There is evidence (level 1b) that non-silicone polyurethane gel dressings are significantly more effective in reducing the cosmetic severity of mature hypertrophic scars than silicone gel dressings

Prepared by; Jill Hackett (email address: jillhackett@optusnet.com.au)
4th year undergraduate occupational therapy student,
University of Western Sydney

Date: May 2005

Review date: May 2007

CLINICAL SCENARIO: Hypertrophic and keloid scars can lead to significant functional and psychological impairments, which impact on occupational performance. Numerous articles have been published establishing silicone gel dressings as an effective treatment in reducing both the molecular state and cosmetic appearance of scars. Surprisingly, improvements have occurred not only in newly developed scars but also in mature scars. Nevertheless, the mechanism of action of silicone dressings is still unknown. The silicone is not believed to dissipate through the skin, so theoretically it should be possible for other occlusive dressings to have similar benefits. Are non-silicone gel dressings as effective in reducing the undesirable cosmetic aspects of a scar compared to silicone gel dressings?

FOCUSSED CLINICAL QUESTION: Do non-silicone gel dressings produce equal improvements in the cosmetic appearance of hypertrophic scars compared to silicone based gel dressings?

SUMMARY of Search, 'Best' Evidence appraised, and Key Findings:

- 3 citations were located that met the inclusion/exclusion criteria.
- 2 randomised controlled trials were located and reviewed to determine trial quality.
- The randomised controlled trial (RCT) by Klopp, Niemer, Fraenkel, and Von der Weth (2000) was deemed to be the "best" evidence and was appraised.
- This RCT measured multiple outcomes however this CAT focuses only on the cosmetic changes as measured by skin surface roughness.
- This RCT reported that conventional compression combined with a polyurethane dressing reduced the surface roughness and visible aspects of mature hypertrophic scars on average by 52.7% (±4.03%) when worn for eight weeks, compared to 22.8% (±3.97%) with compression alone.
- Polyurethane dressings used in combination with compression were found to be more effective in reducing the surface roughness and visible aspects of mature hypertrophic scars than silicone dressings in combination with compression, and this difference was significant at the 0.01 level

CLINICAL BOTTOM LINE: Non-silicone polyurethane dressings are significantly more effective than silicone dressings in reducing the adverse cosmetic effects of mature hypertrophic scars when worn for a period of eight weeks, especially when used in conjunction with compression.

Limitation of this CAT: This critically appraised paper has been individually prepared as part of a university subject, reviewed and marked by a lecturer, but has not been externally peer-reviewed.

SEARCH STRATEGY:

Using the levels of evidence as defined by the Oxford Centre for Evidence-based Medicine (Phillips, Ball, Sackett, et al., 1998), the search strategy aimed to locate the following study designs:

- Systematic reviews and meta-analyses of randomised controlled trials (level 1a);
- Systematic reviews and meta-analyses of randomised and non-randomised controlled trials (level 2a);
- Randomised controlled trials (level 1b or 2b);
- Controlled trials, cohort (level 2b) or case-control studies (level 3b);
- Case series (level 4); or
- Expert opinion including literature/narrative reviews, consensus statements, descriptive studies and individual case studies (level 5).

A search was also conducted for clinical practice guidelines based on these levels of evidence.

Terms used to guide Search Strategy:

- **P**atient/Client: Patients with post-operative keloid or hypertrophic scars
- **I**ntervention: Non-silicone gel dressings
- **C**omparison: Silicone gel dressings
- **O**utcome(s): Reduction in appearance of the scar

Table 1: Summary of search

Databases and sites searched	Search Terms Used
* National Guideline Clearinghouse * Cochrane Library * Database of Abstracts of Reviews of Effectiveness (DARE) * Joanna Briggs Institute * PEDro (Physiotherapy Evidence database) * OTseeker (Occupational Therapy Systematic Evaluation of Evidence) * Google scholar	Scar AND silicone AND (nonsilicone OR non-silicone OR (non silicone))
……	……..
* EMBASE, PubMed, CINAHL, Pre CINAHL, Art Abstracts, * MEDLINE	1. scar 2. silicone 3. #1 AND #2 4. non silicone OR non-silicone OR nonsilicone 5. #3 AND #4

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria:

- Studies published in English
- Patients had a hypertrophic or keloid scar
- Comparison of non-silicone and silicone gel dressings
- Cosmetic appearance measured as an outcome.

