A Prospective Randomized Clinical Trial to Compare the Effectiveness of Pressure Therapy, Silicone Gel Sheeting and the Combined Therapy on Post-Surgical Hypertrophic Scar

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A thesis submitted in partial fulfilment of the requirements for the Degree of Master of Philosophy

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CERTIFICATE OF ORIGINALITY

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it reproduces no material previously published or written nor material which has been accepted for the award of any other degree or diploma, except where due acknowledgement has been made in the text.

_____(Signed)

Lau Chung Man, Joy (Name of student)

DEDICATION

I dedicate this work to my family who encouraged me throughout my study.

OUTPUTS RELATED TO THE STUDY

PUBLISHED JOURNAL ARTICLES

Li-Tsang, C. W. P., Lau, J. C. M., & Liu, S. K. Y. (2003). Validation of an objective scar pigmentation measurement by using a spectrocolorimeter. *Burns, 29*(8), 785-791.

Lau, J. C. M., Li-Tsang, C. W. P., & Zheng, W. P. (2005). Application of tissue ultrasound palpation system (tups) in objective scar evaluation. *Burns, 31*(4), 446-452.

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Sep 2002 "Prevalence of hypertrophic scar formation among the Chinese population" accepted for poster presentation at The 3rd Conference of European Club for Paediatric Burns. Hong Kong, China. Sep 2002. Li-Tsang, C.W.P., Lau, J.C.M., Liu, S.K.Y. & Wu, S.W.C. (2002)

Sep 2002 "Application of TUPS (Tissue ultrasound palpation system) in objective scar evaluation" accepted for the platform presentation at The 3rd conference of European Club for Paediatric Burns. Hong Kong, China., Sep 2002. Lau, J.C.M., Li-Tsang, C.W.P., Zheng, Y.P. & Liu, S.K.Y. (2002).

Abstract of dissertation entitled:
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ABSTRACT

Hypertrophic scar is very common among the Chinese population after surgeries or deep skin injuries such as burns. It causes pain, itchiness, contractures and deformities. Pressure therapy and silicone gel sheeting are often prescribed as conservative intervention for management of scars. This study aimed to compare the effects of these intervention techniques and its combined effect on scar maturation based on objective scar evaluation methods and using a randomized clinical trial.

The prevalence rate of hypertrophic scar formation among Chinese population was high as 74.67% (115 out of 154). 101 subjects agreed to participate in this RCT study. There were 40 males and 61 females with mean age 56.78±20.73. They were then randomly assigned into four groups, namely, the silicone gel group (n=26), the pressure therapy group (n=28), the combined treatment group (n=24) and the control group (n=23). Scar maturation can be measured based on its pigmentation, thickness, vascularity and pliability. An objective scar assessment protocol was developed in this study. The Tissue Ultrasound Palpation System (TUPS) was used to assess the scar thickness. The spectrocolormeter was validated to measure the scar pigmentation and vascularity while the scar pliability based on the Vancouver Scar score (VSS). Pain and itchiness were measured using the VSS score. The TUPS and the spectrocolorimeter were validated prior to their application on the subjects. All subjects were assessed monthly in the initial month, then bi-monthly till the end of the 5th month.

Two-way ANOVA in mixed model was used to analyze the progress of scars among 4 groups. There was a significant difference in scar thickness among 4 groups after the intervention programme, with $F(9,236) = 2.69$, $p = 0.005$. The post-hoc comparison analysis showed that the scar thickness of the pressure therapy group, $F(1,236) = 15.33$, $p < 0.001$, and the silicone gel group, $F(1,236) = 10.44$, $p = 0.001$ were significantly thinner than the control group (Mean=5.10, SD=0.15). The pressure therapy group was found significantly lower than the control group, $F(1,236) = 8.34$, $p = 0.004$, at the three month assessment. However, there was no significant difference in terms of vascularity (redness) and pigmentation (yellowness, lightness) among the four groups of subjects after the intervention. Regarding the scar pliability, the two-way repeated ANOVA in mixed model showed that there is a significant difference among four groups over 5 months with $F(9, 236)=3.48$, $p <0.01$. Silicone gel sheeting group was softer than the control group all along 5-month time. There was no significant difference in terms of pain and itchiness among 4 groups. However, it was also found that the combined intervention group did not show better improvement on scar maturation outcomes when compared to silicone gel or pressure therapy intervention.

In this study, pressure therapy was found to be the most effective in control of scar thickness and it has taken its effect at the three months intervention when compared to the other intervention group. The silicone gel group was also found effective in control of scar thickness and pliability. The combined therapy group did not demonstrate better or similar effect as the pressure therapy or silicone gel sheeting groups. The two interventions might have different effect on scars. The silicone gel sheeting added underneath the garment may reduce the pressure exerted onto the scar, thus reducing its effect to control the vascular blood flow onto the scar, whereas the padding of pressure therapy affected the hydration effect and oxygen permeability of silicone gel sheeting

and lessen the effect on the stratum corneum. Further investigation is warranted to explore their effects on scar.

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CHAPTER ONE

INTRODUCTION

Hypertrophic scars are described as raised, rigid and red skin which brings about pain and itchiness. They were often developed following deep skin injury. According to the report of Hospital Authority, there were around 350,000 surgeries conducted each year, all of which might create wounds on the skin and result in hypertrophic scar formation. Early intervention is necessary to shorten the process of scar maturation. Hypertrophic scars and keloids are the excessive deposition of collagen resulting in exaggerated wound healing response with progressive increase in collagen synthesis after skin injury. They are characterized by their red appearance, increase in thickness, and pliability of the tissues (Beldon, 2000). An exuberant scar that remains in the area after injury often leads to puritis and pain; increased thickness, redness and stiffness (Azad, Geriish, & Dziewulski, 2000). Scar contracture, the collagen synthesis over joints, leads to a reduction in functional performance in daily activities (Giele, Currie, Wood, & Hansen, 1995; Haverstock, 2001; Tejero-Trujeque, 2001). The impact to the physical and psychological functions of patients is great, some have vey low self-esteem, thus affecting their level of independence. .

Surgical excision, radiation and steroid injection are considered as the invasive treatments for hypertrophic scars. Pressure therapy and silicone gel sheeting are the most common conservative and non-invasive interventions in local clinical practice

(Beldon, 1999; Cheng et al., 1999).. A local survey showed that patients who developed hypertrophic scar would likely be referred to the department of occupational therapy for treatment. More than 94.8% patients were given pressure garments and 30.5% were given silicone gel sheeting (Cheng et al., 1999). Early intervention was recommended to shorten the duration of treatment (Deitch, Wheelahan, Rose, Clothier, & Cotter, 1983; Fulton, 1995; Gold, Foster, Adair, Burlison, & Lewis, 2001). From previous studies, both pressure therapy and silicone gel sheeting were reported as effective in management of hypertrophic scar. However, the duration of treatment duration vary from six months to several years in clinical practice. In order to maximize the intervention outcome, a combined intervention may be seen viable. This combined protocol has not been explored in previous studies. Therefore, this study aims to investigate and compare the effects of combined pressure therapy and silicone gel sheeting on control of hypertrophic scar formation. .Their individual effects would also be investigated through a randomized clinical trial. The outcomes of the study may shred light to the clinicians on the management of scar problems based on evidence.

Researchers reported the prevalence of hypertrophic scar in the non-Caucasian population was higher than in the Caucasians. However, most of the studies contain a heterogenous sample of subjects with different scar severity. In our study, we would like to explore the prevalence of scar formation on a homogenous group of Chinese patients

with post-operation surgical scar.

Over the years, there has been a lack of assessments carried out to measure scar maturation. The Vancouver Scar Scale was most commonly used in clinical practice and suggested as a useful guide to observe scar progress in terms of thickness, pliability, pigmentation and vascularity. However, it was considered subjective since it was based on therapists' observation skills. Therfore, in this study, a more objective evaluation protocol should be adopted in order to document the progress of scar conditions. .

Aims of the study

- To validate of an objective assessment protocol on scar conditions
- To study the prevalence of hypertrophic scar formation among the Chinese population
- To study the effect of pressure therapy, silicone gel sheeting and their combined effect on promoting the healing of post-surgical hypertrophic scars.

Objectives of the study

- To validate the spectrocolorimeter for measurement of scar pigmentation.
- To validate the Tissue Ultrasound Palpation System (TUPS) for measurement of scar thickness.
- To study the prevalence of post surgical hypertrophic scar among the Chinese population.
- To study the effect of pressure therapy on post-surgical hypertrophic scar.
- To study the effect of silicone gel sheeting on post-surgical hypertrophic scar.
- To study the combined effect of pressure therapy and silicone gel sheeting on post-surgical hypertrophic scar.

Structure of the human skin

The skin is the largest organ in the human body. It is about two meters square in surface area and less than 2mm thick in most areas over the body (Falkel, 1994; Johnstone, Farley, & Hendry, 2005; Oland, 1991). It is comprised of three different layers: the epidermis, the dermis, and the subcutaneous layers (Figure 2.1). The epidermis serves the function of protection to prevent the microorganism getting inside the body. It is composed of the stratum corneum, the stratum lucidum, the stratum granulosum, the stratum gerninativum and the basement membrane, which form the congested structure of the epidermis. The outer, protective layer, the stratum corneum, is migrated by keratinocyte, and the normal epidermis is in balance between the desquamation of the stratum corneum and the production of keratinocyte (Holbrook, 1991). The dermis is the layer composed of intercellular proteins and a fibroblastic connective tissue with extensibility. The papillary dermis and reticular dermis manifest the function of the dermis. The dermis is full of collagen, produced by fibroblasts, which can be considered as the “mater cell” in the dermis. They produce the reticular collagen, elastic fibers, and the ground substance that comprise the dermis. The dermis is full of nervous innervations and a vascular network of skin (Falkel, 1994).

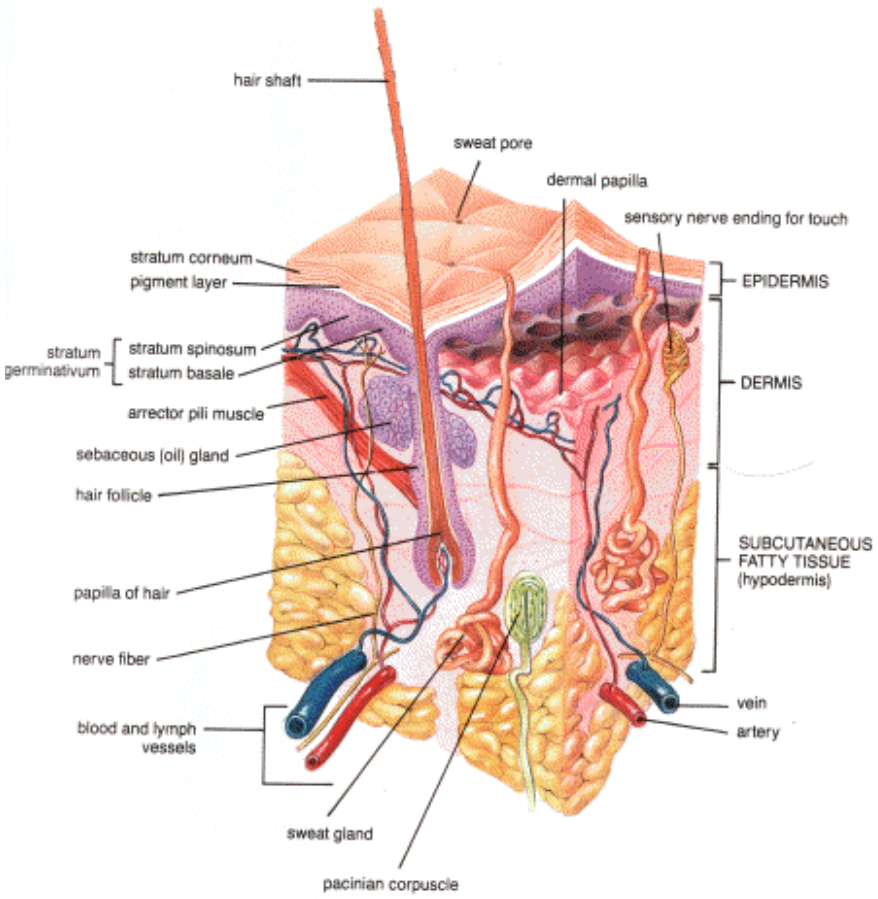


Figure 1.1

The structure of skin from

http://www.bpghs.moe.edu.sg/teacher/QHC/homeos/structure%20of%20skin.htm

Definition of hypertrophic scar

There is no single definition for the term hypertrophic scar. It can be/has been described as excessive collagen tissue growing within the injured skin area. Its physical characteristics include being raised, stiff and red, and it also leads to pain and pruritus (Beldon, 2000). It is caused by prolonged wound healing and leads to the excessive growth of small blood vessels and collagen. Hypertrophic scar that develops over the joints leads to contracture that reduces the range of motion of the joints and thus one's

functional performance (Haverstock, 2001). This skin abnormality is unique to humans, in whom the wound deposits excessive collagen fibers over the area of traumatic or surgical injuries: this is rarely seen in other animal models such as rabbits and pigs (Sullivan, Eaglstein, Davis, & Mertz, 2001). Until now, there was very few studies carried out on hypertrophic scars when compared to other diseases.

Prevalence of hypertrophic scar

Hypertrophic scar is a common consequence of deep skin injury, such as second or third degree burns and scalds (Devlin-Rooney K, 2005). Alhady & Sivnantharajah's study in 1969 showed a relatively higher incidence of hypertrophic scar formation among the Chinese population, and 98 out of 175 patients in a multi-racial population were found to develop keloids. This study only observed the number of cases in a cross-sectional manner. Therefore, the prevalence rate in the Chinese population was not fully investigated.

The prevalence rate of hypertrophic scar in the Caucasian population was reported to be 15% to 38% in past studies (Deitch, Wheelahan, Rose, Clothier, & Cotter, 1983; Elliot, Pearce, & Ree, 1985). However, in a recent study, the prevalence among Caucasians was as high as 67% (Bombaro et al., 2003). Some researchers have commented that non-Caucasians are more prone to develop hypertrophic scars. Other

factors such as race, the location of injured site, and depth of injury were also suggested. Researchers also found that upper back and pre-sternal area are subjected to a higher chance of hypertrophic scar formation after injury (Munro, 1995). The local researchers implemented a genetic study on hypertrophic scars (Lewis & Sun, 1990). Results from their study indicated that the incidence rate was 91.4% among 58 patients with post-deep thermal injuries scars and 44.6% among 83 with surgical scars. Bombaro and his colleagues (2003) found that more than 75% of 25 non-Caucasians developed hypertrophic scar after a burn. It is noted that there was no attempt to validate the severity, size or location of the hypertrophic scar in either study.

Etiology of hypertrophic scar

Although the etiology of the hypertrophic scar is not clearly known, several variables can serve as a guideline to enable clinicians to identify patients at high risk after a deep skin injury. The time taken for wound healing is considered a common guideline for clinicians to predict the hypertrophic scar formation (Deitch et al., 1983). If these stages of wound healing are prolonged, it might lead to the formation of hypertrophic scar (Deitch et al., 1983; Rockwell, Cohen, & Ehrlich, 1989). In general, it takes around 21 days for the collagen density level in a surgical scar to heal up. In some cases, it might take longer, and sometimes up to a year for the scar to fully mature

(Deitch et al., 1983; Doillon, Dunn, Bender, & Silver, 1985; Dollon, Dunn, Bender, & Silver, 1985; Sommerland & Creasey, 1978). Furthermore, scars crossing the Langer lines are more susceptible to becoming hypertrophic, as the tension of the skin is higher and overstretches the scar (Kischer, 1975). Excessive scarring is more obviously found in areas of high skin tension, such as the upper back and the pre-sternal area (Munro, 1995). Other researchers found that people with darker pigmentation whose wounds were located at the buttock region, the dorsal aspect of the foot, the sternum, upper back, and shoulder, showed a greater tendency to develop hypertrophic scars, and that younger patients were more prone to developing them (Alhady & Sivnantharajah, 1969; Atiyeh, Costagliola, & Hayek, 2005; Deitch et al., 1983; Ketchem, Cohens, & Master, 1974). Depth of injury was also suggested to be one of the factors leading to hypertrophic scar formation, as the deeper the wound was, the longer it took to heal (Cohen & McCoy, 1980). It was suspected that there was a lack of micro-vascularity in the hypertrophic scar, and that this led to the overgrowth of blood vessels: Kischer's study found that there was a higher metabolism rate with the occlusion of the endothelial cells (Kischer, Thies, & Chvapil, 1982).

Pathology of hypertrophic scar

According to the tissue healing process, hypertrophic scarring is caused by an interruption in the wound healing process (Beldon, 2000). When the skin is injured, it undertakes a healing process automatically to regenerate new skin. This process is composed of four stages: 1) the vascularity response, 2) the inflammatory response, 3) proliferation and 4) remodeling.

1. Vascular response

This starts immediately following the injury, helping the scar to repair and stopping the hemorrhage. By releasing the mediators to generate the vasoconstriction, it will reduce bleeding and further promotes blood clots after activation by the molecules exposed in the damaged tissue. It brings the wound edges together to avoid infection, and the ends of the blood vessels contract to minimize bleeding.

2. Inflammatory response

The mediator released by the injured local cell tissue, the blood vessel and the serum increases the permeability of the capillary venules to allow the utrophils, monocytes, lymphocytes, and fibroblasts to move into the wound. This action allows the wound/the body to fight against infection and prevent harm from the microorganism.

3. Proliferation stage

This starts once the fibroblasts are settled in the wound. The new collagens are synthesized to build up the new skin tension and support. At the same time, revascularisation (angiogenesis) takes place to regain the new circulation to supply the nutrition and oxygen necessary to allow for the synthesis activity of the fibroblast.

4. Remodeling stage

This is the last stage of wound healing, in which a dynamic balance of collagen synthesis and degradation is developed. The collagenases and enzymes breakdown the proteins of extra-cellular matrix, when the fibroblasts are less active in producing the collagen. In appearance, the scar is plain, pale and soft. However, the time taken to reach this stage can be from weeks to years.

Normally, it takes 14-21 days for this whole process to reach completion. Prolonged wound healing, that is a prolonged inflammatory or proliferation stage, leads to hypertrophic scar formation (Beldon, 2000; Cuzzell, 2002).

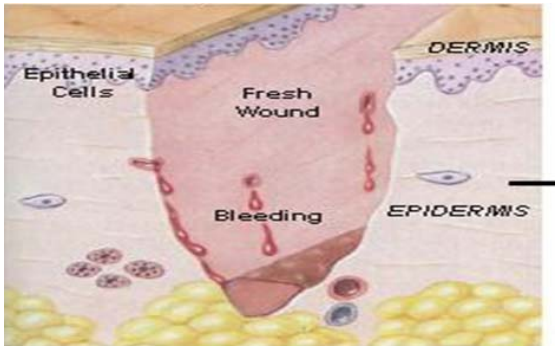


Figure 1.2 Vascular response

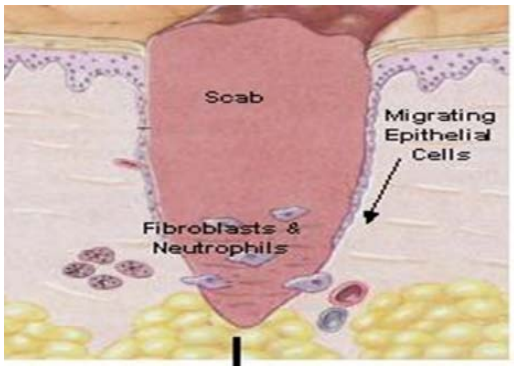


Figure 1.3 Inflammatory response

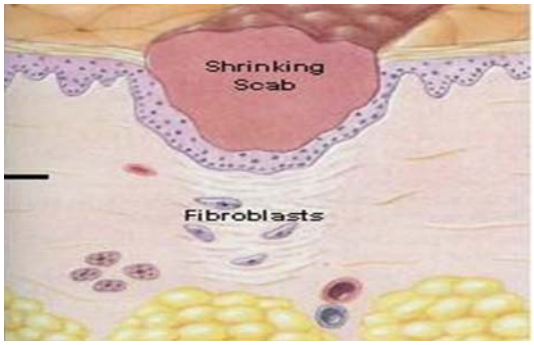


Figure 1.4 Proliferation response

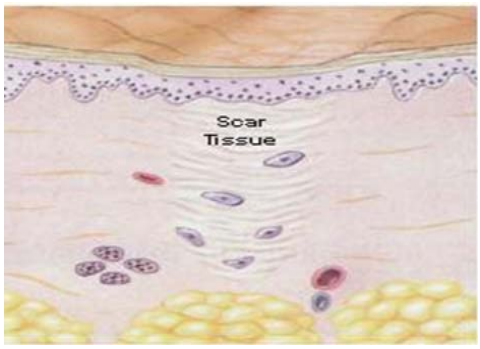


Figure 1.5 Remodeling stage

Figures 1.2-1.5

The wound healing process cited from http://www.topicaid.com/skin.htm

Physical characteristics of hypertrophic scar

The hypertrophic scar is higher in vascularity and with excessive collagen synthesis. The increase in redness on the surface of skin is mainly due to the high amount of blood flow and the increased microvascularity in scar tissue. Past studies have explored the physiological changes of the hypertrophic scar. The pliability of hypertrophic scar was found to be about eight times higher than that of normal skin (Clark, Cheng, & Leung, 1996). The hypertrophic scar is very different from normal skin in terms of its collagen content, structure and vascularity. The structure of the scar tissue as shown by electron microscope remains unclear between the dermis and epidermis. The collagen and numerous vessels are in nodule-like structures, and thicker fibers are developed (Baur, et.a., 1976). A higher amount of collagen and blood vessels, and a more complex collagen structure were found. In previous investigations at the cellular level, the hypertrophic scar was found to contain higher numbers of massive occluded microvessels which were not connected (Kischer, Thies, & Chvapil, 1982). The amount of vascularity reflected by the Laser Doppler Flowmetry was twice as great as that of normal skin (Leung, Sher, Clark, Cheng, & Leung, 1989).

Throughout the course of its maturation, the microcirculation decreases, and the color is changed from pink to red then purple (Leung et al., 1989). Its stiffness and thickness are gradually decreased and the structure of the scar tissue become more like

that of normal skin when it becomes mature (Baur et al., 1976; Clark, Leung, Cheng, & Leung, 1996). However, the time taken for the scar to become mature would vary from six months to several years.

Differences between keloids and hypertrophic scars

Abnormal scars were shown by their increase in redness, raised and rigid due to the increased number of small blood vessels, fibroblasts and abundant ground substances (Young, 1999). It showed that the collagen synthesis was faster than the collagen degradation, which probably led to the keloid or hypertrophic scar formation. They both presented with increased thickness, elevation and color of skin. However, the physical properties were different between the hypertrophic scar and the keloid.

The hypertrophic scar is an overgrowth of dermal constituent that remains within the boundaries of the original wound, whereas a keloid is a scar that extends beyond the boundaries of the original wound and is less responsive to treatment (Limpens & Cormane, 1982). A keloid is more rigid and it is less likely than the hypertrophic scar to become flattened with time. The biological structures of the hypertrophic scar and keloid have been investigated: the collagen fibers in the hypertrophic scars were oriented randomly in a nodular or whorl-like pattern, and those in the keloid ones were even less organized (Costa et al., 1999). In a cellular level investigation, there was

different presentation between the two abnormal scars. The fibroblasts of keloids produce more collagen than those of hypertrophic scars (Cohen, Diegelmann, & L.Johnson, 1977; Cohen, Keiser, & Sjoerdsma, 1971; Craig, Schofield, & Jackson, 1975), and at a higher rate (Diegelmann, Cohen, & Mccoy, 1979). The rate of degradation of keloids was found to be abnormal in that its action was inhibited, though more collagenase was indicated (Atiyeh, Costagliola, & Hayek, 2005; Cohen et al., 1977).

The prevalence of keloid formation is different among different populations. It has been shown that there is a higher incidence among people with darker pigmentation (Murray, 1993). Keloids occur more commonly over the ears, face and chest (Alhady & Sivnantharajah, 1969), and can occur all over the body (Oluwasanmi, 1974). The occurrence of keloids is due to its localized immune response: patients with keloids were found to have antinuclear antibodies, however no similar result was detectable in patients with hypertrophic and normal scars (Limpens & Cormane, 1982).

Impact of hypertrophic scar

Functionally, our skin serves as a protection from the environment; it also provides information regarding sensation and regulates the body temperature and metabolism (Holbrook, 1991; Oland, 1991). The sensory aspect gives us the information necessary

for communication in social context and to maintain bodily function (Hurren, 1995). However, the formation of hypertrophic scars destroys its function, thus resulting in distress because of its poor appearance and inability to provide sensory information.

Hypertrophic scarring developed after an injury involve the dermis layer (Beldon, 2000; Deitch, Wheelahan, Rose, Clothier, & Cotter, 1983). It is raised, stiff and red in appearance, and also leads to pain and pruritus over the scarred area. Severe hypertrophic scars may lead to sleep disturbance, anxiety, depression and disruption of activities (Bell et al., 1988; Sheffield et al., 1988).

Contracture is a common dysfunction resulted from hypertrophic scar. This is common among patients with severe burns over a large area involving the joint surface. Due to scar contracture and prolonged immobilization along the wound healing process, deformities and join stiffness will occur (Sheffield et al., 1988; Tejero-Trujeque, 2001). In the very early stages of wound healing, to avoid inducing pain, it is preferable for the patient to remain in a comfortable position. However, this position often encourage the new fibers to fuse together in a shortened length (Hurren, 1995; Tejero-Trujeque, 2001). The combination of immobilization and fusion of collagen fibres across joint creases may limit the range of motion, thus leading to contracture formation. In turn, it further reduces range of motion, resulting in a reduction of functional performance.

Treatment for hypertrophic scars

Hypertrophic scars cause cosmetic and psychological problems. They take six months to several years to become mature. There are different medical management for hypertrophic scars. Surgical excision, corticosteroid injection, cryosurgery, laser, and radiation are implemented to control abnormal scarring. However these procedures may result in considerable side effects, such as high recurrence rate, hyper- or hypro-pigmentation and extreme pain; in addition, laser treatment has been found to have low efficacy (Beldon, 2000). When hypertrophic scars are treated by pressure therapy or silicone products, fewer complications such as pain and hypo-pigmentation are seen than when using the medical treatment approaches listed above (Kahn, Cohen, & Kaplan, 1991; Rockwell et al., 1989).

Pressure therapy

History of pressure therapy

Pressure therapy has been reported as a non-invasive treatment of hypertrophic scars. Initially it was used for the reduction of edema on wound healing and for the prevention of hypertrophic scar formation. It was used to treat developed hypertrophic scars.

Pressure therapy was not designed for scar treatment in the very initial stages. Blair

found that it provided a positive reinforcement for wound healing in 1924, and Cronin found that neck contracture was prevented by the use of a conforming neck splint in the 1960s (Hurren, 1995). It was suggested that scar prevention was related to pressure exerted on wounds. Later, one of the researchers observed that wounds dressed in elastic bandages did not develop hypertrophic scars. At the same time, Larson and his colleagues showed similar findings on wounds (Hurren, 1995). Larson found further effective evidence on pressure therapy and reinforced the development of pressure garments at the Jobst Institute, Inc., Toledo, Ohio. Jobst is now a famous brand in the commercial production of pressure garments in the U.S. (Ward, 1991). At present, patients with hypertrophic scars can purchase the garments through the internet and hospitals. The garments in standard sizes are prescribed by the Jobst Institute without fitting, and are followed up by occupational therapists. Reviewing past studies, there was a unique method of pressure therapy delivery in local practice. Therapist would not only fabricate the pressure garment for patients, but also add an extra padding underneath garment to generate a higher and localized pressure on hypertrophic scar. Pressure therapy fabricated in Hong Kong was reported to be effective on scar maturation (Cheng et al., 1983; Cheng, Leung, & Leung, 1987; Cheng et al., 1999; Ng & Yu, 1985).

The therapeutic effect of pressure therapy

Pressure therapy has been reported to be a reliable and non-invasive treatment of hypertrophic scar only in a retrospective manner (Chang et al., 1995; Giele et al., 1995; Ng & Yu, 1985; Rose & Deitch, 1983). It is recommended as a standardized treatment for patients who might develop hypertrophic scar. Both western and local studies have found that pressure therapy is a non-invasive and effective treatment for management of scar problems. It has been found to be a reliable and effective modality to manage and prevent scarring (Beldon, 1999; Cheng et al., 1983; Leung, Cheng, Ma, Clark, & Leung, 1984; Rose & Deitch, 1983). In 1983, Dietch and his colleagues reported a success rate of 85% with no evidence of recurrence in patients who had good compliance with pressure therapy. Patients whose wounds took 14-21 days or more than 21 days to become mature were recommended to receive pressure therapy to prevent abnormal scarring (Deitch et al., 1983). A case report illustrated the effectiveness of pressure therapy by showing that using a facial mask could minimize wound contraction before the surgery was performed (Giele et al., 1995). Recently, a study by Cheng proved the efficacy of applying the pressure garment in children's burn scar treatment by the use of ultrasound scanning with a follow-up study design (Cheng et al., 2001). A study conducted by Kerckhove et al (2005) found that 72 scars had shown improvements in redness and thickness after 3-month time of relative higher compression. Though the

above studies described the effectiveness of pressure therapy, there has been no study showing the effectiveness of pressure therapy in a randomized clinical trial or with a control group.

Its effectiveness was questioned by some researchers. A prospective, randomized study conducted by Chang & Kealey in 1995 showed that there was no significant improvement of scar progress and length of hospital stay between patients with and without pressure therapy (Chang & Kealey, 1995). However, in their study, the assessment was too subjective and the length of hospital stay was not a common variable to study the effect of pressure therapy. There were complications suggested by the previous studies leading to the poor compliance and effect on hypertrophic scar. Blistering, abrasions and ulceration of scar tissue were common over the scar area because of the shearing force and poor hygiene (Carr-Collins, 1992). The case study by Leung showed that the growth of children who were treated with pressure therapy was retarded (Leung et al., 1984). Moreover, frequent revision was necessary to maintain the required pressure. As Cheng's study showed that 50% of pressure was lost after a month of application (Cheng et al., 1983). The tailor-made pressure garment was also found to be a labor-intensive treatment which demands both OTs and technical sewing experts in the production of garment. Thus the cost of production of pressure garment remained high (Giele et al., 1995).

