A COMPARISON BETWEEN THE EFFECTIVENESS OF LYCRA AND SILON PRESSURE GARMENTS FOR TREATMENT OF HYPERTROPHIC SCAR IN BURNS

BY

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DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SURGERY (PLASTIC SURGERY)

UNIVERSITI SAINS MALAYSIA

MAY 2011

II ACKNOWLEDGEMENTS

In the name of Allah, the most Gracious and Merciful, I thank the Lord for His blessings. This work is dedicated to my parents, for their patience, prayers and encouragement. Without their undying support, this would not have been possible.

It is a pleasure to thank all those who made this thesis possible. I am heartily thankful to my supervisor, Dr Ananda Dorai, whose commitment, guidance and support from the initial to the final level enabled me to develop an understanding of the subject. I owe my deepest gratitude to Professor Dr. Hj. Ahmad Sukari for his continuous encouragement, advice and constructive criticism throughout my training. I would like to extend my humble and sincere thanks to Datuk Dr. Ahmad Ridzwan Arshad and Madam (Dr.) Normala Basiron for their inspiring attitude and helpful advice.

I am indebted to Puan Nurul Wahida Zulkifli and Puan Vimala Asha for they have given their utmost collaboration. I would also like to extend my gratitude to my statistics advisors, Dr. Kamarul Imran Musa and Miss Premaa Supramaniam for their hard work and commitment.

Lastly, I offer my regards and blessings to all of those who supported me in any respect during the completion of the project.

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VI ABSTRAK

Hypertrophic scar selepas kelecuran merupakan satu cabaran besar bagi pakar rawatan kebakaran. Pakaian tekanan *(pressure garment)* dan lembaran silikon *(silicone gel sheets)* sering digunakan dalan rawatan *hypertrophic scar*. Objektif penyelidikan ini adalah untuk membandingkan keberkesanan pakaian tekanan jenis Lycra (yang biasanya digunakan) dan pakaian tekanan Silon (kain yang telah disulam dengan silikon). Kami juga bertujuan untuk mengkaji tahap kepuasan pesakit setelah memakai pakaian tekanan untuk rawatan kelecuran mereka.

Kajian ini dibahagikan kepada 2 fasa. Fasa I adalah kajian retrospektif, yang melibatkan pesakit yang dirawat dengan pakaian tekanan Lycra dari bulan Jun 2007 sehingga Jun 2009. Sementara itu, fasa II adalah suatu penelitian prospektif, yang melibatkan pesakit yang dirawat dengan pakaian tekanan Silon dari bulan Jun 2008 sehingga Jun 2010. Butiran demografi yang dikumpulkan meliputi umur pesakit, jenis dan kedalaman kelecuran, jumlah luas permukaan kelecuran *(total burn surface area)* dan penyebab kelecuran. Keberkesanan rawatan ditentukan berdasarkan skor *Vancouver Scar Scale*. Parut diperiksa 2 minggu selepas luka pesakit telah sembuh sepenuhnya. Penilaian lanjut adalah pada 4, 8 dan 12 bulan yang berikutnya.

Repeated measures ANOVA menunjukkan perbezaan statistik yang ketara dari aspek vaskulariti, kegatalan dan rasa sakit parut dalam setiap kumpulan kajian ($p < 0.05$). Namun demikian, perbandingan antara kumpulan Lycra dan Silon tidak menunjukkan sebarang perbezaan statistik ($p > 0.05$). Sementara itu, tidak ada perbezaan yang signifikan di dalam kumpulan dan di antara 2 kumpulan pakain tekanan dari segi

ketinggian, pigmentasi dan kelenturan parut. Majoriti pesakit merasa gatal, berpeluh, tidak selesa dan ketat semasa memakai pakaian tekanan. Meskipun demikian, mereka tetap yakin bahawa mematuhi ketetapan yang telah ditentukan berkenaan dengan pakain tekanan adalah sangat penting untuk mendapatkan hasil yang optimum.

Hasil kajian ini tidak dapat membuktikan bahawa pakaian tekanan Silon adalah lebih berkesan berbanding dengan pakaian tekanan Lycra. *Hypertrophic scar* selepas kelecuran boleh memakan masa sehingga 2 tahun untuk mencapai kematangan. Oleh itu, kami mengesyorkan bahawa parut kelecuran harus dipantau dan rawatan dengan pakaian tekanan harus diteruskan untuk sekurang-kurangnya 2 tahun.

