Efficacy of a Polyurethane Dressing on Hypertrophic Scars in Comparison to a Silicone Sheet

Wigger-Alberti, W.[1], Wilhelm, D.[1], Mrowietz, U.[2], Eichhorn, K.[3], Kuhlmann, M.[4], Ortega, J.[4], Bredehorst, A.[4], Wilhelm, K.P.[1]

[1] ProDerm Institut für Angewandte Dermatologische Forschung | [2] Department of Dermatology, University of Schleswig-Holstein, Kiel, Germany
[3] Department of Dermatology, University Hospital Leipzig, Leipzig, Germany | [4] Beiersdorf AG, Hamburg, Germany

Abstract

Adhesive bandages are widely used in the treatment of hypertrophic scars. The objective of the study was to determine the efficacy and safety of a polyurethane dressing (Hansaplast® Scar Reducer) compared to a silicone sheet.

A total of 60 patients participated in the randomised multi-center, controlled, observer blind, intra-individual clinical trial. Patients treated one area of the scar for 24 hours daily over a 12 week study period with the polyurethane dressing while the other area was simultaneously treated with a silicone sheet.

Both therapies were significantly effective on the basis of an overall scar index (SI), the determination of skin redness with a skin color reflectance measurement and a patients´ questionnaire. Therapeutic effect showed a favor for the polyurethane dressing compared to the silicone based product. Especially after 4 and 8 weeks of treatment the scar index decreased significantly more pronounced after therapy with the polyurethane dressing compared to silicone therapy (percentage changes from baseline). For the objective determination of redness by a Chromameter the difference between the two therapies was statistically significant at week 8 with lower skin redness values for the polyurethane dressing.

In conclusion, treatment of hypertrophic scars with a self-adhesive hydroactive polyurethane dressing is safe and results in significant clinical improvement. Both regimes, polyurethane dressing and silicone sheet, were associated with significant improvement of the clinical signs of hypertrophic scars over a 12 week period of treatment. The polyurethane dressing demonstrated a significantly pronounced decrease of clinical signs after 4 and 8 weeks of treatment and was better tolerated compared to the silicone sheet therapy.

Introduction

Hypertrophic scars are a frequent problem following injury or surgery in predisposed individuals. Obviously, prevention of hypertrophic scars in individuals at risk is the most efficient procedure, but once a scar is present, the treatment is characterized by a variety of options such as intralesional corticosteroid injections, interferon and fluorouracil, surgical therapy, radiotherapy, pulsed laser therapy, and cryotherapy. However, therapies such as sustained pressure and topical treatment which have few side effects, are painless, inexpensive, and easily performed, are highly desirable in cases of minor problematic scars and even a moderate improvement might represent a relevant therapeutic effect. Special emphasis has been given to the use of silicone sheets to prevent or at least to reduce scar hypertrophy.

Recently, a self-adhesive hydroactive polyurethane dressing was found to improve 1 to 5 years old scars following daily application for 24 hours and 12 hours over a period of two months. In another study involving 2.5 to 4-year old scars beneficial effects of the polyurethane dressing were demonstrated with respect to cosmetic appearance as well as with skin functional condition, i.e., venous blood flow, skin temperature and surface roughness.

Patients and Methods

Study design

A total of three investigational centres under the same protocol participated in this multicentre open-label, observer blind, randomized, intra-individual comparison study.

Patients

Sixty healthy subjects with a hypertrophic scar older than 6 weeks, 5 – 10 mm wide and 60 mm long or longer were enrolled into the study and randomized. Exclusion criteria included any topical or invasive therapy. Fifty five patients finished the study according to protocol (PP) of whom the results are presented.

Dressing and treatment

Each scar was divided into two areas. The test preparation (Hansaplast® Scar Reducer) and the reference preparation were randomly allocated to the treatment sites. One area of the scar was treated for 24 hours daily over a 12 week study period with the silicone sheet. The other area of the scar was simultaneously treated with the polyurethane dressing.

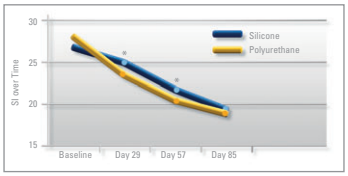
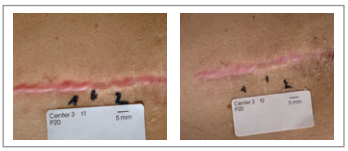


Figure 1: Overall scar index (SI) during therapy phase. *Statistically significant difference according to the one-sided Wilcoxon-signed rank test for superiority between both treatments after 4 weeks ($p<0.0001$) and after 8 weeks ($p=0.012$).

Treatment		Percentage change from baseline	
		Mean	SD
Day 29*	Polyurethane	15.8	14.1
	Silicone	5.6	15.1
Day 57*	Polyurethane	27.1	20.6
	Silicone	20.2	19.4
Day 85	Polyurethane	33.7	19.8
	Silicone	29.4	22.4

Table 1: Percentage changes of the overall scar index (SI) over 12 weeks. *Statistically significant difference according to the one-sided Wilcoxon-signed rank test for superiority between both treatments after day 29 ($p<0.0001$) and day weeks ($p=0.012$).



