

Date: March 13, 2014

Title: Use of pressure therapy for management of hypertrophic scarring¹

Clinical Question

- P (Population/Problem) Among individuals with or at risk for developing active hypertrophic scars*
- I (Intervention) does treatment with pressure therapy*
- C (Comparison) compared to no scar treatment
- O (Outcome) improve aesthetic and functional outcomes?

Definitions for terms marked with * may be found in the Supporting Information section.

Target Population for the Recommendation

Individuals with active hypertrophic scars or those who are at high risk for development of hypertrophic scars

Inclusions: Individuals status-post

- Skin grafts or tissue injury requiring more than 14 days to heal
- Tissue injury with a family history of developing hypertrophic scars
- Tissue injury with darker pigmented skin tones

Exclusions: Individuals with

- Unhealed or infected wounds
- Compromised circulation
- Mature scars*
- Keloid scars*

Recommendations

When to use Pressure Therapy (see Table)

- 1. It is strongly recommended that pressure therapy be used to decrease hypertrophic scar height* (*Anzarut 2009 [1b]*, *Candy 2010 [2a]*, *Engrav 2010 [2a]*, *Van den Kerckhove 2005 [2a]*, *Li-Tsang 2010 [2b]*, *Garcia-Velasco 1978 [2b]*, *Cheng 2001 [4a]*, *Bloemen 2009 [5a]*, *Berman 1998 [5a]*, *Berman 2008 [5b]*).
- 2. It is recommended that pressure therapy be used to decrease hypertrophic scar erythema* (*Candy 2010 [2a], Garcia-Velasco 1978 [2b], Cheng 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 2010 [2b], Garcia-Velasco 1978 [2b], Kloti 1982 [3a], Haq 1990 [3b], Gauglitz 2011 [5a], Bloemen 2009 [5a], Berman 2008 [5b]).*
- 4. It is recommended that pressure therapy not be used:
 - a. For decreasing abnormal scar pigmentation* (Anzarut 2009 [1b], Candy 2010 [2a], Engrav 2010 [2a], Van den Kerckhove 2005 [2a]).
 - b. To hasten the rate or time to scar maturation* (*Chang 1995 [2b]*).

¹ Please cite as: Sharp, P., Cincinnati Children's Hospital Medical Center: Best Evidence Statement Use of pressure therapy for management of hypertrophic scarring, <u>http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/best.htm</u>, BESt 176, pages 1-10, 3/13/14.

How to use Pressure Therapy

- 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 1983 [4a], Bloemen 2009 [5a], Davoodi 2008 [5b], Staley 1997 [5b]*).
 - b. Used as soon as the healing skin can tolerate the pressure and/or shear force generated by the intervention (*Kloti 1982 [3a], Kloti 1979 [3b], Gauglitz 2011 [5a], Ogawa 2010 [5a], Bloemen 2009 [5a], Esselman 2006 [5a], Latenser 2002 [5a], Mustoe 2002 [5a], Davoodi 2008 [5b], Staley 1997 [5b], Robson 1992 [5b]).*
 - c. Used for 23 hours per day for approximately 12 months, or until scar maturation is achieved (*Haq 1990 [3b]*, *Bloemen 2009 [5a]*, *Latenser 2002 [5a]*, *Niessen 1999 [5a]*, *Berman 2008 [5b]*, *Davoodi 2008 [5b]*).
 - d. Custom fit to assure optimal pressure without causing tissue damage by being:
 - i. Fit by skilled/trained/experienced individuals (*Yamaguchi 1986 [2a]*). **Note:** Monitor fit regularly, by the skilled individual, to prevent tissue damage.
 - ii. Fit to achieve compression force near capillary pressure (20 to 30mmHg) (*Candy 2010 [2a], Engrav 2010 [2a], Van den Kerckhove 2005 [2a], Yamaguchi 1986 [2a], Garcia-Velasco 1978 [2b], Bloemen 2009 [5a], Latenser 2002 [5a], Berman 1998 [5a], Davoodi 2008 [5b], Staley 1997 [5b]).*

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 [5]*).

