**Introduction**

**bioCorneum**®+ contains 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. **bioCorneum**®+'s patented silicone gel formulation cross links upon application to form a waterproof, transparent, gas permeable membrane that dries to form a custom-fitted silicone sheet.

**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 the patented silicone gel formulation in **bioCorneum**®+. 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's patented formulation. 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. The patented silicone gel formulation 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 the patented silicone formulation in **bioCorneum**®+. 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 the patented silicone formulation

The majority of patients (80.1%) noted a good to very good efficacy. 75.7% of dermatologists scored the efficacy of the patented silicone gel formulation 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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**RESULTS BY TYPE OF SCAR - EFFICACY**

![Graph showing the efficacy of scar treatment for different types of scars](image)
In the treatment of hypertrophic and keloid scars, the patented silicone formulation in bioCorneum®+ significantly reduces all the key scar measurements using the Vancouver scar scale (VSS).

Conclusions

The efficacy of the patented silicone gel formulation in bioCorneum®+ is comparable with other silicone gel sheets in the treatment of hypertrophic scars and keloids. bioCorneum®+’s silicone gel formulation is easier to use and enhances patient compliance and the prospect of an aesthetically acceptable scar.