Pressure therapy has been considered standard, first-line intervention for the treatment of hypertrophic scars since its introduction in the 1960s. Although widely used, this scar management technique has historically been based on a wide array of anecdotal evidence as opposed to strong scientific support. Evidence has become more prevalent in recent years, necessitating a synthesis to develop an evidence-based clinical guideline. The clinical question was asked, “Among individuals with or at risk to develop active hypertrophic scars, does treatment with pressure therapy improve aesthetic and functional outcomes?” An evidence-based practice project was completed with aims to synthesize relevant literature to determine recommendations for the use of pressure therapy in individuals at risk for hypertrophic scars. A systematic search of the literature was conducted for the dates January 1950 to February 2014 of the following databases: MEDLINE, CINAHL, Cochrane Database for Systematic Reviews, Burntherapist.com, Cochrane Libraries, EbSCO, Google Scholar, OT Seeker, Ovid, MedLine, PEDro.org, Pubmed.gov, Pubmed Clinical Queries, and hand search of relevant articles through use of reference lists. Search terms included scar, hypertroph*, pressure therapy, compression therapy, pressure garment, burn, scald, trauma as well as MeSH terms cicatrix and hypertrophic. Articles were reviewed in terms of ability to answer the clinical question as well as strength of conclusions. A total of 45 articles were found and critiqued, 28 of which were relevant to the clinical question. Evidence strength ranged from level 1 to level 5. Results from the studies were synthesized to create clinical recommendations to guide treatment. Based on best available evidence, it is recommended that pressure therapy is utilized to decrease scar height and erythema that it is used for grafts and wounds requiring 14 to 21 days to heal, for 23 hours/day for 12 months, fit to achieve 20 to 30 mm Hg of pressure, fit by a skilled technician, and replaced every 2–3 months. In addition, it is not recommended that pressure therapy is used to treat abnormal pigmentation, nor used to hasten scar maturation. This literature search revealed insufficient evidence addressing the impact of pressure therapy on scar pliability. Among individuals with or at risk to develop active hypertrophic scars, treatment with pressure therapy does improve outcomes, particularly for aesthetic concerns including scar thickness and erythema. Applicability of research to practice: The practical treatment recommendations presented may improve consistency and efficacy of pressure therapy utilization at the point of care. (J Burn Care Res 2015;XXX:00–00)
compared with the surrounding unaffected or “normal” skin. The prevalence of abnormal hypertrophic scarring has been cited to affect 1.5 to 4.5% of the general population, and is higher at 4.5 to 16% in African-Americans, Asians, and Hispanics. In terms of causative agent, 40 to 70% of individuals develop hypertrophic scarring after surgery, and over 67 to 90% do so after a burn injury. In addition, there is sufficient evidence documenting the potentially disfiguring and debilitating effects of unmanaged scar hypertrophy. Commonly multiple scar characteristics are addressed at once using the same intervention.

Various interventions and products are used to manage and treat abnormal scars. These range from simple techniques like massage, to invasive procedures like surgical excision and resurfacing. Pressure therapy was selected as the focus of this evidence synthesis as it is commonly utilized in clinical practice and is noninvasive. Aesthetic and functional outcomes include a decline or withdrawal of abnormal scar characteristics which simultaneously affect the skin’s appearance and function. For example, changes in vascularity and pigmentation primarily impact aesthesis, whereas alterations in thickness and pliability can impact range of motion and subsequent function.

The goal of intervention is to return the scar to normal skin as closely as possible, both in terms of tissue aesthetics and function. Positive results of pressure therapy on hypertrophic scarring were reported anecdotally as early as 1806. The treatment was formally introduced in the 1960s and has been the standard of care for large scars, especially after burn injuries, since the 1970s due to its noninvasive nature despite lack of strong scientific support.

Histological research has successfully demonstrated changes which occur at the cellular level when scars are formed. However the effect of pressure at the cellular level has not been well-studied, hindering the identification of cellular changes that lead to successful scar treatment. Proposed mechanisms of action for pressure therapy include the following and their histological sequelae: decreased hydration, decreased blood flow, and induction of prostaglandin E2 release. Preliminary research, inspired by anecdotal evidence, has demonstrated that mechanical manipulation of a wound environment using the aforementioned conditions causes hypertrophic scar cells to function more like normal skin cells.

Despite this basic histological knowledge, scar management using pressure therapy remains challenging to study in clinical situations. One contributing factor is that scars have multiple characteristics which may or may not be affected by pressure therapy, and not all studies address all characteristics. Recent research has utilized better study designs and common use of objective outcome measurement tools, but questions persist regarding the effectiveness of this intervention to change visible and cellular characteristics of scar.

