PRESSURE GARMENT THERAPY (PGT) OF BURN SCARS: EVIDENCE-BASED EFFICACY

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SUMMARY. Hypertrophic burn scars pose a challenge for burn survivors and providers. In many cases, they can severely limit a burn survivor’s level of function, including work and recreational activities. A widespread modality of prevention and treatment of hypertrophic scarring is the utilization of pressure garment therapy (PGT). Despite the magnitude of the problem of hypertrophic scarring and the ubiquitous use of pressure garments as therapy, strong clinical evidence of the efficacy of PGT in the literature is lacking. Some of the challenges facing measurement of efficacy of PGT on hypertrophic scarring are lack of clear definitions for degree of hypertrophic scarring, inability to quantify pressure applied to scars, patient noncompliance to strict PGT time schedules, and inability to conduct randomized controlled trials comparing PGT to no therapy for ethical reasons since PGT is considered a standard of care. In this review, we attempt to summarize and analyze evidence-based literature on PGT and its efficacy in burn hypertrophic scars published in English language in the past 15 years.

Keywords: pressure garment therapy, hypertrophic burn scar

Introduction

Hypertrophic scarring can be considered a systemic inflammatory illness regulated by local wound healing factors. It occurs more frequently in women and patients of younger age groups.1 Hypertrophic burn scars remain a problematic challenge for both patients and health care providers and are a very frequent problem of burn survivors who have delayed healing or skin-grafted areas. In many cases, they are a source of morbidity presenting with lifestyle-limiting problems such as pruritus, pain, burning, stiffness and even contractures2,3 and can severely limit a burn survivor’s level of function, including work and recreational activities.4

Major risk factors of pathologic scarring include gender, age, anatomical burn site, number of operations, and skin grafts.5 Although hypertrophic scarring commonly occurs following burns and gives rise to the most notable scars encountered in practice, many aspects such as its incidence and optimal prevention and/or treatment remain unclear.13 Studies report diverging incidence rates varying from 40% to 94% following surgery and from 30% up to 91% following burns. It is estimated that four million patients acquire scars as a result of burns each year in western countries.7 The incidence is even greater in low and middle-income countries in which the majority of burn injuries occur.

Prevention and treatment of hypertrophic scars (HSs) is one of the most important issues in burn rehabilitation.6 Their successful management depends on early and aggressive treatment. Unfortunately, the number of studies related to prevention and/or treatment of HSs with both agreement and consensus are limited.3 No ideal or all-purpose method of scar control exists moreover the unpredictability and non-specificity of all available therapeutic aids in general remain a major problem.1

Traditionally, treatment of hypertrophic burn scars consists among several options of pressure therapy that involves wearing garments made from elasticized fabrics.6 Mechanical loading by applying pressures of between 6 and 50 mmHg is routinely used to treat, control or prevent a number of medical and pathologic conditions.7 Although specific reference to treating HSs with pressure goes as far back as the early 1800s and even as early as the 16th century, pressure garments have not been used prophylactically or to treat hypertrophic burn scars till the early 1970s based on observed increased rate of maturation or lack of HS development under some kind of pressure in individual patients.10 Ever since that time, among all forms of noninvasive conservative management modal-
ities, pressure therapy by means of wearing custom-made or commercially available pressure garments evolved to become one of the main noninvasive scar management options. It is widely used worldwide and is well substantiated in the literature.\textsuperscript{1-15}

Even though there is limited evidence to support the effectiveness of various treatments for prevention or reduction of scarring, there is general consensus on the use of pressure garment therapy (PGT). This treatment modality continues to be a clinically accepted practice. It is the most common therapy used for the treatment and prevention of abnormal scars after burn injury particularly in North America, Europe and Scandinavia where it is considered routine practice and regarded as the preferred conservative management with reported thinning and better pliability ranging from 60\% to 85\%.\textsuperscript{3,9,16-18} At present, PGT is the standard first-line therapy for hypertrophic burn scars in many centers due to its non-invasive characteristics and presumed desirable treatment effects with few associated complications.\textsuperscript{3,19} Prophylactic pressure therapy is generally recommended in burn patients requiring burn wound excision and grafting or in wounds taking longer than 10-14 days for spontaneous closure.\textsuperscript{1}