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

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

Desired Outcome	Strongly Recommended	Recommended	Insufficient evidence and lack of consensus	Not Recommended
Decreased height	X			
Decreased erythema		X		
Increased pliability			Х	
Increased range of motion			Х	
Decreased pigmentation				Х
Decreased time to scar maturation				Х

Table: When to use Pressure Therapy

Discussion/Synthesis of Evidence related to the recommendations

Height

The grade of the body of evidence regarding the beneficial impact of pressure therapy on scarring by decreasing its height or thickness is high. A meaningful reduction in scar height with the use of pressure therapy as compared to no or low-pressure (placebo) is consistently demonstrated in the evidence (*Anzarut 2009 [1b], Candy 2010 [2a], Engrav 2010 [2a], Van den Kerckhove 2005 [2a], Li-Tsang 2010 [2b], Garcia-Velasco 1978 [2b], Cheng 2001 [4a], Bloemen 2009 [5a], Berman 1998 [5a], Berman 2008 [5b]).* A systematic review (*Anzarut 2009 [1b]*) showed that there was a significant decrease (*p*=0.05) 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 (*Candy 2010 [2a], Engrav 2010 [2a], Van den Kerckhove 2005 [2a], Li-Tsang 2010 [2b]*). Additionally, a seminal study, published in 1978 by Garcia-Velasco, demonstrated a 92% improvement in thickness with pressure therapy compared to 50% in the control group (*Garcia-Velasco 1978 [2b]*).

Erythema

The grade of the body of evidence regarding the effect of pressure therapy on decreasing scar vascularity, erythema, or redness is generally low (*Candy 2010 [2a], Garcia-Velasco 1978 [2b], Cheng 2001 [4a]*). One study showed a significant improvement (p<0.05) in erythema for a higher pressure (20 to 25 mmHg) versus lower pressure (10 to 15 mmHg) group (*Candy 2010 [2a]*) which was supported by a longitudinal study in 2001 (*Cheng 2001 [4a]*). However, this is refuted in one study in which the decline in erythema is recognized, but not correlated with the pressure treatment (*Van den Kerckhove 2005 [2a]*).

Pliability and Range of Motion

There is inconclusive and conflicting evidence regarding the usefulness of pressure therapy as a tool to increase scar pliability and joint range of motion (*Engrav 2010 [2a], Li-Tsang 2010 [2b], Garcia-Velasco 1978 [2b], Kloti 1982 [3a], Haq 1990 [3b], Kloti 1979 [3b], Gauglitz 2011 [5a], Bloemen 2009 [5a], Berman 2008 [5b]).*

Pigmentation and Time to Scar Maturation

Recent literature has demonstrated that pressure therapy does not improve scar pigmentation (*Anzarut 2009 [1b]*, *Candy 2010 [2a]*, *Engrav 2010 [2a]*, *Van den Kerckhove 2005 [2a]*), nor does it alter the rate of or ultimate time required for scar maturation (*Chang 1995 [2b]*). A systematic review (*Anzarut 2009 [1b]*) and two randomized control trials (*Candy 2010 [2a]*, *Van den Kerckhove 2005 [2a]*) showed no significant difference between pressure therapy and control groups (p=0.14, p>0.05, p=0.14). In addition, no significant (p=0.5098) difference in time to maturation between pressure therapy groups and control were found in a rigorous randomized prospective study on 122 individuals (*Chang 1995 [2b]*).

Dosing

Prognostic scar literature identifies variables to determine which patients may develop hypertrophic scars and who would benefit from prophylactic pressure therapy. Although genetics plays a role in the propensity to develop hypertrophic scars (*Bombaro 2003 [4a]*, *Deitch 1983 [4a]*, *Gauglitz 2011 [5a]*, *Esselman 2006 [5a]*, *Alster 2003 [5b]*), 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 scarr (*Li-Tsang 2010 [2b]*, *Deitch 1983 [4a]*), with those healing in 14 to 21 days having a 30% prevalence of hypertrophic scarring and those over 21 days with a 78% prevalence (*Deitch 1983 [4a]*). Similarly, studies have shown that severity of scarring is related to the depth of injury (*Li-Tsang 2010 [2b]*, *Deitch 1983 [4a]*, *Baur 1976 [4a]*).