The improved quality of recent evidence and ongoing debate in the literature called for a synthesis of best evidence. An evidence-based practice project was completed with aims to synthesize relevant literature to determine recommendations for the use of pressure therapy in individuals at risk for hypertrophic scars. This article is a presentation and update of the spectrum of abnormal scarring regardless of scar characteristics. This would not only unnecessarily elevate healthcare costs, but give patients and clinicians false hope for improvement in scar characteristics that are not able to be changed with the use of this intervention.

**METHODS**

The clinical question was asked, “Among individuals with or at risk to develop active hypertrophic scars, does treatment with pressure therapy improve aesthetic and functional outcomes?” Inclusion criteria for papers reviewed were those that used pressure therapy to treat patient’s postskin graft or tissue injury requiring more than 14 days to heal, those post-tissue injury with a family history of abnormal scar development, and those with darker pigmented skin tones. To minimize confounding data, studies using other treatments and those of participants with unhealed or infected wounds, compromised circulation, mature scars, or keloid scars were excluded. Also excluded were papers that failed to answer the specific clinical question.

Tools provided by the James M. Anderson Center for Health Systems Excellence at Cincinnati Children’s Hospital were used throughout the evidence synthesis process. This system includes resources for gathering and critically appraising published works, grading the body of evidence found, and ultimately judging the strength of the concluding recommendation statements. The system comprises the Let Evidence Guide Every New Decision (LEGEND) evidence evaluation system. The basic
steps which lead to an evidence-based decision using this method are the development of a specific clinical question, conduction of a strategic and precise literature search, critical appraisal of each article, summarization and synthesis of the evidence found, and finally, development of care recommendations. While a meta-analysis uses statistics to analyze a large collection of analysis results from individual studies for the purpose of integrating the findings, a Best Evidence Statement (BEST), upon which this review article is based, is a synthesis of existing evidence answering a very specific clinical question, with the intent of providing recommendations for treatment provided at the point of care. The BEST process was developed to provide an efficient way to share evidence regarding a specific health question or issue. A BEST answers a specific health or clinical question. Each BEST is designed to assure evidence is captured through a high-quality process using a standardized format and to provide a resource that informs evidence-based decision making at the point of care. Tools can be found at www.cincinnatichildrens.org/ evidence. Uniformity and rigor was ensured during each of these steps.

A systematic search of the literature was conducted for the dates January 1950 to July 2014 of the following databases: MEDLINE, CINAHL, Cochrane Database for Systematic Reviews (CDSR), Burntherapist.com, Cochrane Libraries, Ebsco, Google Scholar, OT Seeker, Ovid, MedLine, PEDro.org, Pubmed.gov, Pubmed Clinical Queries, and hand search of relevant articles through use of reference lists. Search terms included scar, hypertroph*, pressure therapy, compression therapy, pressure garment, burn, scald, trauma as well as MeSH terms cicatrix and hypertrophic. The evidence-based practice team tasked with identifying and reviewing relevant papers was derived from several disciplines, including an occupational therapist, plastic surgeons, and a clinical nurse specialist; all with several years of burn, wound, and plastic surgery experience. However, the objectivity of LEGEND system facilitates clinical recommendations based solely on the strength of the literature as opposed to the reviewers themselves.

Articles were reviewed in terms of ability to answer the clinical question as well as strength of conclusions. Evaluation of the evidence includes critically appraising each applicable study by first determining the study design, ensuring that the study helps to answer the clinical question, and highlighting any notable methods, results, or conclusions that may sway conclusions. In addition, validity, reliability, applicability, and quality of each study were determined, and each study was given a grade based on the Levels of Evidence as defined by the University of Oxford’s Centre for Evidence-Based Medicine31 (Figure 1). Evidence was then compiled and synthesized to create clinical recommendations. The evidence synthesis process starts with compiling studies into a chart with each individual article’s information summarized in one place for comparison of all articles to each other. Summaries include, but are not limited to: population, intervention, comparison, outcomes, results, conclusion, and evidence level. The aim is to gain consistency among how studies answer the clinical question.

The ultimate purpose is to synthesize evidence from the derived summary to answer the clinical question. The evidence-based practice team discussed themes, concepts, commonalities, differences,
and evidentiary gaps from the reviewed articles. The resulting synthesis is not a narrative of each article, but rather a synthesis of the combined articles forming the body of evidence. This body of evidence is then used to develop care recommendations for the asked clinical question. A demand of the LEGEND system is that ultimate recommendation evidence strength is ensured by describing quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.