VII ABSTRACT

Introduction

Hypertrophic scarring after burns remains a major challenge for burn care providers. Pressure garments and silicone sheets have been the mainstay of hypertrophic scar treatment. This study was to compare the effectiveness of the traditional Lycra pressure garment and the silicone incorporated pressure garment (Silon) and also to determine patients' satisfaction with pressure garment among burns patients in Hospital Universiti Sains Malaysia.

Methodology

This is was a two-phased study. Phase I was a retrospective study, which involved patients who were treated with the Lycra pressure garments from June 2007 until Jun 2009. Meanwhile, phase II was a prospective study, involving patients who were treated with the Silon pressure garments from June 2008 until June 2010. Demographic details collected included age, type and depth of burn, total burn surface area (TBSA) and cause of injury. The effectiveness of the treatment was determined based on the Vancouver Scar Scale score. Patients' scars were assessed 2 weeks after complete wound healing, and every 4 months, for up to 1 year.

Results

Repeated measures ANOVA showed significant improvement in terms of scar vascularity, itch and pain within each study group ($p < 0.05$). However, there was no statistical difference between the two pressure garment groups ($p > 0.05$). Meanwhile, there was no significant difference within and between the 2 study

groups in terms of scar height, pigmentation and pliability. Majority of the patient complained of itch, sweating, discomfort and tightness upon wearing the pressure garments. In addition to interfering with their daily activities, they also reported no improvement of their scar appearance. Nevertheless, they still believe that compliance with the treatment is of great importance in order to gain optimal result.

Conclusion

We cannot conclude that the combined pressure garment and silicone therapy (Silon) was more effective than the traditional pressure garment (Lycra). Hypertrophic scars following burns injuries can take up to 2 years to reach maturity. Thus, it is recommended that scars should be monitored and pressure garment treatment should be carried out for at least 2 years.

1. INTRODUCTION AND LITERATURE REVIEW

1.1 Research Background

Burn care, has dramatically changed over the past decades with the introduction of pressure therapy, early excision and grafting, and the use of dermal replacements. Despite these positive changes, hypertrophic scarring after burns remains a major challenge for burn care providers. It is a common and frustrating problem, due to its functional and aesthetic consequences. Hypertrophic scars are itchy, painful, unsightly, and interfere with function and daily activities. The prevalence of hypertrophic scarring after burns has been reported to be as low as 7% (MacDonald and Deitch, 1987) to as high as 91% (Lewis and Sun, 1990).

An array of treatment modalities have been introduced to manage hypertrophic scars (Su et al, 1998, Mustoe et al, 2002). However, these current methods are still time consuming, expensive, and often ineffective.

1.2 Hypertrophic Scar

Peacock et al (1970) defined hypertrophic scarring as a scar raised above the skin level that stays within the confines of the original lesion. It may affect any body part. However, it more commonly occurs after injuries to the extremities and trunk, especially those that cross joints or skin creases at right angles. Hypertrophic scars result from general failure of normal wound healing processes (Van der Veer et al, 2009). Hence, they tend to develop when injuries extend to the reticular dermis or deeper. They frequently follow partial or full thickness burn injuries, or wounds with delayed epithelialisation (Urioste et al, 1999).

1.2.1 Wound Healing – Phases

When the skin is injured, the wound healing process consists of 3 stages—inflammation, granulation, and matrix remodelling (Alster et al, 1997, Kirsner, 2003). The phase of inflammation, produces exudate from damaged vessels that fills the wound. Neutrophils trigger an inflammatory cell cascade and macrophages phagocytose cellular and foreign debris. Subsequently, in the granulation phase, macrophages secrete cytokines that promote granulation tissue formation consisting of re-epithelialization, recreation of an appropriate blood supply, and reinforcement of the injured tissue. In the final stage of wound healing, matrix remodelling, fibroblasts proliferate and deposit new collagen and matrix materials at the wound site. The remodelling process of collagen synthesis and lysis can last up to 2 years after tissue injury (Zurada et al, 2006).

Hypertrophic scars develop when the wound healing processes are prolonged, where excessive deposition of collagen results in exaggerated wound healing responses with progressive increase in collagen synthesis (Beldon, 2000).