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 (*Haq 1990 [3b], Cheng 2001 [4a], Deitch 1983 [4a]*). More recent literature has utilized stronger experimental designs, comparing pressure therapy versus none (*Li-Tsang 2010 [2b], Chang 1995 [2b], Garcia-Velasco 1978 [2b]*) or higher pressure versus lower pressure (*Candy 2010 [2a], Engrav 2010 [2a], Van den Kerckhove 2005 [2a]*). Studies have also addressed timing of intervention by comparing pressure applied immediately after wound healing, to pressure applied well after hypertrophic scar development (*Kloti 1982 [3a], Kloti 1979 [3b]*). All studies identified improvement in scar variables as outcomes. This moderate level evidence supports the above recommendations regarding dosing. Low level evidence shows that pressure appliances and custom garments in particular, lose approximately 50% of their pressure in 2 months.

Health Benefits, Side Effects and Risks

The health benefits following prolonged treatment with pressure therapy are decreased scar height and redness. Work has been done regarding the psychosocial repercussions of abnormal visible scarring (*Leblebici 2007 [4a]*, *Brown 2008 [5a]*, *Rumsey 2003 [5a]*) and it is clear that improving scar aesthetics promotes adjustment and return to participation in age appropriate occupations (*Kawecki 2008 [3a]*). A low grade body of evidence suggests that the beneficial effects of pressure therapy on scar pliability and joint range of motion directly impact functional participation (*Carr 2000 [2a]*, *Bock 2006 [5a]*, *Haverstock 2001 5a [5a]*, *Douglas 2007 [5b]*, *Jensen 1984 [5b]*). Local consensus also supports the use of pressure to increase scar pliability in conjunction with other scar variables, such as height and redness.

The most commonly cited side effect of this treatment is recurrent blistering or ulceration, presumably from the pressure appliance applying too much pressure and ultimately tissue necrosis, especially over bony prominences (*Kloti 1982 [3a], Kloti 1979 [3b], Macintyre 2006 [5a]*). 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 (*Kloti 1982 [3a], Kloti 1979 [3b], Macintyre 2006 [5a]*).

Future Research Agenda

Further investigation of the literature is indicated to determine additional effects of pressure therapy and scar improvement on quality of life, psychosocial adjustment, and overall participation in age-appropriate occupations. In tandem, as improvements on both aesthetic appearance and psychosocial functioning can be identified, it is important to delve into the barriers to adherence to a pressure therapy prescription and the best methods for promoting and facilitating cooperation.

On a larger scale, more 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 clinically difficult to randomize someone to a control group which may deny pressure therapy (*Hambleton 1992 [3a]*). Due to this difficulty, several authors propose well-designed multicenter studies including institutions where scars are most often treated, usually burn centers (*Anzarut 2009 [1b], Engrav 2010 [2a], Van den Kerckhove 2005 [2a], Esselman 2006 [5a], Latenser 2002 [5a]*). Additionally, more basic research is needed to identify the biological mechanisms by which pressure therapy works.

In determining the strength of the r	ecommendation, t	he development group m	ade a considered
judgment in a consensus process which was reflective of critically appraised evidence, clinical			
experience, and these dimensions:			
Given the dimensions below and that more answers t statement above reflect the strength of the recomme left/right logic may be reversed for one or more dime	o the left of the scales indic ndation as judged by the de nsions.)	ate support for a stronger recomment evelopment group. (Note that for neg	dation, the recommendation ative recommendations, the
1. Grade of the Body of Evidence	🗌 High	🔀 Moderate	Low
Rationale: Evidence searched and cited cov level trials. The evidence is relat recommendations to be made. height, which is an important pa	vers studies completed a tively uniform in its ques There is very strong and int of skin appearance an	t the origins of this treatment, as t tions and intents, which allows fo consistent support for the use of d function.	well as more recent high- r several specific pressure to decrease scar
2. Safety/Harm (Side Effects and Risks)	🗌 Minimal	🛛 Moderate	Serious
Rationale: 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.			
3. Health benefit to patient	Significant	Moderate	Minimal
Rationale: Pressure therapy primarily impa and erythema. In addition, pres function in activities of daily life beneficial to the patient as a wh	cts aesthetic component sure therapy fosters imp . While the impact on ea ole depends on the size,	s of the scar, providing significant roved skin health and prevents jo ich scar is significant, the degree t location, and severity of the scar	improvement in scar height int contractures which inhibit to which the improvement is itself.
4. Burden on patient to adhere to recommendation	Low	Unable to determine	🖂 High
Rationale: Adherence to the lengthy, unco	mfortable and conspicuo	us treatment is often difficult for	patients and their caregivers.
5. Cost-effectiveness to healthcare system	Cost-effective	Inconclusive	Not cost-effective
Rationale: Use of these recommendations for treatment. Additionally, pre costly pharmaceutical or surgica	will limit over-utilization ssure therapy can be use l intervention.	of pressure therapy by indicating ed early in treatment and can prev	which scars are appropriate vent or delay the need for
6. Directness of the evidence for this target population	Directly relates	Some concern of directness	Indirectly relates
Rationale: Studies cited consider those with hypertrophic scars.			
7. Impact on morbidity/mortality or quality of life	🗌 High	🔀 Medium	Low
Rationale:			

