

# Evaluation of the SilkPeel™ System in Treating Erythematotelangiectatic and Papulopustular Rosacea

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We present a study designed to evaluate the efficacy of the SilkPeel system in the treatment of erythematotelangiectatic and papulopustular rosacea. The SilkPeel system is an innovative form of microdermabrasion that exfoliates uniformly and simultaneously allows surface penetration of topical infusion agents, which optimizes therapy while maintaining structural integrity. Thirty qualified patients with erythematotelangiectatic or papulopustular rosacea as defined by the National Rosacea Society underwent SilkPeel treatments bimonthly for 12 weeks. Significant clinical reductions in erythema, papules, and pustules were noted as early as week 4 for all patients ( $P < .03$ ).

Rosacea is a chronic inflammatory dermatitis that commonly consists of facial erythema with visible telangiectases, papules, pustules, and sebaceous hyperplasia leading to rhinophyma. A combination of these features is the norm, making classification difficult at times. Additionally, diagnostic criteria have not been elucidated and constantly are evolving. In 2002, the National Rosacea Society standardized rosacea into 4 subtypes: erythematotelangiectatic, papulopustular, phymatous, and ocular.<sup>1</sup> This is a clinically

based taxonomy because no histologic or laboratory markers are available for diagnosis. More etiologic factors have been studied and identified in rosacea. Nevertheless, the exact pathogenesis of this condition has yet to be discovered and is poorly understood.

Studies to establish the efficacy of treatments or combinations of treatments for each rosacea subtype still are needed. Current treatments include avoiding triggers that complicate rosacea, topical agents, oral antibiotics, and laser and light therapies. Overall, a minimum of 4 to 6 weeks of therapy is required before a patient may begin to see improvement. Most rosacea treatments are aimed at decreasing the inflammation associated with the disease.<sup>2-6</sup> Conventional therapies also have been shown to induce long-term effects; antibiotics promote resistance and various topical agents can cause local skin irritation. Rosacea disrupts facial aesthetics and symmetry, which leads to psychosocial implications that may affect a patient's quality of life. Consequently, displeased patients return to their dermatologists requesting alternative treatment modalities.

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## SILKPEEL SYSTEM FOR TREATING ROSACEA

Microdermabrasion has become a popular dermatologic office procedure for a variety of conditions. However, the true benefits of traditional microdermabrasion are limited, and the procedure may not produce consistent results. The SilkPeel system is an innovative therapy that exfoliates uniformly and simultaneously allows surface penetration of topical infusion agents for the treatment of specific skin disorders. It synchronizes microdermabrasion and delivery of soluble medications to optimize therapy.

Results of an isolated histologic study reveal that the SilkPeel system abrades evenly to a depth of approximately 30 to 35  $\mu\text{m}$  within the epidermis of preauricular skin (L.S.M., T.D.D., unpublished data, 2005). This study also has shown that various solutions penetrate the stratum corneum during the SilkPeel procedure, which produces cellular vacuolization of keratinocytes in the epidermis and dermal edema. Penetration of selected solutions is evident. Keratinosomes, the structures responsible for producing the hydrophobic barrier of skin beyond the epidermal deeper layers, are left untouched; thus, the integrity of the skin structure is maintained because the SilkPeel system does not seem to abrade past 35  $\mu\text{m}$  of the epidermis. There are no reports in the literature of clinical trials evaluating the efficacy of a microdermabrasion system used as monotherapy for the treatment of rosacea. The SilkPeel system may be an effective treatment alternative for this condition.

Microdermabrasion generally is not considered as a treatment option for patients with rosacea because deep epidermal penetration causes increased angiogenesis, inflammation, and reactive oxygen species, thereby worsening the clinical outcome.<sup>7-10</sup> Traditional microdermabrasion systems have been reported to penetrate as deep as 100  $\mu\text{m}$  using pressures of up to 12 to 20 psi.<sup>11-12</sup> At these depths and pressures, epidermal layers beyond the granular layer may be affected, causing the loss of Langerhans cells immunocompetence, desmosomes, and gap junctions and causing an increase in various cytokines responsible for cell cycle regulation and wound healing. In addition, a minimum of 5 to 10 days is required for renewal of deeper levels of the epidermis.

