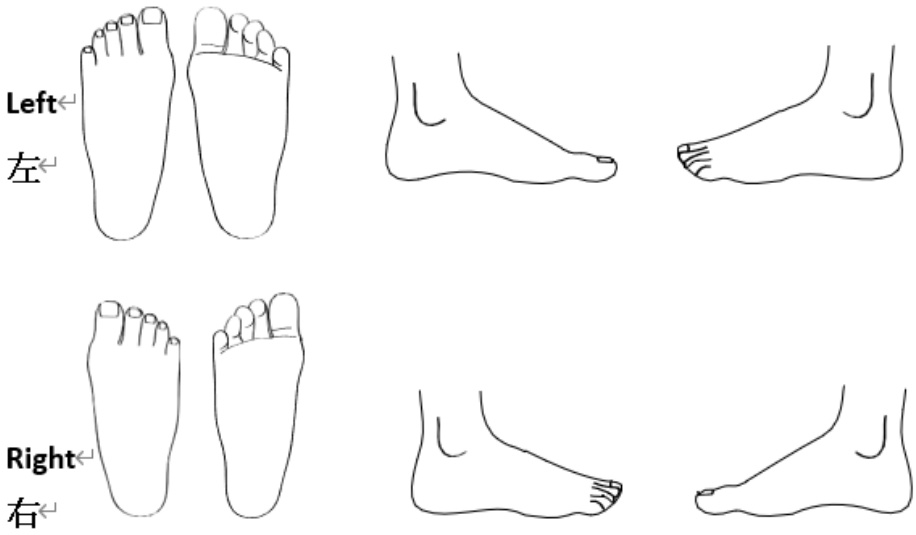
Did your feet feel painful during the experiment? 實驗期間脚部可有感到疼痛？

Yes 是 □

No 否 □

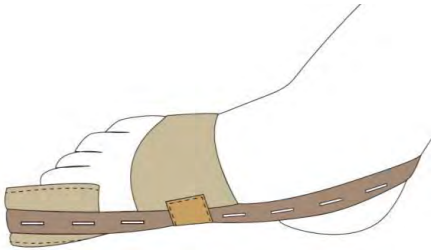
Please circle the area you felt uncomfortable during the experiment.

請圈出您實驗中感到不適的地方 。

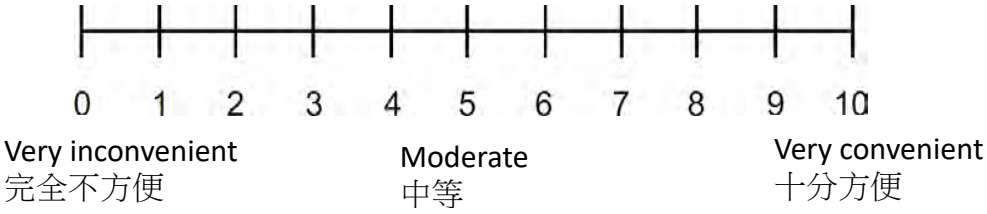


**Condition 3: Sample B**

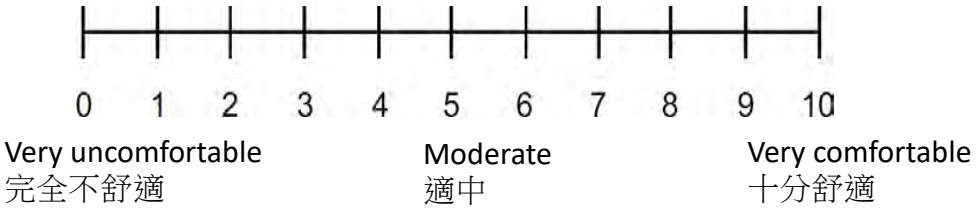
Please rate the following features by 1-10. 請以 1-10 的等級對以下特徵進行評分。