Exclusion Criteria:

- Patients with burns
- Studies measuring only silicone dressings
- Studies measuring only non-silicone dressings
- Studies where only molecular or functional changes were reported as an outcome

RESULTS OF SEARCH

Three relevant studies were located and categorised as shown in Table 2 (based on Levels of Evidence and grades of recommendations, Centre for Evidence Based Medicine, 1998).

Table 2: Summary of Study Designs of Articles retrieved

Level of Evidence	*Study Design/ Methodology of Articles Retrieved*	*Number Located*	*Source(s)*
	Evidence Based Guidelines	0	
1a	Systematic reviews and meta-analyses of randomised controlled trials	0	
2a	Systematic reviews and meta-analyses of randomised and non-randomised controlled trials	0	
1b	Randomised controlled trials (with narrow confidence intervals)	1	Citation appeared in Pubmed (1).
2b	Individual cohort study (including low quality randomised controlled trials)	2	Citation appeared in Pubmed (2,3); OTSeeker (2); EMBASE (2) MEDLINE (2); Google Scholar(2).
3	Case-control studies	0	
4	Case series studies	0	
5	Expert opinion including literature/narrative reviews, consensus statements, descriptive studies and individual case studies	0	

BEST EVIDENCE

The randomised controlled trial by Klopp, Niemer, Fraenkel and Von der Weth (2000) was identified as the 'best' evidence and selected for critical appraisal because:

- It was the most methodologically sound study and the highest level of evidence.
- The study answered the clinical question.
- A primary outcome of the trial was cosmetic changes as measured by roughness of skin.
- Reported within group point estimates and measures of variability which could be analysed, whereas DeOliveira and colleagues (2001) only presented p-values.

SUMMARY OF BEST EVIDENCE

Table 3: Description and appraisal of the randomised controlled trial by Klopp et al. (2000).

Aim of the Study

To quantify the impact of polyurethane dressings, silicone dressings and compression on the structure of hypertrophic scars older than two years.

Intervention Investigated

Interventions were (1) polyurethane dressings alone, (2) polyurethane dressing plus compression, (3) compression alone, and (4) compression plus silicone sheeting. Each of the 12 participants received all of the four treatment modalities on a 6cm portion of their scar with a 15mm gap between each modality. Compression was administered using short stretch bandages with a width of 6cm. Treatments were implemented for a period of eight weeks, during which the use of concomitant topical therapy was not permitted. Measurements were taken in the department of cardiac surgery at a large hospital in Berlin, Germany. The sample was homogenous in age, height and weight.

Outcome Measures (Primary and Secondary)

The outcomes in this randomised controlled trial were (a) microcirculation measurements, (b) skin surface temperature and (c) tissue surface quality. The authors did not choose a primary outcome. The outcome that will be focused on to answer the clinical question posed for this CAT is the tissue surface quality; other measures will not be analysed. Measurements were taken 1, 7, 14, 28 and 56 days after the start of treatment, however it was not stated who took the measurements.

A. Microcirculation measurements:

- Blood cell-perfused nodal points – were defined as an erythrocyte boundary flow velocity of 80µm/second over 20 seconds, identified by microscopic methods.
- Erythrocyte aggregation – defined as cohesion of at least 3 erythrocytes, which were identified by microscopic methods and reported as a percentage of the total.
- Venular flow rate – was measured within a tissue volume of 1mm3 representing prevailing volume flow rate in µm3/second using microscopic methods.
- Total length of the microvessels – were measured in vessels ≤10 µm3 in a tissue volume of 1000 µm3.

