

Kelo-cote® is proudly distributed by:

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Clinical Evaluation of a New Self-Drying Silicone Gel in the Prevention of Hypertrophy in New Scars: A Preliminary Report

Signorini M, Clementoni MT. *Aesthetic Plastic Surgery* 2007; 31: 183-187

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 has demonstrated clinical efficacy over all other forms of topical treatments and has become the gold standard for scar treatment and scar prevention. Kelo-cote is indicated for scars resulting from trauma, surgery, burns or other events that result in broken skin. Kelo-cote gel cross links upon application to form a waterproof, transparent, gas permeable membrane that acts like an extra layer of skin.

Objective

The objective of this 160 patient prospective, randomised, controlled trial was to verify the efficacy of a new topical silicone treatment: a self-drying spreadable gel that needs no means of fixation and cannot be seen because of complete transparency. Hypertrophy rate of fresh surgical scars and patient compliance were also key parameters assessed.

Study Design and Patients

In the period from September 2003 and September 2004, the use of a new self-drying silicone gel was investigated with consenting patients who had recent postsurgical scars. The study enrolled 160 patients ranging in age from 5 to 82 years (average, 53.5 years) who all had undergone surgery 10 days to 3 weeks previously by either Dr. Signorini or Dr. Clementoni. Benign or malignant skin lesions needing excision were the main cause of surgery. However, scar revisions and cosmetic procedures (augmentation and reduction breast surgery) also were included.

Each patient was randomly assigned to one of the two following regimens: scar treatment with the self-drying silicone gel or no treatment initially. The self-drying silicone gel was applied twice a day for four months. All the patients were seen on a monthly basis for 4 months, and the final evaluation was performed by Signorini, Clementoni, a nurse and the patient independently at 6 months.

Methods

Efficacy was assessed by evaluating the evolution of the morphologic features of the scar: difference in color from the surrounding skin, height and hardness. These symptoms were evaluated by the patient, a nurse and the treating physician according to a 4-grade scale (normal, mildly hypertrophic, hypertrophic and keloid). 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.

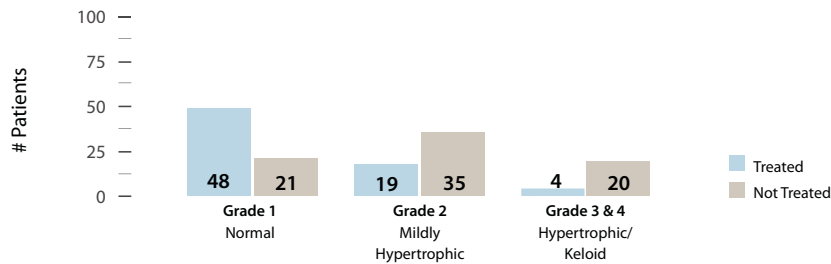
Satisfaction was evaluated by physicians and patients with reference to ease of use, duration of the treatment, cosmetic result of the treatment, and an assessment of general approval with the therapy.

Results

Efficacy: Improvement of scar symptoms using self-drying silicone gel treatment vs. no treatment at all

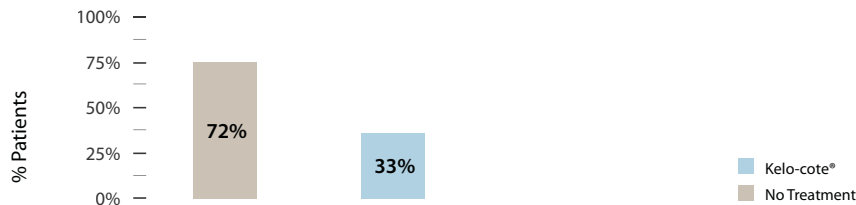
The patients treated with the self-drying silicone gel evidenced grade 1 scars (normal) in 67% of the cases at the end of the observation period, as compared to 28% of the cases in the no initial treatment group. Grade 2 scars (mildly hypertrophic) rated 26% in the treated group, as compared with 46% in the no initial treatment group. Grades 3 and 4 scars (hypertrophic and keloid) rated 7% in the treated group and 26% in the no initial treatment group.

67% of patients treated with silicone gel rated their scars as normal while only 28% of non treated patients rated their scars as normal.



The physicians' results obtained in the study demonstrate that the tested self-drying silicone gel product is effective in speeding up maturation and in reducing the hypertrophy rate of fresh surgical scars.

Percentage of Patients with Some Degree of Hypertrophy



Tolerability

The self-drying silicone gel caused no side effects such as maceration, rashes or infections. Scar irritation was never an issue. All the patients felt the gel was easy to apply but some complained of prolonged drying time particularly in the morning when the patient was rushing which was probably due to excess application of the gel. The use of a hair dryer was suggested, and this solved the problem for most of the patients.

The physicians rated the patient compliance as particularly good, especially for scars on exposed areas such as the face, where the traditional gel sheeting is frequently discontinued at an early stage by patients who object to its visibility.

Physician and Patient Satisfaction with Self-Drying Silicone Gel Treatment

Considering the effective results obtained and the good patient compliance, the physicians currently rate the self-drying silicone gel treatment as the first choice for preventing hypertrophy of recent scars.

Conclusions

Self-drying silicone gel is appealing because no fixation is required; it is invisible when dry; and sun blocks, makeup, or both can be applied in combination. These features suggest that this silicone gel formulation could currently be the most recommendable agent for scar treatment, especially in visible areas.

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