Technical Report:

Efficacy of PracaSil™-Plus in scar therapy treatment: a randomized, double-blind, controlled study - Part 1

Abstract: The efficacy of PracaSil-Plus in scar therapy treatment was evaluated by visual and instrumental methods in an eight-week, randomized, double-blind, controlled study. The evaluations were conducted at week zero (baseline) and at week eight. PracaSil-Plus showed qualitative and quantitative improvements in the following scar attributes: scar length, scar color/ pigment intensity, scar texture/smoothness/roughness, and overall appearance in both old scars and new scars.

Introduction: PracaSil-Plus is a proprietary anhydrous silicone base designed to be applied topically in scar therapy treatment (PCCA, 2013). Silicones have been widely used for their occlusion and hydration properties, which are essential in scar management (Widgerow *et al.*, 2000; Mustoe, 2008). PracaSil-Plus also contains Pracaxi oil, extracted from the oilseed plant *Pentaclethra macroloba*, which has several medicinal applications including skin regeneration and healing (Costa *et al.*, 2014). PracaSil-Plus may be used alone or as a base for the incorporation of active substances in scar therapy treatment (PCCA, 2013).

Methodology: The efficacy of PracaSil-Plus in scar therapy treatment was evaluated by visual and instrumental methods, in an eight-week randomized, double-blind, controlled study conducted on eleven adult Caucasian subject volunteers, who were randomly divided in two groups: test group (n=5) and control group (n=6). The test group used PracaSil-Plus and the control group used a standard moisturizer. All subject volunteers had surgical, traumatic or acne-related scarring, either old scar (n=4) (> 18 months) or new scar (n=7) (< 18 months) and were willing to discontinue the use of moisturizing creams and scar-related treatments for the duration of the study. The evaluations were conducted at week zero (baseline) and at week eight, by a specialised IRSI professional.

Materials and Methods: The visual analogue scale (VAS) was the research instrument used in the visual evaluation method. The VAS is an observer-dependent scar assessment scale, designed to assess subjective parameters in an objective way (Fearmonti *et al.*, 2010). In this study, the subjects' scars were visually graded globally for scar length, scar color intensity and scar texture/smoothness (i) before application of product and (ii) at week eight of application of product (PracaSil-Plus or standard moisturizer).

The Clarity™ Pro and Replica™ were the research instruments used in the instrumental evaluation method.

The Clarity™ Pro is an imaging system that captures images with a hand held scope at 50x in multi-spectral lighting and reveals conditions on the skin's surface layer (Brightex Bio-Photonics, no date). In this study, the subjects' scars were evaluated with regards to average pigment intensity and texture/smoothness (i) before application of product and (ii) at week eight of application of product (PracaSil-Plus or standard moisturizer).

The Replica™ is a sampling technique specifically designed for making Silastic® (silicone elastomer) casts of the skin surface with the purposes of obtaining skin contour replicas and assessing skin texture (Cuderm, 2003; Dow Corning, 2013). In this study, skin contour replicas were made of the subjects' scar area and were evaluated with regards to texture/smoothness (i) before application of product and (ii) at week eight of application of product (PracaSil-Plus or standard moisturizer).

Results and Discussion: At week eight of application of PracaSil-Plus, the scars of all subject volunteers were evaluated by both visual and instrumental methods. No adverse reactions were reported, on or around scarring, by any of the subject volunteers.

Visual Analog Scale (VAS): According to the VAS assessment, 20% of test group volunteers showed an improvement in scar length, 40% in scar color intensity and 80% in scar texture/smoothness. On average, scar length was reduced 2.5%, scar color intensity 20% and scar smoothness was increased 24.08% (Table 1).

Table 1. *Percentage of test group subjects with improvement and average percentage of improvement in relation to scar length, color intensity and texture/smoothness.*

Scar	% subjects (with improvement)	% improvement (from baseline)
Length	20.00%	2.50%
Color intensity	40.00%	20.00%
Texture/ smoothness	80.00%	24.08%

Clarity™ Pro: According to this imaging system, 74.30% of test group volunteers showed an improvement in scar pigment intensity and 100% showed an improvement in scar texture/smoothness. On average, scar pigment intensity was reduced 17.56% whereas texture/smoothness was reduced 22.32% (Table 2).