There is still much confusion and contradictory evidence regarding safe and effective pressures for prevention or management of HSs\textsuperscript{10} and parameters such as the duration and the magnitude of applied pressure remain largely empirical.\textsuperscript{11} Despite the fact that the exact optimal pressure required for effective treatment has never been scientifically established, some authors have noted benefits with 5-15 mm Hg of pressure while others have claimed that an effective pressure of 15 mm Hg is recommended. Generally, it is recommended that pressure should be maintained between 20 and 30 mm Hg, which is above capillary pressure but less than what would diminish peripheral blood circulation. Unspecified higher pressures have also been claimed to give more rapid results in terms of time to scar maturation. However, there is ample evidence that high pressures exceeding 30-40 mmHg cause severe discomfort and are potentially harmful. Shortly after application, high pressure (over 40 mmHg) could cause maceration and paresthesia.\textsuperscript{1-3,10,11,16,21}

It is suggested that custom-made elastic pressure garments are the most effective and comfortable treatment for HSs.\textsuperscript{1,2} For facial scarring, pressure is better exerted through a custom-made, transparent plastic face-mask.\textsuperscript{3} To be effective, PGT should be maintained for at least 6 to 12 months.\textsuperscript{29} Patients are instructed to wear pressure garments 23 hours each day, and better results are observed if PGT is initiated prophylactically as early as 2 weeks following wound closure. Obviously, pressure gradient delivered during this type of treatment determines efficacy and complications that may be due to excess pressure or incorrect pressure gradient application.\textsuperscript{9,16,20} Unfortunately, pressure garments are unattractive and are associated with high costs and potential patient morbidity. PGT has been reported to cause overheating, pruritus, blistering, wound breakdown, and abnormal bone growth.\textsuperscript{12,16} Moreover, pressure garments are highly uncomfortable in hot and humid climates.

Despite extensive literature in favor of its use, the effectiveness of PGT has never been validated and proven scientifically. To date, few studies exist examining the effectiveness of pressure garments and clear scientific proof for their value is lacking.\textsuperscript{1} Current evidence that supports benefits of PGT is largely anecdotal\textsuperscript{12} and its effect on scar maturation remains controversial.\textsuperscript{1} A recent meta-analysis of randomized controlled trials based on six unique trials of high methodological quality involving 316 patients (including one unpublished trial) concluded that PGT does not appear to alter global scar scores.\textsuperscript{16} It does however appear to improve scar height, but this difference is small and is of questionable clinical importance.\textsuperscript{16,17}

Despite the fact that potential morbidity and cost of PGT are not insignificant and that its beneficial effects remain largely unproven,\textsuperscript{16,17} pressure garment protocols are still reported by many burn centers as essential to optimize scar control, alleviate symptoms associated with HSs, and improve general body “homeostasis”.\textsuperscript{1} The present review is aimed at analyzing the available data about PGT of burn HSs in order to possibly establish evidence-based guidelines for this management modality that would balance benefits with costs and possible complications.

Materials and methods

Using the keywords “pressure garment therapy,” “compression,” “burn,” and “hypertrophic scar”; an electronic database search of PubMed, Medline, Scopus, CINAHL, and EMBASE was conducted. The search was limited to papers published in English in the last 15 years. Relevant papers were selected with a special focus on the meta-analysis recently published comparing pressure with no pressure in the prevention and treatment of burn hypertrophic scarring.\textsuperscript{16} Key references cited by some of the retrieved studies were also consulted for their relevance. Studies combining silicone padding with PGT were not considered. It was not possible, however, to retrieve studies making a clear distinction between prevention and treatment of burn hypertrophic scarring.

