

Princess Derma - A Novel, Diamond Peel Microdermabrasion System for Home-use

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Introduction

Non-invasive anti-aging techniques such as those for superficial skin resurfacing, dermal rejuvenation and texture improvement are some of the most sought after applications in aesthetic medicine today. In 2005, Americans spent more than \$12.5 billion on cosmetic procedures, the majority of which were noninvasive.¹ The number of nonsurgical treatments has skyrocketed more than 764 percent since 1997, far outpacing the growth of plastic surgery. With baby boomers and more men looking for creative ways to slow the aging process, the "medical-

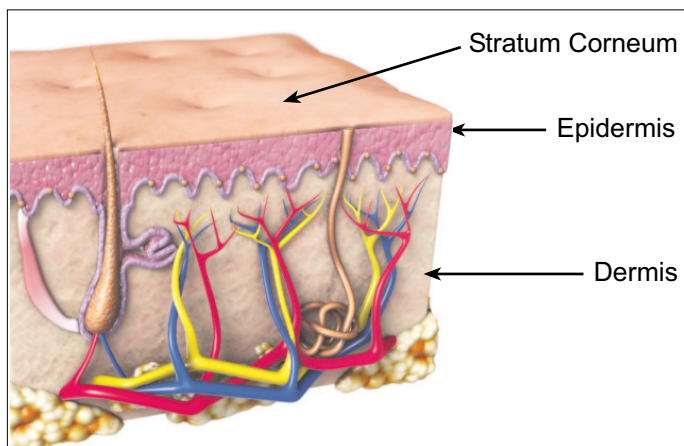
aesthetic" economy--including device sales and doctors' fees--could easily surpass \$20 billion by the end of 2006. "There has been a dramatic move toward minimally invasive procedures," says Shiu-Yik Au, an analyst at Millennium Research Group.² Of these Microdermabrasion is the fourth most popular procedure with 1,023,931 procedures performed in 2005 and continues to remain in the top five demanded procedures regardless of age.

Making this procedure available for home use and giving the consumer the ability to maintain professional results or opt for a complete at home treatment can be expected to impact market trends.

Clinical Background - Skin Aging

The skin is composed of 2 mutually dependent layers, the epidermis and dermis, which rest on a fatty underlying layer. The outermost layer of the epidermis is called the stratum corneum composed of dead, flat skin cells. (Fig. A) The epidermis is entirely dependent on the dermis for nourishment and the primary purpose of the dermis is to sustain and support the epidermis.

Fig. A: Skin Cross Section



With aging, the skin deteriorates. Although imperfections are mainly noticed on the superficial epidermal layers, the most significant changes actually occur in the dermis itself. As the dermis thins with age there is an overall loss of organization. The amount of ground substance decreases and elastic fibers degenerate. Collagen is lost, and the proportion of mature type I collagen relative to type III collagen is reduced.

Damage from the sun through exposure to UVA and UVB radiation also produce degenerative changes in the skin. Actinic keratoses and lentigines form and dermal elastosis results from an accumulation of thickened degraded collagen and elastic fibers. Biochemical alterations in the

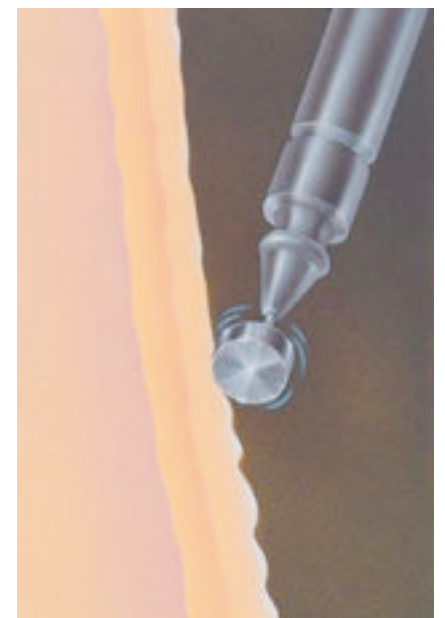
collagen and elastin result in a dermis that is more lax and less elastic and resilient. Skin laxity and loss of elasticity also contribute to the 'aged' appearance of photo-damaged skin by resulting in mild wrinkling on the face and neck.

History of Microdermabrasion

The drive for youthful healthy looking skin is not a new one. Abrading the skin for the purpose of removing blemishes and smoothing it was practiced even in ancient times. Present day microdermabrasion, so popular in spas and salons, hails from turn of the century controlled skin abrasion techniques developed by Kromayer in 1905. Kromayer used motor driven knives, rotating wheels and rasps that except for technical improvements of the equipment, differed very little from present-day dermabrasion³. He treated acne scars, keratoses, and areas of hyperpigmentation. In the early 1950s, Kromayer's techniques were resurrected when Kurtin, McEvvitt, and others published numerous articles on dermabrasion.