Reference List (Evidence Level in []; See <u>Table of Evidence Levels</u>)

- 1. Alster, T. S., and Tanzi, E. L.: Hypertrophic scars and keloids: etiology and management. *Am J Clin Dermatol*, 4(4): 235-43, 2003, [5b]
- 2. Anzarut, A.; Olson, J.; Singh, P.; Rowe, B. H.; and Tredget, E. E.: The effectiveness of pressure garment therapy for the prevention of abnormal scarring after burn injury: a meta-analysis. *J Plast Reconstr Aesthet Surg*, 62(1): 77-84, 2009, [*1b*]_______.
- 3. **Baryza, M. J., and Baryza, G. A.:** The Vancouver Scar Scale: an administration tool and its interrater reliability. *J Burn Care Rehabil*, 16(5): 535-8, 1995, [2a] *.
- 4. Baur, P. S.; Larson, D. L.; Stacey, T. R.; Barratt, G. F.; and Dobrkovsky, M.: Ultrastructural analysis of pressure-treated human hypertrophic scars. *J Trauma*, 16(12): 958-67, 1976, [4a] ~ ~.
- 5. Berman, B., and Flores, F.: The treatment of hypertrophic scars and keloids. Eur J Dermatol, 8(8): 591-5, 1998, [5a] *.
- 6. Berman, B.; Viera, M. H.; Amini, S.; Huo, R.; and Jones, I. S.: Prevention and management of hypertrophic scars and keloids after burns in children. *J Craniofac Surg*, 19(4): 989-1006, 2008, [5b]____ ♥.
- 7. Bloemen, M. C.; van der Veer, W. M.; Ulrich, M. M.; van Zuijlen, P. P.; Niessen, F. B.; and Middelkoop, E.: Prevention and curative management of hypertrophic scar formation. *Burns*, 35(4): 463-75, 2009, [5a]_____*.
- 8. **Bock, O.; Schmid-Ott, G.; Malewski, P.; and Mrowietz, U.:** Quality of life of patients with keloid and hypertrophic scarring. *Arch Dermatol Res,* 297(10): 433-8, 2006, [5a]____ ♥.
- 9. Bombaro, K. M.; Engrav, L. H.; Carrougher, G. J.; Wiechman, S. A.; Faucher, L.; Costa, B. A.; Heimbach, D. M.; Rivara, F. P.; and Honari, S.: What is the prevalence of hypertrophic scarring following burns? *Burns*, 29(4): 299-302, 2003, *[4a]* ~ •.
- 10. Brown, B. C.; McKenna, S. P.; Siddhi, K.; McGrouther, D. A.; and Bayat, A.: The hidden cost of skin scars: quality of life after skin scarring. *J Plast Reconstr Aesthet Surg*, 61(9): 1049-58, 2008, [5a]_____ ♥.