Clinically, hypertrophic scars are raised, erythematous, nodular lesions with numerous telangiectasias and shiny, atrophic surface. These appearances are often cosmetically unappealing to the affected individuals (Clark et al, 1996). In addition, they are frequently associated with pruritus, dysesthesia and pain (Van Loey et al, 2008). Scar contractures commonly develop over the joint areas. These significant functional and cosmetic impairments are all responsible for a decrease in quality of life for many burn survivors (Haverstock, 2001).

Hypertrophic scars usually develop within 1 to 3 months after injury, in contrast with keloid scars that may appear up to 12 months after injury (Brisset et al, 2001). Previous studies reported diverging incidences of hypertrophic scarring following burns (Tables 1 and 2). However, Bombaro et al. (2003) found that 63% of White race patients and 75% of the non-White patients had hypertrophic scar. Many factors such as race, age, genetic factors, hormone levels, atopy and immunologic responses of the individual patient appear to play a role. The type of injury, wound size and depth, anatomic region and mechanical tension on the wound are also important as well. Moreover, complicating factors such as bacterial colonization and infection of the wound seem to induce hypertrophic scarring (Niessen et al, 1999, Brissett et al, 2001, Baker et al, 2007, Berman et al, 2007).

Table 1: Hypertrophic scarring rates after burns in adults (modified from Bloeman, M.C.T., Van der Veer, W.M., Ulrich, M.M.W. et al (2009). Prevention and curative management of hypertrophic scar formation, *Burns*. 35, 463-475)

Study	Patients	Follow-up	Rate (%)	Comment
Lewis and Sun (1990) prospective	58 Chinese patients	3–9 Months	91.4%	+ Scale is used for definition of hypertrophy + Only Chinese patients - Depth, age and treatment not mentioned
Bombaro et al. (2003) retrospective	73 Adults	–	75% In non-white 63% In white	+ Race documented - Depth, follow-up period, time of healing and treatment not mentioned
Gangemi et al. (2008) retrospective	703 Patients	Up to 12 years	72%	+ Treatment and patient characteristics described + Classification for scar is used - Race not documented
Deitch et al. (1983) retrospective	121 Burn sites in 41 adults	9–24 Months	30% In black 16% In white	+ Only superficial or moderate partial thickness depth burns included, all not grafted + Treatment and time of healing are well described - No exclusion of keloids
McDonald and Deitch (1987) prospective	113 Burn sites in? adults	1 Year	25% In black 7% In white	+ Only grafted wounds included + Race, age and time of healing are described
Bombaro et al. (2003) prospective	30 Patients	1–2 Years	0%	- Race, depth and definition of hypertrophic scar not described

Table 2: Hypertrophic scarring rates after burns in children (modified from Bloeman, M.C.T., Van der Veer, W.M., Ulrich, M.M.W. et al (2009). Prevention and curative management of hypertrophic scar formation, *Burns*. 35, 463-475)

Study	Patients	Follow-up	Rate (%)	Comment
Bombaro et al. (2003) retrospective	13 Children <15 years of age	–	100% In non-white 75% In white	+ Race documented - Depth, follow-up period, time of healing and treatment not mentioned
Cubison et al. (2006) retrospective	170 Children	4 Months	74% Wounds healed Spontaneous 57% Wounds grafted	+ Distinction grafted and spontaneous healed wounds + Time of healing and follow-up period documented - Race and depth not mentioned
McDonald and Deitch (1987)] prospective	60 Burn sites in 26 children <14 years of age	1 Year	57% In black 31% In white	+ Only grafted wounds included + Race, age and time of healing are described
Spurr and Shakespeare (1990) retrospective	152 Children <5 years of age	–	51% In 1968 63% In 1984	- No distinction spontaneous healed and grafted wounds - Follow-up period and race not mentioned
Deitch et al. (1983) retrospective	124 Burn sites in 59 children <14 years of age	9–24 Months	31% In black 13% In white	+ Only superficial or moderate partial thickness depth burns included, all not grafted + Treatment and time of healing are well described - No exclusion of keloids