Ease of wear 穿著方便程度

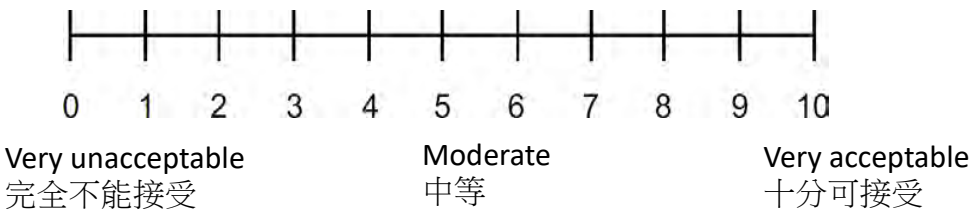



Overall wear comfort 整體設計的舒適度

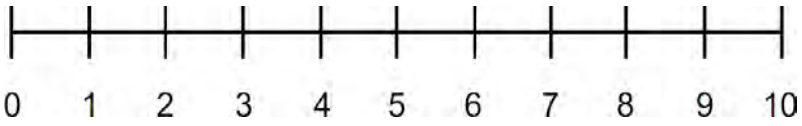



Overall fit 整體設計的合腳程度


Receptiveness 設計的接受程度



Weight 整體設計的重量

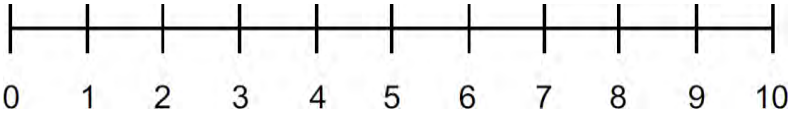



Very heavy
十分重

Moderate
中等

Very light
十分輕

Satisfaction towards appearance 外觀的滿意度

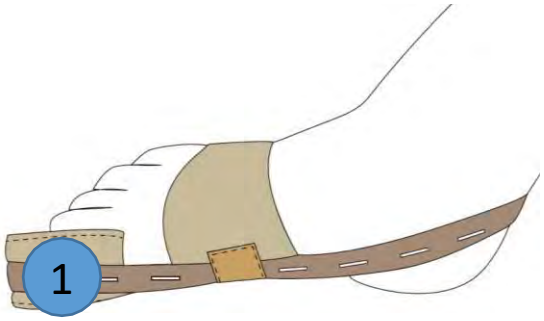



Very dissatisfied

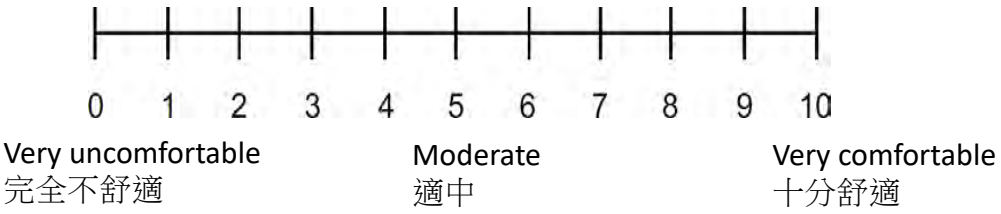
十分不滿意

Moderate
中等

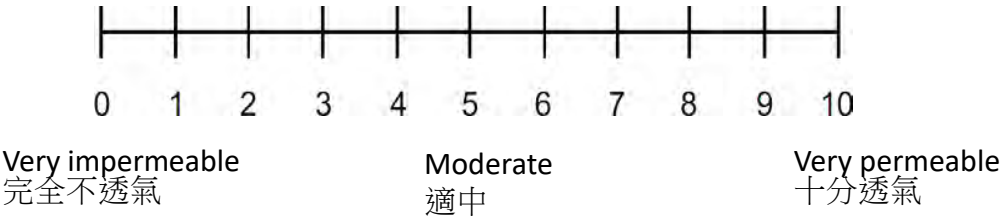
Very satisfied
十分滿意



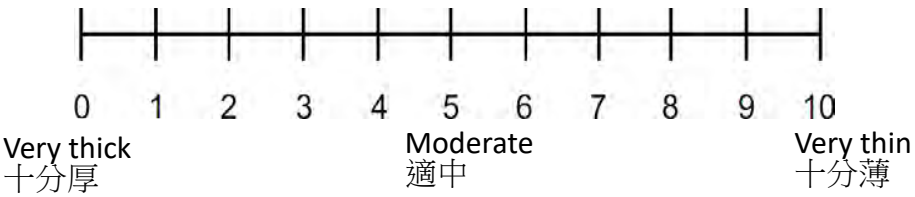

Comfort 物料的舒適度



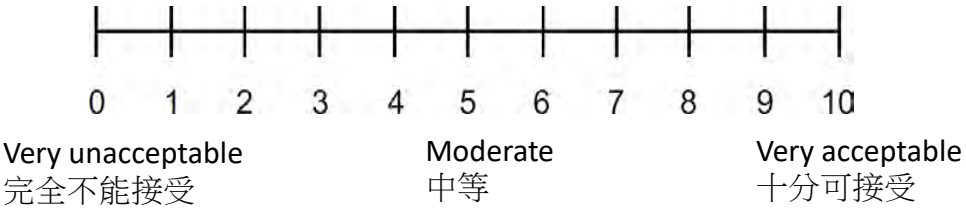

Permeability 物料的透氣度

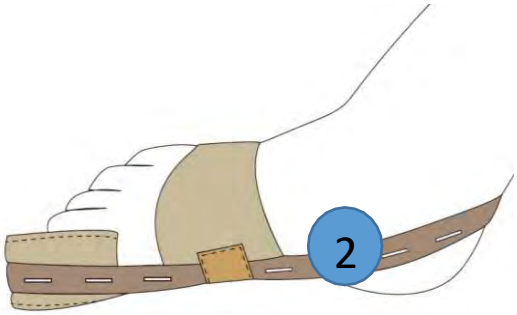



Thickness 物料的厚度

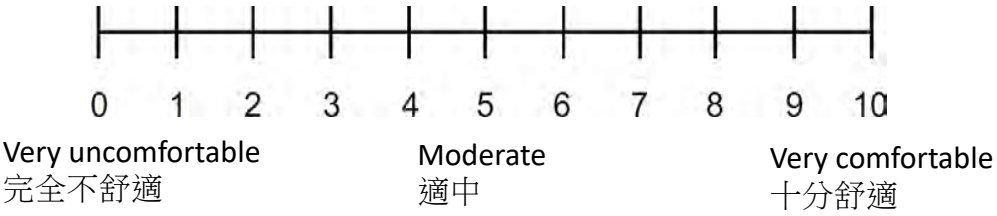



Acceptance of material 物料的接受程度

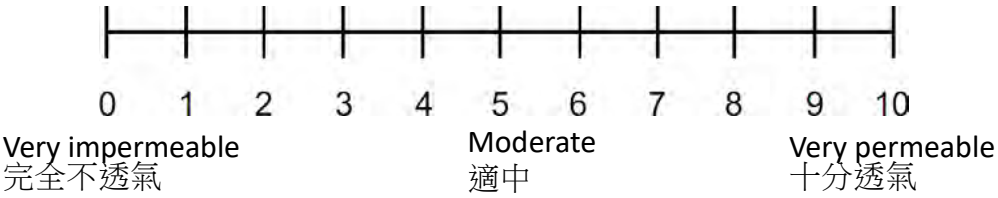




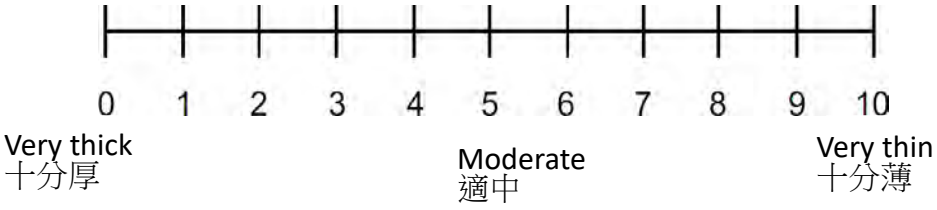

Comfort 物料的舒適度



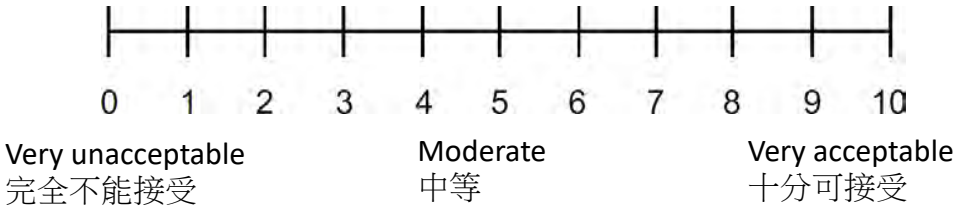

Permeability 物料的透氣度

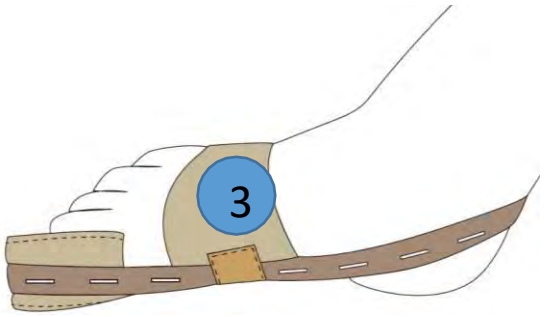



Thickness 物料的厚度



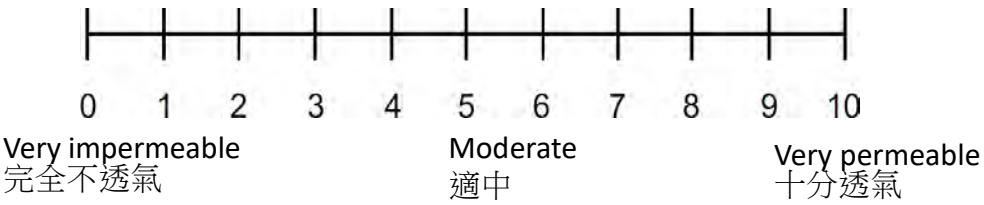

Acceptance of material 物料的接受程度



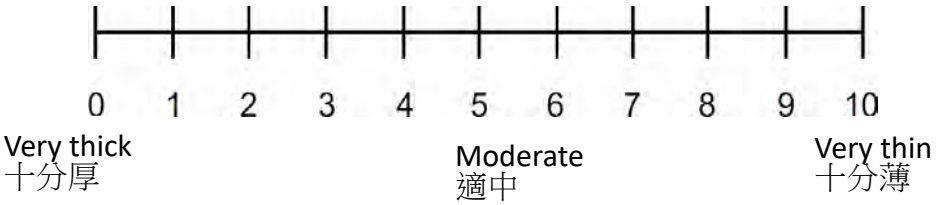



Comfort 物料的舒適度

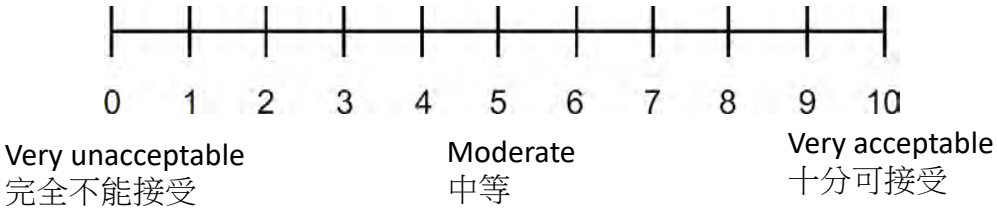

Permeability 物料的透氣度




Thickness 物料的厚度



Acceptance of material 物料的接受程度




Other opinion 其他意見:

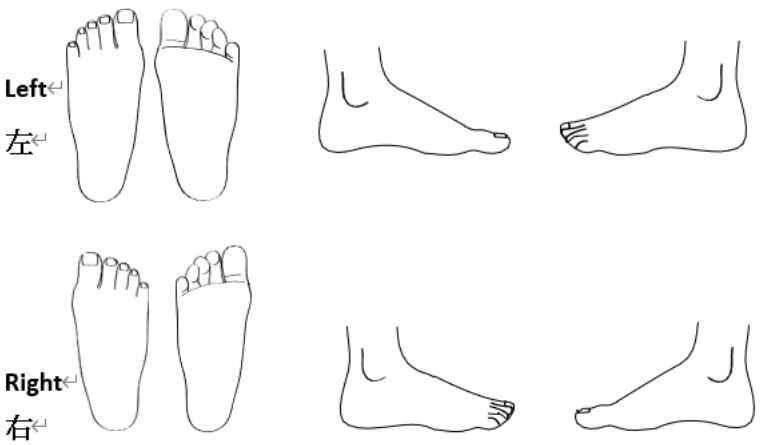
---

Did your feet feel painful or itchy during the experiment? 實驗期間脚部可有感到疼痛或瘙癢？

Yes 是 □

No 否 □

Please circle the area you felt uncomfortable during the experiment. 請圈出您實驗中感到不適的地方 。



Please rank the factors you would consider when purchasing a hallux valgus orthosis (1 is the most important, 5 is the least important; the numbers cannot be repeated). 請把你在選購拇外翻矯形器時會考慮的因素排序 (最重要為 1, 最不重要為 5; 數字不可重複)。

| | |
