

Efficacy and Tolerability of a Novel Silicone Gel for Scar Treatment

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. Having demonstrated its clinical efficacy over all other forms of topical treatments, silicone is now the clinical 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 damaged skin. Kelo-cote gel cross links upon application to form a waterproof, transparent, gas permeable membrane that acts like an extra layer of skin.

Objectives

Hypertrophic scars and keloids result from excessive collagen deposition, the cause of which remains hypothetical. These scars can be aesthetically disfiguring and functionally hindering, or both. The objective of this 111 patient surveillance (63% female, 37% male) was the evaluation of efficacy and collection of safety data in clinical parameter of scars: Redness, Pain, Hardness, Elevation and Itchiness following treatment with Kelo-cote. Different scar types at different ages were evaluated.

Study Design and Patients

In the period between January and September 2003, hypertrophic scars and keloid scars were treated with a novel silicone gel, Kelo-cote. A multicenter evaluation enrolled 111 patients and treatment was conducted in dermatological centers in Austria, Switzerland and Germany. The majority of the scars were caused by surgery, one fifth by accidents or burns. 75% of scars were not older than two years. Kelo-cote was applied on median of 2.3 months.

Methods

Efficacy was documented using the Vancouver scar scale on case report forms by the treating doctors and statistically evaluated. Efficacy was evaluated by the evolution of the following parameters: Redness, Pain, Hardness, Elevation and Itchiness following treatment with Kelo-cote. These symptoms were evaluated by the patient and the treating physician and scored on a range scale (very good, good, moderate, unsatisfactory). Changes in score were compared between baseline and last evaluation.

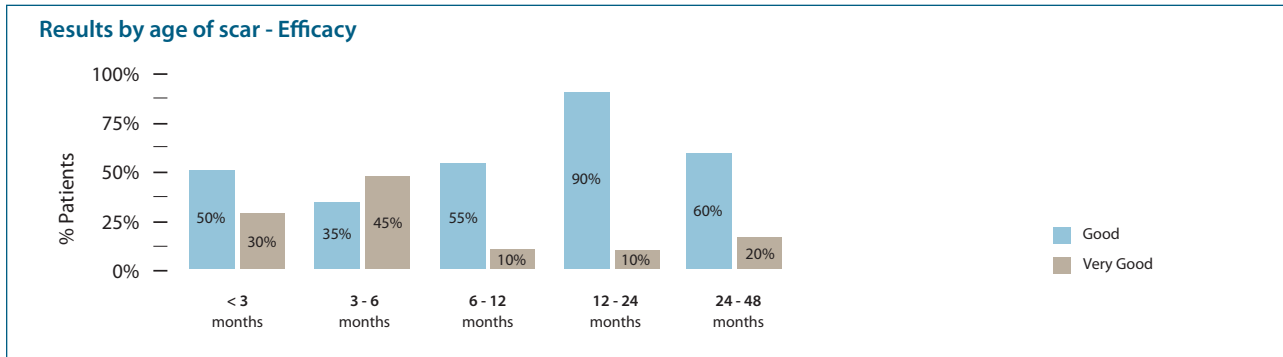
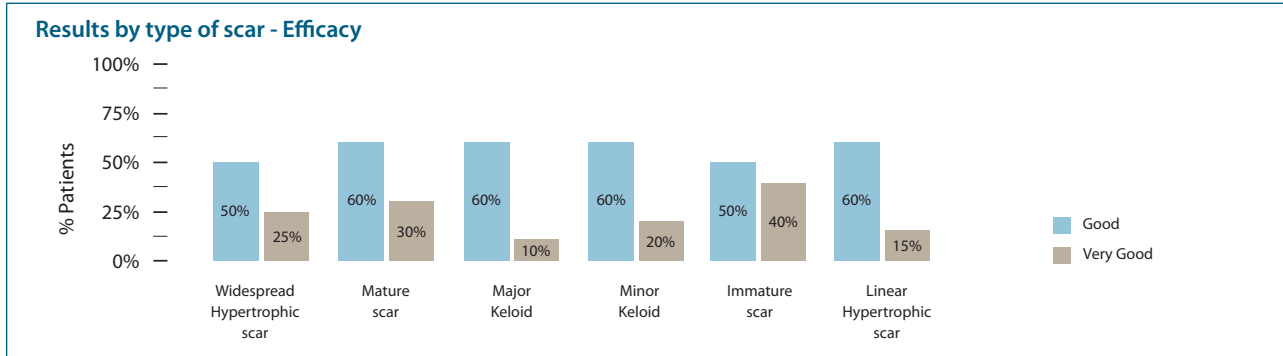
Tolerability was evaluated by adverse event reporting.

Results

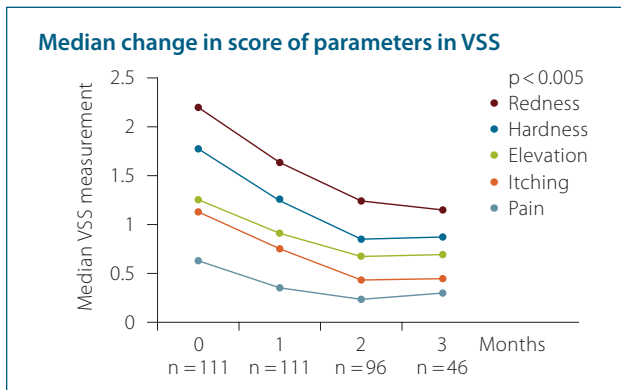
Efficacy on Old and New Scars: Improvement of scar symptoms using Kelo-cote

The majority of patients (80.1%) noted a good to very good efficacy. 75.7% of dermatologists scored the efficacy of Kelo-cote as good to very good for reduction of redness, pain, hardness, elevation and itchiness of treated scars within three months. Efficacy was rated equally for mature and immature scars, with 75% good to very good for mature and 88.9% good to very good for immature scars. These results underline the interest of treating precociously. The dermatologists scored the efficacy 80% good to very good for hypertrophic scars, 82.3% good to very good for minor keloids and 70% good for major keloids.

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In the treatment of hypertrophic and keloid scars, Kelo-cote significantly reduces all the key scar measurements using the Vancouver scar scale (VSS).



Conclusions

The efficacy of Kelo-cote silicone gel is comparable with other silicone gel sheets in the treatment of hypertrophic scars and keloids. Kelo-cote silicone gel is easier to use and enhances patient compliance and the prospect of an aesthetically acceptable scar.



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Kelo-cote® is manufactured and distributed by:



Advanced Bio-Technologies, Inc.

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