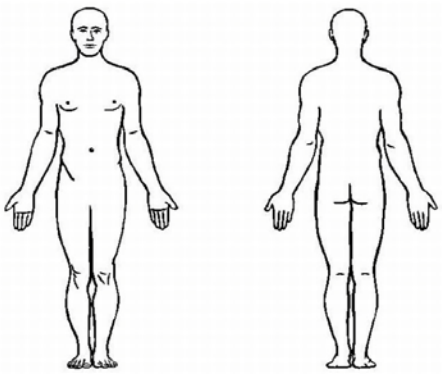
1.3 Scar Evaluation

Various tools are currently available for the assessment of hypertrophic scars, from simple clinical inspection to complex technical assessments (van Zuijlen, 2002). Hypertrophy can be quantified by measurements: scar thickness/volume measured with ultrasound, colour determined by spectrophotometry and assessment of vascularity by laser doppler flowmetry. More complex techniques have also been described in a research setting such as anisotrophy (stiffness) and profilometery (contour). A number of clinical scoring systems have been described and validated, and some are easier to apply than others in the clinic setting (Sullivan et al, 1990, Baryza et al, 1995, Beausang et al, 1998).

The Modified Vancouver Scar Scale (VSS) (Fig. 1) is a validated subjective scale and is the most commonly applied scar scoring system. As our occupational therapists were accustomed to using this technique, we believed that they would be able to use it to provide a reliable objective assessment.

THE MODIFIED VANCOUVER SCAR SCALE

Pigmentation (M)
0 Normal
1 Hypopigmentation
2 Hyperpigmentation



Vascularity (V)
0 Normal
1 Pink
2 Pink to red
3 Red
4 Red to purple
5 Purple

Pliability (P)
0 Normal
1 Supple – flexible with minimal resistance
2 Yielding – giving way to pressure
3 Firm – inflexible, not easily moved, resistant to manual pressure
4 Banding- rope-like tissue that blanches with extension of scar
5 Contracture – permanent shortening of scar producing deformity or distortion

Height (H)
0 Normal to flat
1 < 2mm
2 < 5 mm
3 > 5 mm

Pain & itch
0 None
1 Occasionally
2 Needs medication

Figure 1: Vancouver Scar Scale (Sullivan et al, 1990)

1.4 Treatment Modalities

The management of hypertrophic scar is challenging, hence, early recognition of the potential development of hypertrophic scar is critical. Numerous forms of treatment have been developed in the past several years to minimize tissue growth and wound contraction. Despite these advances, the degree of successes is variable (Mustoe et asl, 2002).

Traditional techniques include (1) pressure garments, (2) intralesional steroids, (3) topical applications of silicone, vitamins A and E, imiquimod 5% cream, and other pharmacologic agents, and (4) surgical intervention. More recently, lasers have gained an increasing role in the treatment of hypertrophic scars (Bloemen et al, 2009). Often, use of multiple modalities is necessary to successfully treat the lesions.

1.5 Pressure Garment

Mechanical compressive force by pressure garments to treat hypertrophic scars in burn patients was already described in 1860 (Linares, 1993). It was only until the early 1970s that this became the mainstay of treatment for burn patients suffering from hypertrophic scars. Pressure therapy seems to accelerate the natural remodelling process and results in flattening of the scar (Reid et al, 1987, Sawada, 1993, Van den Kerckhove et al, 2005). Pressure is also used to obtain better cosmetic results, to soften the scar, to assist in the prevention of skin contractures and to reduce problems of itch and skin hypersensitivity (Ward, 1991).

Pressure therapy is thought to have an effect on the collagen remodeling phase of wound healing. Several mechanisms of action have been described, including hydration, restriction of blood flow and release of prostaglandin E_2 (Table 3).

The hypoxic environment is hypothesized to decrease collagen formation and increase collagen lysis and loosen the collagen fibrils aligned to the skin surface, thereby more closely approximating the elastic requirements of the skin (Staley et al, 1997, Eisenbeiss et al, 1998, Rayner, 2000, Puzey, 2002). This hypothesis remains controversial, however, as other studies have shown that qualitative improvements in scar tissue receiving pressure therapy correlate with increased blood flow (Kealey et al, 1990, Klopp et al, 2000).