To determine the strength of the recommendation, the development group came to a consensus based on critically appraised evidence, clinical experience, and dimensions outlined in Figure 2. To receive a grade of “strong,” a recommendation must be well supported in terms of quantity, quality, and consistency of literature, and the benefits of the therapy must outweigh the risks. When there is a lack of published evidence supporting a recommendation but the development group’s clinical experience strongly endorses, a recommendation can be made using “local consensus” as level 5 evidence.

**RESULTS**

A total of 45 articles were found and critiqued, 28 of which were relevant to the clinical question. Evidence strength ranged from level 1 to level 5. Results from the studies were synthesized to create clinical recommendations to guide treatment. Prognostic scar literature has identified indicators of which patients are at risk for development of hypertrophic scars and would benefit from prophylactic pressure therapy. Although genetics play a role in the propensity to develop hypertrophic scars, the strongest predictor of abnormal scar development is time to wound healing. The literature indicates that time to heal directly correlates to the propensity to form hypertrophic scar with those healing in 14 to 21 days having a 30% incidence of hypertrophic scarring and those over 21 days with a 78% incidence. In addition, studies have shown that both likelihood and severity of scarring is related to the depth of injury. Although age of the patient was once thought to be a factor in scar development, this has not been supported by evidence.

**Recommendations**

Recommendations (Supporting evidence following with level noted in brackets).

**When to Use Pressure Therapy (Figure 3)**

1. It is strongly recommended that pressure therapy be used to decrease hypertrophic scar height (Anzarut et al 2009 [1b], Candy et al 2010 [2a], Engrav et al 2010 [2a], Van den Kerckhove et al 2005 [2a], Li-Tsang et al 2010 [2b], Garcia-Velasco et al 1978 [2b], Cheng et al 2001 [4a], Bloemen et al 2009 [5a], Berman and Flores 1998 [5a], Berman et al 2008 [5b]).

2. It is recommended that pressure therapy be used to decrease hypertrophic scar erythema (Candy et al 2010 [2a], Garcia-Velasco et al 1978 [2b], Cheng et al 2001 [4a]).

3. There is insufficient evidence and a lack of consensus to make a recommendation for the use of pressure therapy to increase scar pliability or joint range of motion (Engrav 2010 [2a], Li-Tsang et al 2010 [2b], Garcia-Velasco et al 1978 [2b], Kloti and Pochon 1982 [3a], Haq and Haq 1990 [3b], Gauglitz et al 2011 [5a], Bloemen et al 2009 [5a], Berman et al 2008 [5b]).

4. It is recommended that pressure therapy not be used:
   a. For decreasing abnormal scar pigmentation (Anzarut et al 2009 [1b], Candy et al 2010 [2a], Engrav 2010 [2a], Van den Kerckhove et al 2005 [2a]).
   b. To hasten the rate or time to scar maturation (Chang et al 1995 [2b]).
How to Use Pressure Therapy (Figure 4)

5. It is recommended that pressure therapy appliances are:

a. Used as a prophylactic measure for wounds that take longer than 14 to 21 days to heal, as well as all skin grafts, as these wounds are more likely to develop hypertrophic scars than those which heal more quickly (Deitch et al 1983 [4a], Bloemen et al 2009 [5a], Monstrey et al 2014 [5a], Davoodi et al 2008 [5b], Staley et al 1997 [5b]).


c. Used for 23 hours per day for approximately 12 months, or until scar maturation is achieved (Haq and Haq 1990 [3b], Bloemen et al 2009 [5a], Latenser and Kowal-Vern 2002 [5a], Mustoe 2002 [5a], Arno et al 2014 [5a], Monstrey et al 2014 [5a], Davoodi et al 2008 [5b], Staley et al 2008 [5b]).

d. Custom fit to assure optimal pressure without causing tissue damage by being:

i. Fit by skilled/trained/experienced individuals (Yamaguchi et al 1986 [2a]).

Note: Monitor fit regularly, by the skilled individual, to prevent tissue damage.


Note: It is impractical to use a pressure mapping device (such as Tekscan®) to determine exact pressure in the clinic environment. Instead, skilled clinicians approximate this by placing a finger between the appliance and the skin and by observing the physical tension on the appliance. This skill can be taught to caregivers to provide safe and optimal care (Local Consensus, 2014 [5b]).

iii. Replaced or modified every 2 to 3 months to maintain the pressure needed to achieve optimal outcome (Candy et al 2010 [2a], Garcia-Velasco et al 1978 [2b], Estelman et al 2006 [5a]).

Note: Pressure appliances can be modified by re-sewing or inserts can be added to assure pressure of 20 to 30mm Hg (Candy et al 2010 [2a], Davoodi et al 2008 [5b]).

