Prospective case-control trial evaluating silicone gel for the treatment of direct brow lift scars

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ABSTRACT

Objective: To evaluate the effectiveness of a topical silicone gel on scars in patients who had undergone bilateral direct brow lift surgery.

Design: A randomized double-blind clinical trial with a placebo applied to one scar and topical silicone gel (Dermatix Ultra; Valeant Pharmaceuticals, Laval, Que.) used on the other scar for 2 months.

Participants: Twelve patients (for a total of 24 surgical scars evaluated) were included in the study.

Methods: This study was performed in 2 academic hospitals of the University of Montreal in Montreal, Que. (Maisonneuve-Rosemont Hospital and Notre-Dame Hospital). Inclusion criteria were all bilateral direct brow lift surgeries performed in our hospitals. Exclusion criteria included revision surgery, silicone or latex allergy, and wound infection. Each patient received 2 tubes (1 with silicone gel and 1 with placebo) and applied 1 tube to their right brow scar and the other tube to their left brow scar, following the preassigned instructions. The patient and surgeon were blinded to the nature of the substance that was applied to each scar. At each visit, pictures of both scars were taken, and a questionnaire titled "The Patient and Observer Scar Assessment Scale" was filled out by the patient and the surgeon. A grade ranging from 0 to 10 was given on the multiple criteria in the questionnaire, and the sum of these grades was subsequently used for the data analysis. A lower sum was interpreted as improved scarring. At the end of the study, an independent evaluator graded both scars based on pictures. Follow-up visits were held on day 7, week 6, month 3, and month 6 after surgery. A comparison of the experimental and placebo group was performed with nonparametric tests of Wilcoxon signed rank.

Results: A total of 24 scars of 12 patients were analyzed (based on 4 follow-up visits). General improvement of scars was reported by the patient, the surgeon, and based on pictures. No statistically significant difference was found between the group treated with silicone gel and the group treated with placebo. All tests had a p value ≥ 0.08.

Conclusions: We did not find a statistically significant difference between scars treated with silicone gel and scars treated with the placebo after direct brow lift surgery.

Hypertrophic scars represent abnormal healing processes that stay within the boundaries of the original wound.[1] They may be associated with an aesthetic impairment, as well as itching, tenderness, and pain.[1] Intralesional steroid injections and topical silicone gel sheeting have been used successfully for decades to improve the appearance of surgical scars, including hypertrophic scars and keloids.[1] However, it is harder to treat facial scars with these modalities: Intralesional steroid injections are painful and can lead to skin atrophy and dyschromies; in addition, silicone gel sheeting can irritate the skin and is cumbersome, resulting in poor patient compliance.[1]

Other treatment modalities are thus needed in the prevention and treatment of facial scars. Topical silicone gel is as effective as silicone gel sheeting and has the advantage of being transparent and drying on the skin within a few minutes.[1,3] Several studies have shown the efficacy of topical silicone gel at improving the appearance of burn scars and surgical scars, including hypertrophic scars and keloids.[1–9,11] That being said, no study has tested the efficacy of topical silicone gel in improving the appearance of brow lift scars. This is of particular interest because brow lift scars are located close to the eyes, in a zone of the face where they tend to be more noticeable.

METHODS

This randomized, placebo-controlled, double-blind prospective clinical trial was conducted from January to November 2012. Thirteen patients undergoing bilateral functional direct brow lift in an academic hospital were included in the study.

Patients

The inclusion criterion were having brow ptosis and undergoing direct brow lift surgery at one of the 2 aforementioned hospitals during the study period. Exclusion criteria were revision surgery, silicone or latex allergy, and wound infection. Fifteen patients underwent a direct brow lift during the study period. Two patients refused to participate in the study. Of the 13 patients included in the study, 1 patient was lost to follow-up after the first follow-up visit. Hence, 12 patients were included in the subsequent statistical analysis.

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The study was approved by the ethics committee of Maisonneuve-Rosemont Hospital and Notre-Dame Hospital. It followed the tenets of the Declaration of Helsinki for good clinical research practice.

Surgery

Two oculoplastic surgeons participated in patient recruitment. Surgeons standardized their wound closure technique, and the same surgeon performed wound closure on both eyebrows of the same patient.