|---|---|
| Price 價錢 | _____ |
| Style (color, design) 款式(顏色、設計) | _____ |
| Wear comfort (permeability, fit) 舒適度 (透氣、合腳) | _____ |
| Function 功能性 (矯形) | _____ |
| Durability 耐用性 | _____ |

**Appendix VII Subject recruitment questionnaires (Effects of New Orthosis)**

You are invited to participate on a postgraduate research study supervised by Dr. Kit-lun YICK, who is the staff member of the School of Fashion and Textiles, The Hong Kong Polytechnic University. The project aims to propose a scientific approach to develop an optimally fitting in-shoe orthosis for Hallux Valgus (HV) with suitable textile materials that provide appropriate corrective forces, wear comfort, and patient satisfaction, and can be used in all sorts of daily activities.

Participants of this study should be female aged between 18 and 65 and feet size from EU 37 to EU 39. Apart from recording personal information, health conditions of your feet and shoe wearing habit will be logged. Initial screening will be conducted by footprint. Subjects with HV angle ranged between 12° and 40° will be invited to this study. An estimated 30 subjects will be recruited. This wearing trial does not require invasive testing, the experimental procedure, equipment, material and design of the orthosis are safe and risk-free. All information collected will be kept confidential. The results will only be reviewed by the research team to obtain essential information. The results will be published in textiles/design referred journals. The study has been reviewed and approved by Research Safety Sub-Committee of Human Subjects Ethics Office, The Hong Kong Polytechnic University. If you have any query, please contact Dr. Kit-lun YICK at 2766 6551. Thank you very much.