References are additionally organized by recommendation as well as evidence level in Figure 5 to foster visualization of the strength of each recommendation.

Strength of the Recommendations

The grade of the evidence located is overall considered moderate. The evidence searched and cited covers studies completed at the origins of this treatment,
as well as more recent high-level trials. The evidence is relatively uniform in its questions and intents, which allows for several specific recommendations to be made. There is consistent support for the use of pressure to decrease scar height, which is an important part of skin appearance and function.

Health benefits and risks are also moderate. Pressure therapy treatment is considered to be conservative in nature and with moderate risks. Most common risks to health target skin integrity and include recurrent mild blistering, rash, eczema, itching, discomfort, and/or embarrassment caused by wearing the appliances.

Alternatively, the health benefit to patient is significant, thereby outweighing moderate risks. Pressure therapy primarily impacts aesthetic components of the scar, providing improvement in scar height and erythema. While the impact on each scar is significant, the degree to which the improvement is beneficial to the patient as a whole depends on the size, location, severity of the scar itself, as well as patient perception. However, the burden on patient to adhere is considered high. Adherence to the lengthy, uncomfortable, and conspicuous treatment is often difficult for patients and their caregivers.

**DISCUSSION**

The body of evidence on pressure therapy as treatment for hypertrophic scars is most easily discussed by the scar characteristic targeted as outcome: height, erythema, pliability and range of motion, or pigmentation. Furthermore, literature exists on dosing of pressure therapy, health benefits and risks, obstacles to implementation, and outcome measures. Areas for future research are suggested.

**Height**

The most agreed upon and demonstrated outcome in the literature is the beneficial impact of pressure therapy on scarring by decreasing its height or thickness; the grade of the body of evidence in this area is high. A meaningful reduction in scar height with the use of pressure therapy as compared with no or low-pressure (placebo) is consistently demonstrated in the evidence.\textsuperscript{22,25,27,32,35–40} A systematic review\textsuperscript{35} showed that there was a statistically significant decrease ($P = .05$) in scar height for scars treated with pressure versus control. This positive effect is consistent with four randomized control trials which demonstrated significant differences ($P$ values ranged from .05 to .001) in height reduction for pressure therapy groups.\textsuperscript{22,26,37} In addition, a seminal study published in 1978 by Garcia-Velasco\textsuperscript{38} demonstrated a 92% improvement in thickness with pressure therapy compared to 50% in the control group.

**Erythema**

The effect of pressure therapy on decreasing scar vascularity, erythema, or redness is also supported by literature and local consensus.\textsuperscript{25,36,38} However, this is refuted in one study in which the decline in erythema is recognized, but not correlated with the pressure treatment.\textsuperscript{22} Therefore, the grade of the body of evidence regarding the effect of pressure therapy on decreasing scar vascularity was decidedly low, though present. One study showed a significant improvement ($P < .05$) in erythema for a higher pressure (20–25 mm Hg) vs lower pressure.
alter the rate of or ultimate time required for scar maturation. A systematic review and two randomized control trials showed no significant difference between pressure therapy and control groups ($P = .14$, $P > .05$, $P = .14$). In addition, no significant ($P = .5098$) difference in time to maturation between pressure therapy groups and control were found in a rigorous randomized prospective study on 122 individuals.

**Dosing**

Questions regarding clinical considerations about dosing include timing of initiation, magnitude of pressure to use and duration of treatment. Early studies used pressure at unspecified or unknown levels and failed to use adequate controls. More recent literature has utilized stronger experimental designs, comparing pressure therapy vs none or higher pressure vs lower pressure. Studies have also addressed timing of intervention by comparing pressure applied immediately after wound healing, to pressure applied well after hypertrophic scar development. All studies identified improvement in scar variables as outcomes. This moderate level evidence supports the above recommendations regarding dosing.

**Health Benefits and Risks**

The health benefits following prolonged treatment with pressure therapy include improved psychosocial...
health subsequent to improved tissue aesthetics and function. Work has been done regarding the psychosocial repercussions of abnormal visible scarring and it is clear that improving scar aesthetics promotes adjustment and return to participation in age appropriate occupations. The most commonly cited risk of this treatment is recurrent blistering or ulceration, presumably from the pressure appliance applying too much pressure or friction and ultimately tissue necrosis, especially over bony prominences. While blistering is very common with use of pressure appliances, it is rare for the small sores to progress to large, open wounds due to the fact that the appliances are changed once or twice daily, allowing ample opportunity for monitoring of the skin condition. The tendency to form blisters decreases with continued wear as the skin becomes conditioned to the pressure and friction. Additional risks associated with this treatment include rash, eczema, itching, discomfort, and/or embarrassment caused by wearing the appliances. Cost–effectiveness to healthcare system is inconclusive at this time. Use of these recommendations will hopefully limit over-utilization of pressure therapy by indicating which scars are appropriate for treatment. In addition, these recommendations encourage pressure therapy use early in treatment, which has the potential to prevent or delay the need for costly pharmaceutical or surgical intervention.