Pressure garments and Laplace’s Law

Fabricating a compression garment with a required pressure is important.\textsuperscript{29} Pressure exerted by a garment is largely determined by the fabric tension per unit length and its anisotropic behavior. It is also influenced by the number of fabric layers used for its construction as well as by fabric grain direction that must be aligned with the
pressures in the range 9–90 mmHg depending on the anatomical site. Garments over soft tissues generate pressures ranging from 9 to 33 mmHg. Over bony prominences the pressures range from 47 to 90 mmHg. However, it is not known how pressures exerted on the surface of a body are diffused into the underlying tissue. Investigations have shown that interface pressures are often higher than those measured subdermally over soft tissue sites while they tend to be lower than subdermal pressures over bony prominences. Moreover, pressures exerted on veins close to the surface of the skin may be considerably higher than those exerted around the limb or other body part. This is because the tension applied to both vein and limb is the same but the radius of curvature of the vein is smaller than that of the limb.

Manufacturers of pressure garments for burn patients report that custom pressure garments provide 25 mm Hg of pressure. However, all pressure garments lose tension and therefore pressure-delivering ability over time and use. Fit must be monitored regularly and carefully as the garments lose about 50% of their compression in 1 month. It is interesting to note also that pressure garments designed to exert greater pressures degrade faster than those designed to exert lower pressures. Moreover, contact between pressure garments and moisturizers accelerate tension degradation. Machine-washing on the other hand tends to prolong their pressure-delivering properties compared with hand washing. To maintain adequate pressure, it is recommended that the garments be replaced every 2 to 3 months. Since pressure garments are expensive for the burn patients or health care units to purchase, to provide more effective pressure therapy, it is essential that the best possible product is supplied to patients in terms of better fit, fewer alterations, less likelihood of stretching, and component parts that are less likely to cause discomfort or deterioration.

Despite precise fitting techniques, pressure garments do not provide a consistent amount of pressure at the scar/garment interface. Therefore, 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. Precise determination of the pressure “dose” must be made before the efficacy of pressure garment therapy can be determined objectively. This means that studies reporting results of pressure therapy without verifying the amount of pressure applied are of limited value.

Compression and its effect on scar modulation and maturation

Compression is reported to produce regression of hypertrophic scars in 60 to 85 percent of patients. However, the basis of the biomechanical theory of pressure ther-
apy has never been proven scientifically and its actual mechanism on scar thickness remains largely unknown. This is exacerbated, as mentioned earlier, by the difficulty in measuring the exact pressure level applied and the changes of HS thickness under various pressures in addition to the persistent controversy between theoretical therapeutic pressure level and practically observed effective pressure magnitude.11

The theory behind the use of pressure garments may be quite simple relying on two main concepts; firstly, the restriction of blood flow to the scar area and secondly, constant compression to inhibit the growth of hypertrophic scar tissue.19 It is widely believed that pressure may facilitate scar maturation and control collagen synthesis by limiting blood supply, oxygen, and nutrients as evidenced by reduced scar redness and edema and by blanching used traditionally as an indicator of adequate pressure application.22

Pressure has been postulated also to reduce collagen production to levels found in normal scar tissue more rapidly than what can be expected with the natural maturation process. Mechanical loading induces alteration in collagen fiber turnover, remodeling, and realignment and reduces development of whorled collagen nodules resulting in thinning and softening of scar tissues.4,11,19,22 It is worth noting that a short daily pressure application is not sufficient to produce significant inhibition of scar cell growth, moreover, the threshold of effective daily application period for pressure therapy depends on the pressure levels; with lower applied pressures, longer application periods are required.11

Available primarily descriptive histologic studies comparing burn scars treated with pressure to scars without pressure treatment, though conducted on a small number of patients have demonstrated pressure-induced modification of collagen fibers.6,13 However, explanations depending on a single intervening factor (e.g., tissue perfusion, cytokine, enzyme) are inadequate for understanding the mechanism of action of PGT.30 Tissue ischemia produced by compression increases collagenase activity by inhibiting α-macroglobulins and decreases tissue metabolism. Furthermore, local hypoxia leads to collagen degeneration, decreases cohesion between collagen fibers, and diminishes the total amount of chondroitin-4-sulfate. Pressure also decreases hydration of the scar, which leads to mast cell stabilization and reduced neovascularization and extracellular matrix production. Moreover, it accelerates the remission phase of the post-burn reparative process.1,3,8,10,32