- 11. Candy, L. H.; Cecilia, L. T.; and Ping, Z. Y.: Effect of different pressure magnitudes on hypertrophic scar in a Chinese population. Burns, 36(8): 1234-41, 2010, [2a] ~ .
- 12. **Carr, T.; Harris, D.; and James, C.:** The Derriford Appearance Scale (DAS-59): a new scale to measure individual responses to living with problems of appearance. *British Journal of Health Psychology*, 5(2): 201-215, 2000, [2a] *****.
- 13. Chang, P.; Laubenthal, K. N.; Lewis, R. W., 2nd; Rosenquist, M. D.; Lindley-Smith, P.; and Kealey, G. P.: Prospective, randomized study of the efficacy of pressure garment therapy in patients with burns. *J Burn Care Rehabil*, 16(5): 473-5, 1995, [2b]____ *****.
- 14. Cheng, W.; Saing, H.; Zhou, H.; Han, Y.; Peh, W.; and Tam, P. K.: Ultrasound assessment of scald scars in Asian children receiving pressure garment therapy. *J Pediatr Surg*, 36(3): 466-9, 2001, [4a]_____*.
- 15. **Davoodi, P.; Fernandez, J. M.; and O, S. J.:** Postburn sequelae in the pediatric patient: clinical presentations and treatment options. *J Craniofac Surg*, 19(4): 1047-52, 2008, [5b]____ **●**.
- 16. **Deitch, E. A.; Wheelahan, T. M.; Rose, M. P.; Clothier, J.; and Cotter, J.:** Hypertrophic burn scars: analysis of variables. *J Trauma,* 23(10): 895-8, 1983, [4a]____ ♥.
- 17. Douglas, V., and Way, L.: Scarring: A patient-centred approach. *Practice Nursing*, 18(2): 78-83, 2007, [5b] *****.
- 18. Draaijers, L. J.; Tempelman, F. R.; Botman, Y. A.; Tuinebreijer, W. E.; Middelkoop, E.; Kreis, R. W.; and van Zuijlen, P. P.: The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. *Plast Reconstr Surg*, 113(7): 1960-5; discussion 1966-7, 2004, [2a]_____*.
- 19. Engrav, L. H. et al.: 12-Year within-wound study of the effectiveness of custom pressure garment therapy. *Burns*, 36(7): 975-83, 2010, [2a] \sim .
- 20. Esselman, P. C.; Thombs, B. D.; Magyar-Russell, G.; and Fauerbach, J. A.: Burn rehabilitation: state of the science. Am J Phys Med Rehabil, 85(4): 383-413, 2006, [5a] *.
- 21. Garcia-Velasco, M.; Ley, R.; Mutch, D.; Surkes, N.; and Williams, H. B.: Compression treatment of hypertrophic scars in burned children. *Can J Surg*, 21(5): 450-2, 1978, [2b]____ ♥.
- 22. Gauglitz, G. G.; Korting, H. C.; Pavicic, T.; Ruzicka, T.; and Jeschke, M. G.: Hypertrophic scarring and keloids: pathomechanisms and current and emerging treatment strategies. *Mol Med*, 17(1-2): 113-25, 2011, [5a] ~ •.
- 23. Hambleton, J.; Shakespeare, P. G.; and Pratt, B. J.: The progress of hypertrophic scars monitored by ultrasound measurements of thickness. *Burns*, 18(4): 301-7, 1992, [3a] ~ •.
- 24. **Haq, M. A., and Haq, A.:** Pressure therapy in treatment of hypertrophic scar, burn contracture and keloid: the Kenyan experience. *East Afr Med J*, 67(11): 785-93, 1990, [3b]____ *****.
- 25. Haverstock, B. D.: Hypertrophic scars and keloids. Clin Podiatr Med Surg, 18(1): 147-59, 2001, [5a] *.
- 26. Holavanahalli, R. K.; Helm, P. A.; Parry, I. S.; Dolezal, C. A.; and Greenhalgh, D. G.: Select practices in management and rehabilitation of burns: a survey report. *J Burn Care Res*, 32(2): 210-23, 2011, [5a] ~ .
- 27. Jensen, L., and Parshley, P.: Postburn scar contractures: histology and effects of pressure treatment. *Journal of Burn Care & Research*, 5(2): 119, 1984, [5b] *****.
- Johnson, J.; Greenspan, B.; Gorga, D.; Nagler, W.; and Goodwin, C.: Compliance with pressure garment use in burn rehabilitation. J Burn Care Rehabil, 15(2): 180-8, 1994, [4b] ____ P.
- 29. Kawecki, M.; Bernad-Wisniewska, T.; Sakiel, S.; Nowak, M.; and Andriessen, A.: Laser in the treatment of hypertrophic burn scars. *Int Wound J*, 5(1): 87-97, 2008, [3a] ~ .
- 30. Kloti, J., and Pochon, J. P.: Conservative treatment using compression suits for second and third degree burns in children. *Burns Incl Therm Inj*, 8(3): 180-7, 1982, [*3a*]____ ♥.
- 31. Kloti, J., and Pochon, J. P.: Long-term therapy of second and third degree burns in children using Jobst-compression suits. *Scand J Plast Reconstr Surg*, 13(1): 163-6, 1979, [3b]_____*.
- 32. Latenser, B. A., and Kowal-Vern, A.: Paediatric burn rehabilitation. *Pediatr Rehabil*, 5(1): 3-10, 2002, [5a] *.
- 33. Law, M., and King, G.: Parent compliance with therapeutic interventions for children with cerebral palsy. *Dev Med Child Neurol*, 35(11): 983-90, 1993, [4a] •.
- 34. Leblebici, B.; Turhan, N.; Adam, M.; and Akman, M. N.: Clinical and epidemiologic evaluation of pressure ulcers in patients at a university hospital in Turkey. *J Wound Ostomy Continence Nurs*, 34(4): 407-11, 2007, [4a]____ ♥.
- 35. Li-Tsang, C. W.; Zheng, Y. P.; and Lau, J. C.: A randomized clinical trial to study the effect of silicone gel dressing and pressure therapy on posttraumatic hypertrophic scars. *J Burn Care Res*, 31(3): 448-57, 2010, [2b]_____*.
- 36. **Macintyre, L., and Baird, M.:** Pressure garments for use in the treatment of hypertrophic scars--a review of the problems associated with their use. *Burns*, 32(1): 10-5, 2006, [5a]_____*.
- 37. **Mustoe, T. A. et al.:** International clinical recommendations on scar management. *Plast Reconstr Surg*, 110(2): 560-71, 2002, [5a]
- Niessen, F. B.; Spauwen, P. H.; Schalkwijk, J.; and Kon, M.: On the nature of hypertrophic scars and keloids: a review. *Plast Reconstr* Surg, 104(5): 1435-58, 1999, [5a]_____*.
- 39. **Ogawa, R.:** The most current algorithms for the treatment and prevention of hypertrophic scars and keloids. *Plast Reconstr Surg*, 125(2): 557-68, 2010, [5a]____ *****.