B. Skin surface temperature measurements: scar tissue was compared to surrounding skin tissue using liquid crystal thermography which is accurate to 0.1K.

C. Tissue surface quality: was measured using a specific incident light microscopic method in combination with computer-aided image processing. A roughness profile (R) was generated by measuring all profile deviations from a line running parallel to the scar. Rmax was the greatest individual roughness depth within a given measured distance.

Results

As this CAT focuses on cosmetic changes, results are displayed only for the tissue surface quality outcome as measured by surface roughness.

Table 3.1: Shows the reduction of surface roughness (Rmax, %) after 14 days of treatment (no SD recorded) and 56 days of treatment (with SD) compared to baseline.

	After 14 days	**After 56 days**
Polyurethane (group 1)	6.1%	34.4 ± 3.41%
Polyurethane plus compression (group 2)	14.3%	52.7 ± 4.03%
Compression (group 3)	4%	22.8 ± 3.97%
Silicone plus compression (group 4)	9.9%	44.5 ± 4.07%

The reduction of the maximum surface roughness differed significantly between the individual treatment modalities (Wilcoxon rank sum test, α=0.05). The most marked reduction in roughness was achieved using the polyurethane dressing plus compression.

Original Authors' Conclusions

Subjective improvements in scar appearance correlated with approximations of the functional state of the scar tissue. All treatment modalities were found to have significant effects both on tissue function and scar tissue surface structure. The most pronounced effects were achieved with the combination of polyurethane dressing plus compression (Gp 2) or silicone sheeting plus compression (Gp 4).

Critical Appraisal:

Validity *(Methodology, rigour, selection, bias)*

- Ethical approval and written informed consent not reported by the authors.
- The authors did not state a clear focused clinical question.
- Participants volunteered to be involved in this study, all of whom were attending the department of cardiac surgery at a large hospital in Berlin, Germany for routine follow-up post removal of veins for heart bypass surgery. This is an adequate form of selection as participants were not hand-picked by the authors and all participants were obtained from a similar sample population (not from varying surgical procedures), therefore all of the participants would have similar scars.
- Inclusion and exclusion criteria used to screen clients study not presented.
- The authors did state that patients were found to be homogenous at baseline for age, height and weight. However, as only the section of the scar was randomised, not the individuals, the groups would be 100% comparable in regards to age, height and weight.

- Lack of assessor blinding, allowing for a measurement detection bias.
- Lack of researcher and subject blinding also creates bias. Blinding of participants to the type of dressing used on each section of the wound would have been possible, however no blinding was reported.
- The authors did not state who took the measurements. Measurers could have had a vested interest in one treatment modality and so the measurements could be biased. If more than one person took measurements, they may not be consistent.
- An intra-individual, comparative study was utilised where each participant received all four treatment modalities along a 30cm scar. 6cm of the scar was allocated for each treatment modality with a 1.5cm gap between each. The authors state that preliminary investigations show that a space of 1.5cm "exclude the influence of compression on the microcirculation in the neighbouring test areas" (p.320). However they do not reference where they have obtained this information from and do not address the potential for the silicone and polyurethane dressings to influence the other treatment areas.
- Although all participants received the 4 treatments, randomisation was still performed. In this situation, randomisation referred to which segment of the scar would receive which treatment. The randomisation process was clearly defined.
- As multiple treatments were given to each individual, the statistical tests should not treat them as independent samples, therefore paired analyses is the appropriate statistical test. The authors took this into consideration by using the Wilcoxon rank sum test.
- The mean number of hours per day that the dressings were worn was not included in the study. The authors also did not mention how often the dressings were replaced or washed. This information would have facilitated directions about how to use the dressings.
- As all 12 participants received all four treatments, it appears that there were 48 participants when this was not the case; the sample size was still 12. The authors stated that "intravital comparison can produce results of statistical significance with even a small number of subjects as each one acts as his or her own control" (p.320).
- The authors make no mention of power calculations.
- Typically, a small sample size may influence the results by preventing identification of results that are both statistically and clinically significant due to a lack of power. However, even with such a small sample size, the results were statistically significant, which implies that non-silicone polyurethane gel dressings are exceptionally effective in reducing the undesirable cosmetic aspects of hypertrophic scars.

