

TOP LINE REVIEW

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Title: Evaluation of the SilkPeel System in Treating Erythematotelangiectatic and Papulopustular Rosacea. (Eryth-emato-telagiec-tatic) (Papulo-pustular) our just say Rosacea.

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Objective: To Evaluate the efficacy of the SilkPeel system in the treatment of Rosacea.

I. *Methods:*

- 30 patients with rosacea defined by the National Rosacea Society
- Underwent bimonthly Silkpeel treatments for 12 weeks (3 months)
- Each patient received a gentle exfoliation with a solution of 2% erythromycin to decrease inflammation and 2% salicylic acid to further aid exfoliation.
- An infusion of 10 – 12 mL/min and a vacuum pressure of 3 to 4 psi were applied.
- Patients were permitted to use an approved sunblock, moisturizer, and gentle cleanser throughout the study.

Exclusion Criteria:

- Patients with cysts or tender or overly weepy lesions
- Patients that complained of burning sensation before treatments
- Patients older than 65 years old
- Patients in hyperestrogenic states (eg, pregnancy, oral contraceptive use, estrogen therapy)
- Patients with facial erythema resulting from various diseases such as lupus
- Patients with moderate to severe rhytides (acne)
- Patients with undiagnosed lesions, skin cancers or active herpes

II. *Assessments*

- Digital photographs were taken at each visit and used as comparison for grading sequent improvement
- Physician and patient global improvement was rated at baseline and at 4, 8, and 12 weeks using a 5 point scale. (4 being marked improvement) did not include erythema.
- A quantification scheme was used at baseline and at 4, 8, and 12 weeks, by one investigator, to grade erythema levels

- Grading for erythematotelangiectatic rosacea was quantified clinically on a 4-point scale (4 being severe).
- For the papulopustular group, lesions were divided into the gross number of papules and pustules.
- Patient satisfaction scores were evaluated on a 4-point scale at study's end. These scores took into consideration therapeutic efficacy, adverse effects, tolerability and overall quality of life.

III. *Results*

- 20 patients completed the 12-week study
- 3 discontinued due to pregnancy, the remaining 7 patients were lost of follow-up for various reasons.
- Clinical reduction in erythema, papules, and pustules was noted in all patients as early as 4 weeks with statistically significant reduction by 12 weeks.
- At the end of 12 weeks:
 - 41% improvement in erythema
 - 69% decrease in papules
 - 55% decrease in pustules
 - 54% improvement rating among patients
 - 74% improvement rating among physicians
- No clinical exacerbations were reported during the treatment period.
- The most commonly reported adverse effect was a transient exacerbation of erythema with an average resolution time of 3-6 hours.
- Male patients in both groups took longer than female patients to reach a clinical end point.

IV. *Conclusion*

- The only limitation of the SilkPeel system is treating aged skin with multiple rhytides.
- Treatments may be cost-effective long term, especially if patients continue to stay disease free, as was the case with this study.
- The SilkPeel system allows the operator to modify the vacuum pressure, flow, and choice of solutions.
- The SilkPeel system can be used as monotherapy for patients with erythematotelangiectatic and papulopustular rosacea.

Key Selling Points:

We are further able to differentiate ourselves from the spa treatments (crystal systems) by conducting and publishing clinical research in a primer journal.

There are no reports in the literature of clinical trials evaluating the efficacy of microdermabrasion system used as monotherapy for the treatment of rosacea. The SilkPeel is an effective treatment alternative for this condition

Remember to ask if they are treating many patients with rosacea. If they are spend more time on this study. But present it on each demonstration because it adds validity and credibility to our company, the system, and you!

Dermatologists will be impressed with the presentation of this data because they are typically sold in this fashion by pharmaceutical companies. However, other specialists will be equally impressed.

Rosacea is a common and difficult to treat disease

Most rosacea treatments are aimed at decreasing the inflammation associated with the disease, not the disease itself.

The true benefits of traditional microdermabrasion are limited and the procedure may not produce consistent results. They are reported to penetrate as deep as 100 microns using pressures up to 12 to 20 psi. At these depths and pressures, epidermal layers beyond the granular layer may be affected. Intense erythema, inflammation, granuloma formation, hypopigmentation, hyperpigmentation, and the potential for vesiculation, are seen.

The silkPeel system abrades to a depth of 20-35 microns (the approximate depth of the upper granular layer). Thus, it does not cause intense erythema, inflammation, granuloma formation, hypopigmentation, hyperpigmentation and the potential for vesiculation, all of which are effects of traditional microdermabrasion.