

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.¹ 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.²

Objectives

The objective of this 160 patient prospective, randomized, 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

In the period from September 2003 to 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 Dr. Signorini or Dr. 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 colour 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, 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.

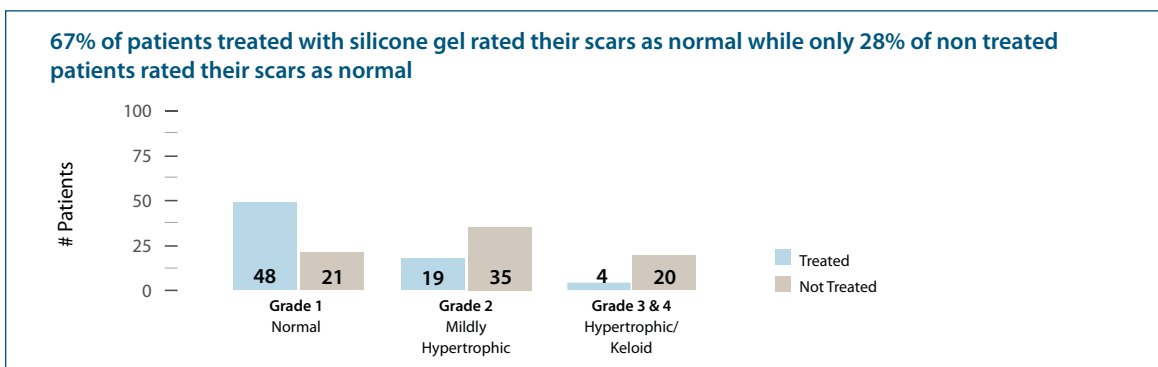
Results

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

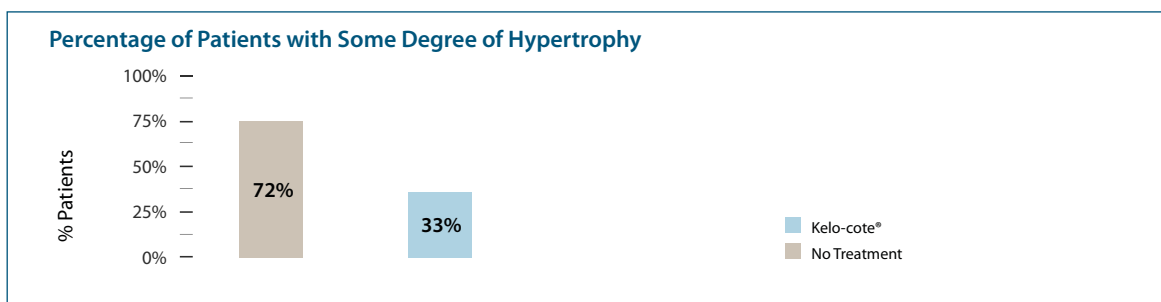
The patients treated with the self-drying, silicone gel evidenced grade 1 scars (normal) in 67% of the cases at the end of the observation period, as compared to 28% of the cases in the no initial treatment group. Grade 2 scars (mildly hypertrophic) rated 26% in the treated group, as compared to 46%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

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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.



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 study 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 block, cosmetics, 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.

For more information please visit www.kelo-cote.ca

1. Mustoe TA et al, Plast Reconstr Surg 2002; 110:560-571
2. Quinn KJ, Burns 1987;13:533-540

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