我們誠意邀請閣下參與一項由香港理工大學時裝及紡織學院教職員易潔倫博士指導的研究。這項研究旨在使用嶄新方法，用合適的紡織材料為拇外翻患者開發鞋內矯形器，以提供適當的矯正力、穿著舒適度和患者滿意度，並可用於各種日常活動。

本研究的參與者需為十八至六十五歲, 鞋尺碼為 EU 37-39 的女性。除了記錄個人信息外，您的足部健康狀況和穿鞋習慣將被記錄下來，並將進行初步篩選。此研究將招募三十名拇外翻角度介乎 12 至 40 度的參加者。佩戴試驗無使用任何侵入性測試，實驗程序、器材、矯形器的材料和設計是安全且無危險性的。凡有關閣下的資料均會保密，結果只會由研究人員審查以獲得必要的信息。實驗結果將會發佈在醫學矯形和紡織品設計期刊上。此研究已通過香港理工大學研究倫理委員會審核。如有任何疑問，請致電 2766 6551 與易潔倫博士聯絡。多謝你的參與。

1. What is your name？你的姓名是？
2. What is your phone number? 你的電話號碼是？
3. What is your gender? 你的性別是？
   A. Female 女　　B. Male 男
4. What is your occupation? 你的職業是?
5. How old are you? 你的年齡是？

6. What is your shoe size (EU)? 你的鞋碼是 (歐洲)?

A. < 37
B. 37
C. 37.5
D. 38
E. 38.5
F. 39
G. >39

7. What is your height (cm)? 你的身高是 (厘米)？
8. What is your body weight (kg)? 你的體重是 (公斤)？
9. If you have the habit of exercising, please fill in the name/ type of exercise; if not, please fill in 'nil'. 如你現在或曾經有做運動的習慣，請填寫運動的名稱或種類；如無，請填無。
10. Have you had any of the following problems with your **right foot** in the past six months? 最近半年你的**右腳**有以下問題嗎？

A. Skin diseases 皮膚病
B. Sprain 扭傷
C. Flat foot 偏平足
D. High arch 高足弓
E. Fracture 骨折
F. Nil 無

11. Have you had any of the following problems with your **left foot** in the past six months? 最近半年你的**左腳**有以下問題嗎？

A. Skin diseases 皮膚病
B. Sprain 扭傷
C. Flat foot 偏平足
D. High arch 高足弓
E. Fracture 骨折
F. Nil 無

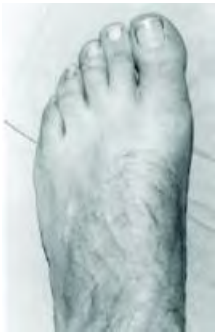
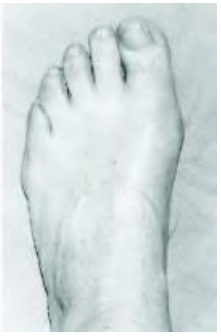
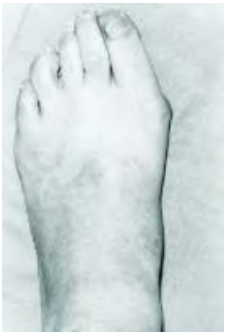
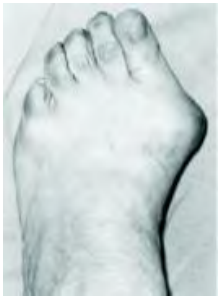
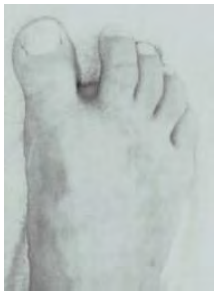
12. Have you had foot surgery? 你是否曾接受足部手術？

C. Yes 是
D. No 否

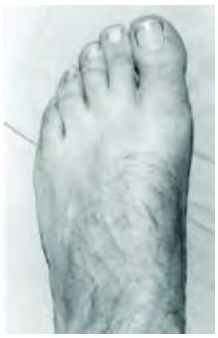
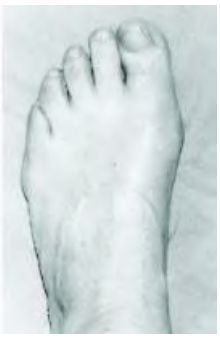
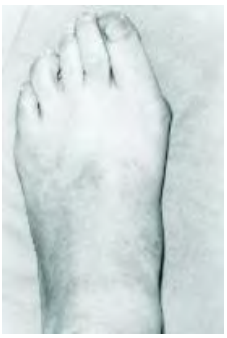
13. Have you had foot pain in the past month? 過去一個月你有腳痛嗎？

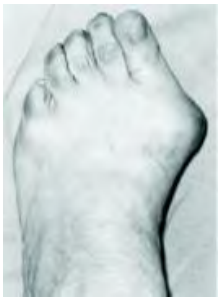
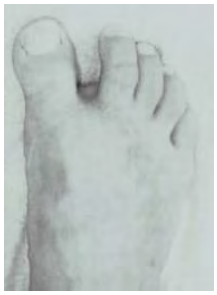
A. Yes 是
B. No 否

14. Which picture below best represents the shape of your **right foot**? 以下那張圖片最能代表您**右腳**的形狀？

A. 
B. 
C. 
D. 
E. 

15. Which picture below best represents the shape of your **left foot**? 以下那張圖片最能代表您左腳的形狀？

A.  B.  C. 

D.  E. 

16. Have you used any of the following products? 你有否使用過以下產品？
    A. Orthosis with arch support 具有足弓支撐的矯形器
    B. Orthosis with toe separator 具有分趾器的矯形器
    C. Semi-rigid hallux valgus orthosis 半剛性拇指外翻矯形器
    D. Soft hallux valgus orthosis 軟性拇指外翻矯形器
    E. Nil 無
17. Which foot do you step with first when you start walking? 當你開始走路時, 你會先邁出哪隻腳？
    A. Left foot 左腳　　B. Right foot 右腳
18. Would you like to participate in the 1-hour foot stress experiment? 你願意參與 1 小時的足部壓力實驗嗎？
    A. Yes 願意　　B. No 不願意
19. Would you like to participate in the 3-month hallux valgus fitting program? 你願意參與爲期 2 星期的拇外翻襪套試穿計劃嗎？
    C. Yes 願意　　D. No 不願意