Sample Preparation

The silicone gel sample and placebo were prepared by an independent pharmacy in the community. The topical silicone gel (Dermatix Ultra; Valeant Pharmaceuticals, Laval, Que.) and placebo were placed in identical white tubes, which were then numbered. The placebo was similar to the silicone gel in smell, appearance, and texture. The gel and placebo were transparent and dried within a few minutes.

Each patient was instructed to apply a small quantity of gel 1 on the right brow scar and gel 2 on the left brow scar. Patients and surgeons were blinded as to which compound (silicone or placebo) was used on either scar.

Patients were recruited in the preoperative period. The study was explained to patients, and instruction sheets were provided. Written consent was obtained from patients, and they received a sheet with the doctor's phone number in case they had questions during the study. Gel application was performed twice daily, once in the morning and once before sleep. Gel application was performed from the fourth week until the third month of the postoperative period.

Assessment of Scars

Follow-up visits were held on day 7, week 6, month 3, and month 6 of the postoperative period. At each visit, pictures of both scars were taken with the patient's eyes closed (Fig. 1). Then, a questionnaire titled "The Patient and Observer Scar Assessment Scale," validated in a study by Bianchi et al.,[3] was filled out by both the surgeon (Fig. 2) and the patient (Fig. 3). A grade ranging from 0 to 10 was given on multiple criteria of the questionnaire, and the sum of these grades was subsequently used for the data analysis. A lower numerical score suggested that the scar had better cosmesis. At the end of the study, an independent evaluator graded both scars using pictures taken at each follow-up visit.

Results

A total of 24 scars in 12 patients were included in this study. Patients included in the study were aged 58 to 85 years (mean, 72 years). Of the 12 patients who participated in the study, 10 were male and 2 were female. Two of the patients smoked. All participants underwent a bilateral direct brow lift surgery for brow ptosis.

Patients rated their silicone-treated scars less favourably than their placebo-treated scar at 6 weeks but rated it more favourably at 3 months (see Fig. 4). At 6 months, patients ranked both scars equally. The difference was not statistically significant, however. A comparison of the experimental and placebo groups was performed with nonparametric tests of Wilcoxon signed rank.

Surgeons rated placebo-treated scars more favourably than silicone-treated scars from 6 weeks onward (see Fig. 5). This difference was not statistically significant, however.

The independent reviewer rated pictures of the patients' scars similarly at the different stages of follow-up, regardless of whether they were treated with placebo or silicone gel (Fig. 6). None of the aforementioned values were statistically significant ($p \geq 0.08$ for all data).

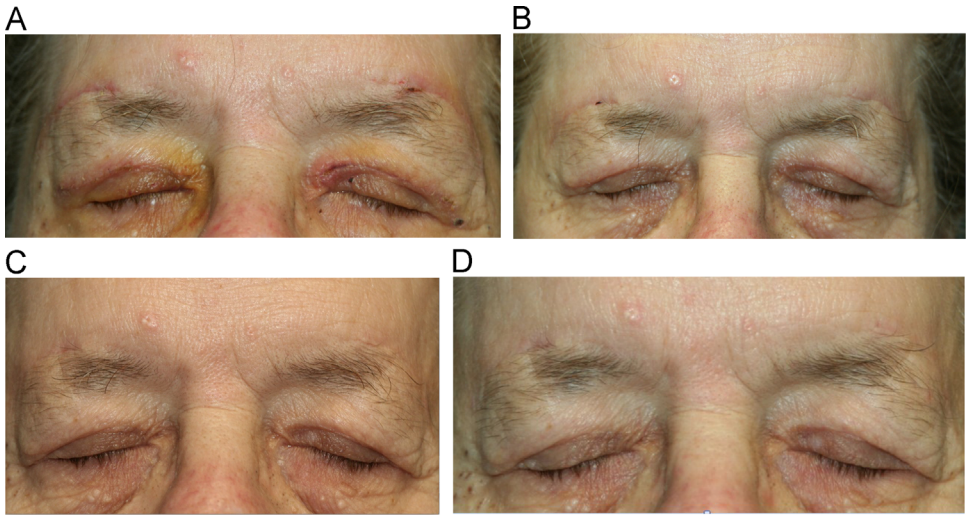

Fig. 1—(A–D) Picture of a patient participating in the study at 1 week, 6 weeks, 3 months, and 6 months after surgery, respectively.