- 42. **Rumsey, N.; Clarke, A.; and White, P.:** Exploring the psychosocial concerns of outpatients with disfiguring conditions. *J Wound Care,* 12(7): 247-52, 2003, [5a]____ ♥.
- 43. Staley, M.; Richard, R.; Billmire, D.; and Warden, G.: Head/face/neck burns: therapist considerations for the pediatric patient. *J Burn Care Rehabil*, 18(2): 164-71, 1997, [5b]____ ♥.
- 44. Stewart, R.; Bhagwanjee, A. M.; Mbakaza, Y.; and Binase, T.: Pressure garment adherence in adult patients with burn injuries: an analysis of patient and clinician perceptions. *Am J Occup Ther*, 54(6): 598-606, 2000, [5a]____ ♥.
- 45. Van den Kerckhove, E.; Stappaerts, K.; Fieuws, S.; Laperre, J.; Massage, P.; Flour, M.; and Boeckx, W.: The assessment of erythema and thickness on burn related scars during pressure garment therapy as a preventive measure for hypertrophic scarring. *Burns*, 31(6): 696-702, 2005, [2a]____ ▼.
- 46. Yamaguchi, K.; Gans, H.; Yamaguchi, Y.; and Hagisawa, S.: External compression with elastic bandages: its effect on the peripheral blood circulation during skin traction. *Arch Phys Med Rehabil*, 67(5): 326-31, 1986, [2a]____ ♥.

IMPLEMENTATION

Applicability & 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 (Kloti 1982 [3a], Kloti 1979 [3b], Macintyre 2006 [5a]). Other articles cited length of treatment, appliance cost and rapid appliance loss of pressure as factors contributing to non-adherence (Candy 2010 [2a], Macintyre 2006 [5a], Staley 1997 [5b]). 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 (Stewart 2000 [5a]). Additionally, studies regarding adherence to other therapy interventions have found similar results, despite minimal risks or unpleasant side effects (Rone-Adams 2004 [4a], Law 1993 [4a]). Therefore, successful remediation of patient non-adherence may be a broader therapeutic problem, rather than one unique to pressure therapy for hypertrophic scars. One study successfully utilized showing patients outcome photos of scars treated with pressure versus no treatment (Johnson 1994 [4b]). Self-management* techniques have also been shown to be helpful in promoting adherence. Self-management is the ability of the client and his/her family to collaborate on and adhere to individualized therapy treatment recommendations and appropriately handle signs/symptoms/difficulties associated with the therapy diagnosis to maximize quality of life and participation in life roles. Two family education handouts (Knowing Notes) have been developed to promote understanding, facilitate communication and maximize adherence (see Relevant Tools: Knowing Notes "Scar Prevention" and "Pressure Therapy").