Mechanical loading induces modulation of IL-1β, tumor necrosis factor-α, and epilisin.7 Pressure significantly reduces scar cell growth and secretion of TGF-β1.11 This inhibits fibroblast activity and multiplication and results in net decrease in collagen fibers deposition.11 Experimental studies have demonstrated that the growth of cultured fibroblasts and TGF-β1 secretion are significantly decreased under a pressure system of at least 20 mm Hg for 18 hours and cell doubling time is significantly decreased under pressure of 20 mm Hg for 24 hours.7 Mechanical compression also induces a significant increase in PGE2 release suggesting a role for PGE2 in the process of hypertrophy remission induced by pressure therapy. This increase seems to be only partially IL-1β-dependent.11 Moreover, the observed modulation of IL-1β and TNF-α release by mechanical loading could play a key role in hypertrophy regression induced by elastoccompression.34

There is increasing evidence that pressure may have also a direct effect on cellular scar components.22 Fibroblasts and keratinocytes respond to mechanical forces with signal transduction by a process known as cellular mechanotransduction. Perceived stimuli are transduced into intracellular biochemical and gene expression signaling pathways thereby altering cellular function or inducing apoptosis. For none excitable cells such as fibroblasts, mechanical stimulation can be converted directly into chemical signaling that increases fibroblast fibrotic gene expression and greatly increases cellular apoptosis.1,20 It has been recently suggested that cellular adhesions, which normally serve as mechanoreceptors, may play also a crucial role in scar modulation following PGT. It is likely that an increase in extracellular matrix rigidity produced by compression garments leads to a higher level of mechanoreceptor activity and increased cellular apoptosis. Increased rigidity has also been shown to affect migration, proliferation, and differentiation of cells in vitro. Increased rigidity caused by compression may as well alter or inhibit the differentiation and proliferation of scar fibroblasts in vivo.25 Moreover, as an adjunctive function, pressure garments that isolate and restrict blood flow to the scar area and secondly, compressional hypoxia, oxygen, and nutrients as evidenced by reduced scar redness and edema and by blanching used traditionally as an indicator of adequate pressure application.22

Patient compliance

Pressure garment therapy requires significant sustained patient involvement and cooperation.13 Long-term patient compliance is an important factor to be considered since the effectiveness of pressure therapy seems to be related to the daily duration of applied pressure for several months.11 Unfortunately, compliance with the recommended wearing schedule is difficult for many reasons to many patients.6,16 Wearing pressure garments is uncomfortable and challenging; problems with movement, appearance, comfort, swelling of extremities, rashes and blistering are common; consequently, low compliance with PGT is to be expected.29,26 Moreover, quality of the garments and a rapid general wear and tear are important contributing factors to low compliance.34 Patients are unlikely to wear pressure garments that do not fit well. It is reported that only 60%
of pressure garments fit perfectly the first time, and 40% require adjustments. Reported compliance for head and neck pressure garments is only 44%, and patients usually apply the garments no more than 10 to 14 hours of the prescribed 23 hours a day. Dealing with negative reactions from the general public, such as being stared at or asked inappropriate questions is a major problem for many patients.

Patient adherence behavior to PGT is negatively influenced by differences in both patient and clinician perceptions regarding the types and consequences of skin problems arising from pressure garment use, levels of satisfaction with garment construction and color, and the issuing and understanding of garment instructions. Other factors compromising adherence behavior include negative effects of visible burn disfigurement, issuing of pressure garments after hypertrophic scarring had developed, lack of patient choice in the selection of scar management techniques, and lack of social support in the wearing of pressure garments.

Much of what is traditionally understood as ‘patient non-adherence’ are deliberate choices made by patients in the face of difficulties they experience with the form and nature of their pressure garment therapy. Clear guidelines for practice and follow-up procedures in out-patient rehabilitation services may help improve patients compliance since lack of information provided about PGT modality has been demonstrated to be one of the possible major causes of low compliance. Moreover, social support and a good doctor–patient relationship are important supportive factors that help patients to persevere with their therapy.