Mechanisms of pressure therapy

The application of pressure appears to suppress the hypertrophic scar development and accelerate its degradation, thereby encouraging the natural remodeling process in the maturation stage of wound healing. Hypoxia and an altered activity level of collagen synthesis and degradation were postulated as the mechanism of pressure therapy (Kischer et al., 1982). The application of pressure therapy has been common in the past 40 years; however, its mechanism is still not fully understood. There are two mechanisms suggested for explaining the effect of pressure therapy on hypertrophic scars: it is thought to accelerate the scar remodeling or produce a hypoxia environment of scar tissue.

The occlusion of vascularity was the first suggestion as a mechanism of pressure therapy. In 1975, Kischer et al. indicated that there was a reduction of inter-collagen fibers and an increase of vesicular fibroblasts in a pressure-treated burn hypertrophic scar (Kischer, 1975; Kischer, Shetlar, & Shetlar, 1975). The authors proposed that pressure might produce hypoxia, leading to fibroblast degeneration and altering the ratio of collagen metabolism. In 1982, Kischer and his colleagues further conducted a subsequent study to examine the microvascularity of hypertrophic scar following pressure therapy. They found that there was a degeneration of the perivascular endothelial satellite cells, stating that the selective cell degeneration was perhaps caused

by the hypoxia environment (Kischer et al., 1982).

In the following years, Baur et al. (1976) postulated a possible metabolism explanation for the effect of pressure without any cell necrosis (Baur et al., 1976). They suggested that pressure decreases blood flow to the scar, resulting in a decreasing delivery of serum, especially lower α-globulins, which suppress the collagenases. The sufficient collagenases mediated the remodeling process of the scar tissue, and no dead cells were found in the biopsy in a short period of time. This disagreed with the postulations of Kischer in 1975. It was suggested that there was a relationship between activity microvascularity and pressure during the treatment of hypertrophic scars. Studies were done to investigate whether an activity level of collagen degradation would be affected by mechanical compression, resulting in a change in the structure of a hypertrophic scar. Studies (Reno et al., 2002; Reno, Grazianetti, & Cannas, 2001) have indicated that hypertrophic scars treated under 10mmHg to 35mmHg of mechanical compression would result in a positive effect. There are more enzymes of collagenase induction to inhibit the collagen synthesis and accelerate the collagen degradation. Yet the hypertrophic scar in these studies was treated for a short duration of compression, and the long-term effect has not been investigated. Costa and his colleagues tried to compare the non-pressure treated and pressure-treated post-burn hypertrophic scars, and the pressure-treated scar was found to have the following characteristics(Costa et al.,

1999):

1) the numbers of vessels was reduced and they were localized in the dermis;
2) the reticular collagen in the dermis was thinner, in an arrangement rather parallel to the skin surface; and
3) apoptosis in the fibroblast cells and collagen degradation were observed in the pressure-treated scar.

At present, there is still no clear theoretical explanation for the mechanism of pressure therapy, but it is believed that its effectiveness is due to the reduction of blood flow on the scar tissues. However, the actions at the cellular level have not been fully understood.

Optimal pressure of pressure therapy

In the past, different techniques have been used in an attempt to measure the range of therapeutic pressure, but it was too low and contradictory results were shown by various studies.

The earlier techniques using electropneumatic pressure transducers and electronic monitors were developed to measure the pressure between the garment and the scar (Cheng et al., 1983; Mann, Yeong, Moore, & Engrav, 1997), however the range of pressure was varied. The therapeutic pressure was reported as being from 5mmHg to

55mmHg in various studies (Cheng et al., 1983; Ferguson-Pell, Hagisawa, & Bain, 2000; Giele, Liddiard, & Wood, 1998; Giele, Liddiard, Currie, & Wood, 1997; Mann et al., 1997; Mann, Yeoung, Moore, Colescott, & Engrav, 1997). The capillary blood pressure was from 24 to 25mmHg and this range was suggested as being the most efficient pressure that was sufficient to bring vessel occlusion; however, this value has not been proven yet (Staley & Richard, 1997). In other studies, the most optimal therapeutic range was from 5 to 15mmHg (Cheng et al., 1983; Reid, Evans, Naismith, Tully, & Sherwin, 1987; Wu, Nelson, Reid, Ruckley, & Gaylor, 1996). Giele and his colleagues reported in a recent study that 15mmHg produced a positive scar response (Giele et al., 1998). Local researchers reported that the optimal pressure was from 10 to 35mmHg (Cheng et al., 1983). In 2005, the School of Textile and Design of Heriot-Watt University showed a wide range of pressure among fabrics, and produced a wide range of pressure from 10mmHg and 55mmHg (Macintyre & Baird, 2005).The authors stated that the technique of pressure measurement is still immature in clinical practice, lack of information of fabrics, therefore the range of optimal pressure has not been explored yet. It was found that different anatomical zones produce different ranges of pressure. For example, greater pressure results in regions with bony prominence than in those with soft tissue underneath (Giele et al., 1998). Furthermore, Ng suggested that the designs of edges would bring various pressure, so that a turned-up edge would result in a similar

pressure to the area beyond 5cm from the edges (Ng et al., 1999). The range of optimal pressure has not been studied. At present, the treatment still relies on an experienced occupational therapist to monitor the pressure.

Silicone gel sheeting

History of silicone gel sheeting

Silicone gel sheeting was first used in the 1960s as a medium for separating the eschar. In the 1980s, pressure therapy was widely used and considered effective in treating hypertrophic scars, whereas silicone gel was used as padding to solve the concavity problem over the body (Kerckhove, Boeckx, & Kochuyt, 1991; Kerckhove et al., 2001). Perkins discovered that the contracture resulting from a burn scar improved after the application of silicone gel sheeting (Perkins, Davey, & Wallis, 1982). This inspired the studies on investigating the effect of silicone gel sheeting alone. Quinn studied its mechanism and its effect on scars (Quinn, 1987). It became a much more popular treatment for patients with hypertrophic scars as it is easy to apply and remove on the skin. Unlike the pressure garment, it does not seem to create any extra discomfort over the body. . A description of its usage on hypertrophic scar and contracture was published by Perkins in 1987. More research studies were implemented to prove its effectiveness on fresh and prolonged scars. It was recommended that the silicone gel sheeting should be applied for 12-24 hours per day (Katz, 1995).

Effectiveness of silicone gel sheeting

Many studies have been conducted from the 1980s to the 2000s to prove its

effectiveness on hypertrophic scars. In 1987, Quinn conducted an extensive 3-year clinical trial research and showed that 81.5% among 92 patients with chronic hypertrophic scars or keloids had improvement within 2 months (Quinn, 1987). Other researchers with less massive studies demonstrated a significant improvement of hypertrophic scar (Ahn, Manafo, & Mustoe, 1989; Gold, 1993). A similar figure, with improvement in 85% of 20 patients, was revealed in 1995 (Fulton, 1995), and a case study by Ahlering confirmed its effectiveness (Ahlering, 1995). The silicone gel sheeting was also effective in prophylactic application (Gold et al., 2001). Silicone gel sheeting was suggested as the standardized treatment of hypertrophic scars in international clinical recommendations in 2002 (Mustoe et al., 2002). In a very recent study, Chan and his colleagues randomized 100 wounds into 50 silicone gels and 50 controls, and it showed the scars under treatment group was improved after 3-month time by subjective scar assessment (Chan, Lau, Sathappan, & Mohd, 2005). Reviewing the studies mentioned in Mustoe et al.'s article, it was found that no evidence proved the effectiveness of silicone gel sheeting using objective assessment and a control group, and the effectiveness was only demonstrated among Caucasian populations or in small samples of non-Caucasians. In Katz' study (1995), the effectiveness was studied in case study manner; similarly, the studies by Berman and Flores (1999), Gobbobs et al. (1994) and Quinn (1987) were conducted without controlled trials (Berman & Flores, 1999;

Gobbons et al., 1994; Katz, 1995; Quinn, 1987). Gold and Ahn et al. showed the effectiveness with control groups (Ahn et al., 1989; Gold, 1994). However, Gold's study (1994) only described the change of scar in a subjective manner by the assessor and subjects, whereas Ahn et al. used a creep bandaging to stabilize the gel and the pressure effect was not eliminated on the hypertrophic scar (1989). Cruz-Korchin (1996) and Borgognoni et al. (2002)'s studies reported the prophylactic effect in a descriptive manner (Borgognoni, 2002; Cruz-Korchin, 1996). Agarwal's study reported the prevention of post-minigraft cobblestoning in vitiligo (Agarwal, Jin, Gulati, Bhargava, & Mathur, 1999).

Mechanisms of silicone gel sheeting

The mechanisms of the gel sheeting were suggested to act as a cooling effect, hydration, and secretion of silicone molecules to the scar tissue. At present, the mechanism is still unclear and the physical and chemical effects of the silicone gel sheeting on scar tissues are being explored. The studies of Quinn and her colleagues in 1985 and 1987 showed that the effectiveness was unrelated to pressure, oxygen tension and the effect of occlusion (Quinn, 1987; Quinn, Evans, Courtney, & Gaylor, 1985). Although the silicone fluid releasing into the scar tissues was suggested (Quinn, 1987), it was ruled out by Fulton in 1995 and Ahn in 1989. Both studies indicated no increased

rate of silicone in the treated scar. Shigeki showed that the excised skins with silicone gel sheeting application had higher concentrations of silicone molecules (Shigeki, Nobuoka, Murakami, & Ikuta, 1999), but its further action was not investigated. Ricketts and his colleagues showed that silicone was not a necessary component of occlusive dressings in the treatment of hypertrophic scars (Ricketts, Martin, Faria, Sead, & Fivenson, 1996).

Its mechanism was assumed as affecting the scar hydration, as there was evidence showing that the water vapor transmission rate of silicone gel sheeting was about half that of normal skin (Katz, 1995). The reduction in water vapor loss was hypothesized to decrease capillary activity, thus reducing collagen deposition and scar hypertrophy (Bieley, Berman, & Florida, 1996; Musgrave, Fish, Gomez, & Cartotto, 2002; Quinn, 1987). Recently a researcher suggested that the silicone gel sheeting could prevent the water loss of skin and allow oxygen access to the skin directly (Gilman, 2003).

Complications of silicone gel sheeting

Minor complications were shown in the silicone gel sheeting. Occasional purities and rashes develop due to poor hygiene (Lee, Ngim, Chan, & Ho, 1996). Compared with pressure therapy, silicone gel sheeting has better concavity and fewer complications.

In summary, pressure therapy and silicone gel sheeting are effective treatments for the hypertrophic scars, however there has been no study on their combined effect, or the fact that non-Caucasians are more prone to developing more severe hypertrophic scars. Without a large sample size of non-Caucasians, the effectiveness of pressure therapy and silicone gel sheeting and pressure therapy combined is still unknown among the Chinese population. Furthermore, the above-mentioned studies mostly adopted a subjective assessment for noting scar progress, thus assessor bias was unavoidable. There is still a need to explore the effectiveness of the conservative treatments on scars in an objective manner using controlled trials.

Combined therapy of pressure therapy and silicone gel sheeting

Pressure therapy was widely used in 1980s, while silicone gel sheeting was acted as a padding to solve the concavity problem over the body (Kerckhove, Boeckx, & Kochuyt, 1991; Kerckhove et al., 2001). When the sheeting was found effective in treating hypertrophic scar, there was no longer combine the two treatments on scar management. Hypertrophic scar was found dehydrated with thick stratum corneum, active in fiber proliferation resulted in raised and red appearance (Alster & Tranzi, 2003; Draaijers et al., 2004; Johnstone, Farley, & Hendry, 2005). It was believed that silicone gel sheeting was to hydrate the layer of stratum corneum and reduce the collagen

synthesis (Quinn, 1987; Suetake, Sasai, Zhen, & Tagami, 2000), whereas pressure therapy was to compress the scar to occlude the vascularity of the scars (Kischer, Shetlar, & Shetlar, 1975; Reno et al., 2002; Reno, Grazianetti, & Cannas, 2001). Combining these two treatments was assumed to affect the hypertrophic scar in terms of hydration and compression, therefore accelerate the scar maturation process in two ways and shorten the treatment period.

CHAPTER TWO

DEVELOPMENT OF OBJECTIVE SCAR ASSESSMENT

The aim of an assessment is to provide objective information on patient progress and to evaluate the effectiveness of treatment intervention. Over the years, scar maturation has been monitored by its characteristics, such as thickness, pliability, pigmentation and vascularity.

Vancouver Scar Scale (VSS)

The Vancouver Scar Scale, also known as the Burn Scar Index initially, was developed by the occupational therapists of the Vancouver General Hospital Burn Unit (Sullivan, Smith, Kermode, McIver, & Courtemanche, 1990). It was most commonly used in that setting for assessing scars in terms of the thickness, pigmentation, vascularity and pliability. The reliability was approximately 0.5±0.1 with Cohen's κ statistics (Sullivan et al., 1990). The inter-rater reliability was found to improve with time. It remains difficult for raters to reach agreement on the parameter of pigmentation. Vancouver Scar Scale was adopted for use in the Shriners' Burns Institute and claimed to provide more reliable information on scar progress (Baryza & Baryza, 1995). It was described as an useful clinical guide for rating scars, but it was unable to quantify changes in the scars upon maturation. Also, it was found too subjective as it relied on

visual inspection and palpation by the rater and self-reports by the patient (Fong, Hung, & Cheng, 1997; Powers, Sarker, Goldgof, Cruse, & Tsap, 1999; Tyack, Pegg, & Ziviani, 1997).

Implications for the development of new measurement instruments

Though the Vancouver Scar Scale was commonly used for assessing scar progress, it was found to be subjective as it depended only on the visual inspection and palpation to record the scar progress by therapists or clinicians. It was not sensitive enough to assess the progress of the scar, as it only provided data at the ordinal level and quantified the scar maturation.

It was therefore necessary to develop an objective scar assessment to quantify the progress of scar maturation. Different techniques were developed to provide objective measurements of scars in terms of thickness, pliability, vascularity and pigmentation. Ultrasound techniques were used to measure the thickness of hypertrophic scars, but the cost was very high (Fong et al., 1997; Powers et al., 1999; Van-Zuijlen, Kreis, Bos, & Middelkoop, 2002), and ultrasound has not been commonly used in clinics. The techniques of using a tonometer, an elastometer and a cutometer were employed to measure the scar pliability, but proper training was needed before their application (Fong et al., 1997; McOwan, Machermid, & Wilton, 2001). A very expensive Doppler

technique was used to measure the vascularity and the speed of blood flow of the hypertrophic scar (Clark et al., 1996; Ehrlich & Kelley, 1992). It was still not possible to quantify the scar pigmentation, and no reliable technique was developed. Therefore, the Vancouver Scar Scale continued to be used but it was difficult to rate the scar with mixed pigmentation and the dark, vascular scar (Davey, Spord, & Neild, 1999; McOwan et al., 2001; Teot, 2002). Taking photos to record scar progress at different intervals was used, but errors remained in different luminance, and this method was still subjective (Castanet & Ortonne, 1997). It is therefore important to use more objective assessment tools to measure the scar thickness, pigmentation, pliability, pain and itchiness. In this study, two objective instruments were adopted to measure the scar pigmentation and thickness.

Measurements of scar pigmentation

Scar pigmentation is an indicator of scar maturation, due to vascularity changes during the process. When a scar is fresh, it appears red and when it gets mature, it turns deeper red (Baryza & Baryza, 1995). In the past, scar measurements were conducted by therapists using criterion referenced rated forms such as the Vancouver Scar Scale, but it was found that the scores might not be reliable in a re-test situation. Other researchers suggested the use of photo recording to monitor scar progress. However, photographic

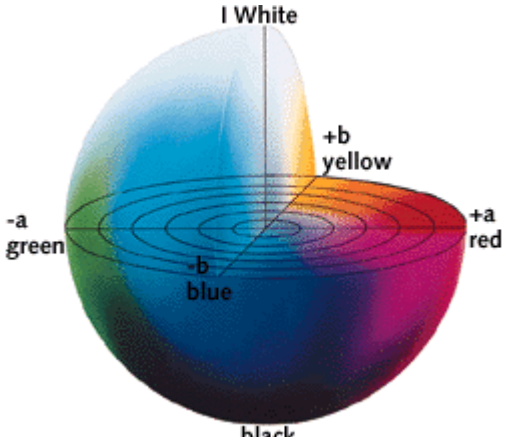
recording might not be reliable due to the variation in imaging techniques at each measurement, changes of background such as luminance, and distance for viewing object changes (Staley & Richard, 1997). Computerized color analysis has been used to quantify the scar pigmentation in terms of lightness, hue and saturation from a digital image (Davey et al., 1999). However, the imaging and interpretation take a long time with the support of a video camera, a pantone color gauge and computer software to interpret the color quantitatively (Davey et al., 1999). A commercial spectrometer, (Minolta, Oska 541, Japan), was used to measure the pigmentation of normal skin. It was reported to give reliable numerical data on skin pigmentation in terms of lightness, redness and yellowness (Takiwaki, Overgaard, & Serup, 1994). Investigations on objective measurements of wound image and erythema on normal skin have been published (Acha & Serrano, 2000; Takiwaki et al., 1994). There seems a potential to employ the commercial spectrocolorimeter to quantify scar pigmentation (Tyack et al., 1997).

Commission **I**nternationale de l'**E**clairage (**CIE)** is the French title of the international commission on color perception. This model has been applied in burn wound color and erythema on normal skin (Acha & Serrano, 2000; Pierard, 1998). There are several approaches to describing color. In this study, we adopted the two common models of scar pigmentation description, CIE L* C* h and CIE L* a* b*. CIE

L* C* h is a polar coordinate representation of the rectangular CIE L* a* b* color scale (Figure 5.1). CIE L*, which represents lightness, is the same in both the CIE L* C* h and the CIE L* a* b*scales. It indicates the relative lightness or darkness of the color. A reading of 0 is black; 100 is white and 50 is middle gray. Based on the opponent colors theory of vision, we cannot see red and green together at the same time, nor yellow and blue. The single value is to represent the red or green, yellow or blue attributes of the object. CIE a* represents the redness reading. The reading is positive when the object is red and it will become negative when it is green. CIE b* indicates yellowness and blueness. Similar to CIE a*, a positive value means that the object appears more yellowish. Skin pigmentation is believed to be in the positive reading a* (red) and b*(yellow) (Pierard, 1998)

Figure 2.1

The color model of CIE L*a*b*



Note: It is cited from http://cit.dixie.edu/vt/reading/gamuts.asp of Dixie State College of Utah.Visual Technology in Computer Information

Another approach to quantify color is the saturation or chroma of color (C*) (Davey et al., 1999; Pierard, 1998). This is a vector magnitude in the chromatic plane calculated from the a* and b* values. C* will increase as the saturation of the color increases, going through pastel to highly saturated or chromatic. h, which is hue, is a vector angle based on a 360-degree circle in the chromatic plane that is calculated from the a* and b* values. This approach is also adopted in this study to look at the chromatic changes of scar pigmentation.

Measurements of scar thickness

Ultrasound technique has been used to measure scar thickness to provide a more objective assessment. The principle of this technique is to capture the information of the reflected ultrasound wave at the interface among different tissues. It has been employed to measure the progress of scar maturation, imaging the severity of the scar and recording the progress of the scar under pressure therapy (Wood, 1996; (Cheng et al., 2001; Diridollou et al., 1998; Fong et al., 1997; van-Zuijlen et al., 2002). However, ultrasound imaging is not commonly used in clinical practice, as professional training is normally required to operate the complex ultrasound imaging device, and the time needed to conduct an assessment is usually very lengthy. The probe of the ultrasound system is usually too big to quantify small area of scar tissue and the probe might

compress the scar and often led to the distortion of scar dimension. Various errors might occur. Recently, a tissue ultrasound palpation system (TUPS) has been developed for the assessment of soft tissue (Zheng & Mak, 1999). It is a portable ultrasound machine equipped with a pen-size palpation probe, which is comprised of an ultrasound transducer at the tip and an in-series load cell. The ultrasound transducer is used to emit and receive ultrasound waves into and from the soft tissue to determine its thickness. The load cell is used to measure the load applied on the probe. TUPS can be used to measure tissue thickness under a controlled loading condition. Its measurement results have been validated (Cheng et al., 2001; Zheng & Mak, 1999). TUPS has been successfully used for the assessment of normal limb tissues under different contraction states and residual limb tissue for prosthesis socket fitting and measuring tissue fiber after cancer radiotherapy (Leung et al., 2002; Zheng, Leung, & Mak, 2000; Zheng & Mak, 1999) and diabetic feet (Zheng, Mak, & Lue, 1999; Zheng, Wong, Wong, Chan, & Mak, 2000).

Objectives

- To validate the application of the spectrocolorimeter measuring scar pigmentation.
- To validate the application of the Tissue Ultrasound Palpation System to measure the thickness of hypertrophic scars.

This study was divided into 2 parts, 1) validation of the spectrocolorimeter and 2) validation of the Tissue Ultrasound Palpation System.

Part I: Validation of spectrocolorimeter

Materials

Miniscan XE plus is the portable spectrocolorimeter (Fig 5.1). It is usually used in industry such as cloth, plastic and coatings to provide objective measurement of a product's color so as to monitor the quality of products and assist in formulating the desired colors. The luminance, distance for viewing object and reflected angle are controlled to provide consistency in capturing the color changes.

Figure 2.2

The spectrocolorimeter, Miniscan XE plus.

Sampling

To test the instruments of differentiating normal skin and hypertrophic scars, with α = 0.05, large power = 0.8, t-value = 0.6, sample size is estimated as a total of 48 (Portney & Watkins, 1995). 24 subjects were recruited from the occupational therapy department of the Pamela Youde Nethersole Eastern Hospital and the rehabilitation clinic of The Hong Kong Polytechnic University. They suffered from burn injuries, other injuries resulting in skin trauma, or those resulting from surgeries.

Inclusion criteria: 1) Hypertrophic scar was still active.

Exclusion criteria:1)Hypertrophic scar was with open wound; 2)Width of scar was less than 3mm.

Procedure

Three raters, two occupational therapists and one rehabilitation doctor were assigned to be the raters in this study. To normalize the scar vascularity, all subjects had to rest for at least 15 minutes without any treatment such as pressure garments or silicone gel sheeting before taking measurements. Each rater would assess the scar and rate it using the VSS. The rater would then position the spectrocolorimeter on the scar, with the porthole just slightly touching the scar without any compression. Three raters repeated the measurement in turns separately on the normal skin and scar. The whole process of measurement would last 30 minutes. Translucent sheets with scar outlines were used to provide measurement consistency.

Data analysis

The independent t-test was used to compare the difference between scar color and normal skin color in terms of the color parameters lightness (L*), redness (a*) and yellowness (b*) to construct validity. A two-way mixed model (2, 2) of intraclass correlation coefficient (ICC) was used to analyze the test-retest reliability, and the ICC (3, 2) was used to analyze the inter-rater reliability. Spearman's correlation coefficient was used to explore the relationship between scar color measurement and the VSS pigmentation score, as well as the VSS vascularity score. Pearson's correlation coefficient was used to analyze the relationship between the TUPS measurement and the VSS thickness score, as well as the VSS total score.

Results

Demographic data

A total of 24 patients, 13 males and 11 females, were recruited. They had a mean age of 36.46±19.61 years old, ranging from 11 to 69 years old. Their scars were caused by burns, scalds, trauma or surgery.

Table 2.1

The cause and frequency of scars among the 24 subjects

Causes	**Frequency**	**Percentages**
Burns	3	12.5
Scald	3	12.5
Surgery	14	58.3
Trauma	4	16.7
Total	24	100
Location		
Upper arm	2	4.2
Forearm	9	18.8
Hand	2	4.2
Chest	4	8.3
Abdomen	4	8.3
Thigh	3	6.3
Total	24	100

Test-retest reliability

The twenty-four hypertrophic scars were measured repeatedly by the same rater to confirm test-retest reliability. The mean of the 6 measurements was generated at each assessment, demonstrating a good test-retest reliability. The intra-class coefficient (2, 2) of the spectrocolorimeter measurement ranged from 0.97 to 0.99.

Table 2.2

The test-retest reliability of the spectrocolorimeter

Parameters	**Mean**	**Lower bound**	**Upper bound**	**F-value**
L*(Lightness)	0.97	0.94	0.99	106.19
a*(Redness)	0.99	0.94	0.99	35.32
b*(Yellowness)	0.97	0.94	0.99	37.12
C*(Chroma)	0.98	0.95	0.99	45.36
h*(Hue)	0.98	0.96	0.99	61.05

Note: df = 23, confidence of interval = 95%

Inter-rater reliability

The spectrocolorimeter showed good inter-rater reliability among the three raters. A total of 48 measurements of scar and normal skin were implemented. The intra-class correlation coefficient (3, 2) was from 0.94 to 0.98.

Table 2.3

The inter-rater reliability of the spectrolcolorimeter

Parameters	**Mean**	**Lower bound**	**Upper bound**	**F-value**
L*(Lightness)	0.96	0.94	0.98	28.36
a*(Redness)	0.94	0.90	0.96	16.65
b*(Yellowness)	0.98	0.96	0.99	46.03
C*(Chroma)	0.95	0.92	0.97	20.68
h*(Hue)	0.96	0.95	0.98	32.42

Note: $df = 47$, confidence of interval = 95%

Discriminant validity

It appeared that the hypertrophic scars were darker and more reddish. Paired t-test showed a significant difference among all parameters, except C*(Chroma). The hypertrophic scars had higher values in redness, and lower values in lightness, yellowness and hue than the normal skin readings. The measurements taken by spectrocolorimeter showed a very good ability to discriminate between hypertrophic scars and normal skin.

Table 2.4

The difference between normal skin and hypertrophic scars

	Normal Skin (n=24) Mean±SD	**Hypertrophic scar (n=24) Mean±SD**	**t-value**	**p-value**
L*(Lightness)	52.12±4.25	60.82±3.24	-7.14	<0.01
a*(Redness)	7.19±2.28	3.56±1.72	5.63	<0.01
b*(Yellowness)	11.95±3.22	14.41±1.83	-3.81	<0.01
C*(Chroma)	14.25±2.61	14.91±2.11	-1.05	0.305
h*(Hue)	58.21±12.56	76.49±5.08	-6.31	<0.01

Note: *df* = 23 and confidence of interval =95%

Correlation with Vancouver Scar Scale

All color parameters were correlated to the pigmentation and vascularity scores of the Vancouver Scar Scale (VSS). The pigmentation score of the VSS had a strong correlation with L* ($r = -0.76$, $p < 0.01$) and C* ($r = -0.73$, $p < 0.01$), and a moderate relation with a* ($r = 0.61$, $p < 0.01$). The vascularity score of the VSS had a strong relation with L* ($r = 0.72$, $p < 0.01$) and hue ($r = 0.70$, $p < 0.01$). It was moderately correlated with a* ($r = 0.56$, $p < 0.01$) and b* ($r = 0.58$, $p < 0.01$).

Table 2.5

The correlation of VSS parameters and color parameters

	L*	**a***	**b***	**C***	**h***	**Pigmentation (VSS)**	**Vascularity (VSS)**
L* (Lightness)	-	-0.87**	0.34*	-0.49	0.89*	-0.76**	-0.72**
a* (Redness)		-	-0.20	-0.22	-0.94**	0.61**	0.56**
b*(Yellowness)			-	-0.87**	-0.42	-0.42**	0.58**
C*(Chroma)				-	0.46	-0.73**	-0.28**
h*(Hue)						-0.66**	-0.70**
Pigmentation (VSS)						-	-0.89**

Note: * with significant level ≤ 0.05

** with significant level ≤0.01

Discussion

Scar color is composed of vascularity and pigmentation (Sullivan et al., 1990). However, it is very difficult to quantify its components objectively. In previous studies, scar pigmentation was usually assessed using subjective rating scales such as the VSS, which used numeric ordinal data to describe whether the scar was pinkish, reddish, purplish or brownish, but such scales were unable to quantify the scar progress as they were subjective and dependent on visual inspection, poor reliability resulted was reported. (Baryza & Baryza, 1995; Powers et al., 1999; Sullivan et al., 1990; Tyack et al., 1997). It was difficult to rate the scar if it was mixed pigmentation or hyperpigmentation, and whether it was red or purple in vascularity score (Sullivan et al., 1990). The scale is less sensitive during the process of scar maturation and it remains difficult to monitor progress using different intervention strategies. This study attempted to use a commercial spectrocolorimeter and the application of a color model to describe and quantify scar color according to the international color mode. The spectrocolorimeter was tested with satisfactory inter-rater reliability and test-retest reliability under a standardized assessment protocol and a structured environment. All the factors, including room lighting, the circulatory system of the subjects and the scar conditions, were controlled in the assessment procedures. The good inter-rater reliability revealed that the spectrocolorimeter was generally consistent for clinicians assessing

scar color. In addition, the spectrocolorimeter also appeared to differentiate well between the normal skin group and the scar group.