**Appendix VIII Questionnaire (Effects of New Orthosis: Stage 1)**

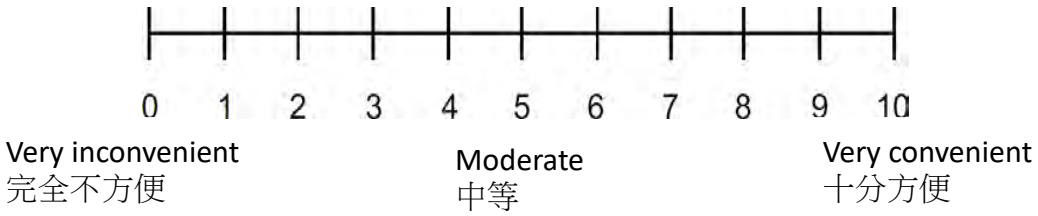
Name 姓名:_____ Dominant leg 慣用腳:_____

| Name 姓名 | Description 説明 | L | R |
|---|---|---|---|
| Full Leg Length | ASIS marker to medial malleolus, via the knee joint, while standing | ___mm | ___mm |
| Knee Width | Medio-lateral width of the knee across the line of the knee axis, while standing | ___mm | ___mm |
| Ankle Width | Medio-lateral distance across the malleoli, while standing | ___mm | ___mm |

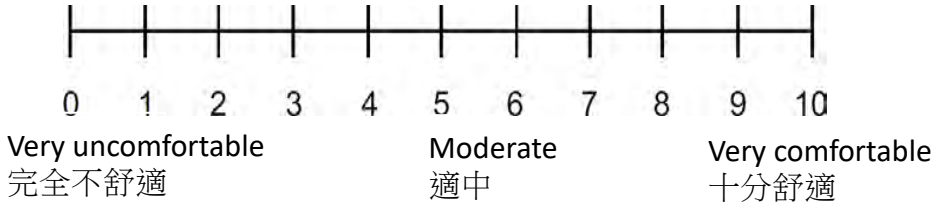
**Orthosis 1**

Please grade the following features by 1-10. 請以 1-10 的等級對以下特徵進行評分。

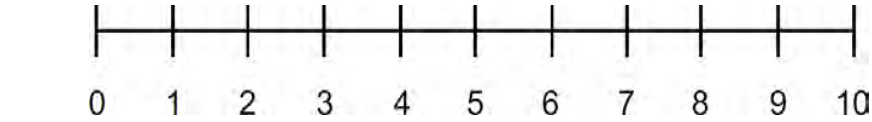
Ease of wear 穿著方便程度




Wear comfort 整體設計的舒適度



Corrective forces 矯形力度

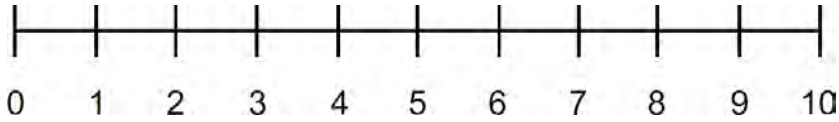



Very insufficient
完全不足

Moderate
中等

Very sufficient
十分足夠

Fit 合腳程度

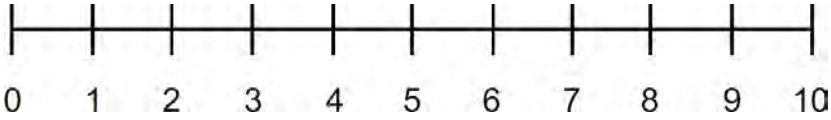



Very tight
十分緊

Very fit
十分合腳

Very loose
十分鬆

Design acceptance 設計的接受程度

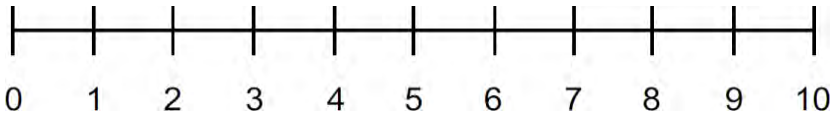



Very unacceptable
完全不能接受

Moderate
中等

Very acceptable
十分可接受

Satisfaction towards appearance 外觀的滿意度



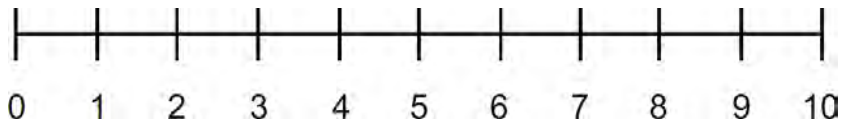

Very dissatisfied

十分不滿意

Moderate
中等

Very satisfied
十分滿意

Permeability of the material 物料的透氣度

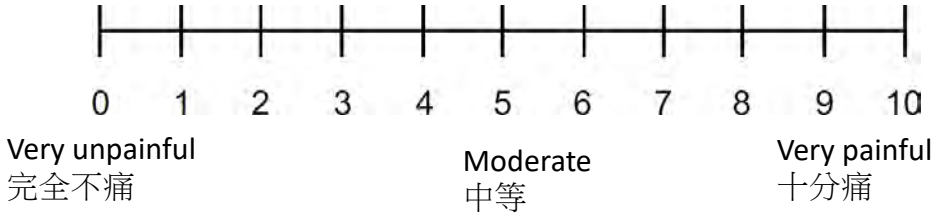



Very impermeable
完全不透氣

Moderate
中等

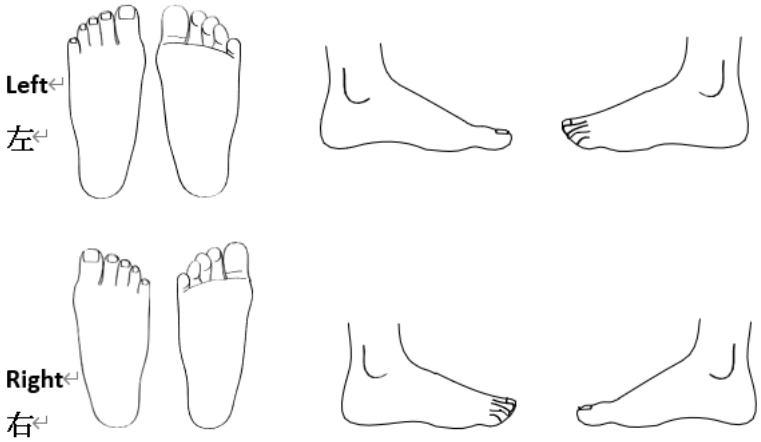
Very permeable
十分透氣

Pain 疼痛程度




Please circle the place you feel painful during the experiment.