Table 3: Possible mechanisms of action in pressure therapy (adapted from Bloeman, M.C.T., Van der Veer, W.M., Ulrich, M.M.W. et al (2009). Prevention and curative management of hypertrophic scar formation, *Burns.* 35, 463-475)

Cause	Hypothesis
Hydration	**PRO:** Decreased scar hydration results in mast cell stabilization and a subsequent decrease in neovascularization and extracellular matrix production (Brissett et al, 2001) **CON:** This hypothesis is in contrast with a mechanism of action of silicon, in which an increase of mast cells causes scar maturation (Brissett et al, 2001, Macintyre et al, 2006, Zurada et al, 2006)
Blood flow	A decrease in blood flow causes a decrease in α_2-macroglobulin and a subsequent increase in collagenase mediated collagen breakdown, normally inhibited by α_2-macroglobulin (Brissett et al, 2001) A decrease in blood flow causes excessive hypoxia resulting in fibroblast degeneration and decreased levels of chondroitin-4-sulfate, with a subsequent increase in collagen degradation. Hypoxia would also loosen the collagen fibrils aligned to the skin surface (Brissett et al, 2001)
Prostaglandine E_2 release	Induction of prostaglandine E_2 release, which can block fibroblast proliferation as well as collagen production (Reno et al, 2001)

As soon as the wounds were fully epithelialised and able to tolerate pressure, patients were fitted with pressure garments. A fair body of evidence supports the use of compression therapy but literature is generally lacking in reports on effectiveness and optimal pressures. Reports on amount of pressure required ranged between 24 and 40 mmHg (Alster et al, 2003, Van den Kerckhove et al, 2005, Macintyre et al, 2006, Atiyeh, 2007). A significant difference was reported regarding thickness of burn scars that were treated with garments with a mean value of 15 mmHg pressure compared with a mean pressure of 10 mmHg (Van den Kerckhove et al, 2005). The consensus is that an applied pressure of 25 mmHg may represent ideal loading (Cheng et al, 1983), but more recent studies suggest that good clinical results may be achieved at much lower compression levels (Ward et al, 1991).

A study by Macintyre (2005) showed pressure garment practitioners were confused over the 'ideal pressure' for pressure garment treatment. Pressures delivered by pressure garments are not normally known or measured due to the lack of a pressure measurement system capable of measuring low interface pressures quickly and accurately. Garments should be changed every 6 to 8 weeks to prevent a decrease in elasticity. The efficacy of the treatment method cannot be evaluated effectively since it is not known whether patients exhibiting a poor response to pressure treatment are indeed receiving optimum pressure. Therefore, one of the objectives of this study is to monitor the changes of pressure exerted by the pressure garment over the period of one year.

Various pressure sensors have been utilised to investigate the effectiveness of pressure garment therapy. In 1984, Cheng et al. developed an electro-pneumatic pressure transducer. The air sac was filled with air, supplied by a hand pump. When the electrodes in the sac separated, the interface was recorded. Thereafter, the pressure transducer coupled to a fluid-filled sensor was published. A flat disc-shaped sensor cell, filled with vegetable cooking oil, and tubing were commercially available electro-pneumatic sensors. The transducer was an integrated circuit piezo-resistive pressure-sensitive device producing an output proportional to the applied pressure (Barbanel and Sockalingham, 1990). In 1993, Sawada used a pneumatic pressure monitor with a rubber balloon, connected to a catheter, and a control-inflator, which could measure pressure from 0 to 120 cmH_2O. Another technique directly measured the subdermal cutaneous pressure. A needle was connected to a continuous low flow pressure transducer and inserted subdermally. Following a short period of equilibration, the resting subdermal pressure was obtained in mmHg. The reading was repeated after application of a custom-fitted pressure garment (Giele et al, 1997, 1998). At the end of the nineties, a new technique, based on ink sensors were introduced. The Iscan system consisted of resistive sensors printed with conductive ink onto a thin, plastic film substrate. Changes in resistance under pressure produced output signals that were proportional to the applied normal pressure (Mann et al, 1997). Another ink based sensor is the FlexiForce Sensor, in which the electrical resistance varied inversely with the applied force (Ferguson-Pell, 2000).

Unfortunately none of the authors have succeeded in showing adequate reproducibility of the measurements in clinical circumstances. In the present study, the Kikuhime pressure sensor was utilised. It is a pneumatic pressure sensor developed in the Harada Company, Japan.

These garments should be worn for at least 23 hours a day until the scar is mature (Van den Kerckhove et al, 2005, Macintyre et al, 2006). Early release of the garments tends to be followed by rebound hypertrophy (Niessen et al, 1999).

