Scar Management: Observational study of 1522 patients using Kelo-cote® Silicone Gel

Sepehrmanesh M. Komp Dermatologie 2006;1:30–32

Introduction

Kelo-cote® is a patented topical silicone gel for the management of scars and for the prevention of abnormal scars in the form of hypertrophic scars and keloids. Silicone is the clinical gold standard for scar treatment and scar prevention having demonstrated clinical efficacy over all other forms of topical treatments and is recommended by the "International Advisory Panel on Scar Management"[1] as the first line therapy for these types of scars. Kelo-cote® is indicated for scars resulting from trauma, surgery, burns or other events that result in broken skin. Kelo-cote® gel self-dries to a waterproof, gas permeable membrane that acts like an extra layer of skin. Kelo-cote® is clinically proven to help soften, flatten and smooth the scar[1,2] while maintaining the moisture balance and elasticity of the adjacent skin. Kelo-cote® has also been shown to reduce the discoloration and itching associated with scars.[2–4] For the management and prevention of scars, Kelo-cote® can be used as soon as the break in the skin is closed (i.e. after stitches are removed).

Objectives

The objective of this 1522 patient study was to evaluate the efficacy of Kelo-cote® in treating redness, itchiness, pain end elevation. Physician and patient tolerability of Kelo-cote® treatment was also a key parameter assessed.

Study Design and Patients

In the period from May 2003 to January 2005, an clinical evaluation was conducted by 66 dermatologists over a period of 20 months. The study included 1522 patients between 1 and 94 years of age (36 ± 16.2 years) who had hypertrophic or keloid scars. Predominantly these were newly formed scars (< 3 months), but also old scarring, that had existed for at least 4 years (8 %). The origins of scar formation included surgical procedures which accounted for approximately two-thirds of the patients, followed by accident, burn/scalding, and other causes.

Kelo-cote® was applied on average twice a day for a treatment and observational period of 2 to 6 months (maximum 10 months). In 83.8 % of the cases, no secondary treatments were instituted.

Methods

Efficacy was evaluated by measuring typical scar symptoms: difference in color from the surrounding skin, pliability and height, itchiness and pain/tenderness. These symptoms were evaluated by both the patient and the treating physician according to a 4-level scale (none, mild, moderate, and severe). The results were evaluated by a comparison of the initial and final evaluations of the respective scar.

Tolerability was evaluated on the basis of adverse reactions and an estimation of the relationship of these reactions to the product, and on the overall evaluation of tolerability by both doctor and patient at the end of the treatment.

Contentment was evaluated by physicians and patients with reference to ease of use, duration of the treatment, cosmetic result of the treatment, and an assessment of general satisfaction with the therapy.

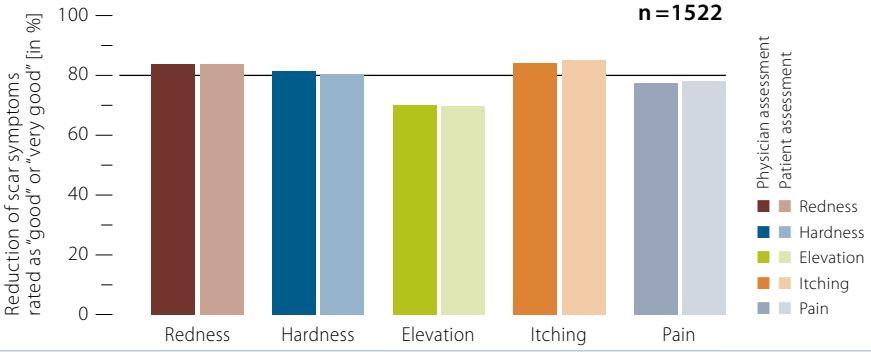
Results

Efficacy: improvement of scar symptoms

Physicians rated the improvement of the various scar symptoms as "good" or "very good" in 70 to 84.2 % of all cases. The evaluation by the patients was almost entirely consistent with the physicians' evaluation (69.8 to 85.1 %). The overall evaluations of effectiveness were also practically identical.