Feasibility Issues
The biggest threat to successful implementation of a pressure therapy protocol is achieving patient/family compliance or adherence. Problems with adherence to pressure therapy may be attributed to the moderate risks of the treatment, mainly regarding skin irritation and discomfort. Other articles cited length of treatment, appliance cost and rapid appliance loss of pressure as factors contributing to nonadherence. However, one study found that only 41% of adults were fully compliant with the prescribed pressure therapy program, due more to “rational choices made by patients in the face of several difficulties” rather than simple irritation. In addition, studies regarding adherence to other therapy interventions have found similar results, despite minimal risks or unpleasant side effects. Therefore, successful remediation of patient nonadherence may be a broader therapeutic problem, rather than one unique to pressure therapy for hypertrophic scars. One study successfully promoted garment adherence by showing patients outcome photos of scars treated with pressure vs no treatment. Self-management techniques have also been shown to be helpful in promoting adherence. Self-management is the ability of the patient and his/her family to collaborate on and adhere to individualized therapy treatment recommendations and appropriately problem-solve difficulties associated with the therapy diagnosis to maximize quality of life and participation in life roles. Educational handouts describing the principles behind pressure therapy and expected outcomes can be used to increase understanding, facilitate self-management, and improve adherence. These handouts should be easy to understand and simple to read (Figure 6).

Outcome and Process Measures
To determine how the use of pressure therapy impacts the overall population of individuals with hypertrophic scars, it is essential to objectively measure the effect of pressure therapy on each person’s scars and their experience living with scars. Literature supports the use of two scales in particular. The Vancouver Scar Scale may be used to quantitatively monitor how the scar changes over time in terms of the four main scar characteristics (height, vascularity, pliability, and pigmentation). This measure can track the percentage of individuals at risk to develop active hypertrophic scars that show improved aesthetic outcomes after pressure therapy as measured by decreased scar height and erythema. The Patient and Observer Scar Assessment Scale may be used to assess how the patient or family views and feels about the scar and its function. The outcome in this case would then be the percentage of individuals at risk for developing active hypertrophic scars that showed improved function and satisfaction. As a process measure, it is recommended that institutions track the percentage of individuals at risk to develop active hypertrophic scars that were fit with a pressure therapy device.

Future Research Agenda
Further investigation of the literature is indicated to determine additional potential effects of pressure therapy and scar improvement on quality of life, psychosocial adjustment, and overall participation in age-appropriate occupations. In tandem, if improvements in both aesthetic appearance and psychosocial functioning are identified, it will be important to delve into the barriers to adherence to a pressure therapy prescription and the best methods for facilitating follow through. In addition, further research is needed to identify the biological mechanisms by which pressure therapy...
works. On a larger scale, strong research in scar biology and therapy is indicated in general. While there may be disagreement among authors regarding the precise use and specific benefits of pressure therapy, all authors agreed on one point—the need for increased quality and quantity of high-level evidence. It is quite difficult to complete strong randomized and well-controlled studies on individuals with scars not only because of the innumerable factors contributing to how a person develops scars but also because of the general acceptance of pressure therapy as a standard for scar management. Because of the prevalence of this treatment, some authors consider it ethically difficult to randomize someone to a control group which may deny pressure therapy. Consequently, several authors instead propose well-designed multicenter studies including institutions where scars are most often treated, usually burn centers.

**CONCLUSIONS**

Based on best available evidence, it is recommended that pressure therapy is utilized to decrease scar height and erythema; that it is used for grafts and wounds requiring 14 to 21 days to heal, for 23 hours/day for 12 months; to achieve 20 to 30 mm Hg of pressure; fit by a skilled technician; and replaced every 2 to 3 months. In addition, it is not recommended that pressure therapy is used to treat abnormal pigmentation, nor used to hasten scar maturation. This literature search revealed insufficient evidence addressing the impact of pressure therapy on scar pliability. Practical recommendations for other aspects of burn care can be made by completing evidence syntheses in a manner similar to that described in this article.

**REFERENCES**

29. Sharp P. Cincinnati Children's Hospital Medical Center: best evidence statement use of pressure therapy for management of hypertrophic scarring; available from http://www.


62. Sharpe et al