In contrast, the SilkPeel system abrades to a depth of 20 to 35  $\mu\text{m}$  (the approximate depth of the upper granular layer) and transfers solutions at an average fluid infusion of 10 to 12 mL/min, with vacuum pressure of 3 to 4 psi. This achieves a characteristic barrier recovery sequence of no more than 72 hours. Furthermore, the SilkPeel system does not cause intense erythema, inflammation, granuloma formation, hypopigmentation, postinflammatory hyperpigmentation, and the potential for vesiculation, all of which are effects of traditional microdermabrasion (L.S.M., T.D.D., unpublished data, 2005).

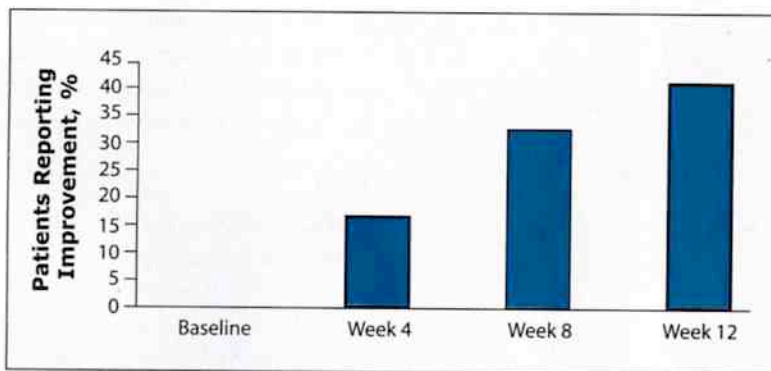
## METHODS

Thirty qualified patients with erythematotelangiectatic or papulopustular rosacea as defined by the National Rosacea Society<sup>1</sup> underwent SilkPeel treatments bimonthly for 12 weeks. Before entering the study, approval from the Institutional Review Board was obtained, and the patients provided written informed consent. Patients older than 65 years were excluded from the study. Patients were allowed to withdraw from the study at any time and were not permitted to use over-the-counter products during the study period without the approval of an investigator.

Patients with cysts or tender or overtly weepy lesions were excluded from the study to prevent complications such as severe pain and infection. Furthermore, patients with symptomatic erythematotelangiectatic rosacea who complained of a burning sensation were excluded, as were patients who used astringents, toners, and other products containing sodium lauryl sulfates, menthol, or camphor because of the potential for adverse reactions. Exclusion criteria also included the use of prescription medications for rosacea within 4 weeks from the start of the study; patients in hyperestrogenic states (eg, pregnancy, oral contraceptive use, estrogen therapy); patients with facial erythema resulting from various diseases (eg, systemic lupus erythematosus) or certain medications (eg, niacin); and patients with moderate to severe rhytides. In addition, patients with undiagnosed lesions, skin cancers (eg, atypical nevi), and active herpes infection were excluded.

The solutions of choice consisted of 2% erythromycin to decrease existing and potential inflammation and 2% salicylic acid to further aid exfoliation. The solutions were prepared in sterile water and obtained from our pharmacy. Patients were permitted to use a sunblock, moisturizer, and gentle cleanser throughout the study. The SilkPeel system was applied to the face of each patient at each visit, and each patient initially received a gentle abrasion with a fluid infusion of 10 to 12 mL/min and a vacuum pressure of 3 to 4 psi. These parameters were tailored to achieve a favorable clinical end point.

Adverse effects were documented at each visit to ensure quality assurance. Informed consent outlining the details of the study was received from each patient prior to the study. Conditions under which patients were permitted to withdraw from the study were fully explained. At any time during the study, investigators were permitted to release patients who did not abide by study protocols or who desired to withdraw. Reasons investigators released patients from the study included inability to keep scheduled treatment appointments, pregnancy, and use of cosmetic agents that may have presented as confounding



**Figure 1.** Percentage improvement in erythematotelangiectatic rosacea after 12 weeks of bimonthly SilkPeel™ treatments.

factors in skin improvement. None of the participants withdrew or were released from the study because of unsatisfactory results.