Our study also attempted to develop constructs for scar assessment based on the CIE color model (Acha & Serrano, 2000; Pierard, 1998; Takiwaki et al., 1994). With this model, it was predicted that normal skin color would be represented on the positive sides of the red-green axis (+ a* scores) and the yellow-blue axis. For hypertrophic scars, the redness (a*) score was expected to be higher as it became more vascular. The results from this study appeared to support this theory and showed that for hypertrophic scars, there will be an increase in redness (a*) scores due to the increase in vascularity of the skin tissue when compared to normal skin. On the yellow-blue axis, it was shown that normal skin had a higher value than the hypertrophic scar, as the melanocytes were destroyed and thus could not perform the function of producing melanin after the injury. Our study revealed that in the two CIE color models, all color parameters were correlated with the Vancouver pigmentation and vascularity scores, except C* (chroma), which only correlated with the vascularity score. The pigmentation of the hypertrophic scar was quantified with the HSV model in the previous study. Davey et al. adopted an image-analytic technique to quantify the scar pigmentation on a computer screen by HSV model, in which H represented the hue, S was saturation and V was the lightness value. The CIE L*C* h model was similar to the HSV model. Our

study result agreed with Davey et al.'s finding that the Vancouver vascularity score correlated significantly with CIE h* (hue). When the scar appeared redder, higher readings in CIE a* and lower reading in CIE h* were obtained. In the Vancouver pigmentation scoring system, the hypertrophic scar was rated either 2 (mixed pigmentation) or 3 (hyperpigmentation). A positive correlation between the Vancouver pigmentation scores and CIE a* (redness) was found, while a negative correlation was seen between the Vancouver pigmentation scoring and CIE h*(hue). CIE C* was the result of CIE a* (redness) and CIE b* (yellowness). The Vancouver pigmentation scoring system was used to describe scar pigmentation in terms of normal, hypopigmentation, hyperpigmentation and mixed pigmentation, so that even if a scar appeared more reddish than others, it did not indicate the depth of redness. It was assumed that no relationship between CIE C* and the Vancouver pigmentation scoring was explored. Our study did reveal a similar result to that of Davey et al., namely that there exists a minimal correlation between CIE C*and the Vancouver vascularity scoring (Davey et al., 1999). An imaging technique was developed to quantify the scar pigmentation (color); however the color of the image changed with the background difference, leading to the need for adjustment by computer software (Davey et al., 1999). Using the commercial spectrocolorimeter, it was unnecessary to consider the setup environment, since luminance was controlled internally by the machine. Past studies

found that hypertrophic scars appeared to be darker in color observation and photographic representation. In our study, it was confirmed that the normal skin showed higher readings in lightness (L*) than the hypertrophic scar group. This might indicate that the normal skin is lighter in color. Yet, this study could not verify the construct validity in view of the limited number of sampled subjects. Further studies would need to be conducted on the construct validation of the color model of hypertrophic scars.

Scar pigmentation is often assessed by visual inspection in clinical practice. Though human eyes can differentiate changes in scar pigmentation, they cannot quantify color change (Tyack et al., 1997). It has been reported that the VSS, the most common clinical scar assessment, is able to measure the progress of the scar with long-term use, but lacks the sensitivity needed to record the changes in the scar (Powers et al., 1999; Tyack et al., 1997). Difficulty was also found in rating the scar based on the description in the scale (Sullivan et al., 1990). It is therefore essential to develop a new technique to quantify scar pigmentation in order to record scar progress. This study attempted to validate the application of a commercial spectrocolorimeter in the assessment of scar pigmentation. It was proven to have good inter-rater and test-retest reliability subject to a standardized assessment procedure.

The study also applied the color property of skin based on the CIE model on color perception and revealed the differences between hypertrophic scars and normal skin

through the measurements of lightness (L*), redness (a*) and yellowness (b*). The color model of CIE L*a*b* was better than the CIE L*C*h as it had better discriminant ability to discriminate. It provided a clearer guideline with regard to the color difference between normal skin and hypertrophic scars. Based on the color model proposed by CIE, a systematic scar assessment model was established. It is evident that scar pigmentation and vascularity could be quantified using the model by the reflection of the lightness (L*), redness (a*) and yellowness (b*). Further study on the construct validity of this CIE model onto human skin is recommended.

Limitation and Conclusion

Due to its limited port size, the spectrocolorimeter could not measure scars of width less than 3mm; furthermore, the slightest variation of the spectrocolorimeter position would cause considerable error in the measurement. The spectrocolorimeter could not be pressed on the measurement site, as if pressure was applied on the scar, a large difference in data would be noted. The rater had to analyze the data with caution and be alert of the positioning of each subject.

The spectrocolorimeter was able to distinguish between normal skin and scars. Its stability of measurement was satisfactory, and it was non-invasive and convenient. It is proposed that it could be used as an objective measurement of scar pigmentation in

future study. Further validation in a longitudinal study to note scar maturation is encouraged.

Two color models suggested to quantify scar pigmentation were shown: CIE L* C* h and CIE L* a* b*. It is suggested that CIE L*C*h be the model used to analyze scar pigmentation, but this is a pilot study, and sufficient evidence is needed to prove which model or which color parameters are best for the interpretation of scar progress. A study should be carried out with a larger sample size in a homogeneous group.

Suggestions for future studies include the following: 1) Use the spectrocolorimeter to evaluate the effectiveness of different treatment modalities on scars, 2) Explore the relationship between normal skin pigmentation and the tendency of hypertrophic scar development, and 3) Explore the different pigmentation in different anatomical sites.

Part 2: Validation of Tissue Ultrasound Palpation System

This part of the study was divided into two phases. Phase I was a laboratory validation, carried out to study its validity using an ultrasound skin scanner which provided images and measurements of different thicknesses of porcine tissue. In phase II, we aimed to assess the inter-rater and test-retest reliability of the scar measurement, and to verify its concurrent validity using the Vancouver Scar Scale. The discriminant validity was explored by its ability to differentiate the traumatic burn scar and post-surgical hypertrophic scar.

Materials

TUPS was comprised of the micro-processor and its pen-size probe. The average sound speed in soft tissues was assumed uniformly to be 1540m/s for the tissue thickness measurement (Zheng & Mak, 1996). For the measurement of scars caused by burns and scalds, a standard probe with a diameter of 9 mm and frequency of 5 MHz was used (Figure 2.2 shows this probe, which had an industrially designed case). A probe with a diameter of 3 mm and a frequency of 10 MHz was specifically designed for the measurement of surgical scars to achieve a more localized measurement and higher resolution (Figure 2.3).

Figure 2.3

Tissue Palpation Ultrasound System (TUPS)

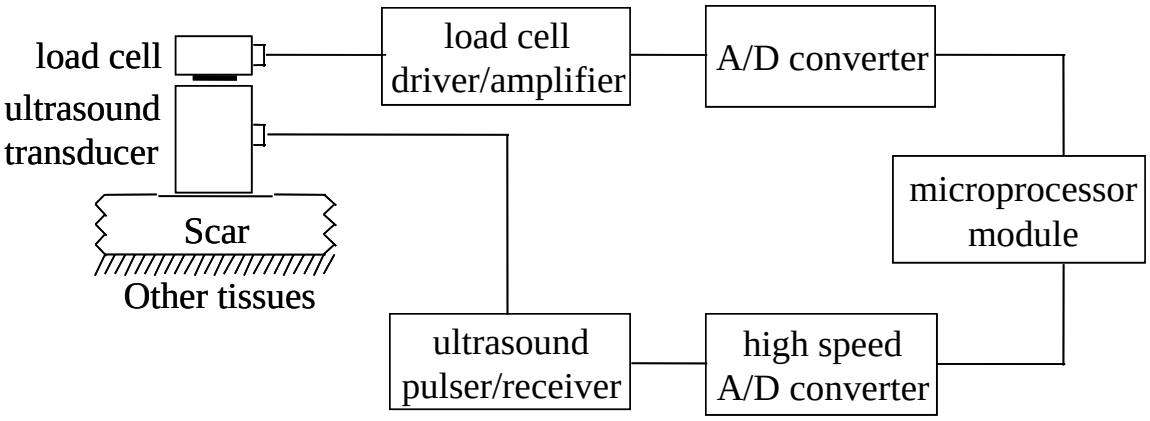
Figure 2.4

The probe with 3mm diameter

TUPS mainly consisted of two measurement channels for collecting ultrasound and load signals (Figure 2.4). A low-profile strain-gauge load cell with a measurement range of 10 N was arranged in series with the ultrasound transducer to sense the load applied on the probe. The load information allowed the operator to measure the scar thickness under a consistent loading condition. The ultrasound signal was emitted from the probe and was reflected at the interface between the scar tissue and the normal skin tissue. The time required for the ultrasound to propagate from the scar surface to that interface was used to calculate the thickness. The scar thickness value was displayed on the LCD display panel of TUPS, together with the value of the applied load.

Figure 2.5

Block diagram of TUPS



Note: It mainly consists of two measurement channels for collecting ultrasound and load signals respectively. A/D converters are used to convert the signals from analog to digital forms so that they can be processed by the

Phase I: Validation by the ultrasound skin scanner (20 MHz)

The tissue thickness measured using the TUPS was compared with that obtained by an ultrasound skin scanner (20 MHz), which could provide a cross-sectional image with a width of 6 mm and a depth of 8 mm in 8 frames per second. Eight pieces of porcine tissue consisting of skin and subcutaneous fat tissues of different thickness (approximately 3 to 7 mm) were prepared. Each of the tissues was first scanned by the imaging device three times at the same site. The TUPS measurement was then conducted at the central portion of the scanning area. The tissue thickness was

calculated as the distance between the skin surface and the bottom of the fat layer which made contact with a supporting surface. The thicknesses measured by the two systems were correlated with each other.

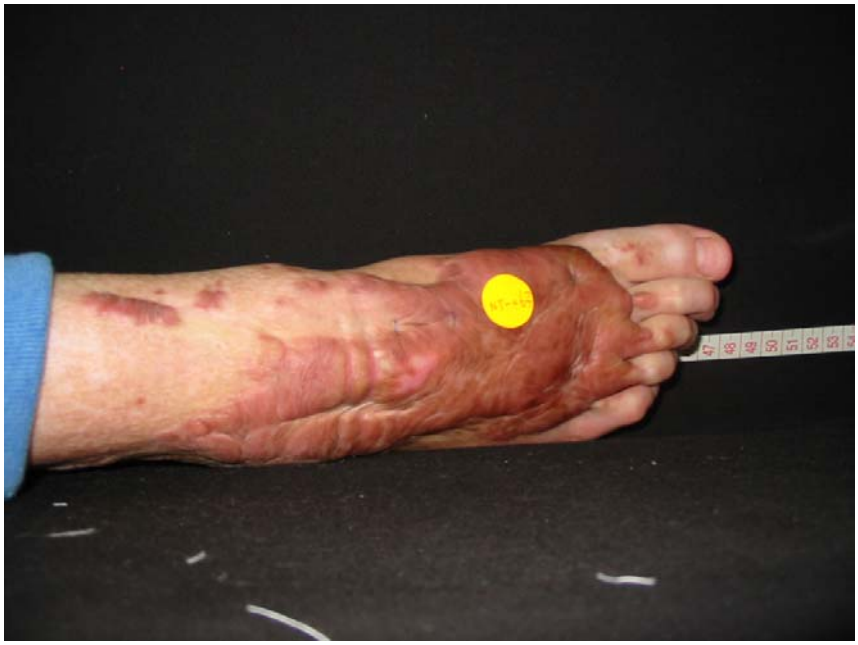
Phase II: Reliability and validity of TUPS on human skin tissue

To assess the inter-rater and test-retest reliability of TUPS, 30 subjects with scars that had been developing for less than one year and without open wounds were recruited from the Pamela Youde Nethersole Eastern Hospital of Hong Kong. The preset load threshold was approximately 0.2N for the measurement in this study. A total of 9 trials were taken for each measurement. The maximum and minimum readings of these trials were removed and the remaining 7 data were used to calculate the mean value of the measurement.

To assess its concurrent and discriminant validity, 100 subjects (50 with traumatic burn scars and 50 with surgical scars) were recruited to construct the discriminant validity of TUPS by using the known group method. The surgical scar is believed to produce fewer scarring problems as they were measured after four weeks' off-stitching, whereas the traumatic burn scars were measured after several months (Figure 2.5). They were recruited from two large hospitals.

Figure 2.6

A typical post-burn hypertrophic scar assessed in this study

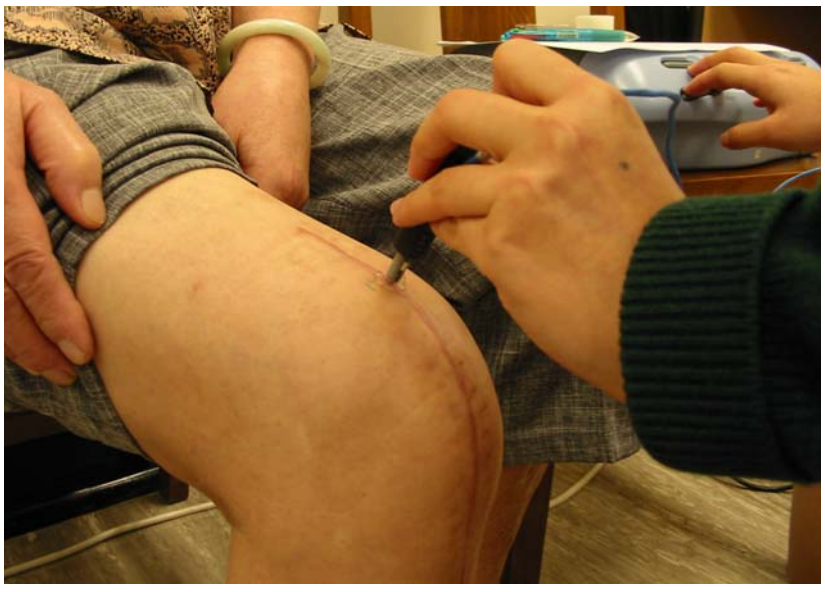


Two therapists and one doctor were assigned to take measurement with TUPS. They received one week of training on the operation of the machine before the assessment. They were blind to the VSS score in the assessment. Another experienced therapist would rate the scar condition using the VSS scoring method. The most severe and prominent site on each scar was chosen for TUPS measurement. Before the assessment, subjects were instructed to remove any pressure garments or dressings on the scar for 15 minutes to allow the scar to regain its original thickness. The rater outlined the scar on a translucent sheet and marked the spot for assessment. In this way, the same spot was used for subsequent assessments to ensure consistent comparison. Each rater took turns measuring the scar thickness using the TUPS.

During the measurement, the TUPS probe was first gently placed on the selected site of the scar (Figure 2.6). The magnitude of the ultrasound echo reflected from the scar-tissue interface was mentioned with the bar indicator on the LCD display. Meanwhile, the applied load was also monitored. Measurement was taken when the applied load reached a threshold value pre-set in TUPS and the reflected ultrasound echo reached approximately its maximum value. The measurement was manually initiated by the operator. The maximum value of the ultrasound echo indicated that the probe was perpendicular to the scar tissue interface.

Figure 2.7

Assessment of a post-surgical hypertrophic scar using TUPS with a 3mm diameter



Data analysis

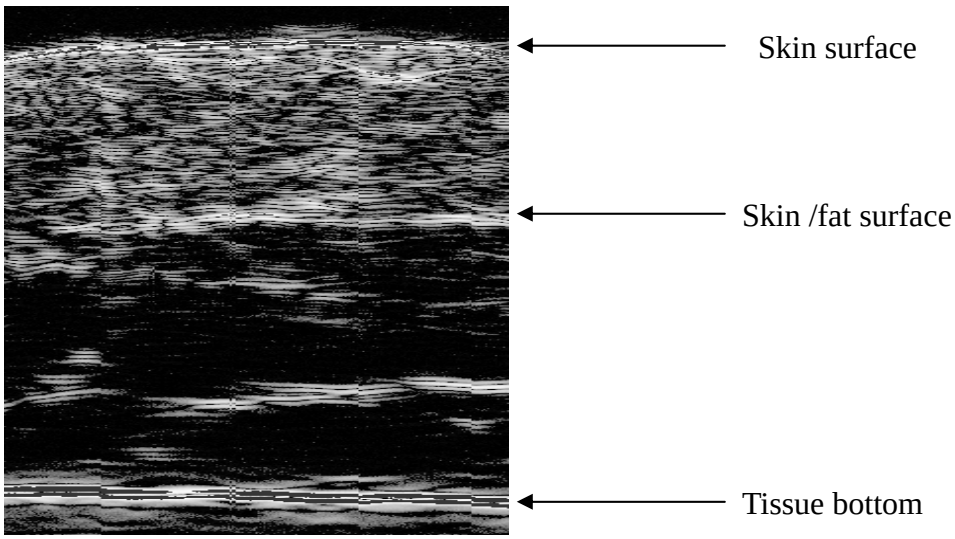
The Pearson correlation coefficient analysis was used to explore the relationship between the ultrasound skin scanner and the TUPS measurements. To assess the test-retest and inter-rater reliability of TUPS application on scar measurement, the data of 30 scars were pooled and analyzed by intraclass correlation coefficient, ICC (3, 7) and intraclass correlation coefficient, ICC (2, 3) analysis respectively. To test the discriminant ability of the TUPS, independent t-test was used to analyze the thickness of scars resulting from (a) burn, scald and trauma, and (b) surgery. The relationships between the thicknesses measured by TUPS and the VSS thickness and total scores score were explored by Spearman correlation coefficient analysis. One-way ANOVA was used to analyze the thickness measurement difference among the VSS thickness group.

Result of Phase I

Figure 2.7 shows a typical image obtained by the ultrasound skin scanner. The upper portion with obvious texture was the skin layer, and the remaining portion was mainly the fat layer. Figure 2.8 shows the correlation between the thickness measured using TUPS and the ultrasound skin scanner. The results demonstrated that there was a very good correlation ($R^2 = 0.96$) between the results obtained by the two systems.

Figure 2.8

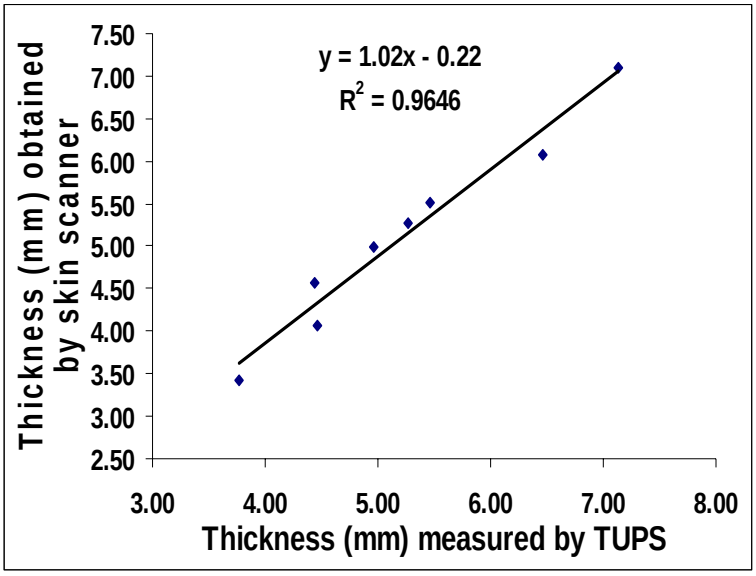
A typical cross-sectional image of a porcine specimen obtained using the ultrasound scanner.



Note: The tissue bottom was in contact with a supporting surface.

Figure 2.9

The correlation between the thickness measured by TUPS and the ultrasound scanner.



Result of Phase II

Among the 100 subjects, there were 55 males and 45 females. Their mean age was 42.24 years (SD = 28.33), ranging from 13 months to 80 years old. Hypertrophic scars had developed after burns, scalds, trauma and various types of surgery. (Table 2.6)

Table 2.6

The distribution of subjects for the causes and location of scars

Causes		**Frequency**	**Percentage**
Burn		10	10.0
Scald		26	26.0
Trauma		13	13.0
Surgery	Total knee surgery	35	35.0
	Total hip surgery	3	3.0
	Surgery on upper limb	11	11.0
Others (e.g. injection, skin disease)		2	2.0
Total		100	100.0
Location		**Frequency**	**Percentage**
Upper limb		38	38.0
Lower limb		55	55.0
Body		7	7.0
Total		100	100.0
Scar assessment		Nature of scar	Mean ± SD
TUPS measurement		Post-surgical scar	4.41±0.52
		Traumatic scar	5.92±2.61
Thickness score of VSS		Post-surgical scar	1.20±0.40
		Traumatic scar	3.30±0.76
Total score of VSS		Post-surgical scar	7.68±0.98
		Traumatic scar	10.38±1.86

Reliability

Thirty scars with two repeated measurements were pooled and analyzed. The test-retest reliability of TUPS was very high with an average ICC(3, 7) = 0.98 ($p < 0.01$). The inter-rater repeatability was also high with an average ICC(2, 3) = 0.84 ($p < 0.01$).

Disciminant validity using known group method in the burn scar group and the surgical scar group

The result of the assessment using both TUPS and VSS demonstrated that the severity of post-surgical scars was significantly lower than that of scars caused by burns, scalds and trauma. The highest t-value was gained in the thickness score of VSS with $t = 17.21$ ($p < 0.01$). The lowest t-value was found in TUPS measurement with $t = 3.99$ ($p < 0.01$), and $t = 9.08$ ($p < 0.01$) was noted in the VSS total score (Table 2.7).

Table 2.7

t-test value between post-surgical hypertrophic scar and traumatic burn scar

Scar assessment	**t-value**	***df***	**p-value**
TUPS thickness measurement	3.09[a]	52.94	<0.01
Thickness score of VSS	17.21[a]	74.50	<0.01
Total score of VSS	3.08[a]	74.14	<0.01

Note: a = Equal variances not assumed

Correlation between the results of VSS and TUPS measurement

According to Spearman's correlation coefficient analysis, a fair correlation resulted between the VSS score and the TUPS measurement. The correlation was 0.42 ($p < 0.01$) between the VSS thickness score and the TUPS measurement, whereas $r = 0.34$ ($p < 0.01$) between the VSS total score and the TUPS measurement. (Table 2.8)

Table 2.8

Correlation between TUPS measurement and Vancouver Scar Scale (VSS) score

	Thickness of TUPS measurement	**Thickness score of VSS**	**Total score of VSS**
Thickness of TUPS measurement	1.00*	0.42*	0.34*
Thickness score of VSS	-	1.00*	0.84*
Total score of VSS	-	-	1.00*

Note: * represents that correlation is significant at 0.01 level.

To further explore the results of TUPS and the VSS thickness scores, the data was analyzed by one-way ANOVA. There was significant difference among VSS thickness score groups ($F = 14.68$, $df = 3$, $p < 0.01$). A multiple post-hoc analysis LSD test demonstrated that a difference in the TUPS measurement was found between the VSS thickness score = 4 and all groups. (Table 2.9 and Table 2.91)

Table 2.9

TUPS measurement among different VSS thickness scoring groups

VSS thickness score	**No. of subjects**	**TUPS measurement Mean±SD**
1	41	4.36±0.51
2	16	4.64±0.94
3	20	4.95±1.25
4	23	7.19±3.19
Total	100	5.17±2.02

Table 2.91

Multiple post-hoc analysis of TUPS measurement among different VSS thickness scoring groups

VSS thickness score (I)	**VSS thickness score (J)**	**Mean Diff. ± Standard Error (I-J)**
VSS score = 1	score = 2	-2.91 ± 0.50
	score = 3	0.60 ± 0.46
	score = 4	-2.84 ± 0.44*
VSS score = 2	score = 3	-0.31 ± 0.57
	score = 4	-2.55 ± 0.55*
VSS score = 3	score = 4	-2.24 ± 0.52*

Note: * represented the significant level ≤ 0.05

Discussion

Phase I of the study showed that there was a fairly good correlation between the ultrasound skin scanner and the TUPS. It was also noted that the thickness measured by the ultrasound skin scanner was slightly less that that obtained by TUPS. This is probably due to the small load applied by the probe during the measurement of the skin scanner. In the case of TUPS, the load was monitored in real time and was minimized during the measurement so that the real original tissue thickness was obtained. Phase II of the study demonstrated the feasibility of using TUPS for scar assessment on human subjects. It showed good test-retest and inter-rater reliability on measurement of scar thickness.

From the study, the severity of hypertrophic scars resulting from burns, trauma or scalds was higher than that of scars resulting from surgery. Sun and Lewis's study (1990) showed that the level of hypertrophy in burn scars was significantly higher than in post-surgical scars. According to the mechanism of tissue repair, traumatic burn scars are often found in larger areas, unclean wounds and irregular wound depth, which is in contrast to fine post-surgical scars with structured and clean wounds created without further infection consequence (Lewis & Sun, 1990) . The wound healing process of a burn is more active and prolonged than that of post-surgical scars, leading to more active collagen synthesis. However the severity of scarring also depends on the injured

site's certain higher mechanical tension, the time of leading wound healing and the patient's age (Deitch et al., 1983).

The moderate correlation between the clinical tool VSS scale and the TUPS may be due to the ceiling effect of the VSS scale (4mm being the highest) when TUPS had no limit on measurement. The ultrasound penetrated the scar tissue to measure the whole scar thickness, whereas the VSS scored only the superficial part of the scar (Sullivan et al., 1990). The t-value of TUPS measurement was lower than that of the VSS thickness scores, since the TUPS measurement provided a continuous measurement, whereas the thickness score of VSS categorized the scar thickness into identical levels.

To better explore the relationship between the TUPS measurement and the VSS thickness scores, a significant difference resulted in scar thickness among groups by one-way ANOVA ($F = 14.68$, $df = 3$, $p < 0.01$). The post-hoc comparison analysis revealed a difference between the VSS thickness score = 4 and others. This was because the VSS scoring system only rated scars protruding over 4mm as 4. By contrast, there was no upper limit of TUPS measurement, which resulted in greater difference in the VSS thickness score = 4 among all groups (Figure 6.91). The thickness of the scar underneath the skin was also taken into account by TUPS measurement, which made less difference in other groups scoring < 4 that had a limited range of scar thickness in

VSS.

The Vancouver Scar Scale has been used for a long time in scar assessment, including scar thickness documentation and being able to reflect the severity of a scar. However, it was unable to quantify the scar sensitively. A previous study also reported that a poor reflection in scar volume was noted using the VSS score (Nedelec, Shankowsky, & Tredget, 2000). Our study found a similar discrepancy between the scar thickness measurement by TUPS and the VSS scale.

TUPS demonstrated its ability to have good correlation with the ultrasound skin scanner. Further, its clinical application showed good ability to discriminate between the thick burn scar and the thinner surgical scar. The ultrasound technique was believed to document the scar thickness in an objective manner, and to provide an image of soft tissue. In comparison with ultrasound techniques used for scar assessment, TUPS was found to be more user-friendly and could provide different sizes of probe for measurement on different sites. It was more convenient in operation and much cheaper in operational cost. One important feature of TUPS was that it could provide the amount of lead applied on the scar during thickness measurement, thus helping to standardize the pressure exerted onto the scar.

There were some limitations in the present study. Firstly, the ultrasound speed in the scar has not been measured due to lack of specimens of hypertrophic scar, and so the

average of the ultrasound speeds for soft tissue was used. Secondly, the small (3mm diameter) probe could not reflect the thickness of the whole scar. Measurement of multiple points along the hypertrophic scar may solve this problem in the future. Further studies are recommended to explore how the ultrasound speed is different between hypertrophic scars and normal soft tissue. It is also important to employ TUPS in a longitudinal research on hypertrophic scar thickness throughout its maturation, to further demonstrate its sensibility in scar assessment.

In conclusion, an ideal technique for scar assessment should be easy to access and non-invasive, and have/carry low operational costs. TUPS was found to have these features, compared with other available ultrasound approaches. More investigation and development are required before it can be become a clinical tool for scar assessment. With the use of a spectrocolorimeter, it may provide the new standardized assessment for noting the course of scar maturation.

Conclusion

In sum, the color and thickness of the hypertrophic scars were able to assessed objectively by Miniscan XE plus and TUPS. However, some variables including the pliability and the subjective feelings over scars were still difficult to be quantified objectively. Cutometer was found failure in suction duration on a stiff surface, a concave and a covex anatomical sites. Furthermore, no objective measurement was able to measure pain and itchiness over the hypertrophic scar. To assess all characteristics of hypertrophic scar, the pliability scoring system of Vancouver Scar Scale (VSS) and VAS were employed to assess the scar pliability and subjective feelings.

VSS was a 5-point scale. It was proposed to provide subjective measurement of scars. It guided the rater in rating the scar maturation in terms of pigmentation, vascularity, pliability and height. The face validity of the assessment is established through rating the scar in terms of its characteristics (pigmentation, vascularity, pliability and height). The inter-rater reliability was high by showing Cohen's k statistic of approximately 0.5+/- 0.1 in each parameter. These values were found to improve with time (Sullivan et al., 1990).

Visual Analouge Scale (VAS) was used to measure the pain and itchiness of the hypertrophic scar. A Visual Analogue Scale (VAS) is a vertical or horizontal line, usually 100mm long, with anchors at each end indicating the extreme sensation under

study. The VAS was developed to measure subjective feelings, such as pain, nausea, fatigue and dyspnea. Validity has been established in various areas; for example, the concurrent validity of the VAS has been established with the McGill pain questionnaire, the Beck Depression Inventory and the depression scale of the Symptom Checklist-90. Its high reliability has also been demonstrated by repeated measurement after one hour and 2 weeks (Cline, Herman, Shaw, & Morton, 1992; Gift, 1989).

With the use of the above measurements, it was able to note the whole profile of hypertrophic scar in terms of thickness, color, pliability, pain and itchiness.

CHAPTER THREE

THE MAIN STUDY

Introduction

The prevalence of hypertrophic scar is believed to be higher among the non-Caucasian population than in Caucasians, but there has been no study purely exploring the prevalence among a Chinese population and studying the severity of scars.

Traditionally, therapists in Hong Kong apply pressure therapy on hypertrophic scars, while western therapists rely on the silicone gel sheeting. There is a debate in clinical practice with regard to which therapy is more effective. The combined therapy was believed to accelerate the scar maturation but not yet proven scientifically. Past researchers have investigated the effects of silicone gel sheeting or pressure therapy, most of the studies did not include a control group or were conducted in a randomized trial manner. They mainly employed subjective assessment using descriptive method to report on the scar progression. This study aimed to study the prevalence of hypertrophic scar among the Chinese population and at the same time, explore the combined effects of pressure therapy and silicone gel sheeting on hypertrophic scars. A homogenous group with a similar severity of wound was recruited. Patients with post-surgical hypertrophic scars developing for less than a year were recruited. They were randomly allocated into either the control group, the pressure therapy group, the silicone gel sheeting group or the combined therapy group. The scars were assessed by a validated

objective scar assessment in scar pigmentation and scar thickness. Assessments were conducted the end of the first month and bi-monthly in the following 4 months. The results of this study would shred light to the clinicians in management of hypertrophic scars using evidenced based approach.