Left: Female (50), in the abdomen before treatment. Right: Scar after 12 weeks of treatment. 1 = Hansaplast® Scar Reducer | 2 = silicone sheet

Evaluation criteria

Grading assessments and determination of skin redness were performed observer-blind on study days 1, 29±3 (week 4), 57±8 (week 8) and 85±10 (week 12). The primary endpoint was the overall scar index (SI), a modified scale for clinical scar assessment from Beausang et al. including the following parameters: colour as difference to surrounding skin, matte, contour, distortion, texture, and an overall assessment on a visual analogue scale. Further, percentage change from baseline and difference in the overall scar index from baseline at study-visits were assessed. Instrumental measurements to objectively determine skin redness were conducted by chromametry. Additionally, patients' subjective perceptions of the intra-individual results were evaluated on a 5 point scale on the last day of the study including colour, prominence, softness, tightness and discomfort of the scar.

Results

Clinical evaluation

The overall scar index (SI) decreased under both therapies with a favour for the polyurethane dressing compared to the silicone sheet (fig. 1). The Wilcoxon-signed rank test resulted in a one-sided p-value of $< 0{,}0001$ for non-inferiority in a range of 10 % indicating that both treatments were equal over the 12 week period. However, after 4 and 8 weeks of treatment the overall SI decreased more pronounced after therapy with polyurethane compared to silicone. Analysis of the changes from baseline to week 4 showed that decrease after therapy with the polyurethane dressing (15.8 %) was significantly more pronounced than treatment with the silicone sheet (5.6 %) ($p<0.0001$) (tab 1). The same findings in favour for polyurethane were seen after 8 weeks of treatment. Twelve weeks after treatment the differences between silicone (29.4 %) and polyurethane (33.7 %) were no longer significant. Specific benefits could be detected for the items colour, contour and texture (fig. 2-4).

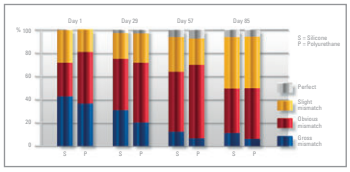


Figure 2: Development of colour over time

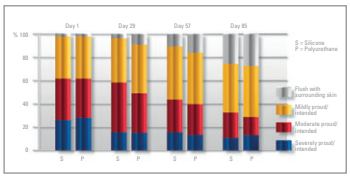


Figure 3: Development of contour over time

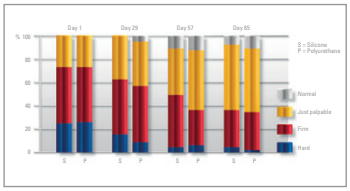


Figure 4: Development of texture over time

Color measurement

The Chromameter measurements, as an indicator for redness, decreased slightly under both therapies in favour of the polyurethane product compared to the silicone product (fig. 5). The differences between the two treatments were most prominent at week 8 compared to baseline ($p=0{,}0016$). A tendency towards lower a*-values after polyurethane dressing compared to silicone sheet was already seen after 4 weeks.

Subjective evaluation

In the questionnaire the patients were asked to evaluate the parameters colour, prominence, softness, tightness and annoyance. While the prominence of the scar was judged as exactly the same between both treatments, all other parameters were judged by the patients in favour of the polyurethane dressing treatment (fig. 6).

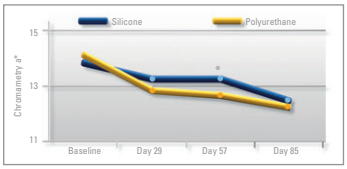


Figure 5. Decrease of chromametric parameter a* as indicator for skin redness. *Statistically significant difference between both treatments after 8 weeks ($p=0.0016$).

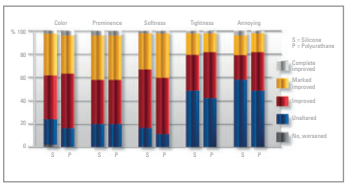


Figure 6: Assessment of treatment effects made by patients for both products.

Adverse events

No serious adverse events were reported. Two adverse events probably related to the treatment with the silicone sheet were documented during the trial. Both appeared as local dermatitis that could not be diagnosed as irritant or allergic without any doubt. No adverse event related to the polyurethane dressing was reported.

Discussion and Conclusion

The benefits of the common treatments to prevent and/or treat hypertrophic scars are lively debated and summarized in two major reviews. In contrast to silicone gel sheetings other non-silicone-based but likewise topical dressings are regarded with scepticism.

In a pilot study of 60 patients a significant improvement in microcirculation and surface qualities have been demonstrated in patients who were treated with a polyurethane dressing for 6 weeks after surgical incisions compared with patients who were treated with either dry gauze or hydroactive dressings. Polyurethane dressing also reduces color, prominence, and hardness of mature hypertrophic scars. These benefits could be confirmed in this multicentre trial.

In this present study the benefit of two adhesive products was proven using an accepted clinical scar index (SI), a standardized objective instrumental measurement for skin colour, and a subjective evaluation by patients themselves, in an observer-blind multicentre trial.

In conclusion, treatment of hypertrophic scars with a self-adhesive hydroactive polyurethane dressing is safe and results in significant clinical improvement. Both regimes, polyurethane dressing and silicone sheet, were associated with significant improvement of the clinical signs of hypertrophic scars over a 12 week period of treatment. The polyurethane dressing demonstrated a significantly pronounced decrease of clinical signs after 4 and 8 weeks of treatment and was better tolerated compared to the silicone sheet therapy.

References available on request.

Filed for publication