Relevant CCHMC Tools (Available on the internal website only)

Knowing Note: Scar Prevention Knowing Note: Pressure Therapy

Outcome Measures and Process Measures

In order 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.

Outcome Measures

- The percentage of individuals at risk for developing active hypertrophic scars that show improved aesthetic outcomes following pressure therapy as measured by decreased scar height and erythema using the Vancouver Scar Scale. The Vancouver Scar Scale (*Baryza 1995 [2a]*) 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).
- The percentage of individuals at risk for developing active hypertrophic scars that showed improved functional and satisfaction outcomes as measured by decrease in Patient and Observer Scar Assessment Scale scores. The Patient and Observer Scar Assessment Scale (*Draaijers 2004 [2a]*) may be used to assess how the patient or family views and feels about the scar and its function.

Process Measures

• The percentage of individuals at risk for developing active hypertrophic scars that were fit with a pressure therapy device.

SUPPORTING INFORMATION

Background/Purpose of BESt Development

While pressure therapy has been considered standard first line therapy for the treatment of hypertrophic scars since its introduction in the 1960s (*Holavanahalli 2011 [5a]*, *Berman 1998 [5a]*), both the efficacy and mechanisms of action remain highly debated. One of the factors that contribute to the difficulty of determining effectiveness of this treatment is the fact that scars have multiple characteristics which may or may not be affected by pressure therapy; not all studies address all characteristics. The ongoing debate and lack of consistency in the literature demanded a need for a synthesis of best available evidence.

The state of the science regarding scar management has grown and expanded over the years due to improved study design and the use of more objective outcome measurement tools. Daily clinical work presents aesthetic and functional problems related to uncontrolled scar, and questions persist regarding the effectiveness of conservative "standard" treatment for improvement of visible and histological characteristics of scar. This Best Evidence Statement (BESt) aims to clarify these questions in order to improve existing care and to promote stronger research in the future. Of particular concern is the fact that pressure therapy may be being over-utilized; used across the spectrum of abnormal scarring regardless of actual abnormal characteristics. This not only unnecessarily elevates health care costs, but provides patients and clinicians hope for improvement in scar characteristics that are not able to be changed with the use of this therapy.

Definitions

<u>Hypertrophic Scar</u>: Abnormal scarring characterized by increased height/thickness, increased vascularity/erythema, decreased pliability/softness and often changes in pigmentation. The severity of scar is graded by the degree of change in any of those characteristics as compared to the surrounding unaffected or "normal" skin.

<u>Pressure Therapy</u>: Constant surface pressure is applied to an area of the body through the use of tight-fitting elastic garments or wrappings. The pressure compresses small blood vessels (capillaries) underlying the skin or scar. The aim of scar treatment with pressure therapy is to bridge the gap between the normal skin and the scar, both in terms of tissue aesthetics and function.

<u>Scar Maturity</u>: When characteristics of the scar approach those of the individual's normal skin or a plateau in progress is noted after several months of treatment. In addition, scar maturity can occur after several months without treatment, in which case there may be limited changes in the abnormal characteristics of the scar.

<u>Keloid</u>: Differentiated from hypertrophic scarring by scar growth beyond the borders of the original wound. These scars are often large and bulbous and do not respond in the same manner as hypertrophic scars to conservative treatment.

<u>Scar Height</u>: Describes the amount that the scar is elevated above the normal skin. Height is typically measured in millimeters. Scars are typically increased in height and can be described as thick.

<u>Scar Erythema</u>: Describes the color provided by presence of blood vessels under the epidermis of the scar. Erythema increases in scars, and they may look red, pink, or even dark purple and can be referred to as hyperemic. This characteristic is often referred to as "vascularity."

<u>Scar Pliability</u>: Describes the stretchiness or movability of the scar compared to surrounding normal skin. Pliability decreases in scars, and they are often described as firm or impliable. This characteristic is often referred to as "firmness."

<u>Scar Pigmentation</u>: Describes the overall natural tone of the skin provided by melanin. Pigmentation can either increase or decrease in scars, which are described as hyperpigmented, hypopigmented or dischromic.