Results *(Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance; minimal clinically important difference)*

- Raw data at baseline and follow-up periods were not included in the results section. This would have been helpful to establish which time period had the greatest reduction in skin roughness. That is, the amount of time the dressings need to be worn to have a positive result. These data would enable us to give recommendations regarding duration of treatment.

- Klopp, Niemer, Fraenkel, and Von der Weth (2000) presented mean differences and standard deviations of maximum skin roughness within groups at 56 days follow-up and stated that these figures differed significantly between the individual treatment modalities (Wilcoxon rank sum test, α=0.05). However this statement was ambiguous as it did not clarify which groups were being compared and did not provide statistics to support this significance.
- From the data available, the table below was produced which compares the three treatment groups with the compression (control) group (Gp 3). It also compares the effect of the polyurethane dressing with compression (Gp 2) against the silicone dressings with compression (Gp 4); and the polyurethane dressing alone (Gp 1).

Table 3.2: Mean differences and p-values of skin roughness between groups.

	% skin roughness reduction at 56 days	n	Mean Difference	95% Confidence Intervals	p-value
Polyurethane vs. Compression	34.4±3.41 22.8±3.97	12 12	11.6	8.47 to 14.73	0.001*
Silicone + Compression vs. Compression	44.5±4.07 22.8±3.97	12 12	21.7	18.3 to 25.1	0.001*
Polyurethane + Compr vs. Compression	52.7±4.03 22.8±3.97	12 12	29.9	26.51 to 33.29	0.001*
Polyurethane + Compr vs. Silicone + Compression	52.7±4.03 44.5±4.07	12 12	8.2	4.77 to 11.63	0.001*
Polyurethane + Compr vs. Polyurethane	52.7±4.03 34.4±3.41	12 12	18.3	15.14 to 21.46	0.001*

* represents statistical significance between the groups at the 0.01 level.

P-values calculated by the effect size calculator (The curriculum, evaluation and management centre, n,d).

- From the above table it is clear that all other treatments were more effective than compression alone, the polyurethane plus compression group (group 2) showing the most pronounced effect with a mean difference of 29.9.
- The most important result to note from the above table in addressing the clinical question under investigation is the comparison between the polyurethane plus compression (group 2) with that of the silicone plus compression (group 4). The mean difference between these two groups was 8.2 (95% confidence interval 4.77 to 11.63) in favour of the polyurethane plus compression group. This difference was significant at the 0.01 level. Therefore we can conclude that non-silicone dressings are as effective as silicone dressings in reducing the adverse cosmetic appearance of hypertrophic scars. Polyurethane dressings were superior to silicone dressings.
- Another important point is that the effects of polyurethane dressings increased when combined with compression. This can be seen by comparing the polyurethane plus compression with polyurethane alone. The mean difference between the groups is 18.3 (95% confidence interval 15.14 to 21.46), which is significant at the 0.01 level.

- There was also a 12-month follow-up period mentioned within the article, however no data were presented for this. A general statement was given that "none of the measured parameters had changed significantly during this period…demonstrating that functional and qualitative changes of the scar tissue were stable" (p.323). The data from this follow-up would have allowed us to see exactly how stable the results were.
- The above data have shown statistical significance of non-silicone dressings; however clinical significance is not addressed. Since we are looking at cosmetic aspects of the scar after treatment, clinical significance would be determined by the participants' perception of the difference in the scar's appearance. For this reason it would have been useful to use a subjective questionnaire of patient satisfaction of the outcomes. The data indicate that polyurethane is equal to, if not superior, to the more expensive silicone dressing. The superior result of 8.2% reduction (95% confidence interval 4.8 to 11.6) for surface roughness of polyurethane compared to silicone is likely to be clinically significant. From the confidence interval we can also be 95% certain that in the worst case scenario, polyurethane dressings are at least 4.8% superior.
- The cost effectiveness of the two dressings was not analysed in this randomised controlled trial. This would have permitted us to compare the two dressings regarding cost effectiveness.