請圈出您實驗中感到疼痛的地方 。




Other opinion 其他意見:

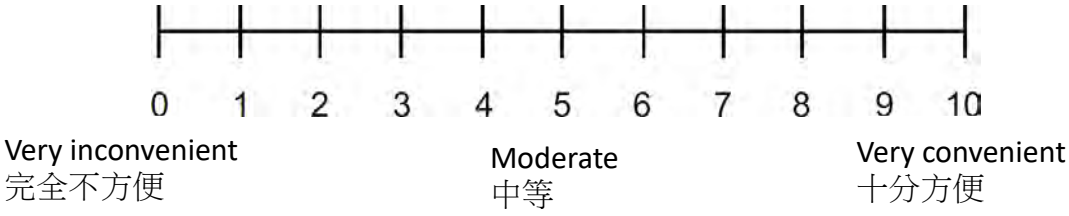
---

**Orthosis 2**

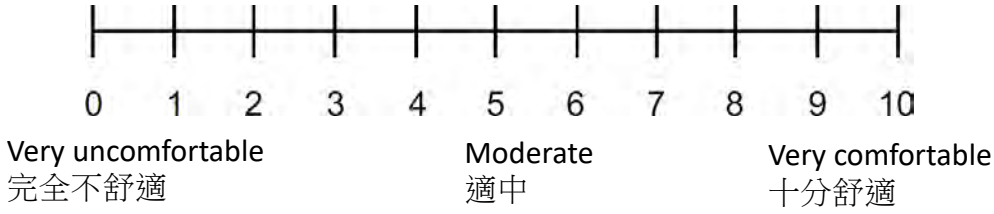
Please grade the following features by 1-10.

請以 1-10 的等級對以下特徵進行評分。

Ease of wear 穿著方便程度

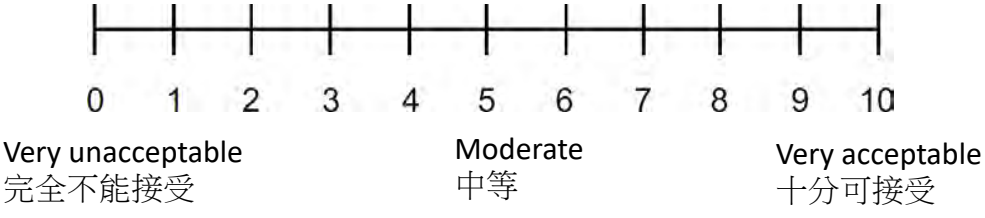



Wear comfort 整體設計的舒適度

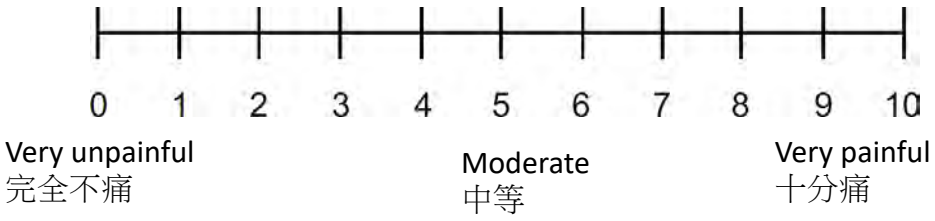



Fit 合腳程度


Design acceptance 設計的接受程度

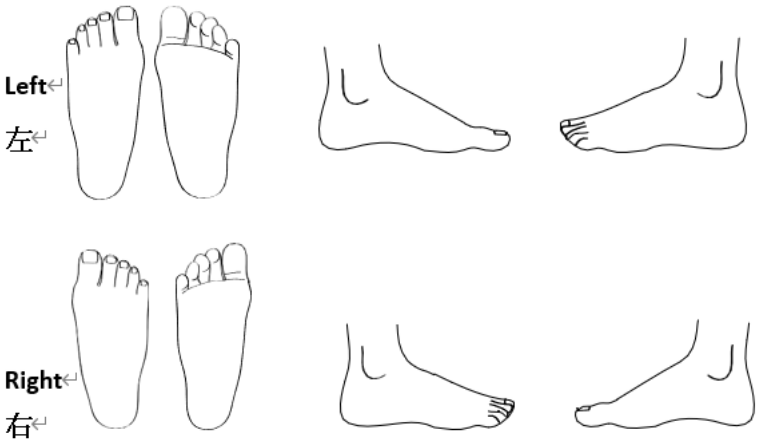


Pain 疼痛程度




Please circle the place you feel painful during the experiment.

請圈出您實驗中感到疼痛的地方 。

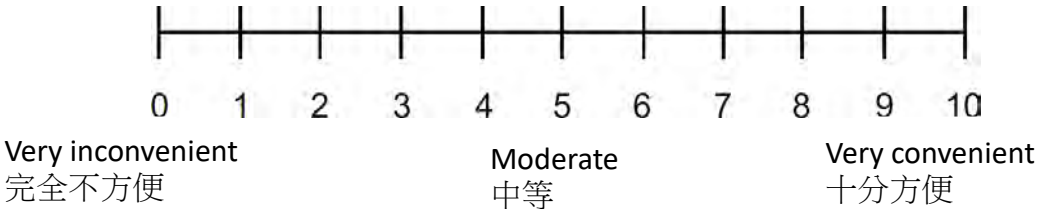



Other opinion 其他意見:

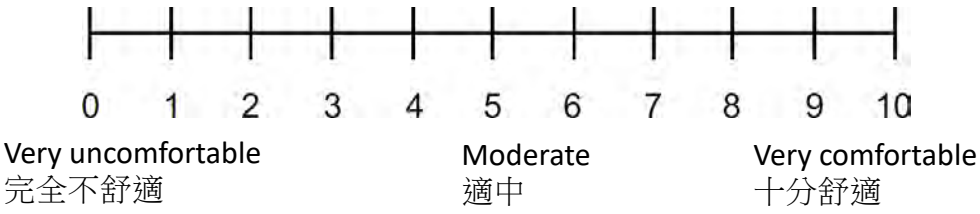
_____

**Orthosis 3**

Ease of wear 穿著方便程度

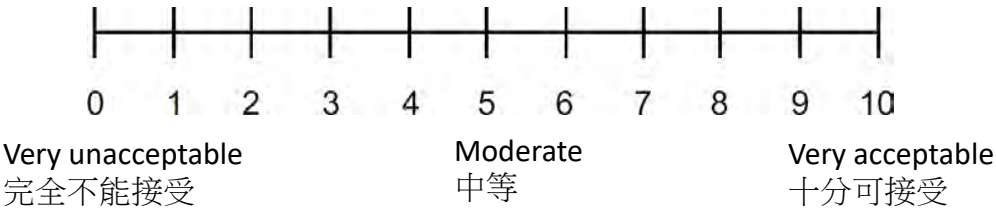



Wear comfort 整體設計的舒適度




Fit 合腳程度

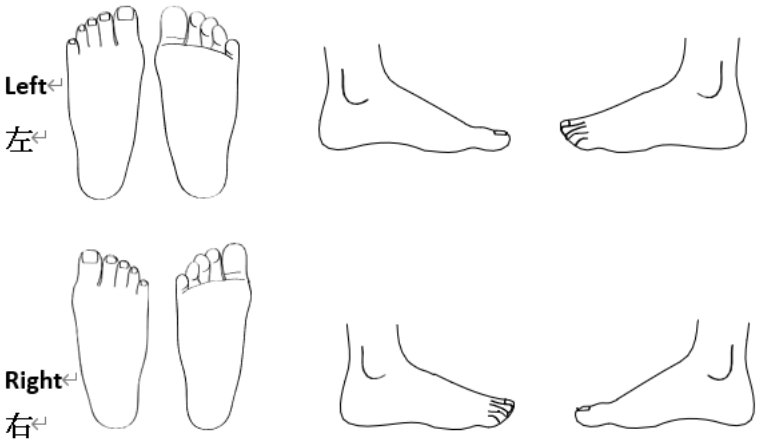

Design acceptance 設計的接受程度




Pain 疼痛程度

Please circle the place you feel painful during the experiment.

請圈出您實驗中感到疼痛的地方 。




Other opinion 其他意見:_____

How often do you experience foot pain? 您多久經歷一次足部疼痛？

None 從不　Every month 每月　Every week 每週　Every day 每天　Always 總是

Did your feel foot pain with the following activities during the past two weeks?

過去兩週您曾否在以下活動經歷足部疼痛？

Walking on flat surfaces 在平面上行走

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

1. Walking up or down stairs 上下樓梯

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

2. Sitting 坐著

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

3. Standing 站立

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

Please indicate how difficult you have been in the past two weeks with the following activities.

請註明您上週在以下活動中遇到的困難程度。

1. Walking on flat surfaces 在平面上行走

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

2. Walking up or down stairs 上下樓梯

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

3. Sitting 坐著

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

4. Standing 站立

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

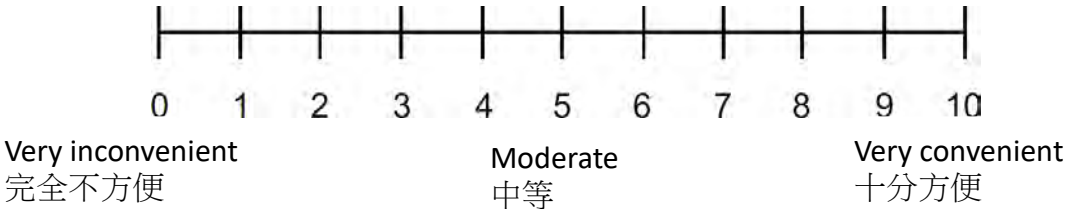
**Appendix IX Questionnaire (Effects of New Orthosis: Stage 2)**

Name 姓名: _____

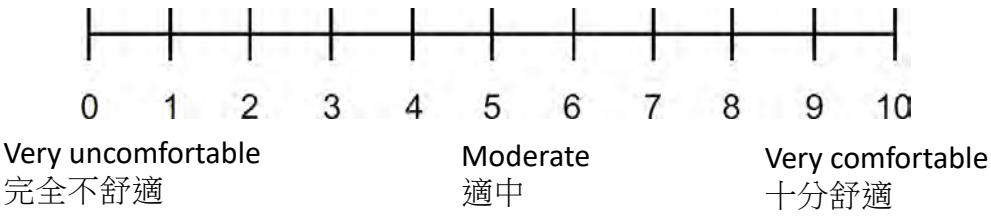
Please grade the following features by 1-10.