<u>Pressure appliance</u>: Any device used to apply therapeutic pressure. Includes wrappings, such as self-adherent or soft elastic wraps; pre-fabricated tubular stockings; pre-fabricated items of clothing; custom made items of clothing or "garments;" custom made semi-rigid or hard plates used to conform to specific body parts such as the neck or face or materials used underneath the former described in order to increase pressure or conformity to the scar, such as foam or gel sheeting.

<u>Self-Management</u>: Self-management is the ability of the client and his/her family to collaborate on and adhere to individualized therapy treatment recommendations and appropriately handle signs/symptoms/difficulties associated with the therapy diagnosis to maximize quality of life and participation in life roles.

Search Strategy

Databases: MEDLINE, CINAHL, Cochrane Libraries, and hand search of relevant articles through use of reference lists.

Search Engines: Burntherapist.com, Google Scholar, OT Seeker, PEDro.org, Pubmed.gov, Pubmed Clinical Queries, Cochrane Database for Systematic Reviews (CDSR)

Search Terms: Scar, hypertroph*, pressure therapy, compression therapy, pressure garment, burn, scald, trauma, MeSH terms: cicatrix, hypertrophic

Limits and Filters: Humans and English Language, no age limitations

Search Dates: 01.01.1970 to 02.01.2014

Group/Team Members

Team Leader/Author

Patricia Sharp, OTD, MS, OTR/L, Division of Occupational Therapy and Physical Therapy

Ad hoc Advisors

Rebecca D. Reder, OTD, OTR/L, Division of Occupational Therapy and Physical Therapy Carol Burch, PT, DPT, Division of Occupational Therapy and Physical Therapy Michelle Kiger, MHS, OTR/L, Division of Occupational Therapy and Physical Therapy

Support / Consultant

Mary Gilene, MBA, Division of Occupational Therapy and Physical Therapy

Ad Hoc Members

Kevin Yakuboff, MD, FACS, Division of Plastic Surgery Brian Pan, MD, Division of Plastic Surgery Dawn Rothchild, CNP, RN, MSN, Division of Plastic Surgery

Conflicts of Interest were declared for each team member

No financial or intellectual conflicts of interest were found.

The following conflicts of interest were disclosed:

Note: Full tables of the LEGEND evidence evaluation system are available in separate documents:

- <u>Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality</u> (abbreviated table below)
- <u>Grading a Body of Evidence to Answer a Clinical Question</u>
- Judging the Strength of a Recommendation (dimensions table below and Rationale)

Table of Evidence Levels (see note above):

Quality level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

†a = good quality study; b = lesser quality study

Table of Language and Definitions for Recommendation Strength (see note above):

Language for Strength	Definition	
It is strongly recommended that	When the dimensions for judging the strength of the evidence are applied,	
It is strongly recommended that not	there is high support that benefits clearly outweigh risks and burdens. (or visa-versa for negative recommendations)	
It is recommended that	When the dimensions for judging the strength of the evidence are applied,	
It is recommended that not	there is moderate support that benefits are closely balanced with risks and burdens.	
There is insufficient evidence and a lack of	consensus to make a recommendation	

Copies of this Best Evidence Statement (BESt) and related tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.

Website address: http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/bests/

Examples of approved uses of the BESt include the following:

- Copies may be provided to anyone involved in the organization's process for developing and implementing evidence based care;
- Hyperlinks to the CCHMC website may be placed on the organization's website;
- The BESt may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and

• Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at EBDMinfo@cchmc.org for any BESt adopted, adapted, implemented, or hyperlinked by the organization is appreciated.

Please cite as: Sharp, P., Cincinnati Children's Hospital Medical Center: Best Evidence Statement Use of pressure therapy for management of hypertrophic scarring, <u>http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/best.htm</u>, BESt 176, pages 1-10, 3/10/14.

This Best Evidence Statement has been reviewed against quality criteria by two independent reviewers from the CCHMC Evidence Collaboration. Conflict of interest declaration forms are filed with the CCHMC EBDM group.

The BESt will be removed from the Cincinnati Children's website, if content has not been revised within five years from the most recent publication date. A revision of the BESt may be initiated at any point that evidence indicates a critical change is needed.

Review History

Date	Event	Outcome
3/13/2014	Original Publication	New BESt developed and published

For more information about CCHMC Best Evidence Statements and the development process, contact the Evidence Collaboration at EBDMinfo@cchmc.org.

Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.