Pressure garments are expensive, uncomfortable and emotionally traumatic. Current recommendations state that pressure garments should be worn for up to 2 years for hypertrophic burn scars. Hence, it is essential that they should be comfortable to wear. The thermophysiological properties of a garment provide comfort by maintaining body temperature and moisture output close to their normal levels. They must not abrade or ulcerate the developing scar or adjacent skin, which is either covered by or in contact with the pressure garment. They should not cause physiological discomfort due to excess warmth or sweat production. Hence, patients' compliance can be a major problem, with reports of non-compliance ranging from 8.5% to 59% (Kealey et al, 1990, Johnson et al, 1994). For these reasons, we conducted a questionnaire to evaluate the patients' satisfaction and understanding with regards to their treatment with the pressure garment.

However, despite their widespread use, the efficacy of pressure garments has never been scientifically proven and many unanswered questions remain as to their effective use and construction.

1.5.1 Lycra Pressure Garment

Lycra or elastane is a synthetic fibre known for its exceptional elasticity. It was invented in 1959 by chemist Joseph Shivers at DuPont's Benger Laboratory in Waynesboro, Virginia as an alternative to the rubber used in corsets (Reisch, 1999). When first introduced, it revolutionized many areas of the clothing industry.

Lycra consists of polyurethane-polyurea chains with rigid and flexible portions, allowing the fibre both to stretch significantly and to retain its shape. It does not breakdown from heat and is the highest quality synthetic compression fiber. Hence, is stronger and more durable than rubber. Lycra is never used alone, but always blended with other fibres, including cotton, wool, silk and nylon.

In addition to its unique stretch and recovery properties, Lycra allows garments to be more lightweight, comfortable, and breathable. It is quick drying and it is resistant to ultraviolet (UV) rays and chlorine.

These unique properties of Lycra make it the ideal material for pressure garment, where it is commonly combined with nylon and cotton. For this purpose, it is designed as a higher stretch resistant fabric, in order to maintain a more consistent pressure.

1.6 Silicone Gel

Silicone gels are thin, soft, semi-occlusive, transparent sheet that adhere well to scars. They are made entirely from synthetic polymers, generally based on cross-linked polydimethylsiloxone polymers that have extensibility similar to that of the skin. In 1982, the use of silicone materials in the treatment of hypertrophic burn scars was first described by Perkins et al. Since its introduction, many authors reported silicone as the key in non-invasive scar management. Topical silicone gel sheeting and ointment have been used widely to minimize the size, induration, erythema, pruritus, and extensibility of pre-existing hypertrophic scars and to prevent the formation of new ones, especially after burns (Quinn et al, 1985 and 1987, Ahn et al, 1989, Gold 1993). Irrespective of the formulations, silicones are easy to apply and painless.

Although there have been several uncontrolled clinical reports stating that silicone gel sheeting promotes resolution of hypertrophic scars (Quinn, 1985, Sawada et al, 1992, Gold, 1993, Dockery et al, 1994, Katz, 1995), a number of more valid controlled studies exists (Ahn et al, 1989 and 1991, Sproat et al, 1992, Li-Tsang et al, 2005).

Silicone sheeting also helps minimize new hypertrophic scarring when applied about 2 weeks after wounding (Dockery et al, 1994, Fulton, 1995, Niessen et al, 1998, Gold et al, 2001).

The exact mechanism of action of silicone in the prevention and management of hypertrophic scars remain unclear, although several hypotheses exist. Published theories include hydration, temperature, polarization, oxygen tension, the presence of silicone oil in the local environment, mast cells and the effect of blood flow and pressure (Table 4).

Table 4: Possible mechanisms of action in silicone treatment (adapted from Bloeman, M.C.T., Van der Veer, W.M., Ulrich, M.M.W. et al (2009). Prevention and curative management of hypertrophic scar formation, *Burns.* 35, 463-475)