Selection of Subjects

Hypertrophic scars become mature from months to years after infliction of the wound, according to the wound severity. The level of scar severity determines the effects of the treatment. It was necessary to constrain the variable of its causes (e.g. chemical burn, scald, burn) in order to have a homogenous group of subjects. A homogenous group of patients who were undertaken surgery in the Orthopedics and Traumatology Department of the Pamela Youde Nethersole Eastern Hospital was recruited. They received either total knee replacement, total hip replacement or surgery over forearm. Their wounds were created by the same team of surgeons following the same surgery protocol, and were under the same nursing care and cleansing. Patients would receive physiotherapy after the surgery and have completed the strengthening sessions after 30 days. At that time, the stitches were removed (after 30 days of surgery), the wound was screened by an experienced occupational therapist using the Vancouver Scar Scale to identify whether it had become a hypertrophic scar or was continuing to heal as a normal wound. Consent was sought from patients with wounds defined as hypertrophic scars when they fit the following criteria. The wound was screened a second time after 14 days if it was described as healing normally in the first screening.

The locations of the hypertrophic scar were confined to knee, hip or forearm areas, as these area were no tendency of hypertrophic scar formation, it reduced the bias of the

treatment., Furthermore, pressure of pressure therapy could be applied evenly and better control on limbs than the human body.

Inclusion criteria

1. The hypertrophic scar developed over the limbs;
2. The hypertrophic scar met the scoring criteria of the screening test:
    a. The total score of the Vancouver Scar Scale was higher than 1, and
    b. each of the items on the scale was equal to or higher than 1;
3. The width of the scar was equal to or larger than 3mm;
4. The patient was complying well with medical intervention and;
5. The patient had no medical history of diabetes mellitus or other skin diseases that affect wound healing.

Exclusion criteria

1. The area of the hypertrophic scar was larger than 4 cm x 10 cm;
2. Patients had received treatments such as steroid injections, pressure therapy and silicone gel sheeting before this study;
3. The hypertrophic scar was still attached to an open wound.

Methodology

A randomized clinical trial was adopted in this study. The subjects were randomly allocated into 4 groups, namely 1) control group; 2) pressure therapy group; 3) silicone gel sheeting group and 4) combined therapy group, by a randomization sheet. The number of 4 groups was listed randomly on the sheet and patients were allocated to the specific group according to the group number. To reduce the bias on treatment, a single-blind study was employed, in which the rater was blind to the all subjects' intervention.

Sample size estimation

There has been no study conducted to compare the effectiveness of pressure therapy, silicone gel sheeting, their combined therapy group and control group. Reviewing the past studies, only very few studies attempted to use ultrasound advancement to measure the scar thickness. Two similar studies (Berry et al., 1985; Phillips, Gerstein, & Lordan, 1996) with the use of ultrasound advancement were selected to estimate the sample size by Power Analysis and Sample Size (PASS).

As difference between groups was mainly investigated in this study, the significant level was adjusted according to pair-wise comparison (0.05/9 =0.0056). In Berry's study, the change of hypertrophic scar thickness after 6-week pressure therapy was Mean =

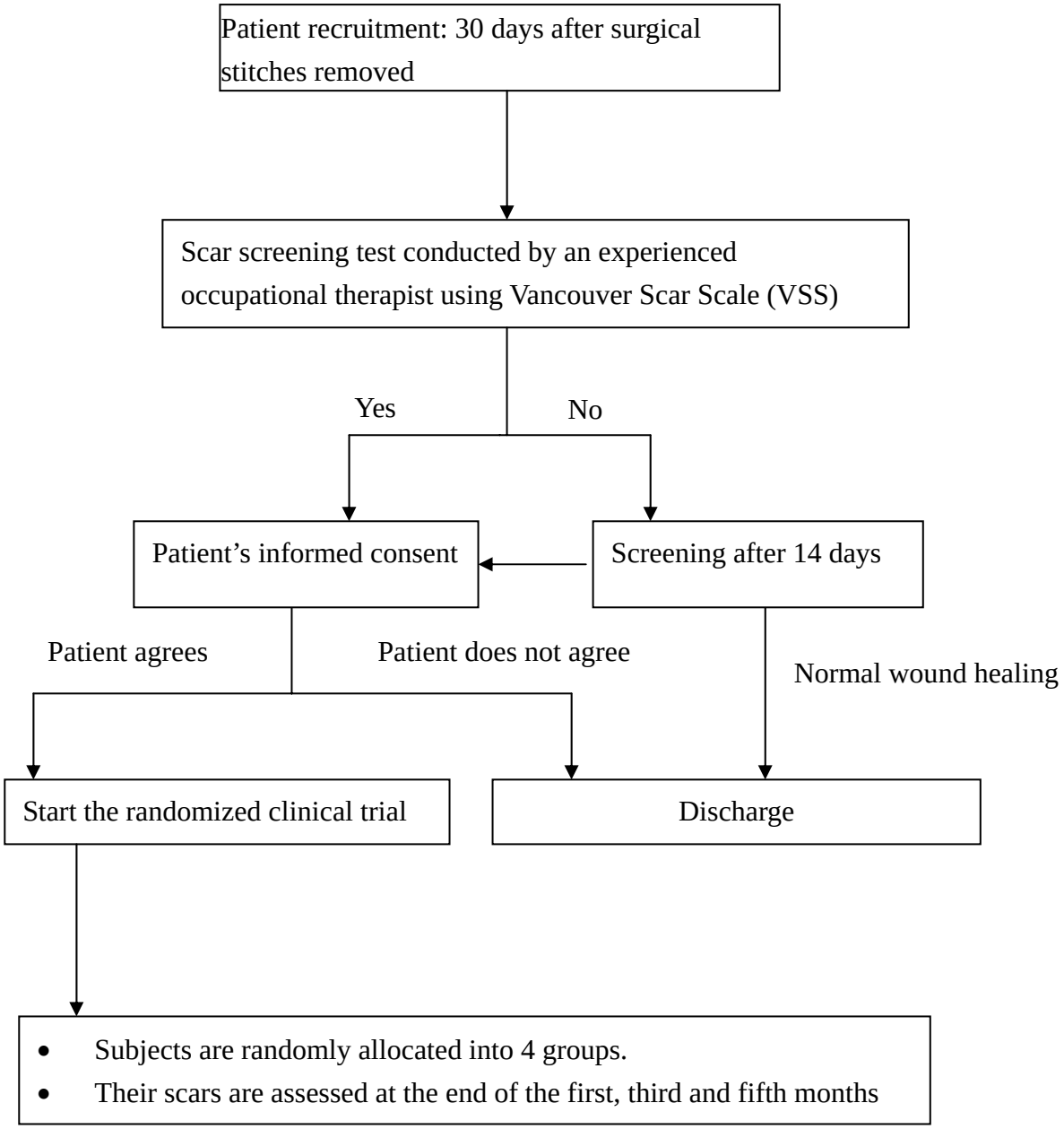
0.69mm, SD = 0.56mm. With power = 0.8, alpha = 0.0056. The result of PASS revealed 17 subjects in each group. Same sample size was calculated with the data of Phillip's study in terms of the thickness change between control group and silicone gel sheeting group was Mean = 0.6mm, SD = 0.6mm after 2 months.

Schedule of assessment

The scar progress was recorded in both subjective and objective manners. The thickness and the color of the scar were measured objectively by the spectrocolorimeter and Tissue Ultrasound Palpation System. Since there was no advancement available in the pliability measurement, the pliability was recorded by the sub-scale of the Vancouver Scar Scale. The pain and itchiness were reported by subjects using the Visual Analogue Scale. The scars were assessed at the end of the first, third and fifth months.

Figure 3.1

The flow of subject recruitment



Treatment protocol

Subjects in the control group, pressure therapy group, silicone gel sheeting group or combined therapy group had to follow the designated treatment protocols stipulated in each group. All subjects were advised to have a 15 minutes massage with lanolin daily to soften the hypertrophic scar. When patients have bilateral limbs' scars, same treatment would be provided to reduce the misunderstanding of treatment to the patients.

Control group (CO)

Subjects were instructed to massage gently their scar with lanolin once a day for 15 minutes.

Pressure therapy group (PT)

A pressure garment was fabricated with a 10% deduction of the circumference over the limb. To generate a highly localized pressure, a padding of 9mm thickness was further applied on the scar. Two pressure garments and paddings were prescribed for subjects, to be worn on alternate days. The pressure garment and padding were taken off only in the bath or when the subjects felt itchy, too humid or hot. They were instructed to hand wash the pressure tubes with soap water. Every two months, all pressure tubes

and paddings were replaced. After fabricating the pressure tube, the subjects were told to stay in the occupational therapy department for 15 minutes to screen if there was any complication and re-check the pressure.

Silicone gel sheeting group (SG)

The subjects were told to apply the silicone gel sheeting (Cica-Care) 24 hours per day except bathing. It had to be gently washed by soapy water once a day. The sheeting was replaced after every month of usage. 3M micropore was used to secure the sheeting over the scar.

Combined therapy group (CT)

The subjects were given a pressure garment, 9mm padding and silicone gel sheeting. The sheeting was placed under the padding. The same treatment regime would be followed as in the pressure therapy and silicone gel sheeting groups.

Statement of hypothesis

1. There was no correlation between scar formation and the variables of gender and age.
2. There was no significant difference of scar condition in terms of the scar thickness, scar color, scar pliability, pain and itchiness among the control, pressure therapy, silicone gel sheeting and combined therapy groups along the 1-month, 3-month and 5-month timeline.

Instrumentation

In this study, the maturation of the hypertrophic scar was assessed objectively and subjectively. The objective measurements included: 1) Miniscan XE Plus measuring scar color and 2) TUPS measuring scar thickness The subjective measurements included: 1) the pliability score of the Vancouver Scar Scale (VSS); 2) the pain intensity of Visual Analogue Scale and 3) itchiness intensity of Visual Analogue Scale. Others measurements included: 1) a digital camera was used to capture the image of the hypertrophic scars over 5 months and 2) a soft tape was used to measure the scar width and length.

Miniscan XE Plus

Miniscan XE Plus is a full-scanning spectrocolorimeter. It is used to quantify the color changes in industry for cloth, plastic, food and coatings. Its reliability in skin measurement and its application in the scar measurement have been proven previously (Li-Tsang, Lau, & Liu, 2003). It was recommended that the difference of color between normal skin and hypertrophic scar is the result of the intervention (Schmidt, Gassmueller, Hughes-Formella, & Bielfeldt, 2001). The formula is shown as follows:

$$\Delta L^* \text{ (lightness)} = \frac{(L^* \text{ of normal skin} - L^* \text{ of hypertrophic scar}) \times 100\%}{L^* \text{ of normal skin}}$$

$$\Delta a^* \text{ (redness)} = \frac{(a^* \text{ of hypertrophic scar} - a^* \text{ of normal skin}) \times 100\%}{a^* \text{ of normal skin}}$$

$$\Delta b^* \text{(yellowness)} = \frac{(b^* \text{ of normal skin} - b^* \text{ of hypertrophic scar}) \times 100\%}{b^* \text{ of normal skin}}$$

Tissue Ultrasound Palpation System (TUPS)

TUPS was used to measure the scar thickness. It includes a finger size palpation probe, comprising of an ultrasound transducer and an in-series load cell. Its application on the hypertrophic scar measurement was testified (Lau, Li-Tsang, & Zheng, 2004).

Vancouver Scar Scale (VSS)

It was used to record the scar pliability. It rated the scar pliability into different level: 0 = normal, 1 = supple, 2 = yielding, 3 = firm, 4 = banding rope and 5 = contracture. The inter-rater reliability was high by showing Cohen's k statistic of approximately 0.5+/- 0.1 in each parameter. These values were found to improve with time (Sullivan et al., 1990). To enhance the accuracy of scoring the scar pliability, the assessor was trained by an experienced occupational therapist until reaching 90% agreement on rating 10 hypertrophic scars.

Visual Analogue Scale (VAS)

A 100mm horizontal Visual Analogue Scale (VAS) with anchors at each end was used in this study to measure the level of pain and itchiness. Each subject was instructed to indicate the intensity of pain and itchiness he/she perceived using the VAS scale. The more discomfort the subject felt, the longer distance VAS recorded. A very high reliability (ICC = 0.9) was resulted in repeated measurement after one hour and 2 weeks (Cline, Herman, Shaw, & Morton, 1992; Gift, 1989).

Digital Recording

A digital camera was used to capture images of the hypertrophic scar over the 5-month study duration. The technique of using photography has been reported to be unreliable, as the background color and the images shown vary in color standard in terms of the proportions of cyan, magenta and yellow (Davey et al., 1999). Hence, background, lighting, position of scar and method of showing image should be standardized in order to provide reliable images of scars.

Measurement of scar dimensions

A tape measure was used to measure the length and width of the scar in the initial assessment for screening purposes. .

Collection of demographic data

A record sheet was used to record patient information: a) Demographic data: age, sex, occupation, hypertrophic scar location, time of hypertrophic scar development and b) Medical history: nature of injuries, types of surgery.

Data analysis

Descriptive statistics were used to describe the prevalence among the sampled group of subjects with hypertrophic scar. A non-parametric test, the Kruskal-Wallis one-way analysis, was used to compare the prevalence distribution of 2 gender and age groups. A paired t-test was conducted to reveal the color difference between normal skin and the hypertrophic scar.

One-way analysis of variance (ANOVA) was used to testify the baseline of the data, namely the scar thickness measured by TUPS, the difference in the color parameters between normal skin and the hypertrophic scar measured by the spectrocolorimeter, and the pain and itchiness recorded by the visual analogue scale.

The progress of the scar conditions among the 4 groups was compared by two-way repeated ANOVA. To fully analyze the whole data set with dropout rate, two-way repeated ANOVA in a mixed model was chosen. The following variables reflecting scar characteristics would be compared among the 4 groups.

- Scar thickness measured by Tissue Ultrasound Palpation System (TUPS)
- Scar color in terms of lightness (ΔL*), redness (Δa*) and yellowness (Δb*) measured by the spectrocolorimeter, Miniscan XE Plus
- The pliability score of the Vancouver Scar Scale (VSS)
- Pain intensity recorded by Visual Analogue Scale (VAS)

- Itchiness intensity recorded by Visual Analogue Scale(VAS)

Tukey’s post-hoc comparison analysis was used for finding differences between two groups or more. To protect against a type I error, Bonferroni correction was needed for adjustment of significance level.

Result of prevalence rate of hypertrophic scars

The demographic data

154 patients (68 males and 86 females) were referred from the Department of Orthorpedic and Traumatology of the PYNEH during the period from May 2002 to December 2003. 59.7% had received total knee replacement, 13.6% total hip replacement and 22.7% surgery in their upper limbs. They were aged from 14 to 85, with a mean age of 57.35 (SD = 19.74) years old. Among the 154 patients, 115 (74.67%) were found to have developed hypertrophic scars based on the VSS screening criteria. 39 patients (24.68%) were found to have normal wound healing without scar problems (Figures 3.2.1 and 3.2..2). 101 patients (65.58%) agreed to conduct the scar assessment, while 15 refused to join the study.

Figure 3.2.1

Hypertrophic scar with red, raised appearance

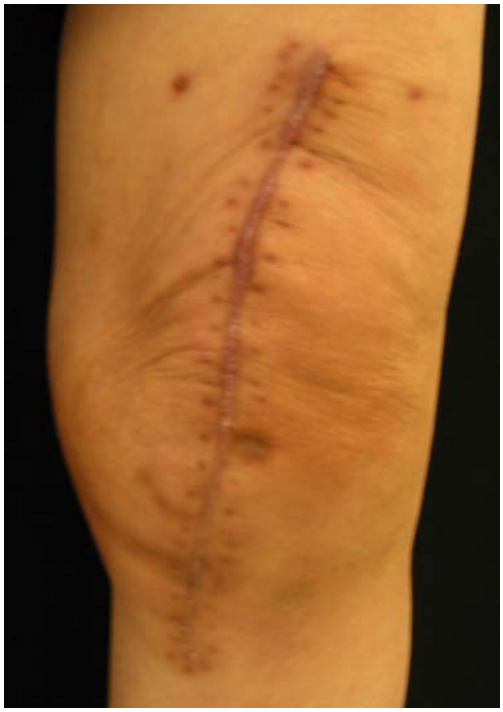
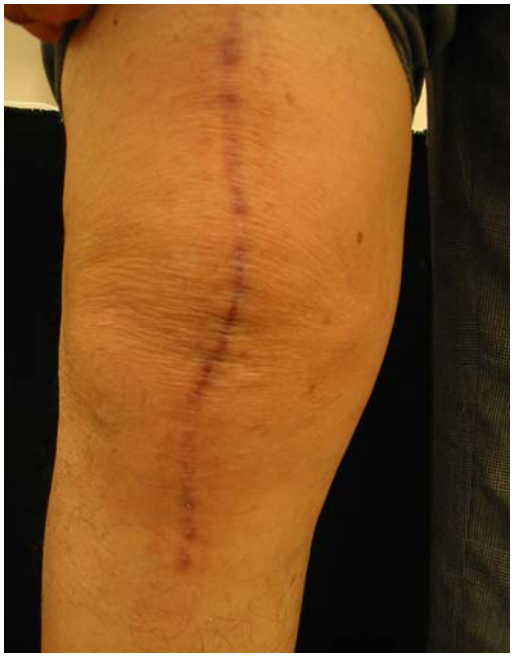


Figure 3.2.2

The normal wound healing with plain and rash appearance



Gender difference of incidence rate

There were 68 male (44.16%) and 86 female (55.8%) patients who had developed hypertrophic scars after surgery. The incidence rate was 76.74% and 72.05% among females and males respectively. There was no significant difference in incidence rate between the female and male groups ($p = 0.51$).

Incidence rate between two age groups

All patients were clustered into two age groups (a) age ≤ 45 and (b) age > 45 years old. Thirty-nine subjects were in the group aged ≤ 45 and 115 subjects were in that aged > 45. There was no significant difference in the rate of incidence between the two groups (with 79.49% for the younger group and 73.04% for the older group).

Table 3. 1

Incidence rate of hypertrophic scar among different types of surgery

		Number of subjects whose wounds formed hypertrophic scars	Number of subjects whose wounds underwent normal healing	Incidence rate
Age	≤ 45 years old	31	8	79.49%
	>45 years old	84	31	73.04%
Gender	Female	66	20	76.74%
	Male	49	19	72.05%

Subjective characteristics of post-surgical hypertrophic scars

Among the 101 subjects who consented to the comprehensive scar assessment, the mean total score of the Vancouver Scar Scale after 1 month of surgery was 7.54 (SD = 1.16). For each item on the VSS, the mean score of pigmentation was 2.71 (SD = 0.54), height was 1.45 (SD = 0.54), vascularity was 1.82 (SD = 0.52) and pliability was 1.78 (SD = 0.52) (Table 3.2). 47 patients (46.53%) reported pain over the scar although the pain level was 2 out of 10 (2.19±2.74), and 34 patients (33.66%) reported itchiness over the scar (1.47±2.53). One subject reported extreme pain over the scar, and 1 subject reported extreme itchiness.

Table 3.2

The scores on different items of Vancouver Scar Scale

Vancouver Scar Scale items	Mean of score
Pigmentation	2.71±0.54
Height	1.45±0.54
Vascularity	1.82±0.52
Pliability	1.78±0.52
Total score	7.54 ±1.16

Objective characteristics of post-surgical hypertrophic scar

There was significant difference among all color parameters (L*,a* and b*) between the hypertrophic scar and normal skin, with lightness (*df* = 100, t = -19.36, p<0.01), redness (*df* = 100, t = 15.74, p<0.01) and yellowness (*df* = 100, t =11.48, p<0.01). The hypertrophic scar was more reddish and darker but less yellow than normal skin. The scar thickness measured by TUPS was 4.91mm (SD = 1.03), the mean length was 17.26cm (SD = 7.18cm), and the widest part of the scar was 4.80mm (SD = 4.74mm).

Result of the prospective randomized clinical trial

Demographic data

A total of 101 subjects were recruited: 40 males and 61 females with a mean age of 56.78±20.73 years. The hypertrophic scars were mostly caused by total knee replacement and upper limb surgery. The discontinuance of the follow-up (dropout rate) was 26.73%, thus 74 subjects (73.27%) completed the whole study. (Table 3.3 and Figure 3.3)

Table 3.3

Causes of hypertrophic scar formation

Causes	Frequency	Percentage
Total knee replacement	58	57.4%
Total hip replacement	13	12.9%
Upper limb surgery	26	25.7%
Others	4	4.0%
Total	101	100%

The patients with bilateral limbs surgery, their scars would be undergone the same group of treatment to avoid misleading the patients to follow treatment protocol. Subjects were randomly allocated into 3 experimental groups and 1 control group. There were 23 subjects allocated into the control (CO) group, 28 to the pressure therapy (PT) group, 26 to the silicone gel sheeting (SG) group and 24 to the combined therapy

(CT) group. The distribution of subjects in terms of age and gender was as follows.

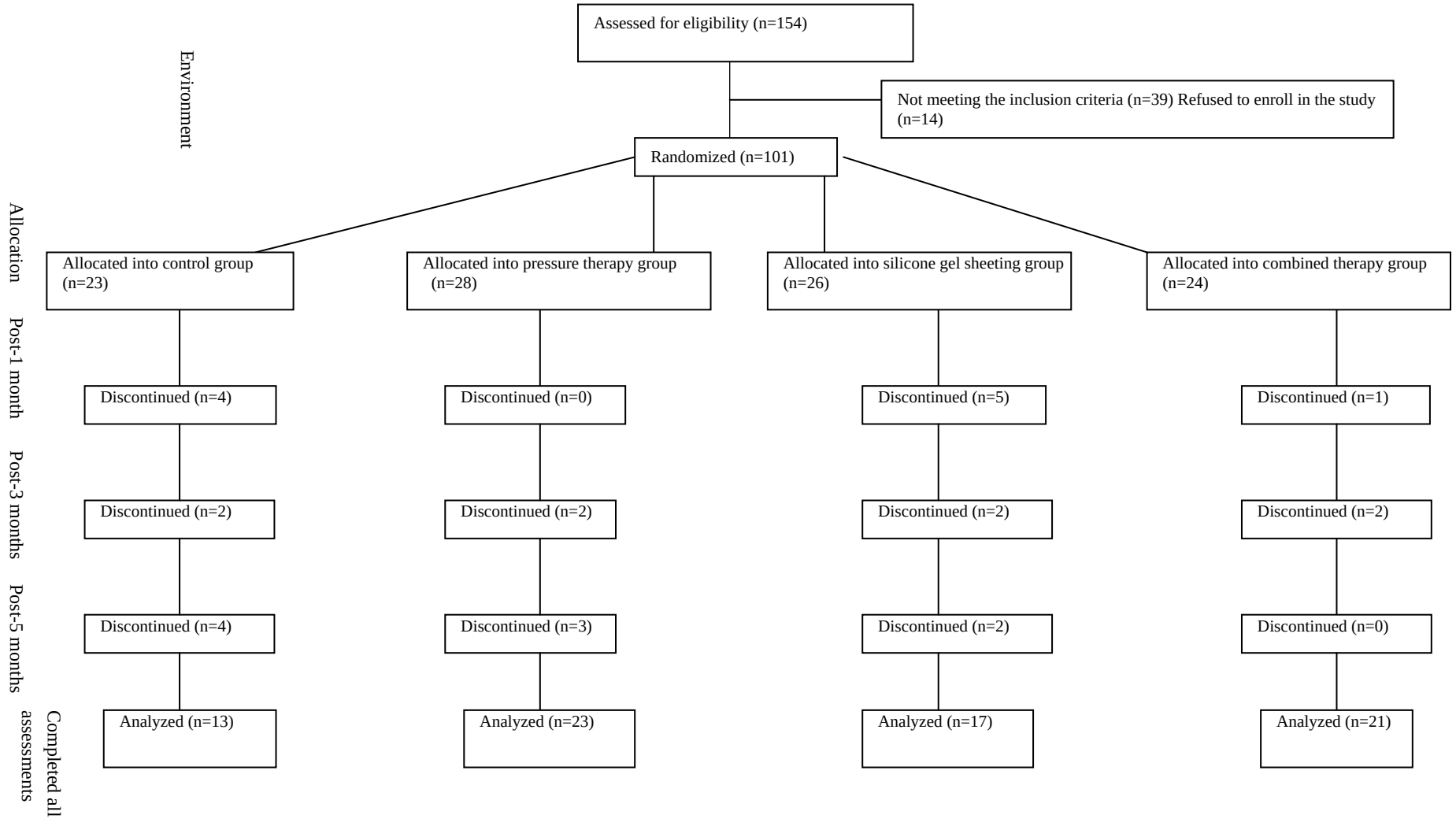
Table 3.4

Age and gender distribution among the 4 groups

Groups	Age (Years)	Gender
Control group (n = 23)	69.30±13.62	Male: 3
		Female: 20
Pressure therapy group (n = 28)	45.21±22.90	Male: 15
		Female: 13
Silicone gel sheeting group (n = 26)	61.62±15.81	Male: 6
		Female: 13
Combined therapy group (n = 24)	53.04±21.06	Male: 13
		Female: 11

Figure 3.2.3

Consort diagram showing the flow of participants



Demographic difference among 4 groups

Results of the one-way ANOVA analysis showed that there were significant differences among the 4 groups in age with $F(3,8296.51) = 7.74$, $p < 0.01$. The Tukey post-hoc comparison analysis showed that the PT group was significantly younger than the CO group (mean difference = 24.09, $p < 0.01$) and the CT group (mean difference = 24.09, $p = 0.21$).

The Kruskal-Wallis analysis using one-way analysis of variance (ANOVA) was used to compare the frequency of gender differences among the 4 groups. There was significant difference among the 4 groups ($r = 11.35$, $p = 0.010$). The Mann-Whitney U test for post-hoc comparison showed a significant difference between the CO and PT groups ($U = 191.5$, $p = 0.003$) and the CT group ($U = 162.5$, $p = 0.003$) after Bonferroni correction ($0.05/6 = 0.0083$). There were fewer male subjects in the CO group than in the PT and CT groups.

Baseline measurements

One-way analysis of variance (ANOVA) showed that there was significant difference in the pliability score of the Vancouver Scar Scale (VSS) and the Δyellowness measurement among the 4 groups, with $F(3,97) = 4.40$, $p = 0.01$, and $F(3,97) = 3.01$, $p = 0.034$. Tukey's post-hoc comparison analysis showed that the VSS

pliability score of the CO group (Mean = 1.48, SD = 0.51) was significantly lower than that of the CT group (Mean = 1.78, SD = 0.52), F(1,97) = 0.48, p = 0.01, and the Δyellowness of the CO group (Mean = 17.11, SD = 17.15) was significantly higher than that of the PT group (Mean = 32.71, SD = 22.42), F(1,97) = 15.61, p = 0.036.

The scars of the subjects in the CO group were relatively softer and less yellowish when compared with those of the CT and PT groups respectively.

Table 3.5

Baseline measurements of scar thickness and scar pliability among the 4 groups

Variables	**Group**	**Mean±SD**	**Min**	**Max**	**F**	**p-value**
Scar thickness measured by TUPS	control	4.57±0.48	3.40	5.40	2.46	0.07
	pressure therapy	5.24±1.28	3.83	9.49		
	silicone gel sheeting	4.95±0.80	3.07	6.40		
	combined therapy	4.71±0.98	3.60	8.13		
1st assessment: pliability score of VSS	control	1.48±0.51	1	2	4.04	0.01
	pressure therapy	1.82±0.55	1	3		
	silicone gel sheeting	1.85±0.47	1	3		
	combined therapy	1.96±0.47	1	3		

Table 3.6

Baseline measurement of color parameters among the 4 groups

Color parameters	**Group**	**Mean±SD**	**Min**	**Max**	**F-value**	**p-value**
Δ*L	control	14.72±8.37	-1.88	42.59	1.00	0.31
(Lightness)	pressure therapy	17.27±7.52	4.51	32.29		
	silicone gel sheet	13.35±7.65	2.46	41.34		
	combined therapy	15.77±7.71	2.43	33.93		
Δ*a	control	154.86±136.79	-13.68	456.00	0.46	0.33
(Redness)	pressure therapy	109.94±123.31	-5.48	435.29		
	silicone gel sheet	96.17±95.62	-6.95	434.74		
	combined therapy	106.05±152.72	-16.44	707.34		
Δ*b	control	17.11±17.15	-16.15	41.66	3.88	0.034
(Yellowness)	pressure therapy	32.72±22.42	70.99	26.03		
	silicone gel sheet	20.25±23.16	-18.44	67.03		
	combined therapy	26.52±16.69	1.19	61.76		

Table 3.7

Baseline measurement of VAS pain and itchiness among the 4 groups

Variables	**Group**	**Mean±SD**	**Min**	**Max**	**F**	**p-value**
1st assessment: visual analogue scale of itchiness	control	1.23±2.90	.00	10.0	1.41	0.24
	pressure therapy	0.98±1.95	.00	9.40		
	silicone gel sheeting	1.38±2.29	.00	7.30		
	combined therapy	2.35±2.92	.00	7.30		
1st assessment: visual analogue scale of pain	control	1.51±2.76	.00	9.50	1.15	0.33
	pressure therapy	2.21±2.69	.00	8.50		
	silicone gel sheeting	2.06±2.76	.00	10.0		
	combined therapy	2.98±2.73	.00	7.60		

Types of surgeries performed among the 4 groups of subjects

Chi-square analysis was used to compare the number of types of surgery among four groups. There was a significant difference among groups ($r = 17.74$, $p = 0.38$) , meaning that types of surgery were not evenly distributed among the four groups.