The physicians evaluated the overall effectiveness as "very good" or "good" in 82.6 % of cases, the patients gave an evaluation of "very good" or "good" in 81.4 % of the cases.

Efficacy of Kelo-cote®, measured by the reduction of scar symptoms (rated as "good" or "very good" by physicians and patients)



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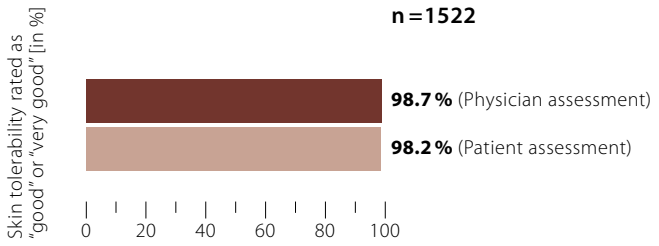
Tolerability

A total of 26 adverse reactions were observed in 23 of the 1522 patients (1.5 %) who received the gel treatment. In the judgment of the treating physicians, 10 of the reactions were in a probable and 5 more in a possible causal relationship with the use of the product under study. In all cases, these adverse reactions were skin reactions, e.g. burning, redness, or itching. These symptoms are commonly associated side effects of keloid and hypertrophic scar treatment.

Physicians evaluated tolerability as "very good" or "good" in 98.7 % of the cases, patients reported "very good" or "good" tolerability of scar treatment with Kelo-cote® in 98.2 % of the cases, representing high consistency in the evaluations.

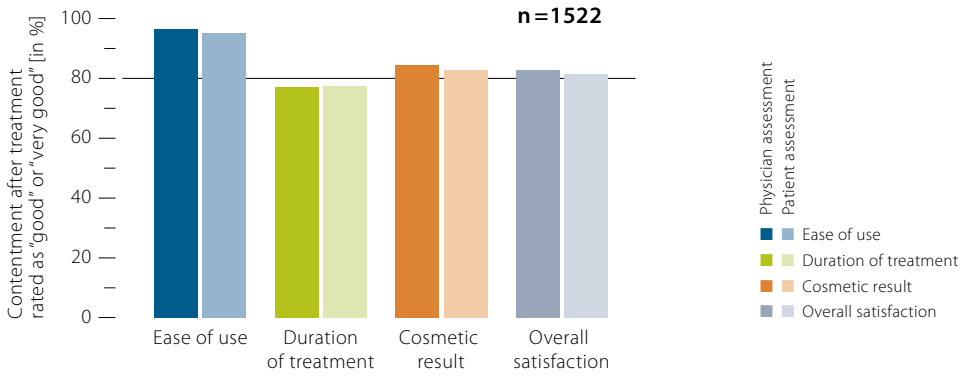
Evaluation of tolerability (rated as "good" or "very good" by physicians and patients)



Physician and patient satisfaction with Kelo-cote® treatment

Ease of use was evaluated positively by the physicians and the patients alike. The physicians also rated patient compliance very positively, followed by duration of treatment and cosmetic result.

Evaluation of contentment after treatment with Kelo-cote® (rated as "good" or "very good" by physicians and patients)



Conclusions

The observational study with 1522 patients of the use of Kelo-cote® to treat scars demonstrates the good effectiveness of the product, as evidenced by the marked relief of scar symptoms. The product is highly tolerable in use, and both physicians and patients are satisfied with the product the therapeutic success achieved by its use.

www.kelo-cote.com

1. Mustoe TA et al. Plast Reconstr Surg 2002; 110:560–571
2. Fulton JE. Dermatol Surg 1995; 21:947–951
3. Quinn KJ. et al. Burns 1985; 12:102–108
4. Sebastian G et al. Akt. Dermatol 2004; Bd. 30:450

Kelo-cote® is manufactured and distributed by:
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www.advancedbiotech.com