A quantification scheme was used at baseline and at 4, 8, and 12 weeks by one investigator who graded erythema levels. Grading for erythematotelangiectatic rosacea was quantified clinically on a 4-point scale (1=trace erythema; 2=mild erythema; 3=moderate erythema; 4=severe erythema). For the papulopustular group, lesions were divided into the gross number of papules and pustules. Patients received SilkPeel treatment on the entire face; no control sites on the face were used for comparison when grading improvement. However, digital photographs were taken at each visit and used as comparison for grading subsequent improvement. Physician and patient global improvement was rated at baseline and at 4, 8, and 12 weeks using a 5-point scale (0=no improvement; 1=slight improvement; 2=mild improvement; 3=moderate improvement; 4=marked improvement). Percentage of improvement was calculated as  $(\text{end point score} - \text{baseline score}) / \text{baseline score} \cdot 100\%$ . A mean of the percentages at each end point was taken as the reported value at 4, 8, and 12 weeks. Physician grading for improvement was performed by one investigator and did not include erythema. Patient satisfaction scores were evaluated on a 4-point scale at the study's end (0=dissatisfied; 1=fair; 2=good; 3=excellent). Patient satisfaction scores took into consideration therapeutic efficacy, adverse effects, tolerability, and overall quality of life.

## RESULTS

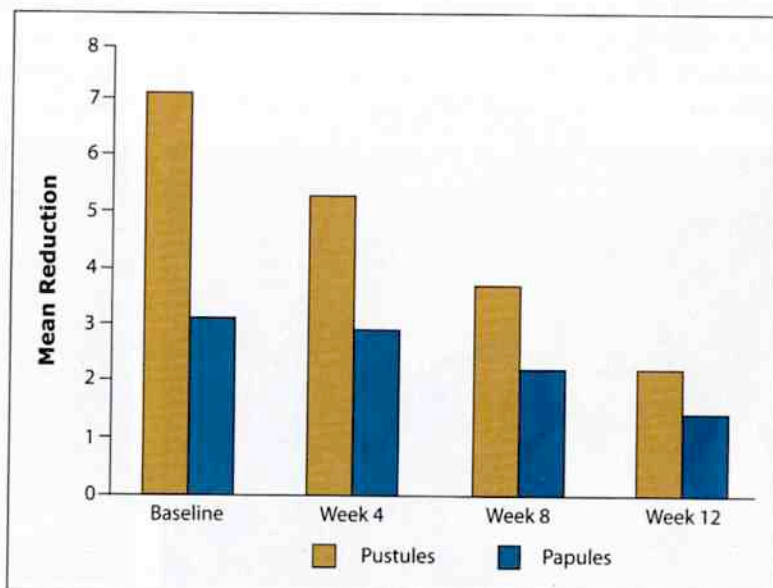
Twenty patients completed the 12-week study. Six patients (30%) presented with

erythematotelangiectatic rosacea, and 14 patients (70%) had papulopustular rosacea. Three patients became pregnant and were subsequently disqualified. The remaining 7 patients were lost to follow-up for various reasons. The mean age for all patients was 42.1 years (range, 31–61 years). All of the study participants were white, and most were of Irish descent.