Table 3.8

Number of types of surgery among the 4 groups

	Total knee replacement (TKR)	**Total hip replacement (THR)**	**Surgery in forearm (SF)**	**Others**
Control group	19	2	2	0
Pressure therapy	11	3	11	3
Silicone gel sheeting	16	5	4	1
Combined therapy	12	3	9	0

Scar conditions among patients with different surgeries

One-way analysis of variance (ANOVA) showed that there was only significant difference in scar color parameters in terms of ΔL*, $F(3, 97) = 5.45$, $p<0.01$, and Δb*, $F(3.97) = 5.08$, $p=0.03$. Tukey post-hoc comparison showed that the significant difference was between other surgeries and all types of surgeries (total knee replacement, total hip replacement and surgery in forearm) in ΔL* and Δb*. The scars generated by other surgeries appeared to be darker and less yellownish than all types of surgery.

Table 3.9

Turkey post-hoc comparison of ΔL* and Δb* with mean difference and p-value

Variables		**Mean difference (I-J)**	**p-value**
ΔL*	Other (I) – TKR (J)	0.12	0.01
	Other (I) – THR (J)	0.15	<0.01
	Other (I) – SF (J)	0.15	<0.01
Variables		**Mean difference (I-J)**	**p-value**
Δb*	Other (I) – TKR (J)	0.10	<0.01
	Other (I) – THR (J)	0.11	0.01
	Other (I) – SF (J)	0.11	<0.01

Scar thickness after intervention (TUPS)

A mixed model of two-way repeated ANOVA revealed that there was significant difference among the four groups over a 5-month intervention with F (9,236) = 2.69, and p = 0.005. (Figure 3.4). Bonferroni correction was adopted in Tukey's post-hoc comparison analysis (0.05/9 = 0.0056). The result indicated that after one month, the CO group's scars were thicker (Mean = 5.10, SD = 0.15) than those of the PT group (Mean = 4.78, SD = 0.11), F (1,236) = 15.33, p < 0.001, and the SG group (Mean = 4.70. SD = 0.11), F (1,236) = 10.44, p = 0.001. Furthermore, in the 3-month intervention period, the scar thickness of the PT group was continuously and significantly reduced (Mean = 4.49. SD = 0.12) when compared with that of the CO group (Mean = 4.67, SD = 0.16), F (1,236) = 8.34, p = 0.004. No significant difference was shown between the CT and CO groups.

Figure 3.3.1

Scar thickness among the four groups of subjects over the five-month intervention

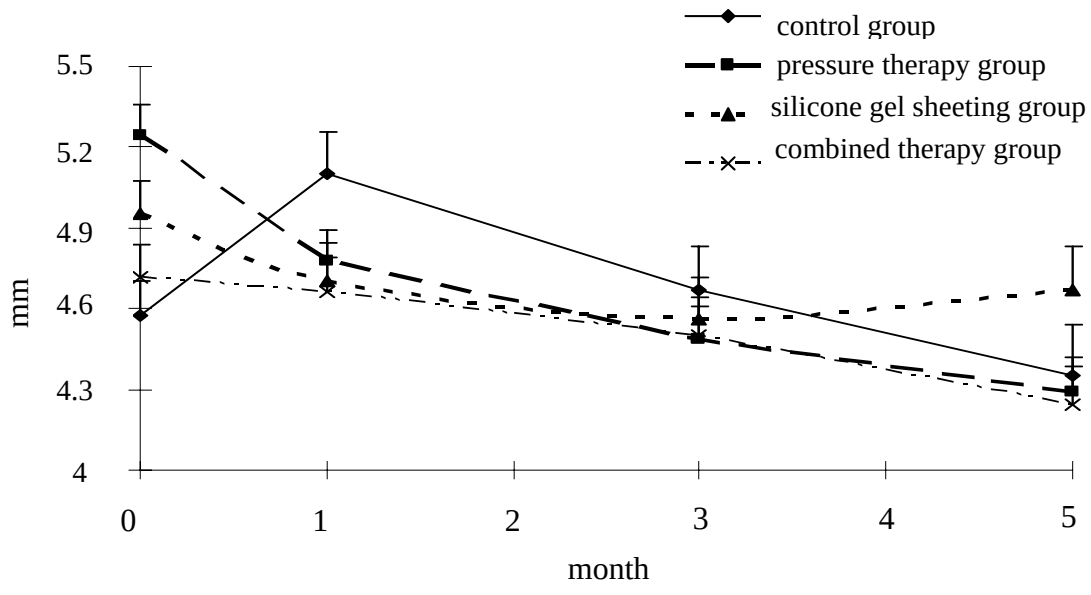


Table 3.91

Scar thickness among the four groups of subjects over the five-month intervention

Assessment	**Groups**	**Mean±SD**	**CV(%)**
Initial	Control group	4.57±0.13	2.84
	Pressure therapy	5.24±0.11	2.10
	Silicone gel sheeting	4.95±0.12	2.42
	Combined therapy	4.72±0.12	2.54
Post-1-month	Control group	5.10±0.15	2.94
	Pressure therapy	4.78±0.11	2.30
	Silicone gel sheeting	4.70±0.14	2.98
	Combined therapy	4.66±0.13	2.79
Post-3-month	Control group	4.67±0.16	3.42
	Pressure therapy	4.49±0.12	2.67
	Silicone gel sheeting	4.56±0.15	3.29
	Combined therapy	4.50±0.13	2.89
Post-5-month	Control group	4.35±0.19	4.37
	Pressure therapy	4.29±0.13	3.03
	Silicone gel sheeting	4.67±0.16	3.43
	Combined therapy	4.25±0.14	3.29

Scar pliability after intervention (VSS)

The mixed model of two-way repeated ANOVA resulted in a significant difference among the four groups over 5 months, with $F(9, 236) = 3.48$, $p < 0.01$.Tukey's post-hoc comparison analysis showed a significant difference after Bonferroni alpha levels adjustment of 0.0056. It was revealed that the CO group's scars (Mean = 1.69, SD = 0.10) were harder than those of the SG group (Mean = 1.56, SD = 0.099) after 1 month, $F (1, 236) = 12.36$, $p < 0.001$. After 3 months, the scars of the SG group (Mean = 1.38, SD = 0.11) were softer than those of the control group (Mean = 1.58, SD = 0.11), $F(1,236) = 8.55$, $p = 0.004$, and pliability improved continuously through the post-5 month measurement (Mean = 1.38, SD = 0.11) when compared with the CO group (Mean = 1.58, SD = 0.11), $F (1,236) = 13.68$, $p < 0.001$. The scars of the PT group (Mean =1.03,SD =0.09) were significantly softer than those of the CO group (Mean = 1.58, SD = 0.11), $F(1,236) = 18.29$, $p < 0.001$ after 5 months.

The scars of the CT group were significantly softer than those of the CO group at the 1-month (Mean = 1.39, SD=0.088), $F(1,236) = 13.77$, $p < 0.001$ and 5-month time points (Mean = 1.13, SD = 0.094), $F(1,236) = 14.40$, $p < 0.001$.

Figure 3.3.2

Scar pliability among the four groups of subjects over the five-month intervention

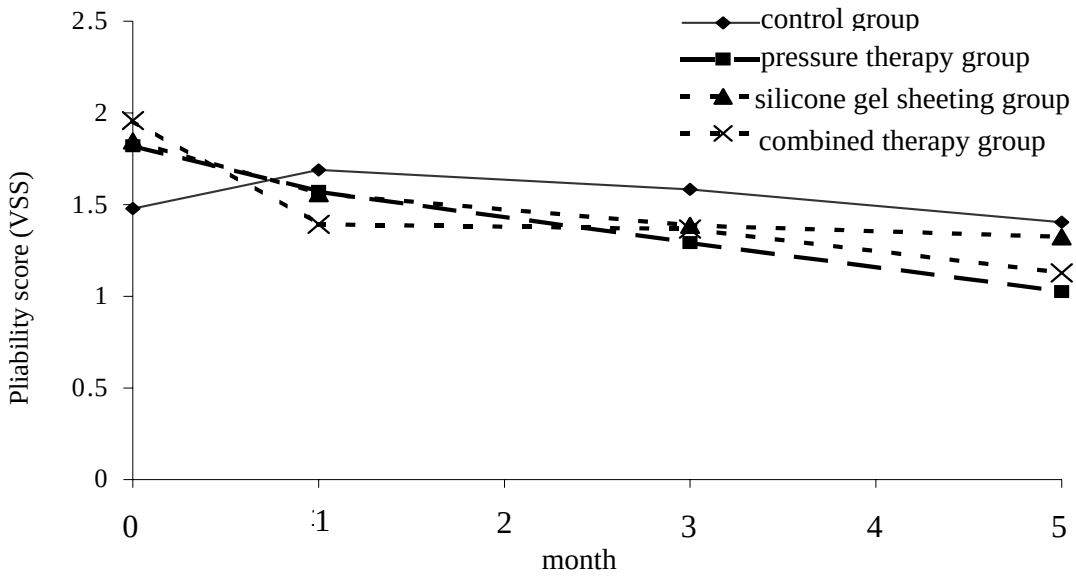


Table 3.92

Scar pliability among the four groups of subjects over the five-month intervention

Assessment	**Groups**	**Mean±SD**	**CV(%)**
Initial	Control group	1.48±0.086	6.01
	Pressure therapy	1.82±0.078	4.29
	Silicone gel sheeting	1.85±0.081	4.38
	Combined therapy	1.96±0.084	4.29
Post-1-month	Control group	1.69±0.10	5.92
	Pressure therapy	1.57±0.078	4.97
	Silicone gel sheeting	1.56±0.099	6.35
	Combined therapy	1.39±0.088	6.33
Post-3-month	Control group	1.58±0.11	6.96
	Pressure therapy	1.29±0.083	6.43
	Silicone gel sheeting	1.39±0.11	7.91
	Combined therapy	1.37±0.094	6.86
Post-5-month	Control group	1.40±0.13	9.29
	Pressure therapy	1.03±0.089	8.64
	Silicone gel sheeting	1.32±0.11	8.33
	Combined therapy	1.13±0.094	8.32

Scar color: difference in lightness (ΔL*)

Two-way repeated ANOVA showed no significant intercept of assessments and treatments in lightness change $F(9,236) = 1.54$, $p = 0.135$. The main effect of treatment and assessment did not yield any significant difference. A decreasing trend was noted in the PT group. The percentage difference dropped from 17.26% (initial assessment) to 15.03% (post-3 months) and 16.07% (post-5 months).

Figure 3.3.3

Scar color (lightness) among the four groups of subjects over the five-month intervention

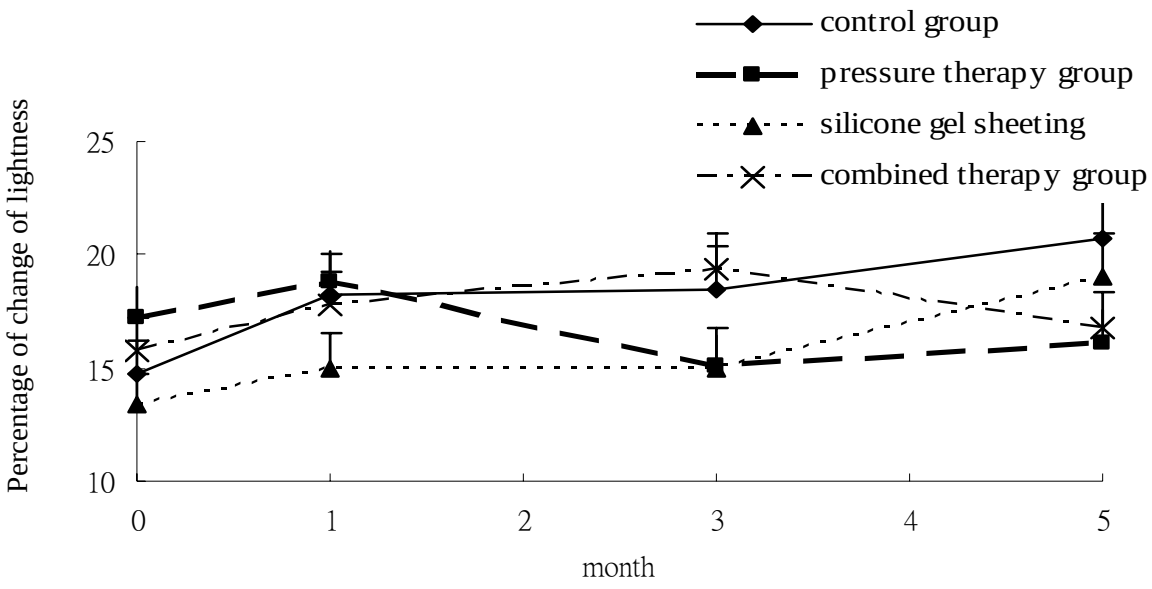


Table 3.93

Scar color (lightness) among the four groups of subjects over the five-month intervention

Assessment	**Groups**	**Mean±SD**	**CV(%)**
Initial	Control group	8.55±0.91	10.64
	Pressure therapy	9.98±0.82	8.22
	Silicone gel sheeting	7.85±0.85	10.83
	Combined therapy	9.32±0.89	9.55
Post-1-month	Control group	10.27±1.08	9.74
	Pressure therapy	10.72±0.82	7.64
	Silicone gel sheeting	8.78±1.04	11.84
	Combined therapy	11.09±0.93	8.39
Post-3-month	Control group	10.84±1.16	10.70
	Pressure therapy	8.89±0.87	9.79
	Silicone gel sheeting	8.98±1.10	12.25
	Combined therapy	11.62±1.02	8.78
Post-5-month	Control group	12.53±1.34	10.61
	Pressure therapy	9.67±0.94	9.24
	Silicone gel sheeting	12.02±1.17	9.73
	Combined therapy	10.62±1.02	9.60

Scar color: difference in redness (a*)

No significant difference in the main effect of treatments and assessments and no interaction effects were found, $F(9,236) = 0.527$, $p = 0.86$. The scars of the PT and CT groups showed a tendency to decrease. The PT group dropped from 92.86% (initial assessment) to 45.47% (post-5 months assessment), while the CT group dropped from 106.05% (initial assessment) to 67.2% (post-5 months assessment). The CO and SG groups remained in the high percentages of difference.

Figure 3.3.4

Scar color (redness) among the four groups of subjects over the five-month intervention

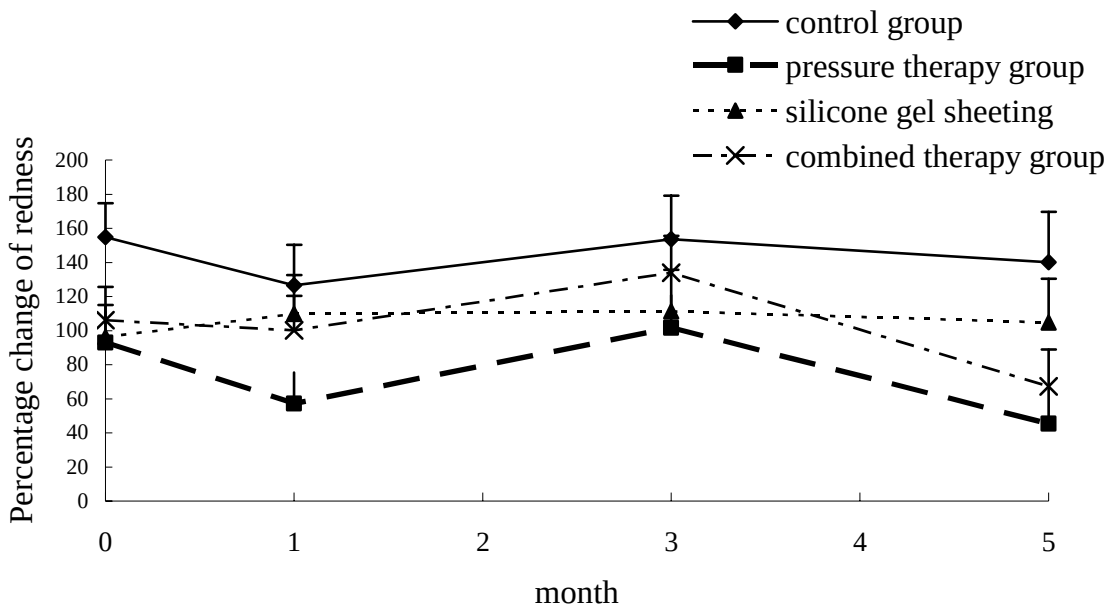


Table 3.94

Scar color (redness) among the four groups of subjects over the five-month intervention

Assessment	**Groups**	**Mean±SD**	**CV(%)**
Initial	Control group	3.27±0.34	10.40
	Pressure therapy	3.13±0.31	9.90
	Silicone gel sheeting	2.68±0.32	11.94
	Combined therapy	2.90±0.33	11.38
Post-1-month	Control group	3.16±0.41	12.97
	Pressure therapy	3.21±0.31	9.66
	Silicone gel sheeting	3.04±0.39	12.83
	Combined therapy	3.27± 0.35	10.70
Post-3-month	Control group	3.34±0.44	13.17
	Pressure therapy	3.12±0.33	10.57
	Silicone gel sheeting	3.30±0.42	12.72
	Combined therapy	3.31±0.39	11.78
Post-5-month	Control group	3.34±0.51	15.27
	Pressure therapy	2.64±0.36	13.64
	Silicone gel sheeting	3.36±0.44	13.10
	Combined therapy	2.97±0.39	13.13

Scar color: difference in yellowness (b*)

Two-way mixed model repeated ANOVA indicated no significant interaction of treatment and time, and the main effect of treatment or time. There were fluctuating changes among groups. The SG and PT groups yielded more to the yellowness of normal skin, and less difference was noted in the 3rd month. The difference of the SG group was reduced from 20.25% (initial assessment) to 13.29% (post-3 months assessment), while the PT group changed from 32.25% (initial assessment) to 22.10% (post-3 months assessment). The CT group still presented a great difference until the 3rd month, and increased difference was shown in the CO group.

Figure 3.3.5

Scar color (yellowness) among the four groups of subjects over the five-month intervention

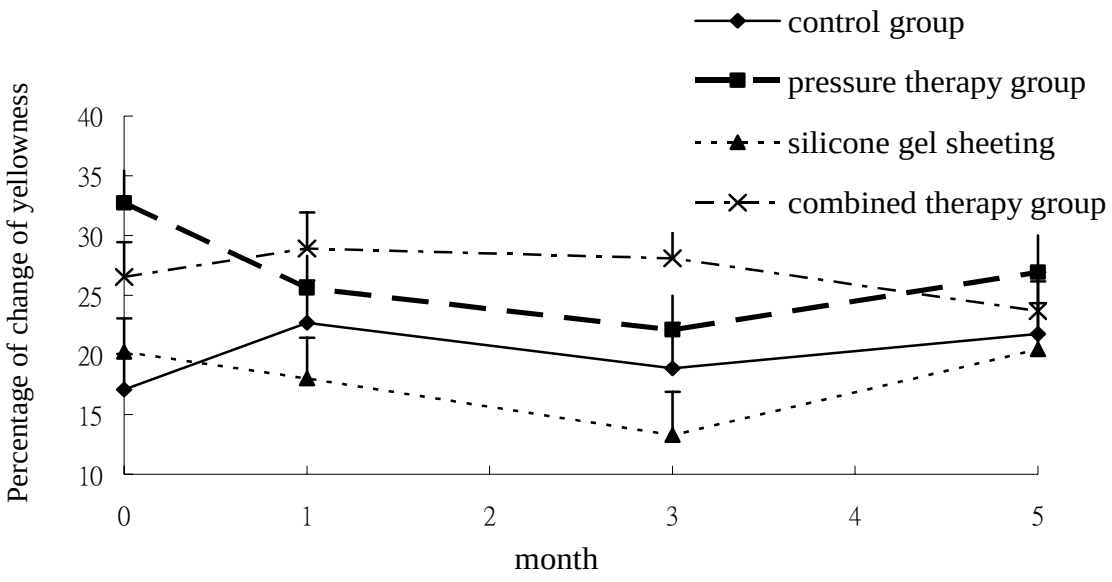


Table 3.95

Scar color (yellowness) among the four groups of subjects over the five-month intervention

Assessment	**Groups**	**Mean±SD**	**CV(%)**
Initial	Control group	2.24±0.48	21.43
	Pressure therapy	4.79±0.43	8.97
	Silicone gel sheeting	2.82±0.45	16.96
	Combined therapy	3.36±0.47	13.99
Post-1-month	Control group	3.20±0.57	17.81
	Pressure therapy	3.90±0.43	11.03
	Silicone gel sheeting	2.66±0.55	20.68
	Combined therapy	4.20±0.49	11.67
Post-3-month	Control group	2.53±0.61	39.53
	Pressure therapy	2.60±0.46	17.69
	Silicone gel sheeting	2.20±0.58	26.36
	Combined therapy	4.09±0.54	13.20
Post-5-month	Control group	3.13±0.71	22.68
	Pressure therapy	3.93±0.49	12.47
	Silicone gel sheeting	3.25±0.62	19.08
	Combined therapy	3.47±0.54	15.56

Pain measured by Visual Analogue Scale

No significant interaction was found in the two-way repeated ANOVA in mixed model, $F(9,236) = 1.30$, $p = 0.24$. No treatment effect was found, and the time was significantly different over the 5-month period, $F(3,236) = 35.84$, $p < 0.01$. All subjects in the SG group reported no pain after 1-month sheeting application. Tukey's post-hoc comparison revealed a difference between the initial assessment and all later assessments, $F(3,345) = 33.34$, $p < 0.01$. The VAS pain measurements post 1 (Mean = 0.46, SD =1.33), 3 (Mean = 0.17,SD = 0.78) and 5 months (Mean = 0.06, SD = 0.36) were significantly lower than in the initial assessment (Mean = 2.19, SD = 2.74).

Figure 3.3.6

The change of pain scores (VAS) among the four groups over the five month intervention

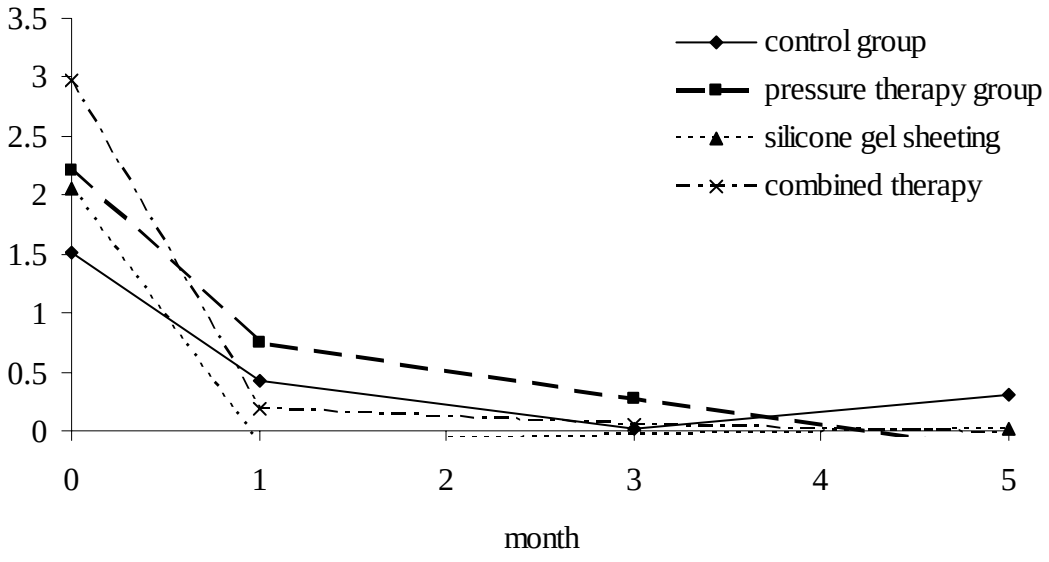


Table 3.96

The change of pain scores (VAS) among the four groups over the five month interventions

Assessment	**Groups**	**Mean±SD**	**CV(%)**
Initial	Control group	1.51±0.32	21.19
	Pressure therapy	2.21±0.29	13.12
	Silicone gel sheeting	2.06±0.30	14.56
	Combined therapy	2.98±0.32	10.74
Post-1-month	Control group	0.43±0.34	79.07
	Pressure therapy	0.74±0.29	39.19
	Silicone gel sheeting	0.00	0.00
	Combined therapy	0.19±0.32	168.42
Post-3-month	Control group	0.011±0.03	300.00
	Pressure therapy	0.27±0.31	114.81
	Silicone gel sheeting	0.00	0.00
	Combined therapy	0.045±0.04	88.89
Post-5-month	Control group	0.31±0.47	151.61
	Pressure therapy	0.16±0.33	206.25
	Silicone gel sheeting	0.00	0.00
	Combined therapy	0.02±0.04	200

Itchiness measured by Visual Analogue Scale

The main effect of time was indicated by the mixed model two-way repeated ANOVA $F(3,236) = 14.92$, $p < 0.01$. No interaction of treatment and time resulted, $F(9,236) = 14.92$, $p < 0.01$. It was found that no subjects in the SG group reported itchiness after 1-month intervention. The Tukey post-hoc comparison showed that the difference was between initial assessment and all post assessments, $F(3, 345) = 14.32$, $p < 0.01$. The VAS itchiness reports post 1 (Mean = 0.41, SD = 1.28), 3 (Mean = 0.20, SD=0.79) and 6 months (Mean = 0.13, SD = 0.69) were significantly lower than the initial assessment (Mean = 1.47, SD = 2.53).

Figure 3.3.7

The change of itchiness scores (VAS) among the four groups over the five month intervention

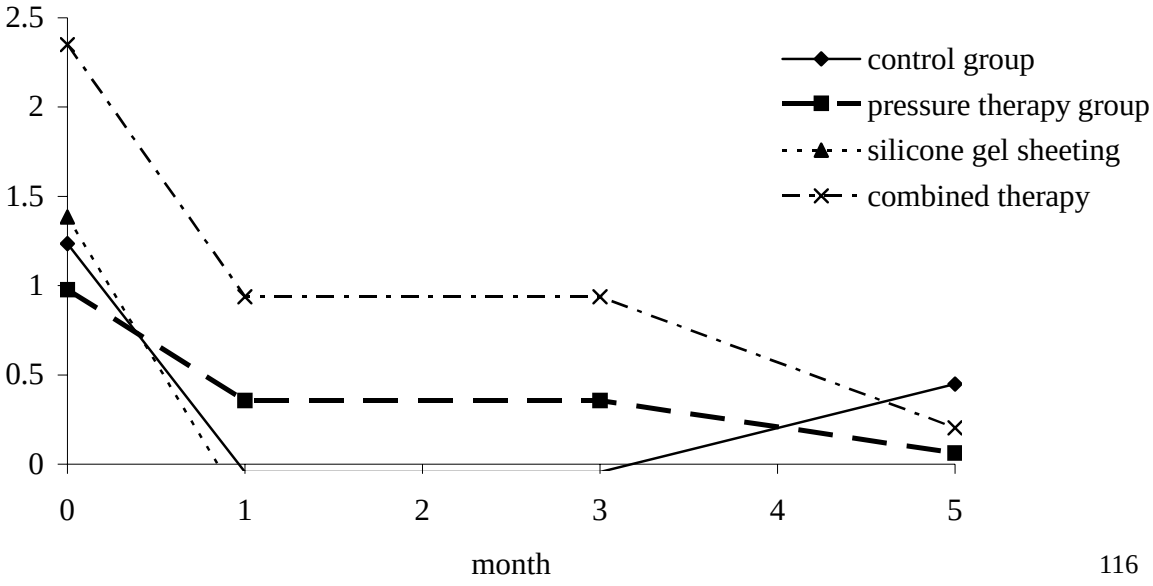


Table 3.97

The change of itchiness scores (VAS) among the four groups over the five month intervention

Assessment	**Groups**	**Mean±SD**	**CV(%)**
Initial	Control group	1.24±0.31	25.00
	Pressure therapy	0.98± 0.28	28.57
	Silicone gel sheeting	1.39±0.30	21.58
	Combined therapy	2.35±0.31	13.19
Post-1-month	Control group	0.18±0.37	205.50
	Pressure therapy	0.36±0.28	77.78
	Silicone gel sheeting	0.00	0.00
	Combined therapy	0.94±0.32	34.04
Post-3-month	Control group	0.18±0.40	222.22
	Pressure therapy	0.254±0.30	120.00
	Silicone gel sheeting	0.00	0.00
	Combined therapy	0.45±0.34	77.56
Post-5-month	Control group	0.41±0.46	112.20
	Pressure therapy	0.062±0.33	550.00
	Silicone gel sheeting	0.00	0.00
	Combined therapy	0.20±0.34	170.00

Follow up of drop-out cases

The dropout rate was high, with 26.73% (27 out of 101) quitting the follow-up assessment due to the episode of SARS. Most patients are reluctant to return to the outpatient centers for follow up assessment. A phone interview was conducted to find out the reason for the discontinuity: 22 subjects were contacted and 5 had moved or given the wrong contact number. Of the 22, 63.3% (14 subjects) were satisfied the scar condition of no pain or itchiness and had no concern with regard to the cosmetics issue, and 18.2% (4 subjects) were unable to undergo follow-up checking due to work and schooling. 13.6% (3 subjects) found it difficult to get access the hospital from home using public transportation. 9.1% (2 subjects) suffered a subsequent injury and was readmitted to hospital for surgery. 4.5% (1 subject) found that he/she was allergic to the silicone gel sheeting, and quitted this study. In this study, most subjects were elderly. Without their relatives accompanying them, most were unable to attend the hospital for treatment regime and assessment.

Summary of results

In summary, the scars in the control group (CO) became worse after one month of study. Subjects in the control group had a significantly thicker scar tissue when compared with subjects in the pressure therapy (PT) and silicone gel sheeting groups (SG). The scar tissues looked more reddish and harder especially in the first month after intervention. Subjects in the SG group did not complain of any pain or itchiness after intervention for one month.

Three months after the intervention, the PT group still showed greatest improvement in scar thickness, and SG group continuously showed improvement in scar pliability. Subjects in the control group did not show any significant progress when compared to the SG or PT group. At the five month assessment, the pliability of SG and CT group were shown to be better than CO group. All groups had similar scar thickness after the five month of intervention. and scar thickness improvement was not found in any groups. There was no group difference in the scar pigmentation including redness, lightness and yellowness. There showed a decreasing trend of redness and lightness in the PT group while the SG group showed a decreasing trend of yellowish. This study showed that PG appeared to be more effective than the SG group but the combined group did not yield the best results on scar maturation. Further discussion on the results will be described in the next chapter.