**Discussion**

Pressure therapy for hypertrophic burn scars was first popularized at the Shriners Galveston Burn Hospital. Although it has been employed for several decades for scar control and management, its clinical effectiveness has never been scientifically proven and the questions of whether custom-fitted pressure garments provide adequate pressure, and how effective pressure can be obtained from garments for scar treatments remain a key concern in PGT. There is a clear discrepancy between the extensive clinical experience from Galveston and Cincinnati in the 1970s and the more recent clinical comparative studies that did not demonstrate any significant differences between PGT and no pressure. In fact, there is little objective data that confirms PGT effectiveness. At present, prescription of the pressure magnitudes in current practice is largely empirical. Moreover, the gradual loss of pressure during pressure garment application and the difficulty in applying known constant compression to moving, three-dimensional body parts over a long period of time have been largely overlooked.

As reported by Anzarut et al., there is a small number of published PGT trials comparing pressure with no pressure. In their meta-analysis published in 2009, they were able to identify only two level II randomized patients to pressure/no pressure or to high-pressure/low-pressure treatment studies with Medline search. Outcome measures in these studies were however subjective based on a clinical judgment by a member of the burn team regarding the number of days of continued pressure therapy to scar maturation. Four additional studies were identified through searches of the grey literature, including data from an unpublished trial. Despite this extensive search and the inclusion of both published and unpublished data, only six trials involving 316 patients were identified, which is negligible considering the magnitude of burn scar problems and the widespread use of PGT. A subsequent search conducted by Engrav et al. failed to uncover any other recent studies randomly comparing pressure with no pressure.

After an international panel of experts reviewed the literature on scar management in 2002, it was concluded that: “Widespread burn scars should be treated with first-line therapy of silicone gel sheeting and pressure garments, although there remains limited significant evidence for the effectiveness of pressure garments”. This stance remains unchanged thus conducting a clinical trial at present comparing PGT of HS to no compression would be considered unethical because PGT is regarded as the standard of care. Rigorous research methodology, such as randomization and blinding of prospective comparative studies to demonstrate effectiveness of PGT is therefore not possible. Only principles of evidence-based medicine apply. Though the number of high-level studies examining the effectiveness of PGT of burn scars is sparse similarly to other therapeutic options in plastic surgery in general, evidence-based medicine can still highlight the value of this treatment option to guide surgeons in practice as is the case in other clinical situations when it is logistically difficult or ethically unfeasible to perform randomized clinical trials.

Clinical expertise, research evidence, and patient preferences are the basic principles of evidence-based medicine, which focuses on the highest levels of evidence to guide decisions on treatment effectiveness. Clinically, PGT was reported to be effective in many studies, however insignificant improvements in excessive scarring were demonstrated by others. Although experimental research has uncovered important effects of mechanical loading by pressure on scar modulation, clinical research is less than conclusive. The meta-analysis conducted by Anzarut et al. concluded that there is insufficient evidence to support the widespread use of pressure garment therapy. Despite demonstrating that PGT improves scar height, it failed to show improvement in global scar score, pliability, vascularity or pigmentation. Macintyre has also extensively reviewed the literature on PGT and agreed that scientific ev-
idence of effectiveness is lacking and that optimum pressure is unknown.

For their part, Engrav et al. have conducted a study over 12 years published recently comparing ‘normal compression’ (25 mm Hg) of HSs to ‘low compression’ (<10 mm Hg). Candy et al. have conducted a similar study about the effect of different pressure magnitudes on HSs in a Chinese population. The conclusions of these 2 studies were that PGT is effective in the management of HSs but is dependent on the amount of pressure applied. The pressure differential between normal and low compression zones was significant and scars/grafts under ‘normal compression’ were softer and thinner. High pressure was demonstrated to be more effective for scar management, but it was also more prone to higher garment pressure loss. As far as patient preferences, most feel that pressure garments contributed positively to mobility as well as to the look and feel of scars even though they do not feel comfortable wearing the pressure garments and face masks outside of their home. Patient compliance, however, remains a main issue.