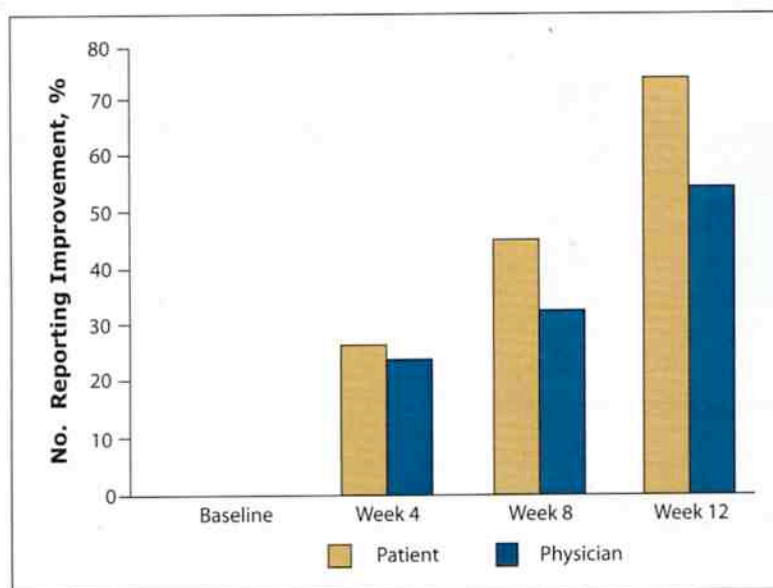
Clinical reduction in erythema, papules, and pustules was noted in all patients as early as 4 weeks, with statistically significant ( $P < .03$ ) reduction by 12 weeks. By the end of the study, patients with erythematotelan-

giectatic rosacea had a mean of 41.7% improvement in erythema (Figure 1); patients with papulopustular rosacea had a mean 69% decrease in papules and 55% decrease in pustules. The degree of erythema was defined as an overall reduction percentage. Percentage of improvement was calculated as  $(\text{end point score} - \text{baseline score}) / \text{baseline score} \cdot 100\%$ . A mean of the percentages at each end point was taken as the reported value at 4, 8, and 12 weeks. Patients had a mean starting score of 2.8 and a mean end-treatment score of 2. A wide spectrum of erythema along the scoring scale was observed.

More patients had papules (mean starting count, 7.1) than pustules (mean starting count, 3.1). Not all patients enrolled in the papulopustular group had pustules, but papules were noted in all patients. The range of papules was 1 to 9, and the range of pustules was 1 to 5. At week 12, the end-treatment papule count decreased to 2.2, and



**Figure 2.** Mean reduction of papules and pustules after 12 weeks of bimonthly SilkPeel™ treatments.



**Figure 3.** Physician and patient evaluation of global improvement from baseline.

the end-treatment pustule count decreased to 1.4. Mean reduction in papule and pustule counts are shown in Figure 2. No clinical exacerbations were reported during the treatment period. Male patients in both groups took longer than female patients to reach a clinical end point.

Patient and physician global improvement assessments were closely correlated (Figure 3). There was an overall tendency toward improvement, with a 53.8% improvement rating among patients and a 74% improvement rating among physicians at week 12.

Photographs taken throughout the course of the study confirmed an overall improvement (Figures 4 and 5). Patients provided positive feedback regarding tolerability, satisfaction, and overall quality of life (Figure 6). The most commonly reported adverse effect was a transient

exacerbation of erythema with an average resolution time of 3 to 6 hours. None of the study participants experienced extreme pruritus, erythema, or other adverse effects.

### COMMENT

Studies to enhance transdermal drug delivery processes such as iontophoresis and sonophoresis have been equivocal.<sup>13</sup> The low permeability of the stratum corneum resides in its hydrophobic nature, which consists of ceramides, cholesterol, and free fatty acids.<sup>14</sup> The SilkPeel system temporarily inhibits extracellular processing, preventing lipid precursors from transforming into the hydrophobic barrier. Histologic samples taken during the SilkPeel procedure show that solutions penetrate the stratum corneum and thus produce dermal edema and vacuolization of keratinocytes in

the epidermis (L.S.M., T.D.D., unpublished data, 2005). Under ideal conditions, one proposed mechanism of action for the SilkPeel system involves the disruption of desmosomes in the corneal and often the granular layers, while the keratinosomes, desmosomes, and gap junctions of deeper layers are left untouched. This preserves hydrophobic barrier function, epidermal scaffolding, and intercellular communication. Furthermore, according to the domain mosaic model, the hydrophobic barrier contains discontinuous aqueous pores arranged in the lacunae that have the potential to transform into continuous pores. Interconnections between adjacent lacunae are formed by prolonged permeability, which promotes continuity and thereby allows hydrophilic materials to penetrate the stratum corneum.<sup>15</sup> A subclinical SilkPeel



**Figure 4.** A 57-year-old woman with longstanding erythematotelangiectatic rosacea refractory to standard forms of therapy before (A) and after (B) 12 weeks of bimonthly SilkPeel™ treatments.