Discussion of prevalence of hypertrophic scars

From our study, the prevalence rate of hypertrophic scar among the Chinese population was 74.67%. There was 115 out of 154 subjects found to have hypertrophic scar problems after one month of surgery based on our screening criteria stated earlier. When compared to the western studies, the range of prevalence of hypertrophic scar was reported to be 5% to 63% among all injured Caucasian and black pigmented population after burns, scald, trauma and surgery (Alhady & Sivnantharajah, 1969; Bombaro et al., 2003; Deitch, Wheelahan, Rose, Clothier, & Cotter, 1983; Munro, 1995), our findings indicated a much higher percentage of hypertrophic scar formation among the Chinese population. The present findings supported the previous observation that people with pigmentation were more prone to develop hypertrophic scar. The rate of hypertrophic scar formation are expected to be higher on burn scars, as the surface area was larger with deeper injuries. There might be complications during the healing process when compared with surgical scars. Second-degree deep burn and third-degree burn were also reported to develop hypertrophic scar (Lewis & Sun, 1990).

Part I: Screening assessment of hypertrophic scar formation

Most patients develop hypertrophic scars after surgery, but there seems little mechanisms to formally assess the scar conditions (Alhady & Sivnantharajah, 1969;

Bombaro et al., 2003; Elliot, Pearce, & Ree, 1985). In this study, the Vancouver Scar Scale was used only for screening of scar conditions. (Sullivan, Smith, Kermode, McIver, & Courtemanche, 1990). It served as a guideline to identify early hypertrophic scars in terms of thickness, vascularity, pigmentation and pliability. Normal wound healing of surgical scar would take around 21 days (Elliot et al., 1985). In this study, we started the screening process one month after the surgery using the VSS to rate the scar on its thickness, pliability, and abnormal pigmentation.

Physical characteristics of hypertrophic scars

For years, clinicians have assessed scar progress using the Vancouver Scar Scale (VSS) (Sullivan et al., 1990). However, the VSS has been criticized as too subjective and unable to quantify scar maturation (McOwan, Machermid, & Wilton, 2001; Powers, Sarker, Goldgof, Cruse, & Tsap, 1999). It might be useful mainly for screening and identification of scar problems but it might not be sensitive to record the process of scar maturation. Previous literature reported that VSS demonstrated low inter-rater reliability, and was unable to track the change of hypertrophic scar in a short period of time. In this study, the scars were assessed on their pigmentation and thicknees using the spectrocolorimeter and TUPS.

From the data collected from the spectrocolorimeter, the hypertrophic scars

appeared to look more reddish and pale, and less yellowish when compared to the adjacent normal skin. Results of the study did not indicate significant changes on scar conditions even with both silicone gel or pressure garment. The pigmentation of the scar seemed to be a major problem among the Chinese subjects.

The mean scar thickness revealed among the subjects was 4.82mm (normal skin thickness is less than 3 mm). Some scars were firm and tough on palpation. More than 40% of patients reported pain and itchiness 1 month after surgery. Early intervention should therefore be started to minimize cosmetic problems and the effect of hypertrophic scars on the skin. There was little follow-up consultation to examine the scar conditions. Patients also regarded the “scar” as showing signs of normal wound healing, and often accepted the unsightly appearance of the thick and reddish scar. Itchiness and pain due to the humid and hot climate were common, and some patients would consult the medical services only when the scar became extremely hard and raised. However, it would prolong the conservative management and surgical excision may be needed (Mafong & Ashinoff, 2000).

Gender and age difference in prevalence rate of hypertrophic scars

Some studies reported that there was a gender difference in the incidence rates of hypertrophic scar formation. A study on a group of North Europeans reported a

difference between males (24%) and females (53%) (Elliot et al., 1985). However, another study on the population with darker pigmentation indicated that there was no difference between the male and female patients (Munro, 1995). Our study demonstrated similar result that the incidence rate was more or less the same between the female (76.74 %) and male patients (72.05%).

The subjects recruited in this study were mostly elderly, with a mean age of 57.35 (SD = 19.74) years. In a previous study, it was reported that the chance of the elderly developing hypertrophic scars was very low because of their slow metabolc rate and the fact that they have less tensile strength over their skin (Oluwasanmi, 1974; Rockwell, Cohen, & Ehrlich, 1989). However, our study found that there was a relatively high prevalence of scars for this elderly group. There is a need to further study whether age is regardless to scar formation among Chinese population, and the mechanism of scar formation.

In summary, the Chinese population appeared to have a higher tendency to develop the hypertrophic scar. The surgical scars could become more severe without early intervention (Figure 3.4.1 and 3.4.4). Early treatment of hypertrophic scars is deemed necessary to avoid excessive surgical or rehabilitation costs on the late complications of hypertrophic scars. In this study, limitations were found. The subjects recruited were mostly elderly, and scar formation was not fully investigated in various age groups.

There was an uneven distribution of types of surgeries among the four group and the number of subjects with upper limb extremity injuries was smaller than those with surgeries of the lower limb extremities. Location did not seem to be the main factor leading to hypertrophic scar formation in our findings. However, it was observed that hypertrophic scars developed on muscles with high frequency and power of contraction. To gain a better understanding of the pattern of hypertrophic scar formation, it is essential to conduct an epidemiological study exploring the cellular change and mechanical base to hypertrophic scar formation, such as the collagen change and the skin tension. It is to yield more quantitative information with more biomechanical details.

Figure 3.4.1

A screened scar 30 days after stitch removal

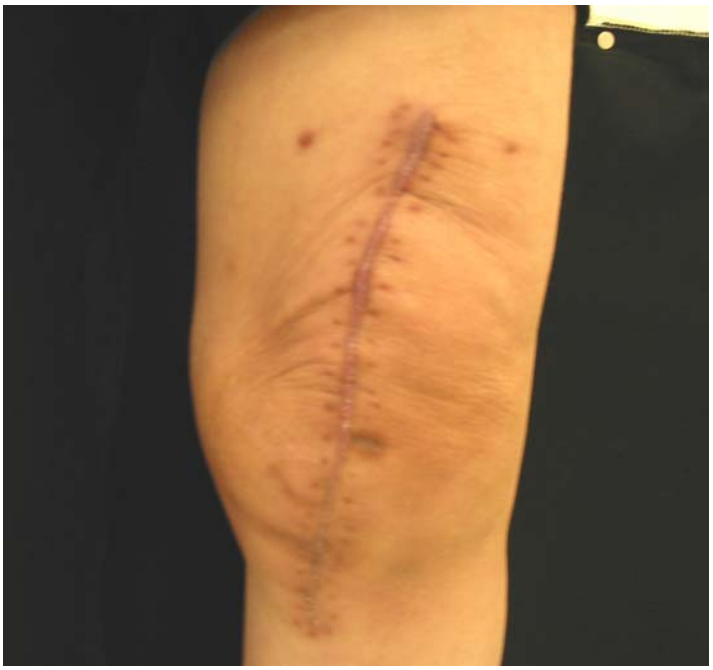
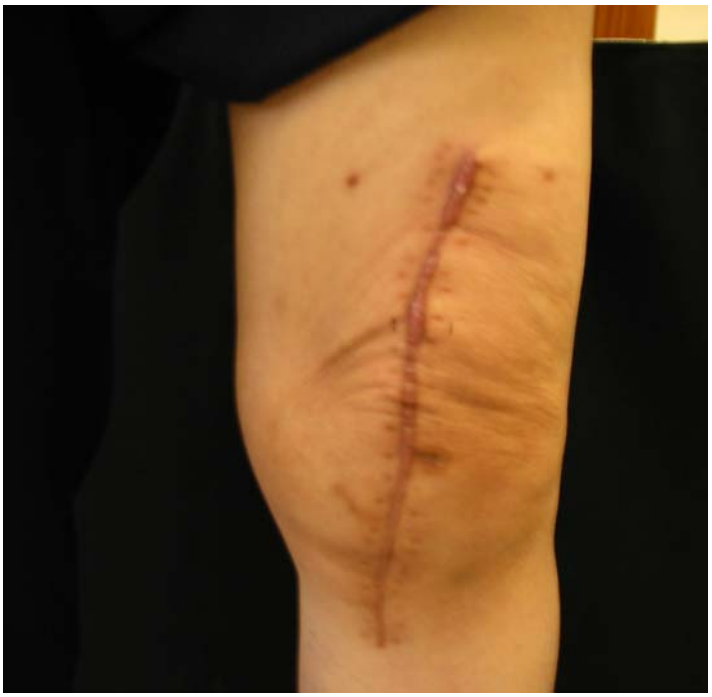


Figure 3.4.2

The same scar after 1-month time



Discussion of the prospective randomized clinical trial among 4 groups on post-surgical hypertrophic scars

The surgical scars became red and raised around 30 days after removal of stitches. The post-surgical hypertrophic scars did not only create any cosmetic disturbance, but also pain and itchiness. Pressure therapy and silicone gel sheeting were commonly prescribed to patients with hypertrophic scars. Reviewing the research mentioned in the article published in BURNS (2002) titled “International clinical recommendation scar management” (2002) and the literature related to these conservative treatments, it was found that no randomized clinical trial with objective measurement had been conducted to investigate the effect of pressure therapy or silicone gel sheeting. Silicone gel sheeting was recommended by the panel as the most effective therapy used to control hypertrophic scars (Mustoe et al., 2002).

The review highlighted some of the main problems in research design of most of the studies related to scar management. These problems include heterogeneity of subjects in terms of ethnicity and severity of the injuries, lack of a control group and no long-term follow up after the intervention, and not using objective outcomes. This present study was therefore designed to address these problems by adopting a randomized clinical trial study design, which was ranked as the highest level in evidence-based practice for demonstrating a treatment effect (Chan, Lee, Li-Tsang, &

Lam, 1999). Furthermore, our study had selected a group of homogenous Chinese subject with similar surgical procedures on the skin such that the results could be comparable. In addition, we had introduced the spectrocolorimeter and TUPS as objective outcome measures on scar pigmentation and thickness. The interventions were also controlled by using three treatment group and one control group In this study, the schedule of assessment was assigned for 5-month time, as previous studies showed that surgical scars would take 6-month time for recovery (Bayat, McGrouther, & Ferguson, 2003; Chen, Tsai, Yeh, Wang, & Tang, 2001; Dollon, Dunn, Bender, & Silver, 1985) (Bayat, McGrouther, & Ferguson, 2003; Chen, Tsai, Yeh, Wang, & Tang, 2001; Dollon, Dunn, Bender, & Silver, 1985). If the period of intervention is standardized within six months, wound strength and collagen would be similar as the structure of normal skin. It was believed that scar maturation would be accelerated under intervention; therefore 5-month time assessment was designed.

Effect of pressure therapy on hypertrophic scar

From our study, results indicated that the effect of pressure therapy was significant on reducing the thickness of the scars (Figures from 3.5.1 to 3.5.4). There were also changes in the pigmentation and the scar became less shiny and purplish. The treatment effects appeared to occur within the first month after applying pressure therapy on the

subjects. Such effects continued to occur in the 3rd month, and the pliability was significantly improved in the 5th month follow up when compared with control group.

As this study is the first randomized controlled trial in interventions for hypertrophic scars, a direct comparison of its results with other studies was not possible. Nevertheless, the comparison with other case studies or single-group studies on pressure therapy would be possible. Previous studies supported the effectiveness of pressure therapy as a conservative treatment for hypertrophic scars (Berry et al., 1985; Cheng et al., 2001; Garcia-Valasco, Ley, Mutch, Surkes, & Williams, 1978; Giele, Currie, Wood, & Hansen, 1995; Rose & Deitch, 1983; Staley & Richard, 1997). Cheng et al. attempted to use ultrasound to measure the thickness of the scars during pressure therapy intervention. The pressure of their treatment protocol was produced by taken 5% to 7% on the lycra of tensile strain. In their findings, there was a significant correlation between the thickness score of VSS and the ultrasound measurement, of which the improvements were noted over 1 to $4^1/_2$ years. They further suggested that pressure therapy would take more than 1 year to bring the therapeutic effect on the burn and scald scars. In our study, the intervention lasted only for six months but the effect was found. It might be due to the difference in scar severity on surgical and burn scar. Burn scar may take longer period to mature. Kerckhove et al's study (2005) showed that a high pressure of pressure therapy group (Mean = 19.75 mmHg, SD = 3.55 mmHg)

improved the scars in terms of erythema and thickness measurement for 3-month time. The pressure of PT group in our study was produced by taken 10% tensile strain on the lycra and 9mm padding. The unique practice of extra 9mm padding usage in Hong Kong was able to improve scar thickness within 3 months. Pressure to be regulated during the intervention was an important indicator for success.

In our study, the pressure of pressure therapy was not recorded during the treatment interphase mainly because of lack of equipment to monitor pressure accurately (Chan, Lau, Sathappan, & Mohd, 2005; Kerckhove et al., 2005; McOwan, Machermid, & Wilton, 2001). Further study on the amount of pressure generated onto the skin tissue and its effect should be conducted to find out their relationships.

The mechanism of the effects of pressure therapy on scar is still not fully understood. The most common hypothesis is that pressure exerted by the external pressure reduces the blood supply to the fibroblasts which are the key substance for re-structuring of the collagen alignment, resulting in acceleration production of collagenases which mediates scar remodeling (Costa et al., 1999; Kischer, 1973; Kischer, 1974; Kischer, 1975; Kischer & Bailey, 1972; Kischer, Shetlar, & Shetlar, 1975; Kischer, Thies, & Chvapil, 1982; Reno, Grazianetti, & Cannas, 2001). Further studies may be needed to find out its mechanisms.

An interesting finding of the present study was that there were no significant

differences in the scar pigmentation despite the thickness was significantly reduced in the 1st and the 3rd months follow up. The only differences observed were changes in ΔL*and Δa*, suggesting that the scars were less hyperaemic and shiny. Previous studies using Laser Doppler indicated that the redness of the scar was highly correlated to its vascularity (Clark, Leung, Cheng, & Leung, 1996; Ehrlich & Kelley, 1992; Hosoda, Holloway, & Heimbach, 1986). Other study also showed that the redness representation was proportional to its vascularity (Barachini, Vezzoni, Palombo, Franzoni, & Bigalli, 2004; Hosoda et al., 1986). Furthermore, Berry et al.'s study (1985) revealed that the decreased oxygen tension of the hypertrophic scar in pressure therapy would reduce the redness. This implied that the compression of pressure therapy modulated the vascularity of the hypertrophic scar under compression but when the PG is removed, the vascularity returns. The actual mechanism involved in the whole scar remodeling process remained unknown. In the study of Costa et al. (1999), scars that had undergone pressure therapy were found to have a structural pattern similar to that of normal skin, in which fibers were in parallel alignment with the normal skin with fewer fibers deposited than the non-treated scars, therefore the scars became much thinner and softer in appearance (Costa et al., 1999).

The subjects who received pressure therapy reported more pain and itchiness than those in the control group in the 3rd month. They further indicated that the pain and

itchiness was mostly felt when the pressure tube had been removed. Bell et al. (1988) offered an explanation to this phenomenon that the pain and itchiness might be due to the flush of blood flown to the hypertrophic scar once when the PG was removed from the scar. The mechanism mediating this perhaps was the initiation of the A and C afferent fibers by the flush of blood which would increase the histamine of the inflammatory wound, and ultimately result in an increase in the pain and itchiness of the scar.

Figure 3.5.1

The scar over knee of PT group in the initial assessment

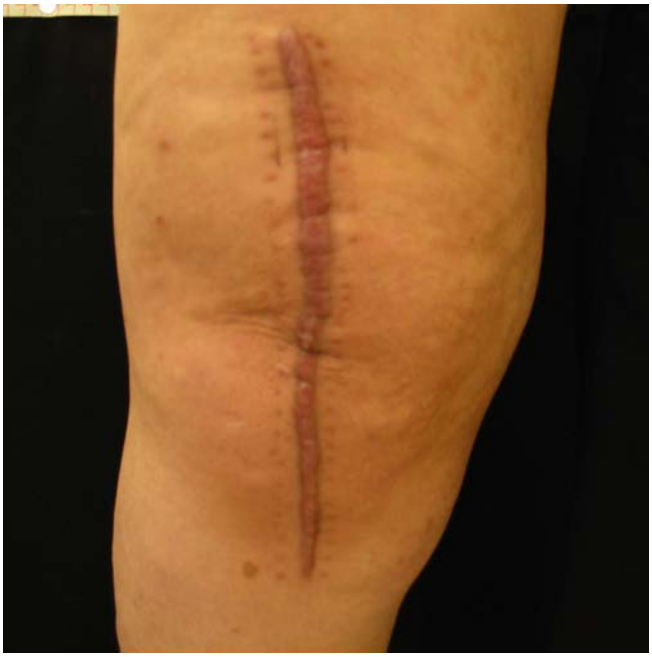


Figure 3.5.2

The scar over knee of PT group in the post-1-month assessment

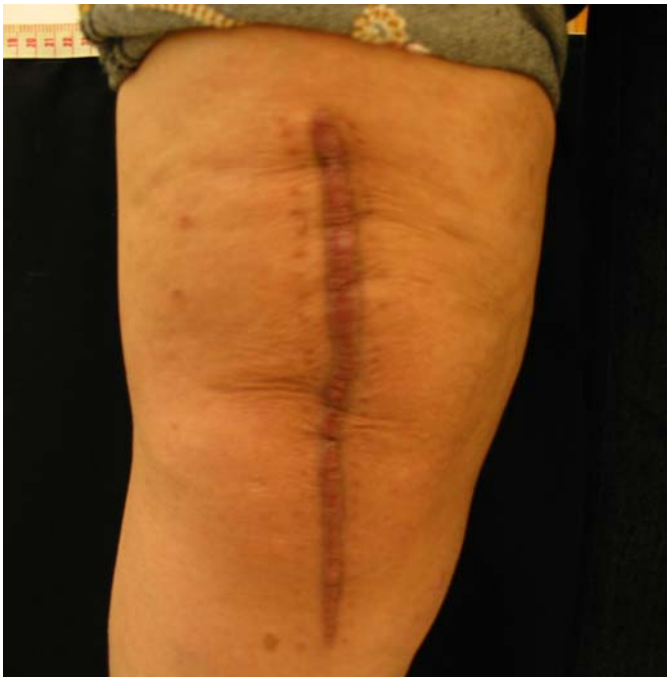


Figure 3.5.3

The scar over knee of PT group in the post-3-month assessment

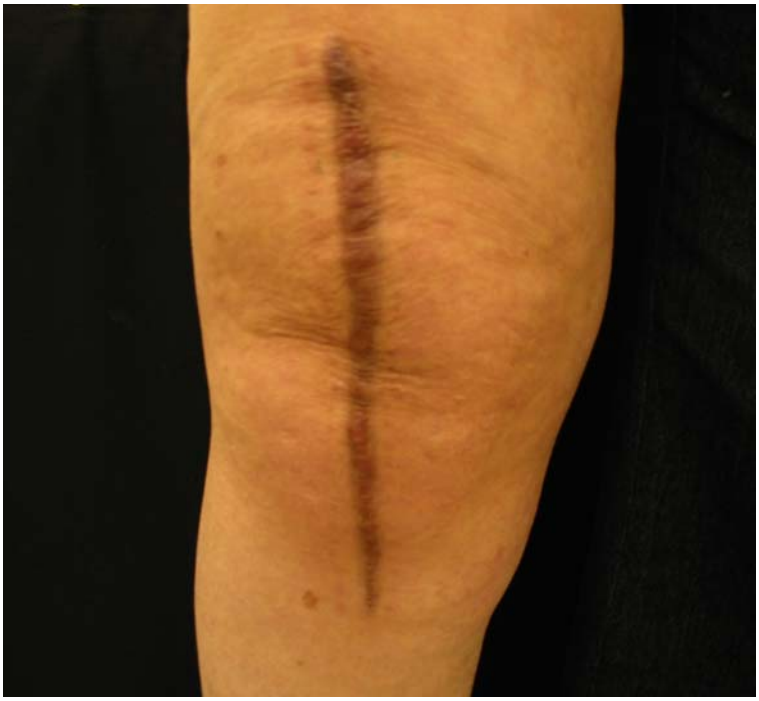


Figure 3.5.4

The scar over knee of PT group in the post-5-month assessment

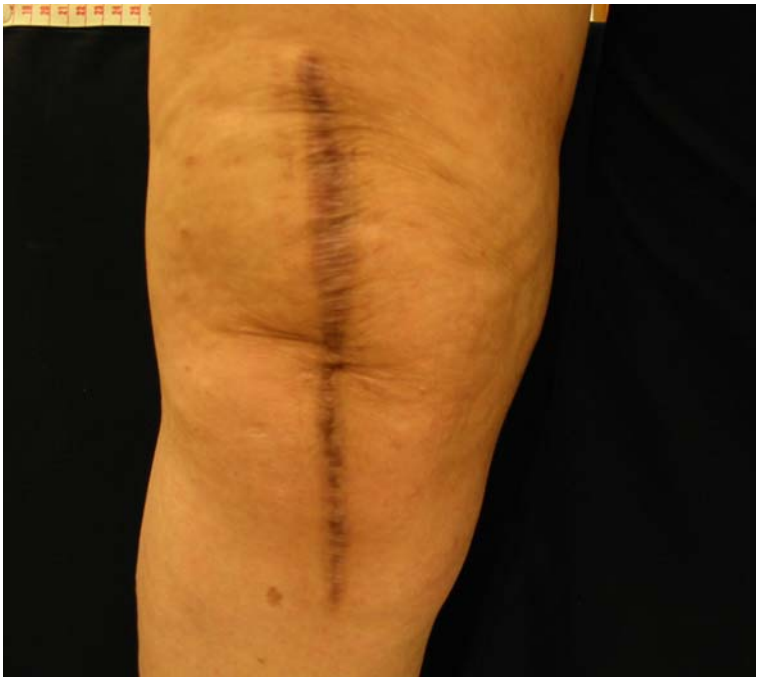


Figure 3.5.5

The scar over hip of PT group in the initial assessment

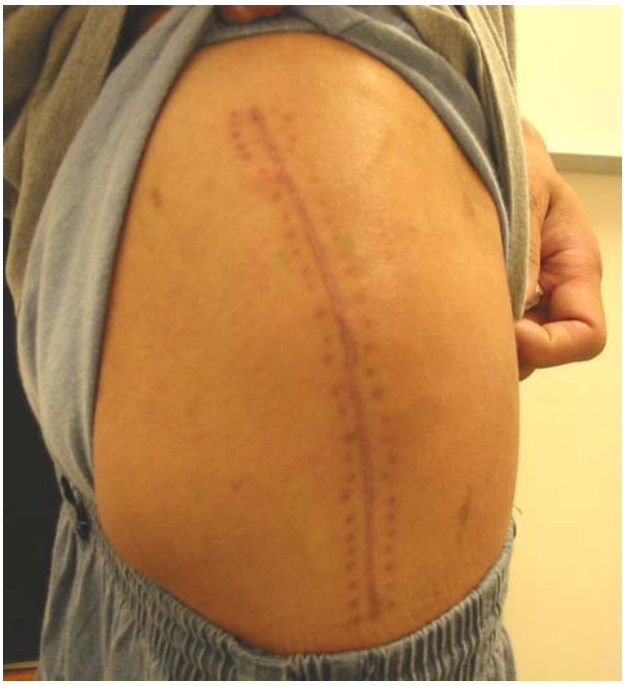


Figure 3.5.6

The scar over hip of PT group in the post-1-month assessment

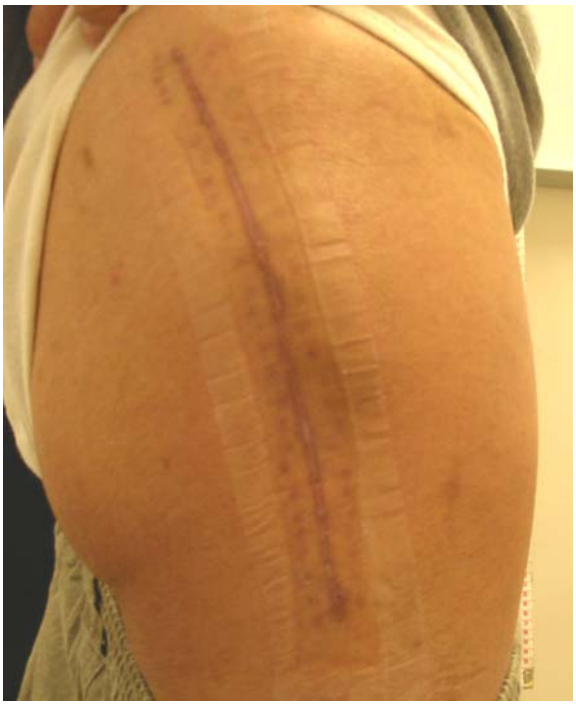


Figure 3.5.7

The scar over hip of PT group in the post-3-month assessment

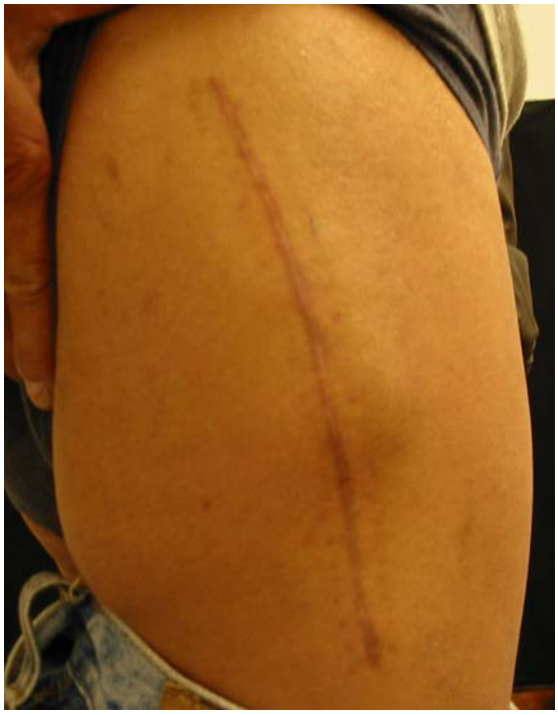
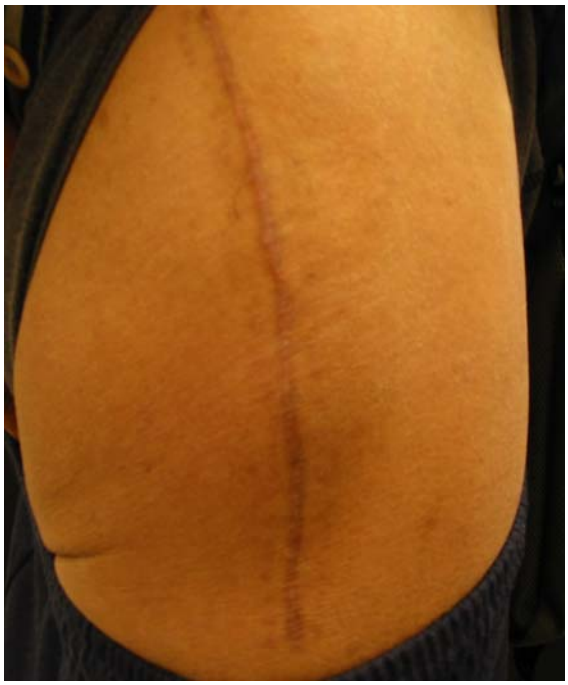


Figure 3.5.7

The scar over hip of PT group in the post-5-month assessment



Effect of silicone gel sheeting on hypertrophic scar

Results of this study indicated that the effect of silicone gel sheeting was able to reduce the scar thickness in the first month and carry along a continuous therapeutic effect on scar pliability over the 5-month period. The scars of SG group appeared to resemble to the normal skin with less purplish and more yellowish color reported (Figure from 3.6.1 to 3.6.4). All subjects in SG group reported no pain and itchiness after 1-month application.

Pressure therapy was seemed to be better in treating scar thickness while silicone gel sheeting was found more effective in improving scar pliability than pressure therapy. Silicone gel sheeting was recommended as a standard conservative treatment of scar management by the International Advisory Panel on Scar Management (Mustoe et al., 2002). However in the finding of this study, the scar thickness of the SG group was improved only after the first month. The long term effect of SG remained questionable as there was no RCT studies to prove its therapeutic effect in a long term follow up study. Katz (1995) used photographs and description to illustrate the effect of silicone gel sheeting (Katz, 1995). In the studies of Quinn (1987), Berman (1999) and Gibbon (1994), the efficacy was showed without a control group or an objective assessment (Berman & Flores, 1999; Gibbons et al., 1994; Quinn, 1987) . Further studies by Cruz-Korchin (1996) and Borgognoni et al (2002) described the scar progress to report

its prophylactic effect without any objective findings (Borgognoni, 2002; Cruz-Korchin, 1996).

In our study, only short-term effect of scar thickness was illustrated. A controlled clinical trial was conducted by Gold in 1994, 21 hypertrophic scars were divided into two equal halves. The silicone gel sheeting was placed on a half scar, and the treated area was randomly assigned. The progress was recorded by a physician and patients with 3-point scale. No significant results in terms of scar thickness and scar pigmentation were reported by the physician evaluation. The result of scar thickness was found that 42.9% had minimal improvement and 47.6% had improvement after 3-month. In our study, no prolonged significant improvement was demonstrated after 1-month application of silicone gel sheeting. The SG may not be effective in reducing the scar thickness. Another controlled clinical trial designed by Ahn et al (1989) showed the efficacy of silicone gel sheeting in scar pliability. The scar was divided into 2 halves and assigned to control and treatment groups randomly. The scar pliability of 14 scars undertaken 3-month silicone gel sheeting was significantly improved on the 1st, 2nd and 3rd month. The findings of our study also demonstrated similar effect of silicone gel sheeting, that the pliability of SG groups was significantly improved along 5 months.