Conclusion

The accurate, reliable, and valid measurement of HSs remains a clinical and research challenge. Current understanding of post-burn scarring is deficient in many aspects. Our understanding of the pathophysiology of hypertrophic scarring is limited, both locally and systemically, and we are also unable to determine which scars will become hypertrophic. Moreover, there are no useful, objective definitions that consistently distinguish between atrrophic, wide, normotrophic and hypertrophic scars and keloids. Certainly, a major problem in determining the effectiveness of costly scar management techniques, such as pressure garments, is the inability to measure the properties of the hypertrophic scar and the changes in those properties over time. Even though reliable, valid, and feasible scar assessment has become more prevalent in recent decades, at present, we have neither a standardized method to measure the severity of hypertrophic scarring nor an objective reproducible burn scar outcome measure to determine scar maturation. We are therefore unable to objectively monitor the effectiveness of pressure therapy, justify the use of pressure garments, and compare burn scar treatment methods.

Monitoring of pressure exerted by pressure garments is currently difficult and time consuming and not routinely done and currently, the optimal pressure magnitude for PGT remains unsolved. Even though it seems that pressure dosage is a determining factor for successful scar control, it is hard to evaluate the performance of pressure therapy and to achieve the best treatment outcomes without knowing the pressure level administered. Failure to document the pressure magnitude with an accurate and reliable pressure-monitoring instrument in most of the reported studies might lead to variations in the treatment outcomes and might explain the inconsistency in the therapeutic efficacy of PGT. Certainly, pressure therapy integrated with regular monitoring of the interface pressures exerted and noting objectively the clinical outcome would enable clinicians to improve therapeutic efficacy of PGT and build an understanding of the implications of particular pressures on scar outcome, maturation times and patient compliance rates.

Recent evidence suggests that pressure garment therapy is effective for the prevention and/or treatment of abnormal scarring after burn injury but that the clinical benefit is restricted to those patients with moderate or severe scarring. However, there is insufficient evidence to recommend its widespread use. In conjunction with the problem of moderate compliance with the garments and potential complications, it is not surprising that some authors question the cost-effectiveness of the therapy. Until further evidence is available, physicians treating patients will need to balance the costs and potential complications of PGT with presumed benefits. Additional research is needed to establish an optimal scar assessment tool for clinical use and to measure the efficacy of burn therapy protocols for compression, inserts, and other modalities. Studies are also required to clearly demonstrate whether pressure therapy is more effective when applied prophylactically or as a treatment of established HSs. Available studies so far do not make a clear distinction in that regard though it is suggested that pressure therapy is better initiated as early as wound healing has been secured. The stage of HS maturation beyond which pressure therapy has minimal effects needs to be determined as well. It is surprising that such a widely applied therapeutic modality has so little valid evidence in its support.

It must be mentioned though that the use of pressure is only one segment of the total rehabilitation of the thermally injured patient. Its use in conjunction with exercise, splinting, positioning, and reconstructive surgery allows an optimal level of function and cosmesis to be achieved. In any event, selection of a given scar treatment must follow discussion and agreement with the patient who will be required to continue his treatment at home.

RÉSUMÉ. Les cicatrices de brûlures hypertrophiques représentent un défi pour les survivants de brûlures et les fournisseurs. Dans de nombreux cas, ils peuvent gravement limiter le niveau de fonction d’un survivant de brûlure, y compris au travail et pendant les loisirs. Une modalité généralisée de la prévention et le traitement des cicatrices hypertrophiques est l’utilisation de la thérapie de vêtement de compression (TVC). Malgré l’ampleur du problème des cicatrices hypertrophiques et l’utilisation omniprésente de
vêtements compressifs en tant que thérapie, dans la littérature il n’y a pas de preuves cliniques solides de l’efficacité de la TVC. Quelques-uns des défis auxquels fait face la mesure de l’efficacité de ce traitement sur les cicatrices hypertrophiques sont : le manque de définitions claires pour degré de cicatrisation hypertrophique, l’incapacité de quantifier la pression appliquée sur les cicatrices, la non-conformité des patients en ce qui concerne les horaires strictes du traitement, et l’incapacité de mener des essais comparatifs randomisés comparant cette thérapie à aucun traitement pour des raisons éthiques car la TVC est considérée comme une norme de soins. Dans cette revue, nous tentons de résumer et d’analyser la littérature fondée sur des preuves de la TVC et son efficacité dans les cicatrices hypertrophiques des brûlures publiés en langue anglaise au cours des 15 dernières années.

Mots-clés: thérapie de vêtement de compression, cicatrice hypertrophique de brûlure

BIBLIOGRAPHY


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