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


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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 intracutaneous 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.

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-individ-ual 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 simul-taneously 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 patient’s 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.

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 years, 5 – 10 cm wide and 60 mm long or 6 weeks 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.

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 (15.9 %) 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).

Discussion and Conclusion

The benefits of the common treatments to prevent and/or to treat hypertrophic scars are largely 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.