The silicone gel sheeting was found effective to soften the scars but the actual mechanism was not explored. The assumed mechanism of the silicone gel sheeting

mainly is its hydration effect on the skin tissue. The hard and outset layer of skin, stratum corneum is able to retain water and being hydrated under silicone gel sheeting. According to Quinn and Tagami (Quinn, 1987; Suetake, Sasai, Zhen, & Tagami, 2000), the silicone gel sheeting hydrated the stratum corneum and slowed the deposition of this layer resulted in softer scar, and provides oxygen permeability. Following the reduction of the activity of keratinocytes and slowed the activity of fibroblasts for collagen synthesis indirectly. A study by Gisele et al. confirmed its hydration effect, and showed no significant difference between the hypertrophic scars based on whether Deroderm or silicone gel sheeting was applied (Gisele et al., 2001). In our findings, the scar pliability was improved due to the direct effect of silicone gel sheeting.

Regarding the color parameters, no obvious change resulted. The scars of the SG group had a greater resemblance to normal skin color, with less Δyellowness than the 3 groups. The improvement of scar pigmentation was reported in previous studies with ordinal scales or in a case-study manner. In Gold's study (1994), no significant progress reported by 3-point scale was noted after 3-month application, 47.6% were reported minimal change and 42.9% in moderate level (Gold, 1994). The studies of Ahn et al (1989) and Gibbon's study (1994) demonstrated improvement of scar color in case study manner (Ahn, Manafo, & Mustoe, 1989; Gibbons et al., 1994). The scar pigmentation was noted along the treatment of silicone gel sheeting in previous years.

However, there was no long term and controlled study. There was a positive finding on scar pigmentation under silicone gel sheeting, but only the most severe site was taken measurement to represent whole scar pigmentation. There is a need to investigate the long-term effect of SG on scar pigmentation.

In this study, the pain and itchiness of SG group's subjects subsided within a month. Similar result was reported in Eishi et al's study (2003). Pain and itchiness of six prolonged scars recorded by 4-point quartile scale were reduced significantly after 1 month, and disappeared after 3 months of silicone gel sheeting application. The researchers further investigated the number of mast cells, which is believed to induce itchiness of the scar (Kischer & Bailey, 1972). It was significantly decreased after the silicone gel sheeting application. The authors also suggested that the silicone gel sheeting served a protective layer over the scars, which less irritation made by friction between clothing and scars, resulted in disappearance of pain. Its application was easy and no flush of blood induced and heating up the afferents (Bell et al., 1988). Again, as the cellular base study was not implemented, the mechanism of silicone gel sheeting has not been confirmed yet.

Figure 3.6.1

The scar over knee of SG group in the initial assessment

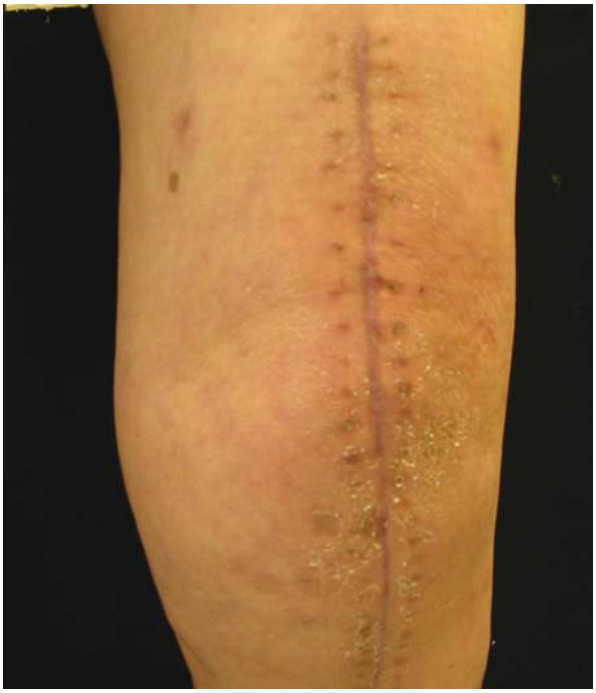


Figure 3.6.2

The scar over knee of SG group in the post-1-month assessment

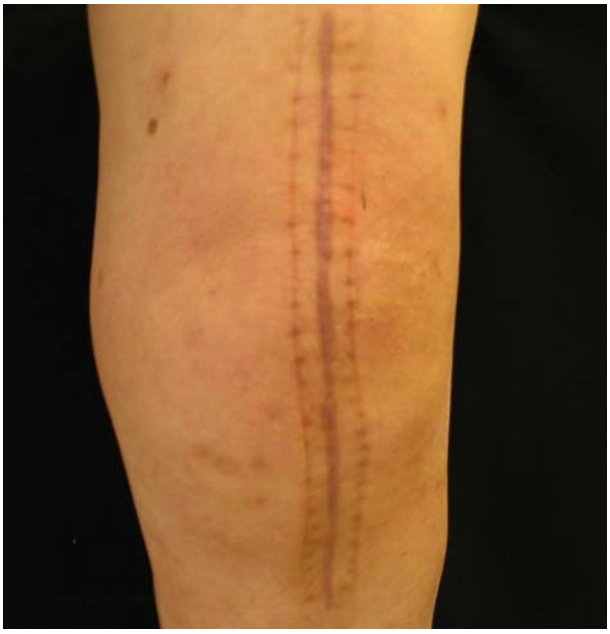


Figure 3.6.3

The scar over knee of SG group in the post-3-month assessment

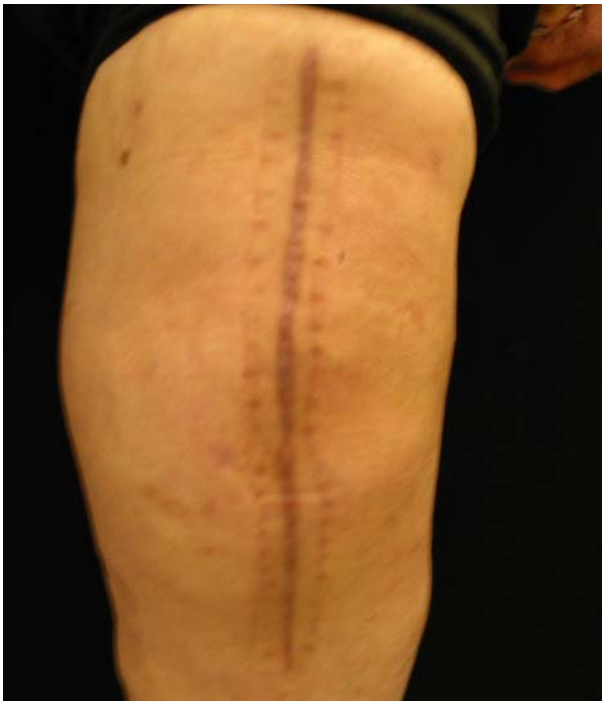


Figure 3.6.4

The scar over knee of SG group in the post-5-month assessment

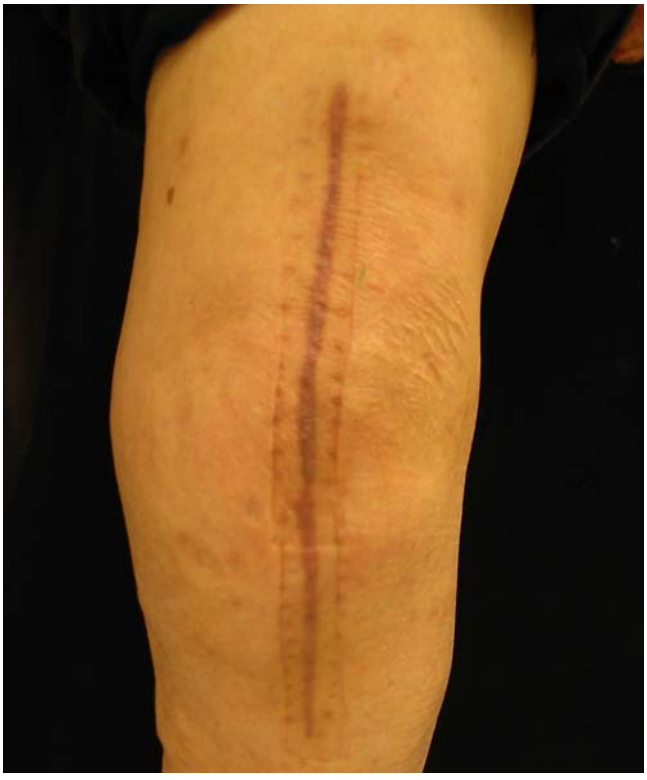


Figure 3.6.5

The scar over wrist of SG group in the initial assessment

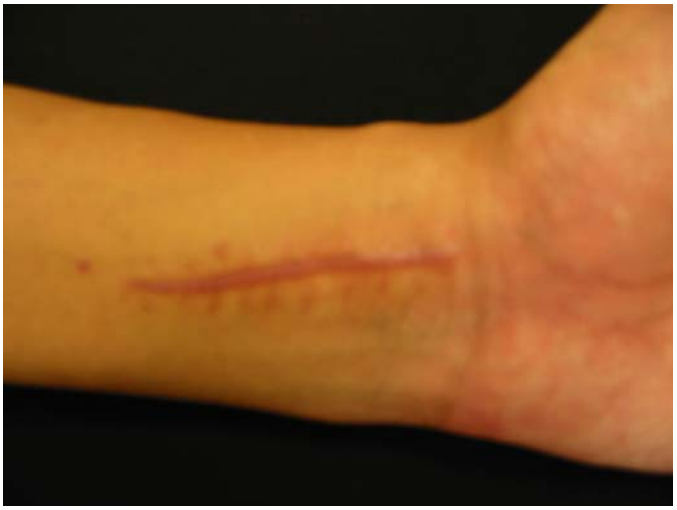


Figure 3.6.6

The scar over wrist of SG group in the post-1-month assessment

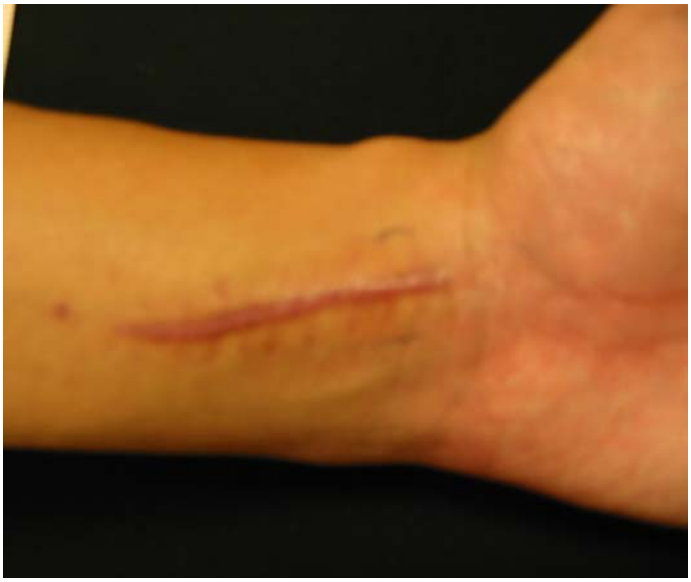


Figure 3.6.7

The scar over wrist of SG group in the post-3-month assessment

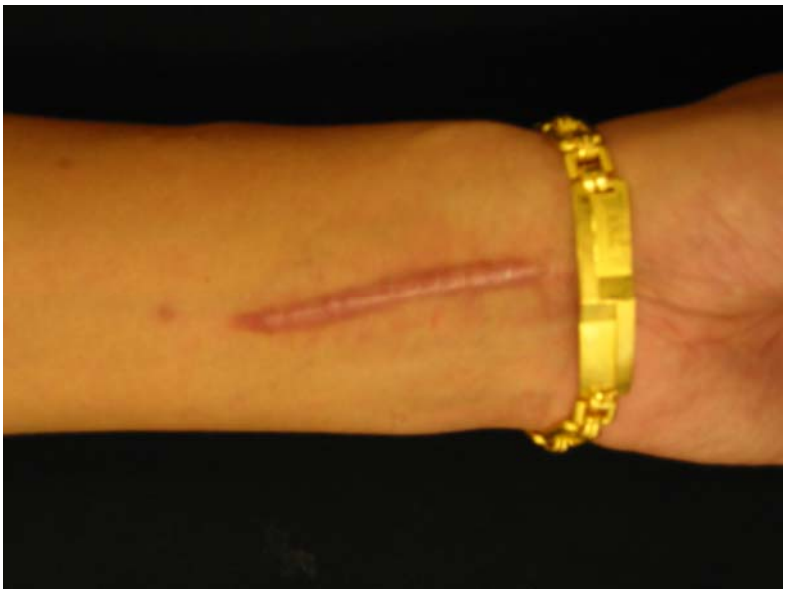
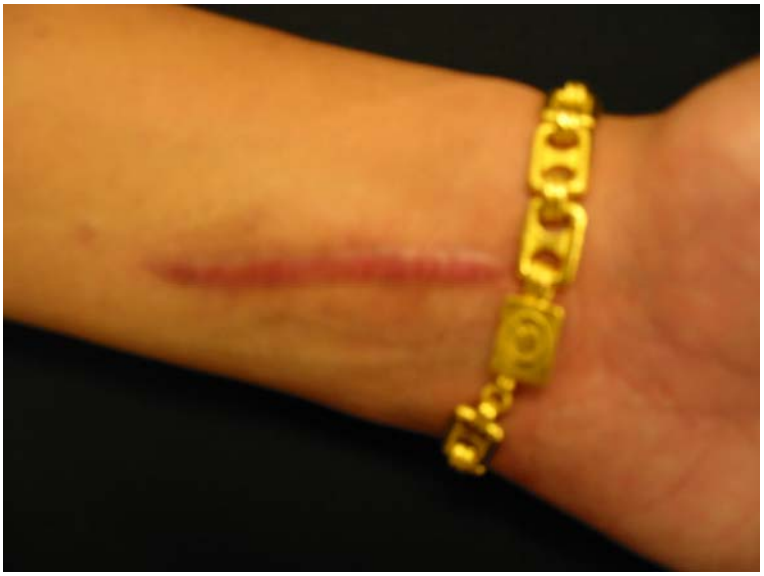


Figure 3.6.8

The scar over wrist of SG group in the post-5-month assessment



Effect of combined PG and SG therapy on hypertrophic scar

Though the scars of the combined therapy group was found thinner from the graphical presentation, its effect was less favourable than PG alone. In the past, silicone gel sheeting was used in addition to pressure therapy when there was a concave area on the skin surface and the results were usually favourable (Kerckhove et al., 2001). In this study, there was no prominent change of scars under combined therapy (Figure 3.7.1 to 3.7.4). The scars of the CT group were only shown to be softer than those of the control (CO) group in the initial month and the 5^{th} month, and no improvement in the scar was noted when compared with the CO group.

The poor result shown in CT group may be explained by the poor compliance of subjects. This was verified through a phone survey after the completion of the study. Subjects mainly complained of discomfort and problems of applying both the SG, the padding and the pressure garment onto the scar limb especially in the hot weather. As a result, most subjects reported that they could only tolerate at most 8-hour of wear during the day. They reported the scars as being hot, itchy and sweated after a short period of time and they need to remove the pressure garment and padding, plus removing the SG for washing off the sweat. The combination of pressure therapy and silicone gel sheeting did not work as effectively as we expect. Hydration effect from silicone gel sheeting and compression from pressure therapy did not seem to comply

with each other in enhancing early scar maturation. The other reason for the poor outcome might be due to the reduction of pressure onto the scar tissue when an additional SG sheet is applied. It might create a cushioning effect on the scar tissue, thus the pressure was redistributed to other skin surface rather than directly onto the scar tissue. The third possible explanation of the poor outcome may be due to the interruption of hydration effect of SG. The hydration was the assumed mechanisms of the silicone gel sheeting (Quinn, 1987), and better oxygen permeability allows less allergy of skin (Musgrave, Fish, Gomez, & Cartotto, 2002). The 9mm padding put on top of the SG sheeting might interrupt the hydration and the oxygen permeability of the scars. Eventually the scars became sweaty and hot, disrupting the effect of the silicone gel sheeting. Thus, the outcomes of the CT group was not favourable.

Figure 3.7.1

The scar over knee of CT group in the initial assessment

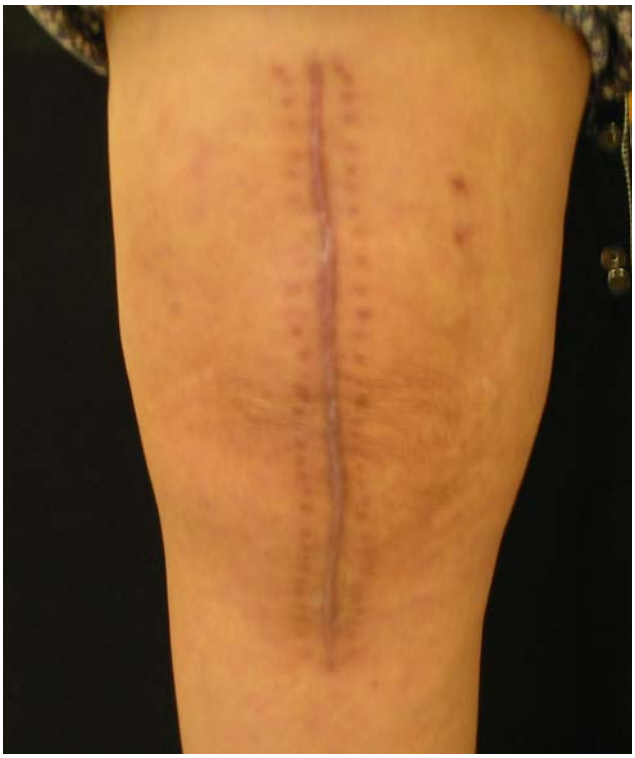


Figure 3.7.2

The scar over knee of CT group in the post-1-month assessment

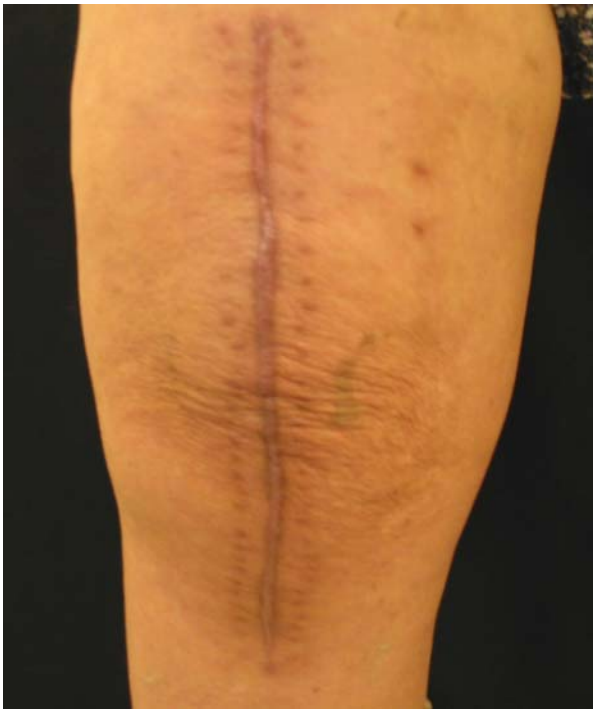


Figure 3.7.3

The scar over knee of CT group in the post-3-month assessment

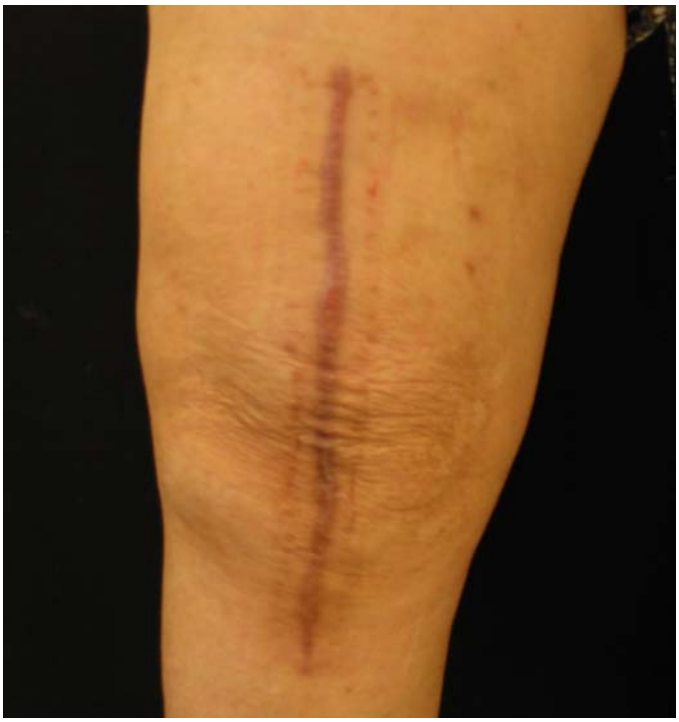


Figure 3.7.4

The scar over knee of CT group in the post-5-month assessment

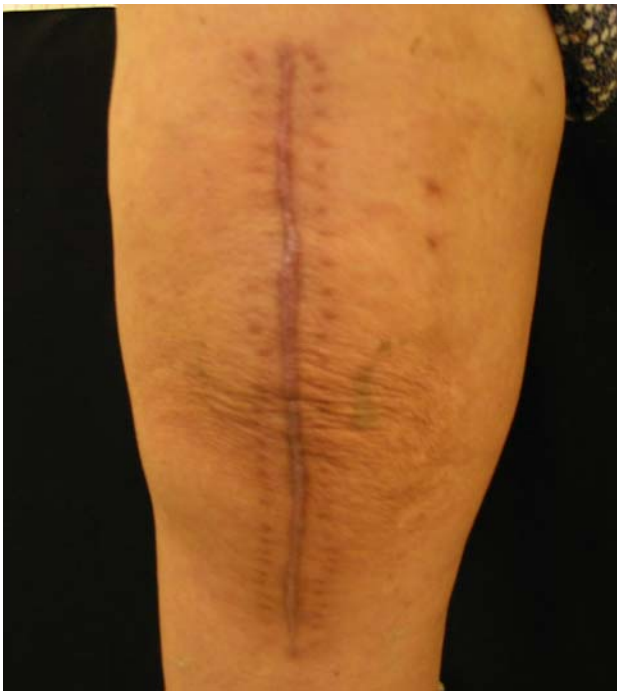


Figure 3.7.5

The scar over wrist of CT group in the initial assessment

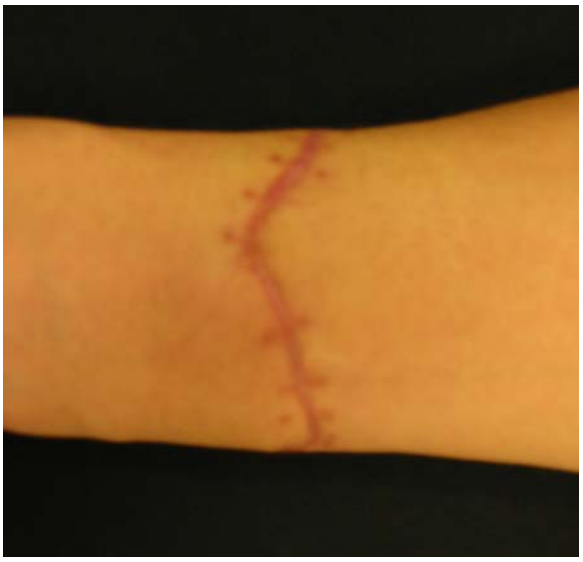


Figure 3.7.6

The scar over wrist of CT group in the post-1-month assessment

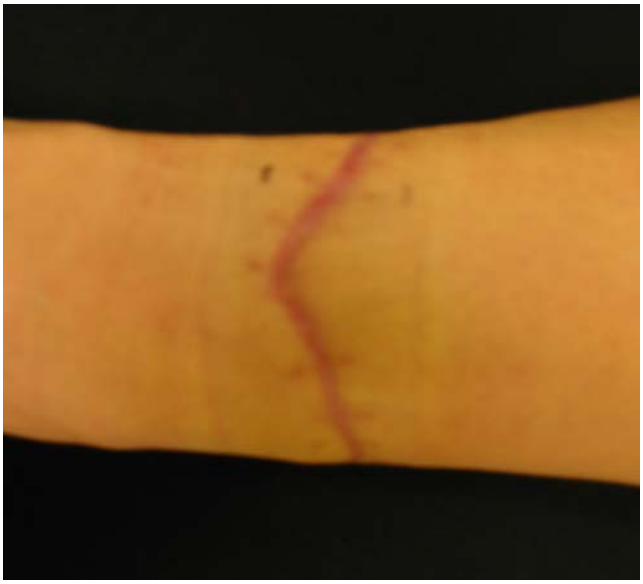


Figure 3.7.7

The scar over wrist of CT group in the post-3-month assessment

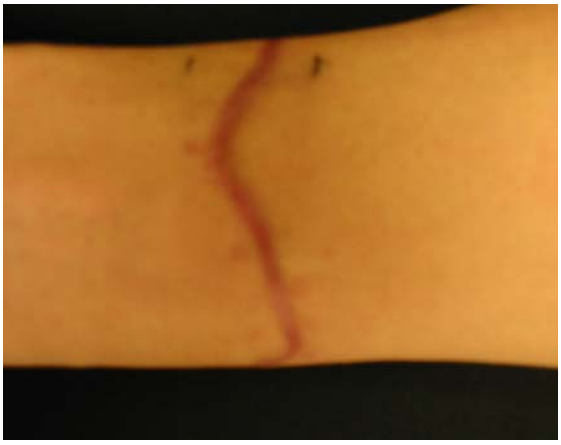
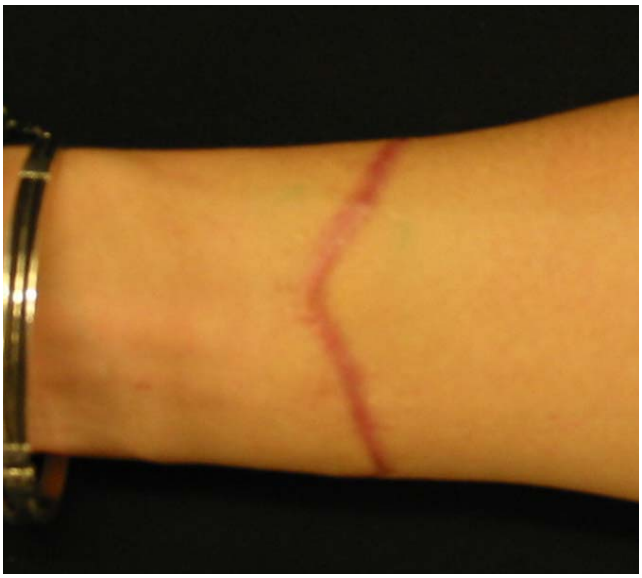


Figure 3.7.8

The scar over wrist of CT group in the post-5-month assessment



Progress of scar conditions in the control group

Subjects in the control (CO) group were assigned to gently massage their scars once per day. Past studies showed that even deep massage was unable to improve the condition of hypertrophic scars in terms of vascularity, pliability and thickness. It might only produce an instant effect to increase mobility over the joint after massage therapy (Patino, Novick, Merlo, & Benaim, 1998; Roques, 2002). Subjective feelings such as pain and itchiness were relieved by regular deep massage therapy (Field et al., 2000). No evidence on lanolin gentle massage was effective on pain and itchiness over the hypertrophic scar (Bayat, McGrouther, & Ferguson, 2003; Mustoe et al., 2002). As a result, subjects in control group (CO) were told to massage the scars gently as a placebo treatment. Furthermore, all treatment groups were prescribed the same gentle massage with lanolin, in order to reduce the effect on the massage therapy.

In the baseline measurement, the scars of the CO group were softer and less yellowish when compared with those of the CT and PT groups respectively; however the scars were become worse within a month. The result indicated that the scar thickness of the CO group increased within 1 month, apparently the scars were stiffer and in the most reddish among 4 groups (Figure 3.8.1 to 3.8.4). The mechanism of hypertrophic scar formation was assumed that the environment of the scar lacked oxygen, inducing a higher microvascularity. Consequently, a higher metabolism rate of

fibroblasts was stimulated, creating an imbalance of collagen synthesis and degradation (Beldon, 2000; Berry et al., 1985). The earlier study of Sloan and his colleagues (1978) suggested observing the O_2 tension and the CO_2 tension between immature hypertrophic scars and normal skin (Sloan, Brown, Wells, & Hilton, 1978). Lower O_2 and higher CO_2 tensions were recorded. The increased metabolism rate of the hypertrophic scar was supplemented by the lack of oxygen, then an excessive formation of small blood vessels and fibers resulted (Baur, Larson, Stacey, Barratt, & Dobrkovsky, 1976; Kischer et al., 1982). The more in-depth physiological study was not conducted in our study, but the appearance of the scars of CO group in the first month might implicate the mechanism of the hypertrophic scar formation. In the wound healing process, the scars of the CO group were active in the proliferation stage in the first month, with a higher amount of collagen fibers produced and small blood vessels formed. Beldon (2000) claimed that the imbalance of collagen synthesis would lead to increased scar thickness. Undertaking the rest of the wound healing process, the scars naturally proceeded to the remodeling stage when they reached a balance between collagen synthesis and degradation. Smaller difference of scar thickness was found among groups comparison. The scar of CO became thinner naturally and less reddish. The remodeling stage of the post-surgical hypertrophic scar lasted for more than 4 months.