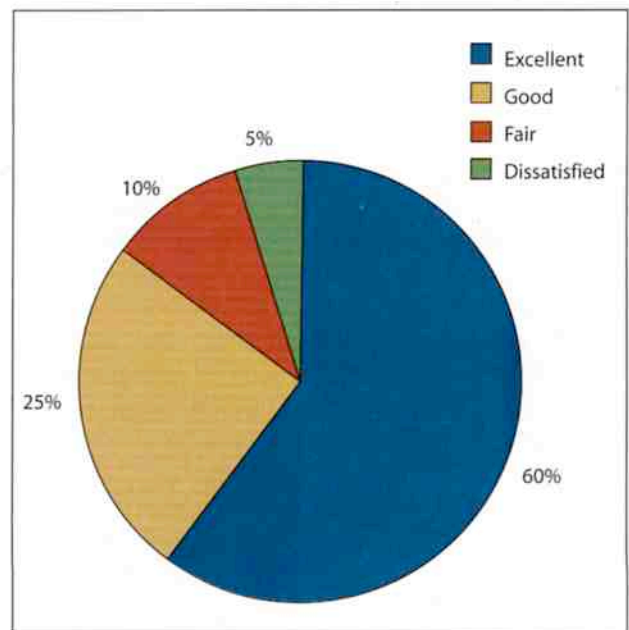
**Figure 5.** A 42-year-old woman with longstanding papulopustular rosacea refractory to standard modes of therapy before (A) and after (B) 12 weeks of bimonthly SilkPeel™ treatments.

treatment (ie, using one pass for patients with sensitive skin or spot suction treatments) may act as the permeable stimulus necessary for continuity within the lacunae so that a clinical end point can be reached even though the hydrophobic barrier persists. What makes microdermabrasion effective may have nothing to do with abrasion; the vehicle's suction with concurrent solution flow may provide the impetus for a unique treatment.

Fick's first law of diffusion states that absorption of a substance across barriers is directly proportional to the concentration difference across that barrier. This law can be represented by the equation  $J = KpCv$ , where  $Kp$  is the permeability coefficient and  $Cv$  is the concentration of the drug in any given vehicle. However, the permeability coefficient  $Kp$  is a function of the partition coefficient  $Km$ , the diffusion coefficient  $D$ , and the length of the diffusion pathway  $L$ . This equation may be rewritten as  $J = (DKm/L)Cv$ . Theoretically, the mechanism of action of the SilkPeel system increases the diffusion coefficient  $D$  and may cause the diffusion pathway  $L$  to approximate zero, which creates the potential for infinite absorption. Therefore, though the SilkPeel system administers medications in a solution form that is diluted, only small quantities are required for increased absorption. Furthermore, the SilkPeel system minimizes the distances that medicinal solutions have to travel, which makes it an attractive vehicle.

Traditional microdermabrasion uses the mechanics of vacuum pressure and abrasives. Aluminum oxide microcrystals commonly are used, but other types of substances serve the same function. These insoluble microcrystals are about 100  $\mu\text{m}$  in size and are instrumental in the utility of the system.<sup>16-19</sup> Depending on the circumstance, patients may receive full-thickness microdermabrasion therapy from the corneal layer to the basal cell layer.<sup>9,10,20-22</sup> This can result in several consequences if each epidermal layer

(specifically, the spinous and basal cell layer) is affected. The spinous layer is rich in desmosomes, and loss of cohesion between keratinocytes will occur if abrasion is too aggressive. Spinous layer depletion also will make the epidermis more prone to mechanical stresses. Gap junctions also may be affected, leading to a lack of intercellular communication. The basal cell layer is seldom affected, but when destroyed, terminal differentiation and signaling will not transpire, and abundant Langerhans cells will not execute adequate immune surveillance. In addition, high molecular weight microdermabrasion particles may remain dormant on the skin, causing granuloma formation and eye changes, such as conjunctivitis, keratitis, and even



**Figure 6.** Percentage of patients rating their satisfaction as excellent, good, fair, or dissatisfied after 12 weeks of bimonthly SilkPeel™ treatments.