Table 2. *Percentage of test group subjects with improvement and average percentage of improvement in relation to scar pigment intensity and texture/smoothness.*

Scar	% subjects (with improvement)	% improvement (from baseline)
Pigment intensity	74.30%	17.56%
Texture/ smoothness	100.00%	22.32%

The scar images of two test group volunteers (A and B) are displayed in Figure 1 and Figure 2 (respectively). Both figures show evident overall improvements in scar management.

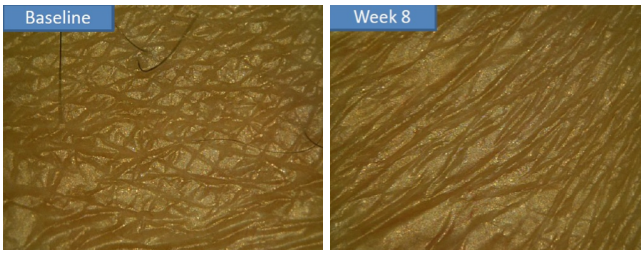

Figure 1. *Subject's scar (A) before application of PracaSil-Plus (left) and at week eight of application of PracaSil-Plus (right).*

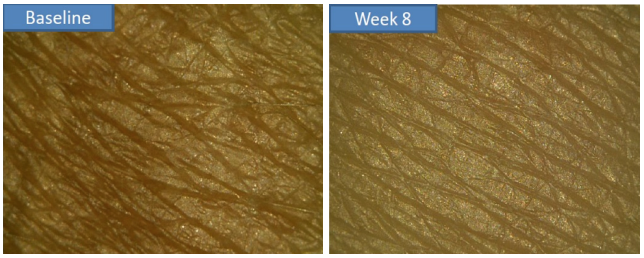

Figure 2. *Subject's scar (B) before application of PracaSil-Plus (left) and at week eight of application of PracaSil-Plus (right).*

Replica™: The skin contour replicas of two test group volunteers (A and B) are displayed in Figure 3 and Figure 4 (respectively). Both figures show evident overall improvements in scar texture/roughness.

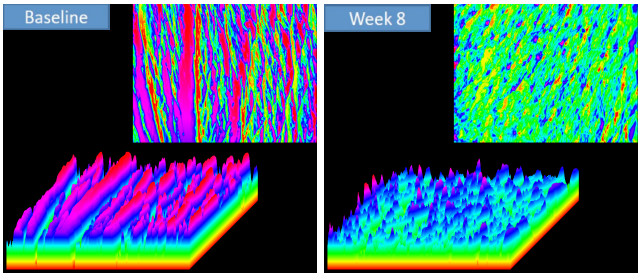

Figure 3. *Subject's scar (A) before application of PracaSil-Plus (left) and at week eight of application of PracaSil-Plus (right).*

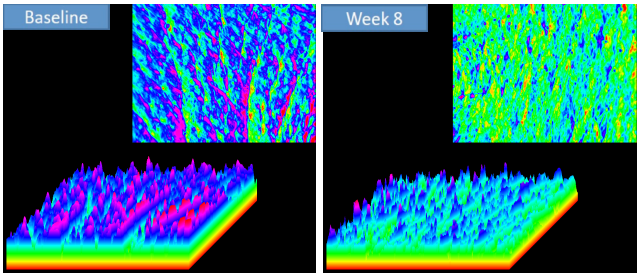

Figure 4. *Subject's scar (B) before application of PracaSil-Plus (left) and at week eight of application of PracaSil-Plus (right).*

According to this sampling technique, 100% of test group volunteers showed an improvement in scar texture/roughness, which was reduced, on average, 16.01% (Table 3).

Table 3. *Percentage of test group subjects with improvement and average percentage of improvement in relation to scar texture/roughness.*

Scar	% subjects (with improvement)	% improvement (from baseline)
Texture/ roughness	100.00%	16.01%

Conclusions: PracaSil-Plus, a proprietary base constituted by silicones and Pracaxi oil, showed qualitative and quantitative improvements in the following scar attributes: scar length, scar color/pigment intensity, scar texture/ smoothness/roughness and overall appearance in both old scars and new scars. PracaSil-Plus is therefore recommended in scar therapy treatment, to be used alone or as a base for the incorporation of active substances.

Financial Disclosure: PCCA contracted the International Research Services, Inc. (ISRI, Port Chester, NY) to conduct this study. ISRI has no proprietary or financial interests in the test products, or equity interest in PCCA, the sponsor of the study.

References:

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