請以 1-10 的等級對以下特徵進行評分。

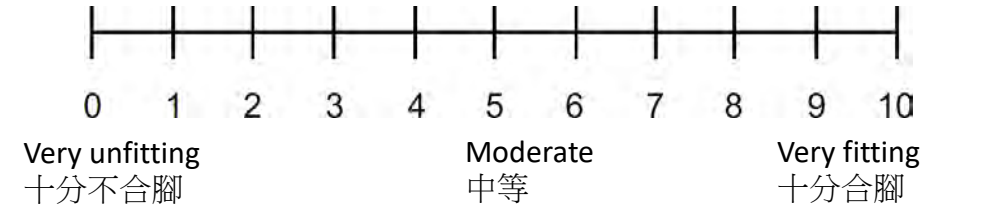
Ease of wear 穿著方便程度




Wear comfort 整體設計的舒適度

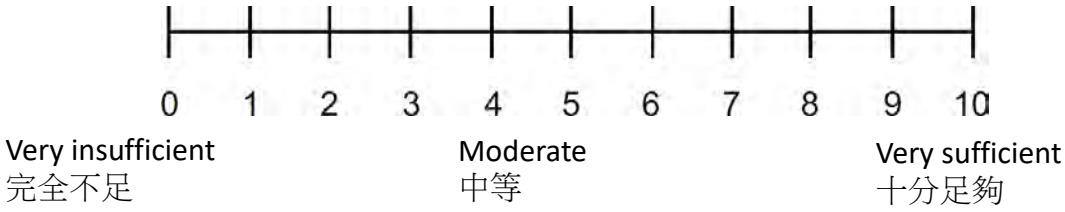



Fit 合腳程度

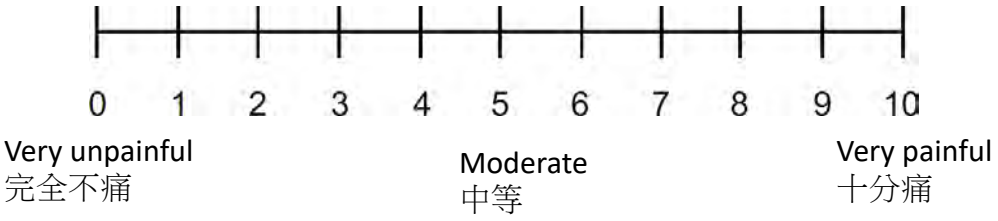



Design acceptance 設計的接受程度

Corrective forces 矯形力

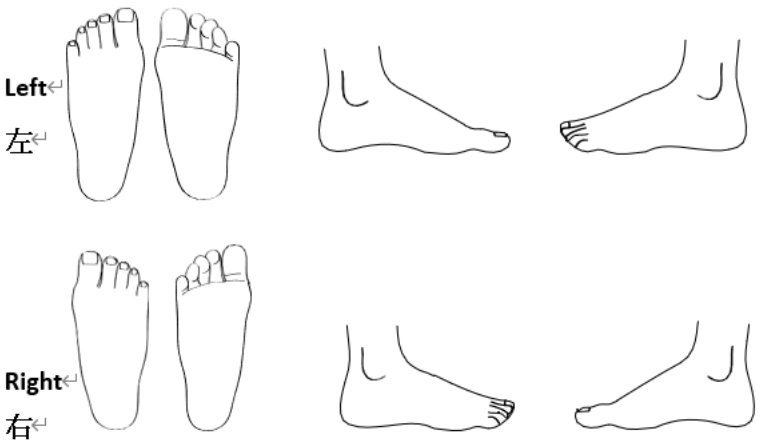



Pain 疼痛程度




Please circle the place you feel painful during the experiment.

請圈出您實驗中感到疼痛的地方 。




Other opinion 其他意見:

---

P1. How often do you experience foot pain? 您多久經歷一次足部疼痛？

None 從不　Every month 每月　Every week 每週　Every day 每天　Always 總是

P1. How often do you experience foot pain? 您多久經歷一次足部疼痛？

None 從不　Every month 每月　Every week 每週　Every day 每天　Always 總是

Did your feel foot pain with the following activities during the past two weeks?
過去兩週您曾否在以下活動經歷足部疼痛？

1. Walking on flat surfaces 在平面上行走

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

2. Walking up or down stairs 上下樓梯

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

3. Sitting 坐著

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

4. Standing 站立

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

Please indicate how difficult you have been in the past two weeks with the following activities.
請註明您過去兩週在以下活動中遇到的困難程度。

1. Walking on flat surfaces 在平面上行走

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

2. Walking up or down stairs 上下樓梯

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

3. Sitting 坐著

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

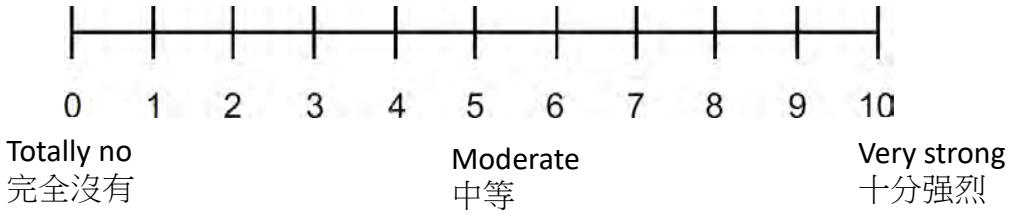
4. Standing 站立

None 無　Very Mild 輕度　Mild 中度　Moderate 嚴重　Severe 極度

Suggestions 建議:_____

_____

Willingness of continue wearing 繼續穿著的意願




Please rank the following features according to the importance (1 is the most important; 8 is the least important). 請以 1-8 的等級對以下元素的重要性進行排序 (1 為最重要; 8 為不重要)。

☐ Ease of wear 穿著的方便程度
☐ Fit 合腳程度
☐ Wear comfort 舒適度
☐ Appearance 外觀
☐ Cost 價錢
☐ Material 物料的選取
☐ Corrective forces 矯形力度
☐ Durability 耐用度

The style of shoes you usually wears 平日穿著的鞋子款式: _____

Are you having other medical treatment? 有否同時接受其他療程?

☐ Yes 有 ☐ No 沒有

## Appendix X Subject usage form (Effects of New Orthosis: Stage 2)

THE HONG KONG POLYTECHNIC UNIVERSITY 香港理工大學

School of Fashion & Textiles 時裝及紡織學院

NOT FOR SALE 非賣品

ERGONOMIC DESIGN OF HALLUX VALGUS TEXTILE ORTHOSES

人體工學設計的拇指外翻矯形套

WASHING INSTRUCTIONS 洗滌說明

METHOD 1 方法一：

Press and wipe with a cloth dampened with alcohol or disinfectant spray 以沾酒精或消毒噴霧的布按壓擦拭

METHOD 1 方法二：

1. Gently hand wash with water or with a mild detergent 用清水或搭配溫和的清潔劑輕柔手洗
2. Wipe with a dry cloth and air dry 用乾布擦拭后自然晾乾

Contains a pair of sock-like orthoses and toe separators 內含矯形襪套及分趾器各一對

Please return it with this form after two weeks 請於兩周后連同此表交還

CONTACT & INQUIRY 聯絡及查詢

LILY +852 6748

DAILY USE RECORD 使用記錄表

Please record the daily usage hours 請記錄每天的使用時數

| DAY | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Product used 使用的產品 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 | Hours 時數 |
| Sock-like orthosis 矯形襪套 | 5 | | | | | | | | | | | | | | | |
| Toe separator 分趾器 | 5 | | | | | | | | | | | | | | | |

Comments 評價:

## Appendix XI Acknowledgement of receipt

This is to acknowledge receipt of _____ cash coupons that worth HK$ _____ as an expression of thanks for participating in the research on "Ergonomic Design of Textile Orthoses for Patients with Hallux Valgus" dated _____.

_____ cash coupons no.: _____

| _____ | _____ | _____ |
|---|---|---|
| Name of participant | Date | Signature |
| _____ | _____ | _____ |
| Name of researcher | Date | Signature |

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