IMPLICATIONS FOR PRACTICE/APPLICABILITY

- From the data in this randomised controlled trial it can be concluded that non-silicone polyurethane dressings were equally, if not more effective in improving the cosmetic appearance of hypertrophic scars after surgical procedures when compared to silicone dressings. This corresponds with findings of the other two articles published on the topic. DeOliveira and colleagues (2001) concluded that silicone and non-silicone gel sheets were similar, effective methods in the treatment of keloid and hypertrophic scars resulting in a significant change in the colour of the scar. Ricketts et al., (1996) also found that similar clinical improvements occurred with silicone and non-silicone dressings.
- The fact that this study evaluated participants with scars older than 2.5 years shows that gel dressings were effective for use on mature scars, even though responsiveness to treatment is generally accepted to be limited to the first two years. It can be hypothesised that they would be even more effective in younger scars which are still considered to be responsive to treatment.
- From the author's fieldwork, it has been found that non-silicone gel dressings are less expensive than silicone dressings. If non-silicone dressings are equally as effective as silicone dressings, these findings are important for cost cutting in public health occupational therapy departments where large quantities of gel dressings would be purchased to provide to patients. They are also important to reduce costs for patients who might purchase the product from private settings.
- As there are a relatively small number of studies published which compare silicone and non-silicone dressings on scars, it is recommended that a larger, more rigorous randomised controlled trial be performed to verify these findings.

- Although this article did not mention the length of time per day that the dressings should be worn, DeOliveira and colleagues (2001) found that participants had positive results from wearing the non-silicone dressings for 24 hours a day, replacing the dressing every week. There was no basis for their chosen time periods, so this is also an area which should be considered for future research. In the meantime, dressings should be worn as directed in the DeOliveira and colleagues (2001) study as this is the highest level of evidence which discusses a time period for dressing use.
- Also, the required duration of the treatment period for the dressings to have a positive result were not mentioned in this study, however DeOliveira and colleagues (2001) found that 91% of participants had their last changes in appearance within 90 days of treatment, the remaining 9% experienced changes up to 135 days of treatment. Therefore the recommended duration of treatment should be 3 months.
- At university in Australia, occupational therapy students learn about silicone dressings to reduce the severity of scars, however are not informed about the non-silicone alternatives. This raises a question about whether therapists are aware of the silicone dressing alternatives available. If not, increased awareness of this product is required in both universities and within the profession.

REFERENCES

Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, Dawes M. (1998). Levels of evidence and grades of recommendations. Retrieved May 16, 2005, from http://cebm.jr2.ox.ac.uk/docs/levels.html.

The curriculum, evaluation and management centre. Evidence-based education UK. (n,d). The *effect size calculator*. Retrieved May 25, 2005, from http://www.cemcentre.org/ebeuk/research/effectsize/Calculator.htm

Article that was critically appraised:

1. Klopp, R., Niemer, W., Fraenkel, M., & VonderWeth, A. (2000). Effect of four treatment variants on the functional and cosmetic state of mature scars. *Journal of Wound Care, 9*(7), 319-324.

Related Articles (not individually appraised)

Level 1 Evidence Nil

Level 2 Evidence Nil

2. DeOliveira, G.V., Nunes, T.A., Magna, L.A., Cintra, M.L., Kitten, G.T., Sarpellon, S., & DoAmaral, C.M.R. (2001). Silicone versus nonsilicone gel dressings: A controlled trial. *Dermatologic Surgery, 27*(8), 721-726.

3. Ricketts C.H., Martin, L., Faria, D.T., Saed, G.M., & Fivenson, D.P. (1996). Cytokine mRNA changes during the treatment of hypertrophic scars with silicone and nonsilicone gel dressings. *Dermatologic Surgery, 22*(11), 955-999.

Levels 3, 4 and 5 Evidence = Nil