Cause	Hypothesis
Hydration	Hydration can be caused by the occlusion of the underlying skin. It decreases capillary activity and collagen production, through inhibition of the proliferation of fibroblasts (MacDonald et al, 1987, Chan et al, 2005, Bernan et al, 2007)
Temperature	A rise in temperature increases collagenase activity and therefore silicone reduces hypertrophic scars by breaking down collagen (Musgrave et al, 2002)
Polarization	The negative charge within silicone causes polarization of the scar tissue, resulting in involution of the scar (Hirshowitz et al, 1998, Har-Shai et al, 1999, Mustoe et al, 2008)
Silicone oil	**PRO**: The presence of silicone has been detected in the stratum corneum of skin exposed to silicone (Musgrave et al, 2002) **CON:** Other researchers suggest the effects are not likely to be due to silicone release, as other occlusive products without silicone have also shown good results (Ahn et al, 1989, Sawada et al, 1992, Fulton et al, 1995, De Oliveira et al, 2001)
Oxygen tension	**PRO**: After silicone treatment the hydrated stratum corneum is more permeable to oxygen and thus oxygen tension in the epidermis and upper dermis rises. Increased oxygen tension will inhibit the ''hypoxia signal'' from this tissue. Hypoxia is a stimulus to angiogenesis and tissue growth in wound healing, as a consequence removing the hypoxia stops new tissue growth (Gilman et al, 2003, Berman et al, 2007) **CON:** The contrary has also been described (Quinn et al, 1985)
Mast cells	**PRO:** Some reports have suggested that silicone has influence on the number of mast cells in hypertrophic scar tissue. A higher number of mast cells in hypertrophic scars compared with normal scars has been reported in several studies. An increased number of mast cells was found in keloid and hypertrophic scars treated with silicone and it was suggested that silicone results in an increase of mast cells in the cellular matrix of the scar with subsequent accelerated remodeling of the tissue (Kischer et al, 1982, Tredget et al, 1998, Chernoff et al, 2007) **CON**: Some studies have reported no difference of the number of mast cells in hypertrophic scars compared with normal scars (Beer et al, 1998, Niessen et al, 2004)
Blood flow and pressure effect	Beneficial effects of silicone are not mediated by changes in blood flow and a pressure effect (Quinn et al, 1987, Musgrave et al, 2002)

However, Quinn (1987) demonstrated that the efficacy of silicone gel sheeting was unrelated to pressure, oxygen tension, and temperature. He also documented increased hydration of the wound with use of silicone sheeting, but it is unknown how this might affect scar formation or remodeling. No systemic or local absorption of the silicone products has been detected in scars treated with silicone. Silicone sheets have an evaporative water loss almost half that of skin and have been compared with the stratum corneum. Most researchers believe that silicone acts by creating a hydrated, occluded environment that decreases capillary activity, thereby reducing fibroblast-induced collagen deposition and scar hypertrophy (Quinn et al, 1985, Sawada et al, 1990, Chang et al, 2001). Thus, silicone sheets decrease hyperaemia and minimize fibroblast production of collagen and promote wound flattening (Chang et al, 2001).

Interestingly, the use of silicone cream alone compared with silicone cream with occlusive dressing showed 22% and 82% scar improvement, respectively, with respect to erythema, tenderness, pruritus, and hardness (Sawada et al, 1990). These results supported that occlusion may be synergistic in wound healing and suggested that silicone gel alone may not be as effective as silicone sheeting. Wounds treated with silicone gel sheeting have negligible amounts of silica in histologic sections. Therefore, the presence of silicone itself may not be necessary (Ahn et al, 1989, Fulton, 1995).

Hirshowitz et al (1993) proposed that silicone sheets produce a static electric field (resulting from friction of the silicone material) that might have an effect on wound healing.

It is recommended to apply silicone gel twice daily or to wear silicone gel sheeting 12–24 h per day for 6–12 months with temporary interruption when adverse effects appear. Daily cleaning of the material and underlying skin is necessary to prevent irritation and heat rash. Other side effects of silicone are skin maceration and itching (Fette, 2006).

Currently, combined therapy of silicone sheets with classical pressure garments are widely practised. When combined therapy is used, the working mechanisms of the individual modalities (pressure, hydration and occlusion) combine and reinforce each other. At present, textile materials for pressure garments bonded with silicone are available. An example of this silicone textile composite is the Silon pressure garment.

Therefore, given the current trends in burn scar management it would be useful to perform a comparative study between the traditional Lycra pressure garment with the silicone incorporated Silon pressure garment treatment, with regards to their effects on scarring.

2. OBJECTIVES OF THE STUDY

2.1 General Objective

To compare the effectiveness of Silon (silicone impregnated) and Lycra pressure garments for treatment of hypertrophic scar in burns.