Figure 3.8.1

The scar over knee of CO group in the initial assessment

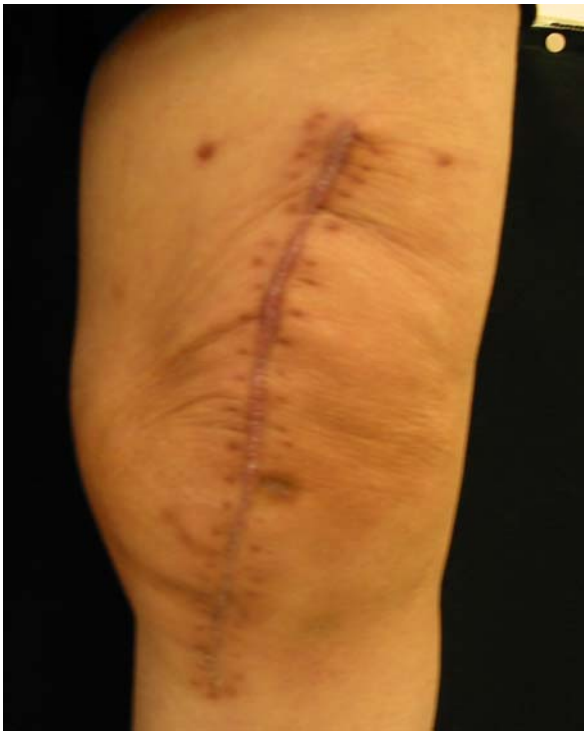


Figure 3.8.2

The scar over knee of CO group in the post-1-month assessment

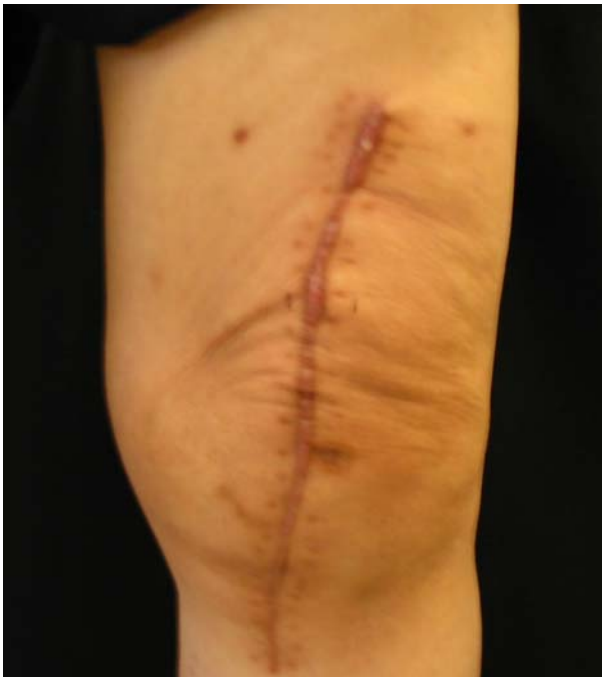


Figure 3.8.3

The scar over knee of CO group in the post-3-month assessment

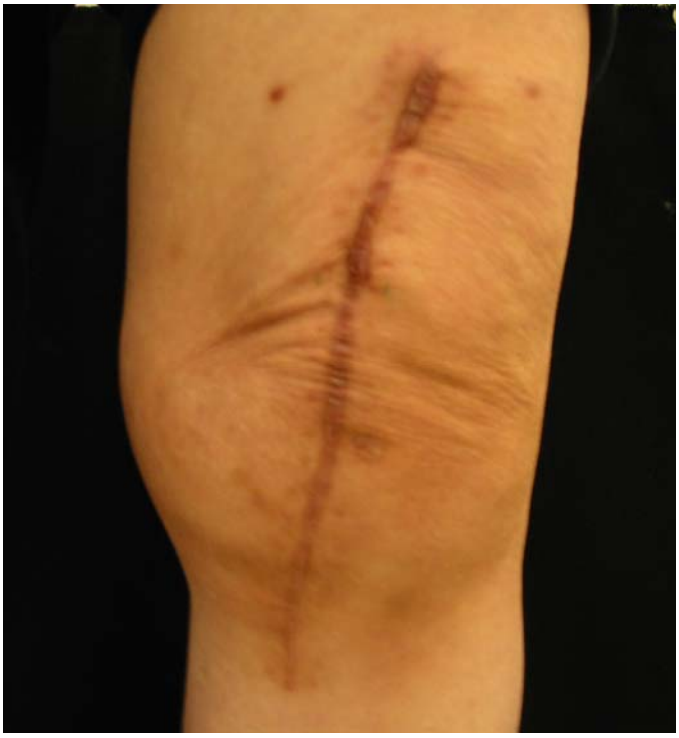


Figure 3.8.4

The scar over knee of CO group in the post-5-month assessment

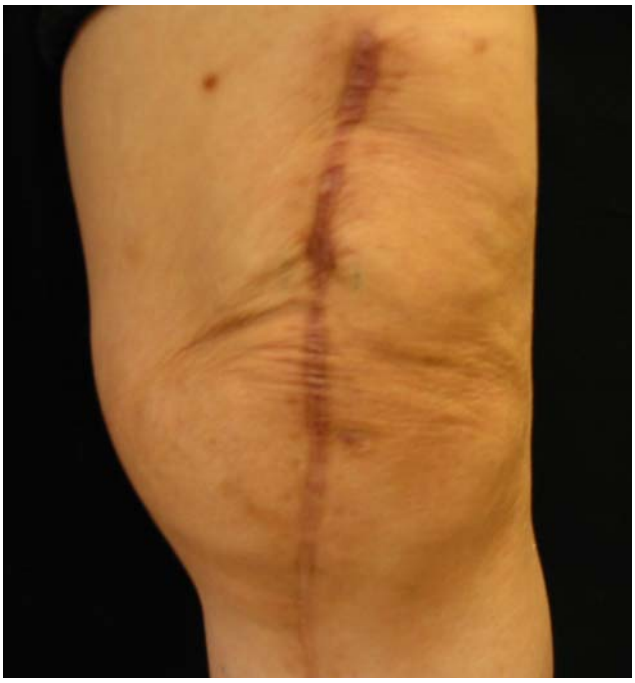


Figure 3.8.5

The scar over hip of CO group in the initial assessment

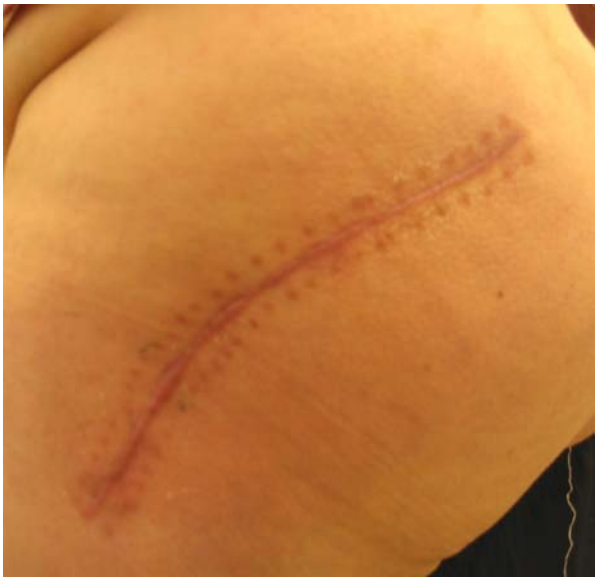


Figure 3.8.6

The scar over hip of CO group in the post-1-month assessment

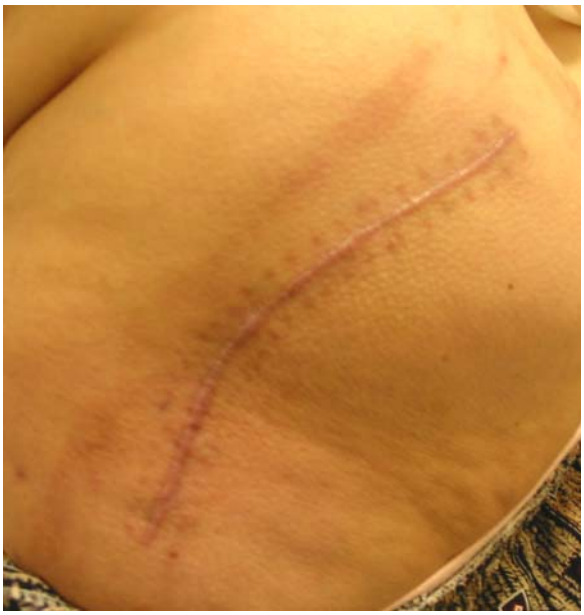


Figure 3.8.7

The scar over hip of CO group in the post-3-month assessment

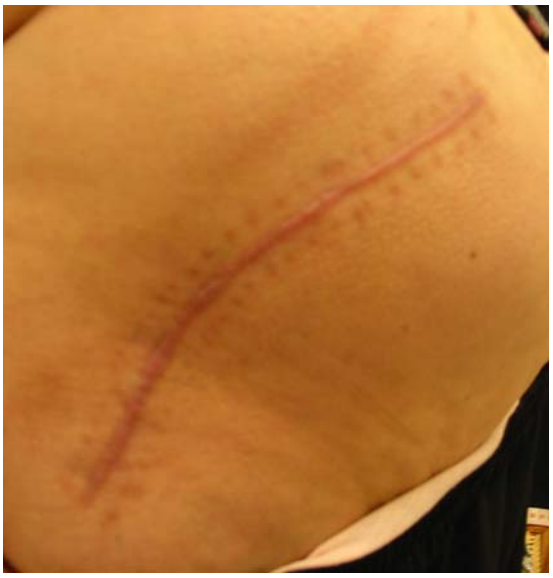
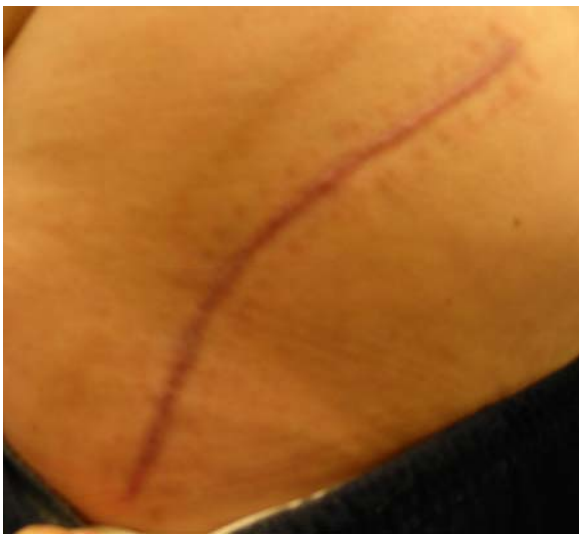


Figure 3.8.8

The scar over hip of CO group in the post-5-month assessment



Summary

In this study, the prevalence of hypertrophic scars among the Chinese population was found to be 74.67%, which is very high when compared to the Caucasians. The scars were found to have increase in thickness, rigid and extreme pigmentation in terms of lightness, redness and yellowness.

This study has adopted a randomized clinical trial design to find out the efficacy of pressure therapy and silicone gel treatment on hypertrophic scar. Subjects were assigned randomly into the control and the treatment groups to reduce the bias with the same condition. The TUPS and spectrocolorimeter were used to measure the scar thickness and pigmentation respectively. Pressure therapy was found to be effective in control of scar thickness while SG was found effective in reducing discomfort and improving pliability; however the combined therapy was neither better nor even the same as pressure therapy or silicone gel sheeting in its effect. Scar thickness was often considered as the main indicator of scar maturation process. Within a 3-month time, the scar thickness was significantly improved in the PG group. The scars managed using silicone gel sheeting were found to have improved in thickness in the initial month when compared with the control group but no significant difference was noted in the five month intervention. The post-1-month result of the control group showed that the hypertrophic scars became more severe than previously in terms of increased thickness

and pliability. The scars needed to receive treatment in order to accelerate the maturation process.

Other than the objective outcome indicators, subjects reported improvement in functions and satisfaction towards the scar. They reported that if the scar was thinner and more pliable, they could move better over the joints. They also reported less pain and itchiness over the scar tissues, thus allowing them to better perform daily tasks such as bathing and dressing. The dropout rate was high, with 26.73% (27 out of 101) and the main reasons were mainly due to the episode of SARS and the poor follow up attendance among the subjects. Some of the subjects were elderly clients and they found it difficult to travel to the hospital for follow up assessment. However, on phone survey, they still comply with the therapy prescribed by the therapists. As a conclusion, this study was able to prove the efficacy of PG and SG onto surgical scar using a RCT study with a control group. Further study on the exact mechanisms of these two intervention strategies would deem necessary.

CHAPTER FOUR

LIMITATIONS AND FURTHER STUDIES

This study was intended to develop the objective assessment protocol on assessing scar, studying the prevalence of hypertrophic scar among Chinese population and comparing the effectiveness of the pressure therapy and silicone gel sheeting. Though there were interesting findings in this study, there were still some limitations in the study.

Development of objective assessment protocol

The physical characteristics of hypertrophic scar were red, raised and rigid. By the use of the spectrocolorimeter and Tissue Ultrasound Palpation System, the scar color and thickness were quantified; however our study still could not find out an objective device to measure the scar pliability. In the very initial phase of this study, a cutometer was employed to quantify the scar pliability but it was found that the cutometer was unable to measure the stiff scar. Moreover, the scars located in concave or convex areas such as the mid chest and joints were unable to contact the probe resulted in failure of the assessment. As a result, the scar pliability could only be recorded using the Vancouver Scar Scale in a descriptive and ordinal manner.

The other limitation of the study is that by using the spectrocolorimeter and TUPS,

only one or two spots of scar tissues could be measured. It remained difficult to measure the whole scar tissue due to the problems of repeating the procedures of assessments. Therefore, only the most severe spot was measured and it was selected based on the visual inspection by the therapist. Since a small part of the scar was assessed, it was still believed that the whole scar severity could not be fully reflected by the objective assessment.

The objective advancements provided the quantitative data of scar thickness and color parameters. The spectrocolorimeter and TUPS could not report on the physiological changes of hypertrophic scar. The data only served as a reference of physical characteristics of hypertrophic scar in terms of lightness, redness, yellowness and thickness along 5-month time. The mechanisms of the pressure therapy and silicone gel sheeting onto the scar were not examined.

The spectrocolorimeter was failed to report the scar color parameters along 5-month time. It was because the translucent feature of skin and hypertrophic scar would reflect the light of spectrocolorimeter leading to variation. The more hypertrophic scar would be much translucent and pinkish in appearance, however the measurement of spectrocolorimeter was unable to differentiate the translucent part of the scar. The redness of the hypertrophic scar was composed of its translucent feature of the skin, vascularity of the hypertrophic scar and the skin pigmentation. It was a complex system

of skin color. Though normalization of the color parameters were conducted before data analysis, still the translucent part of skin was unable to be fully normalized. The readings of color parameters would be affected by the reflected angle of the emitted light from spectrocolorimeter to skin. The rater positioned the spectrocoloriemter perpendicular to the joint, but the convex surface of the joint would make difficulty in positioning the spectrocoloriemeter and remained the same angle of emission and reflection. Therefore, there was still a variation in sprectrocolourimeter on color measurements and failure of reporting the scar color in longitudinal manner.

To improve the scar assessment protocol, further studies should be implemented. Firstly, it was important to explore the new advancement for quantifying scar pliability. Secondly, to reflect the whole scar severity, it was suggested not only to measure the most severe site of spot over the hypertrophic scar, but also to take random spots for recording overall scar severity. Lastly, as the scar colour was hardly to be quantified, it was recommended to use Laser Doppler advancement to measure the mircovascularity of hypertrophic scar directly.

The main study

In the phase II of the main study, it aimed to investigate the prevalence of hypertrophic scar formation among Chinese population. However the limited population was recruited for minimizing the confounding variables of affecting scar formation. The

prevalence was very high, but it was still difficult to generalize to post-traumatic and post-burnt patients. It was because the wounds resulted from trauma or burn were more complicated, and higher prevalence was assumed. Nevertheless, the exact prevalence was still unknown.

To demonstrate the effectiveness of pressure therapy and silicone gel sheeting in an objective manner, this study adopted a randomized clinical trial (RCT) approach. There were many constrains in this study leading to poor generalization.

In the worldwide prospective, the impact of hypertrophic scar was more severe among the patients with post-burn hypertrophic scars, and the younger patients would develop more severe hypertrophic scar due to higher metabolism rate and skin tension. Firstly, to limit the confounding variables in this study (for example the scar location and the causes), the subjects were selected homogenously, that they would given the same surgical procedures. Most of the patients were elderly and had to undergo total hip or total knee surgeries. Therefore, the results may not infer to burn scar and to younger patients. Secondly, to gain a better control of pressure from pressure garment, limb scars were recruited. Scars located on back, shoulders and abdomen were found to be more susceptible to scar formation. In this study, the scar conditions were confined only to limb scars. Thus, the results may not be able to generalise to scars over the other body parts.

Most patients received total knee or hip replacement, and the causes leading to joint replacement were not investigated. The scar resulted from osteoporosis or rheumatoid joint might have different healing processes when compared to other patients. Patients with immune system disorders may have prolonged inflammation over the body, thus the scar conditions may be worse than other types of patients. In this study, the causes of operation were not explored, which may affect the outcomes of the study.

In the RCT study, all recruited patients were randomly allocated into four groups. However, the baseline of the measurements on scar conditions were still uneven. The scar conditions in the control group was shown to be more yellowish and softer than subjects from the other groups. Moreover, subjects recruited had different types of surgeries and the distribution was not even among the four groups of subjects. though only colour difference was found between others and all types of surgeries. Again, as the causes of the surgeries were not reported in this study and that there was uneven distribution among four groups of subjects, it may affect the outcomes of the study.

Regarding to the treatment effects, this study demonstrated the effects of pressure therapy and silicone gel sheeting on post-surgical hypertrophic scar. However, the actual mechanism of the two interventions were not clear. The disappointing results of the combined therapy were discouraging. There are a few factors affecting the outcomes of

this combined group but detailed analysis would need to be followed. The pressure therapy showed the best results when compared with silicone gel sheeting and combined therapy. The pressure compression generated by the garment and the padding appeared to reduce the thickness of the scar though the actual pressure range was not documented in this study. The local practice of additional padding application to generate high pressure and hydration effect over hypertrophic scar was unique. Yet, the effect of padding was not been explored.

In order to provide better generalization of the study, a world wide research was suggested in future study. The focus would be on post burn or post traumatic hypertrophic scar and it would be interested to compare the response from different races (eg. Asians versus caucausians). They would be allocated in experimental group and control grou with scar severity, matched age, location and gender to reduce all bias against the treatments effect.

At present, there was a lack of advancement in pressure measurement. It was necessary to validate pressure measurement with high sensitivity and reliability in order to quantify the optimal range of pressure therapy. More ultrasound advancements of viewing scar tissue and showing the microvascularity were also highly recommended to be developed.

In summary, this study was only served a very limited generalization to the

treatments of hypertrophic scars. It could provide a reference of treating post-surgical hypertrophic scar in a more objective manner.

CHAPTER FIVE

CONCLUSION

This study aimed at developing the objective assessment protocol, investigating the prevalence of scar among the Chinese population, and exploring the effect of pressure therapy, silicone gel sheeting, and their combined therapy on post-surgical hypertrophic scar. A total of 101 patients consented to participate and were allocated into 4 groups randomly. The results of the interventions were reported and analyzed.

Development of objective assessment protocol

The Tissue Ultrasound Palpation System (TUPS) and the spectrocolorimeter were employed to develop an objective assessment protocol. They were validated to provide quantitative measurement of scar thickness and pigmentation. Their good reliabilities in terms of inter-rater and test-retest were confirmed by 3 different raters. Regarding the validation, TUPS was cross-validated with a scanning ultrasound machine on porcine tissue, resulting in a high correlation. This was the first method to assess the scar thickness, including the scar underneath the skin. Further concurrent validation of the spectrocolorimeter and the TUPS was conducted using the most common assessment tool of hypertrophic scars, the Vancouver Scar Scale (VSS). The parameters of the objective assessment protocol were significantly correlated with the result of VSS

grading. This proved their application on scar assessment and provided a more objective way to assess the hypertrophic scar. With the sensitivity and reliability of the advancements, the scar progress was noted in a quantitative and objective way.

The main study

Many predisposing factors contribute to the formation of hypertrophic scars, for example, race, age, and the location, depth and severity of the injury. In this study, a homogenous group of patients was studied after total knee surgery, total hip surgery or surgery in the upper extremities. The whole recruitment process lasted for one and a half years and 74.67% (115 patients) of 154 patients were found to develop hypertrophic scars. This result not only shows a higher incidence of hypertrophic scar formation, but also provides a rough estimation of the number of patients developing hypertrophic scars each year. Around 350,000 surgeries are conducted per year in Hong Kong. According to the projection of our findings, around 250,000 surgical scars may become hypertrophic. Additional follow-up after surgery in the form of early scar screening is necessary to avoid excessive surgical or rehabilitation costs related to the late complications of hypertrophic scars.

Randomized clinical trial provided the best evidence of treatment efficacy and it helps to eliminate the potential biases attributable to differences. This study adopted the

randomized clinical trial (RCT) research design to study the treatment efficacy of Pressure therapy and silicone gel on hypertrophic scar. One hundred and one patients were consented to join this study and were randomly allocated into 4 groups, namely the control (CO) group, the pressure therapy (PT) group, the silicone gel sheeting (SG) group and the combined therapy (CT) group. Their scars were assessed once at the end of the first month, then bi-monthly until the 5^{th} month. By adopting the objective assessment protocol, the scar thickness and color was measured. Since there was no objective tool available for measuring the scar pliability, the pliability score of the Vancouver Scar Scale (VSS) was used. Pain and itchiness were recorded by Visual Analogue Scale. In the first month, the scars in the CO group became worse, with significantly thicker scar tissue when compared with the PT and SG groups, and increased pliability and redness. By the 3^{rd} month, the PT group had continued in the scar thickness, whereas the SG group had been alleviated in terms of the pain and itchiness: no subjects complained of pain or itchiness after 1 month's application of the sheeting. The 3 color parameters did not show a significant change, but different trends were noted: a descending trend of redness and lightness in the PT group, and a descending trend of yellowness in the SG group. The CT group did not show similar effects to the silicone gel sheeting or pressure therapy groups. It was assumed that the pressure therapy and silicone gel sheeting affected each other and it was further found

that the CT group had poor compliance with the therapy.

According to this study, pressure therapy was more effective in treating hypertrophic scar and reducing its thickness within 3 months' time, and silicone gel sheeting was more effective in reducing pain and itchiness within one month's time. It is recommended that all post-surgical hypertrophic scars receive pressure therapy for 3 months to accelerate the maturation process. For patients who complain of severe pain or itchiness over the scar, silicone gel sheeting is prescribed for reducing the irritation. Thereafter, pressure therapy is recommended following the treatment of silicone gel sheeting. The treatment period would last for 3 to 5 months instead of a year, except for scars that are still active or become keloid.

Appendix I

香港理工大學康復治療科學系及

東區尤德夫人那打素醫院職業治療部

比較硅酮膠化體敷料與壓力治療在手術後增生疤痕療效的臨床測試

本人是香港理工大學康復治療科學系副教授，現正與東區尤德夫人那打素醫院合作一項臨床研究硅酮敷料與壓力治療對手術後增生疤痕之療效。研究內容包括硅酮敷料與壓力治療是否能減少病人手術後所帶來的疤痕問題，特別是中國藉病人。研究結果有助醫護人員發展增生疤痕之最佳治療。

此項研究需要測試病人身體上疤痕的狀況，包括以下程序：

1. 測試疤痕情況包括疤痕厚度及色澤
2. 在疤痕上施行硅酮膠化體敷料及/或壓力治療
3. 每月定期檢查疤痕情況直至疤痕成熟
4. 疤痕成熟後三個月進行跟進測試

這個治療過程約需半年至一年完成，包括 8 至 10 次測試及治療節數，所有測試結果將會保密及不會公開。如果閣下同意參加這項研究，請在以下同意書上簽名。此項研究之成功，有賴閣下之參與。謹致予衷心感謝。

李曾慧平博士

香港理工大學康復治療科學系副教授

廖國英

東區尤德夫人那打素醫院職業治療部一級職業治療師

日期_____

同意書

本人_____同意參與這次研究量度硅酮敷料與壓力治療在手術後增生疤痕之療效。本人明白這次研究目的和內容，測試結果將會保密。本人有權要求一份測試撮要報告拷貝和在沒有懲罰及不公平治療情況下終止參與此項調查。如對這個計劃有疑問，本人可向劉頌文姑娘(電話:2766　　)或廖國英姑娘(電話:2595　　)查詢。

_____　　_____

簽名　　見證人

_____　　_____

姓名　　日期

Appendix II

香港理工大學康復治療科學系職業治療學部及
東區尤德夫人那打素醫院職業治療部

標籤

手術後增生疤痕評估表

病人姓名:_____ 病人編號:_____

ID no._____

	第一次評估	第二次評估	第三次評估	第四次評估
預定日期	/	/	/	/
進行評估日期	/	/	/	/
手術/燒傷/創傷後疤痕資料表				
病人對疤痕滿意度評估				
視覺評估疤痕痛楚及痕癢程度				
溫哥華普通科醫院疤痕測試表				
疤痕拍照位置量化表				
疤痕及普通皮膚顏色量化記錄表				
超聲波疤痕厚度評估				
疤痕面積評估				

Appendix III

香港理工大學康復治療科學系職業治療學部及
東區尤德夫人那打素醫院職業治療部

第一次手術疤痕評估評估

日期:_____

病人姓名:_____ 病人編號:_____

手術/受傷後疤痕資料表

年齡：_____

性別： ❑男性 ❑女性

出生日期: ___年___月___日

疤痕出現了多久：___年___月___星期____日

疤痕出現原因:

❑燙傷 ❑燒傷 ❑外傷

❑股關節手術 ❑膝關節手術 ❑足踝關節手術

❑上臂手術 ❑肘關節手術 ❑前臂手術 ❑手腕關節手術

何時受傷/接受手術 ___年___月___日

香港理工大學康復治療科學系職業治療學部及
東區尤德夫人那打素醫院職業治療部

日期:_____

病人姓名:_____ **病人編號:**_____

第一次手術疤痕評估評估

疤痕位置 (加上" √ " 在適當的格子內)
( )左 ( ) 右

	大腿	小腿	上臂	前臂
內側				
外側				
前方				
後方				

溫哥華疤痕測試分數

	分數
色澤 (M)	
厚度 (H)	
血管分佈 (V)	
柔軟度 (P)	
總分	

視覺評估疤痕痛楚及痕癢程度比例尺

	讀數(mm)
視覺評估疤痕痛楚程度	
視覺評估痕痕癢程度	

疤痕顏色量化記錄表

測試	L*	C*	H*	a*	b*
第一次					
第二次					
第三次					
第四次					
第五次					
第六次					
平均值					

普通皮膚顏色量化記錄表

測試	L*	C*	H*	a*	b*
第一次					
第二次					
第三次					
第四次					
第五次					
第六次					
平均值					

超聲波疤痕厚度評估

測試	讀數(mm)
第一次	
第二次	
第三次	
第四次	
第五次	

測試	讀數(mm)
第六次	
第七次	
第八次	
第九次	
平均值	

疤痕面積

最長: _____ **最闊:_____**

香港理工大學康復治療科學系職業治療學部及
東區尤德夫人那打素醫院職業治療部

日期:_____

病人姓名:_____ **病人編號:**_____

第　次手術疤痕評估評估

疤痕拍照 ❑

溫哥華疤痕測試分數

	分數
色澤（M）	
厚度（H）	
血管分佈（V）	
柔軟度（P）	
總分	

視覺評估疤痕痛楚及痕癢程度比例尺

	讀數(mm)
視覺評估疤痕痛楚程度	
視覺評估痕痕癢程度	

疤痕顏色量化記錄表

測試	L*	C*	H*	a*	b*
第一次					
第二次					
第三次					
第四次					
第五次					
第六次					
平均值					

普通皮膚顏色顏色量化記錄表

測試	L*	C*	H*	a*	b*
第一次					
第二次					
第三次					
第四次					
第五次					
第六次					
平均值					

超聲波疤痕厚度評估

測試	讀數(mm)
第一次	
第二次	
第三次	
第四次	
第五次	

測試	讀數(mm)
第六次	
第七次	
第八次	
第九次	

疤痕面積

最長: _____　　**最闊:_____**

香港理工大學康復治療科學系職業治療學部及
東區尤德夫人那打素醫院職業治療部

視覺評估疤痕痛楚及痕癢程度比例尺

視覺評估疤痕痛楚

如果 0 等於沒有痛楚 , 10 等於極度不可接受之痛楚 , 你現在的疤痕痛楚程度是多少？

0 10

視覺評估疤痕痕癢程度

如果 0 等於沒有痕癢 , 10 等於極度不可接受之痕癢 , 你現在的疤痕痕癢程度是多少？

0 10

香港理工大學康復治療科學系職業治療學部及

東區尤德夫人那打素醫院職業治療部

疤痕測試表

溫哥華普通科醫院

英屬哥倫比亞健康科學中心

作業治療

病人姓名：_____

病房編號：_____

評估人員姓名_____

色澤（M）

0 皮膚顏色與身體其他部份比較近似正常

1 色澤較淺

2 混合色澤

3 色澤較深

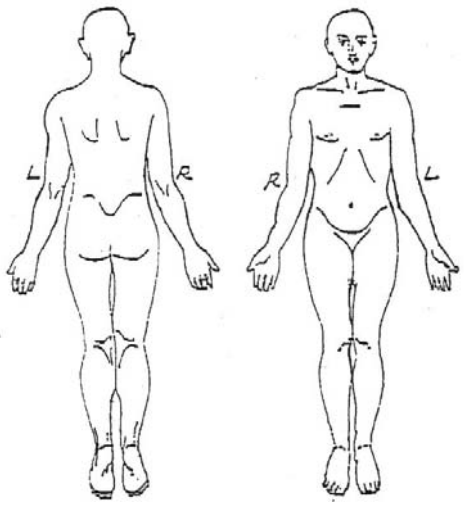
厚度（H）

0 正常

1 1=>0 至 1mm

2 >1 至 2mm

3 >2 至 4mm



血管分佈（V）

0 正常膚色與身體其他部份近似

1 膚色偏粉紅

2 膚色偏紅

3 膚色呈紫色

柔軟度（P）

0 正常

1 柔軟的(在最少阻力下皮膚能變形的)

2 柔順的（在壓力下能變形的)

3 硬的(不能變形的，移動呈塊狀，對壓力有阻力)

4 彎曲(組織如繩狀，疤痕伸展時會退縮)

5 攣縮(疤痕永久性縮短引致

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