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blindness. An unusual case of urticaria also has been reported as a result of deep microdermabrasion.<sup>23</sup>

Rosacea has deep dermal components; thus, it is difficult to penetrate the stratum corneum of patients with rosacea using conventional vehicles without harming the epidermis.  $\alpha$ -Hydroxy acids (eg, low-percentage glycolic acids) have been used as keratolytics but commonly cause irritation and may penetrate to the dermis.<sup>8</sup>  $\alpha$ -Hydroxy acids diminish cellular cohesion at the lowest levels of the stratum corneum whereas  $\beta$ -hydroxy acids such as salicylic acid remove layer by layer from the outermost level downward.<sup>15</sup> Therefore, salicylic acid applications can produce favorable results for patients with sensitive skin such as those with rosacea.

Another advantage of salicylic acid is its inherently acidic nature; acidity maintains barrier homeostasis, promotes differentiation, and hastens the recovery of keratinocytes.<sup>24,25</sup> Lower pH favors sequential enzymatic steps that lead to the formation of mature stratum corneum. Once SilkPeel treatments have stripped the stratum corneum, salicylic acid may accelerate recovery of barrier function. Certain bacteria, including *Propionibacterium acnes* which has been shown to contribute to the signs and symptoms of rosacea through direct invasion or by galvanizing the inflammatory process, cannot thrive at low pH levels.

Topical erythromycin has been shown to act as an antimicrobial and anti-inflammatory agent in the treatment of rosacea. In a study by Mills and Kligman,<sup>24</sup> reduction of erythema and suppression of papules and pustules occurred in 13 of 15 patients (87%) after 4 weeks of twice-daily treatments with a combined 2% salicylic acid and 2% erythromycin solution. Clindamycin, tetracycline, and sulfur solutions were not reported to produce more satisfactory results than the combined salicylic acid and erythromycin solution.

Etiologic factors involved in the pathogenesis of rosacea include alteration of vasculature homeostasis, climatic exposures, matrix degeneration, chemicals and ingested agents, pilosebaceous abnormalities, and microbial organisms. Exfoliation with the SilkPeel system does not alter vasculature, blood flow, or heat exchange, and inflammatory mediating factors such as substance P, histamine, and serotonin are not released.

In our study, papules rather than pustules and erythema showed the most significant ( $P < .03$ ) clinical reduction in most patients. This may be due to the fact that papules show less inflammation than pustules, and erythema is difficult to control because heat exchange and baseline blood flow are multifactorial, dynamic processes. Nevertheless, there was an overall improvement in facial erythema, with no decline in symptoms with each treatment. This may be

attributable to the superficial exfoliation of the stratum corneum and the excellent delivery of erythromycin to the deeper levels of the epidermis and dermis. This combination discourages interference with the dermal vasculature, while erythromycin theoretically inhibits angiogenic growth factors such as fibroblast growth factor-1, vascular endothelial growth factor, and other cytokines.<sup>26</sup>

Overall patient satisfaction with the SilkPeel system was favorable. Only 5% of patients were dissatisfied with the overall results of the SilkPeel system. In fact, most patients preferred the SilkPeel system to their previous rosacea treatments. Compliance was excellent because the procedure was performed on-site and resulted in minimal downtime and no side effects.

## CONCLUSION

Perhaps the only limitation of the SilkPeel system is treating aged skin with multiple rhytides. Loose or slack skin poses a dilemma because proper procedure is difficult to perform in such cases. Treatments may be cost-effective long term, especially if patients continue to stay disease free during each procedure, as was the case in our study. The SilkPeel system allows the operator to modify the vacuum pressure, flow, and choice of solutions. Future trends are being investigated for alternative therapies, though principles of barrier function may offer a distinctive advantage. The SilkPeel system can be used as monotherapy for patients with erythematotelangiectatic and papulopustular rosacea.

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