2.2 Specific Objectives

1) To determine the Vancouver Scar Scale among patients receiving pressure garment therapy following burns in Hospital Universiti Sains Malaysia.
2) To compare the Vancouver Scar Scale score between patients treated with Silon (silicone impregnated) pressure garments versus patients with Lycra pressure garments.
3) To evaluate whether our in-house custom made pressure garment exerts the recommended pressure of 25mmHg.
4) To determine patients' satisfaction with pressure garment among burns patients in Hospital Universiti Sains Malaysia.

3. MATERIALS AND METHODS

3.1 Ethical Approval

The study was a two-phased study involving patients attending the Burns and Reconstructive Sciences Unit, Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan. The study had been approved by the Medical Ethics Committee of the School of Medical Sciences, Universiti Sains Malaysia. Data was kept confidential and only to be used for this study. Refusal to participate will not jeopardize the management of the patient.

3.2 Design – Phases of Study

3.2.1 PHASE I

Prior to the commencement of the project, the Lycra pressure garment was utilised for hypertrophic scar treatment. Thus, Phase I was a retrospective study, which involved patients who were treated with the Lycra pressure garments for their hypertrophic scars following burn injuries, from June 2007 until Jun 2009. Lycra pressure garment therapy was started approximately 2 weeks after epithelialisation of the wound. Demographic data were extracted from their medical records (Appendix I). Their hypertrophic scars were assessed using the Vancouver Scar Scale (Appendix II) during their 4-monthly visit with the occupational therapist, for up to 1 year (i.e. 3

follow up sessions). Hence, the scar assessment data were extracted from the occupational therapist's record. During their routine follow up to our clinic, patients or their parents/guardians were asked, if agreeable, to answer a questionnaire regarding their satisfaction following treatment with the pressure garments (Appendix III).

3.2.2 PHASE II

Phase II was a prospective study, involving patients who were treated with the Silon pressure garments for their hypertrophic scars following burn injuries, from June 2008 until June 2010. The selection of the participants was done after strictly fulfilling the inclusion and exclusion criteria. As with the Lycra pressure garment, Silon pressure garment therapy was started approximately 2 weeks after epithelialisation of the wound. Demographic data were extracted from their medical records (Appendix I). Meanwhile, their hypertrophic scars were assessed using the Vancouver Scar Scale (Appendix II) during their 4-monthly visit with the occupational therapist, for up to 1 year (i.e. 3 follow up sessions). In contrast to Phase I of the study, the pressure exerted by the pressure garments were also measured at the same setting. At the end of the study, patients or their parents/guardians were also asked, if agreeable, to answer a questionnaire regarding their satisfaction following treatment with the pressure garments (Appendix III).

3.3 Sample Size

Sample size calculation was based on the Two Means (Independent Observations) formula.

$$n = \frac{2\sigma^2}{\Delta^2} [z_\alpha + z_\beta]^2$$

$$= \frac{2 (1.55)^2}{1} [1.96 + 0.84]^2$$

$$= 37.67$$

σ = the biggest SD in pliability score in operated patients (Vloemans et al., 2001)
Δ = expected difference in pliability score between Silon and Lycra pressure garment
z_α = 1.96 for α = 0.05 (two-tailed)
z_β = 0.84 for 80% power

Therefore, the sample size for **each study group** was

n = 38 + drop out
= 38 + 4
= 42

3.4 Subjects

The source of population were all cases of partial thickness or full thickness burns admitted to Hospital Universiti Sains Malaysia, who were eventually treated with pressure garment once their wounds were healed.

3.4.1 Inclusion Criteria

1. All patients with recently healed (2 weeks after the wound has fully epithelialised). These wounds could be
    - partial thickness, or
    - full thickness burn wounds
2. Patients with at least 2% total body surface area of burns (TBSA)
3. Patients with burns involving the trunks, upper limbs and/or lower limbs
4. Consented patients
5. Patients compliant with the treatment protocol

3.4.2 Exclusion Criteria

1. Patients who developed severe wound infection
2. Burns involving face and/or perineum
3. Non-compliant patients (not using pressure garment for > 1 month)
4. Cases which were referred from outside of the state
5. Non-residents of Kelantan (eg. holiday-makers)