Dermabrasion⁴, which must be performed under anesthesia by a doctor, is the process of mechanically removing the damaged outer layers of skin using a rotating grinding stone. (Fig. B) The exfoliated epidermis regenerates after a period of 7-10 days with greater organization. Regeneration of the

Fig. B: Dermabrasion Technology



dermis takes an additional several months to complete. The regenerated dermis shows improved elasticity and organization with horizontally arranged bundles of collagen scattered with elastic fibers. Wound healing after dermabrasion is a lengthy process and can be fraught with complications. Postoperative care includes the continual application of ointments to keep the skin moist and may require the use of antiviral therapy. The patient is required to visit the doctor frequently during the initial stages of healing and can expect erythema for up to 90 days. The many complications and drawbacks of dermabrasion led, in 1985, to the development of microdermabrasion.

Microdermabrasion

The introduction of microdermabrasion greatly reduced the downtime and complications of dermabrasion. Clinically performed microdermabrasion, encompasses two simultaneously occurring processes. Using a specialized tool, the practitioner 'sand blasts' the skin by shooting a stream of tiny crystals of aluminum oxide, sodium chloride or sodium bicarbonate. The crystals abrade and exfoliate the superficial layer of the epidermis evening skin tone, while a vacuum action removes exfoliated cells and used crystals. In addition to providing a small raised surface to work on, the vacuum action also creates mild swelling and brings impurities to the surface. More importantly the suction created by the vacuum stimulates collagen regeneration and reorganization in the dermis layer. This reorganized collagen fills in fine lines, improves texture and elasticity, which gives the skin a more youthful appearance. Crystals from the treatment, however, may become embedded in the skin, irritating it and clogging pores. In addition, loose particles remain in the environment and may be inhaled by the patient. In spite of or perhaps because of the excellent results received with Microdermabrasion, the technology was once again retooled to overcome its minor drawbacks.

Diamond Peel

Diamond Peel is a next generation technology developed in the late nineties, based on the experience gained with traditional dermabrasion techniques and crystal microdermabrasion technology. Similar to the dermabrasion grinding stone, Diamond Peel uses a diamond wand to exfoliate the stratum corneum layer allowing precision layering of the epidermis for more uniform results. (Fig. C) As the technician steadily moves the tool over the target

Fig. C: Diamond Peel Microdermabrasion



area, applying an even, steady pressure the skin is raised and held against the diamond tip with a gentle vacuum action that removes dead cells stimulates circulation and rejuvenates the skin structure. The dual actions of exfoliation and suction replace old dull skin with fresh, younger cells and encourage the regeneration of collagen and elastin for firmer, healthier looking skin.

Princess Derma Diamond Peel Technology for Home-use

Developed by DermaDream, Princess Derma is a safe, easy to use, novel Diamond Peel microdermabrasion device for personal-use. Princess Derma relies on the same principles, of micro exfoliation combined with a suction feature, as professional Diamond Peel systems. An all-natural diamond tip is steadily moved over the desired treatment area. As in professional systems, the vacuum feature raises the skin against the diamond tip, which in turn exfoliates the superficial epidermal layer and stimulates collagen and elastin renewal by increasing blood flow to the dermis for subsequent restructuring of the dermal and epidermal layers of the skin. The Princess Derma device is equipped with 5 suction level settings that enable varying ablations depths and personal comfort levels and two treatment tips; one course and one fine. Sophisticated micro circuitry controls the suction level settings. These options have been modified from professional systems to limit ablation depth to levels considered safe for home use. Princess Derma is expected to provide the user with immediate acceptable exfoliation results and repeated treatments with dermal restructuring of collagen and elastin similar to professional systems.

Clinical Study

Protocol

To test the efficacy and safety of the Princess Derma device, a group of 27 women aged 35 to 55 with Fitzpatrick⁴ skin types I -IV were recruited for a clinical trial. All participants presented with superficial facial wrinkles and chronological aging of the skin classified as moderate according to the Glogau Classification (Fig D). In addition, 8 of 27 women had mild to moderate acne scarring. All had used conventional over-the-counter topical cosmetic solutions with unsatisfactory or mixed results.

Fig D: Glogau Classification³

Mild (typically aged 28-35 y)

- Little wrinkling or scarring
- No keratosis
- Requires little or no makeup

Moderate (aged 35-50 y)

- Early wrinkling, mild scarring
- Sallow color with early actinic keratosis
- Requires little makeup

Advanced (aged 50-65 y)

- Persistent wrinkling
- Discoloration with telangiectasias and actinic keratosis
- Wears makeup always

Severe (aged 60-75 y)

- Wrinkling - Photoaging, gravitational, dynamic
- Actinic keratoses with or without skin cancer
- Wears makeup with poor coverage

In order to test results and skin tolerance based on frequency of use subjects were divided into three groups and instructed to perform treatments for three full months as follows:

Group one - one time per week.

Group two - two times per week.

Group three - three times per week

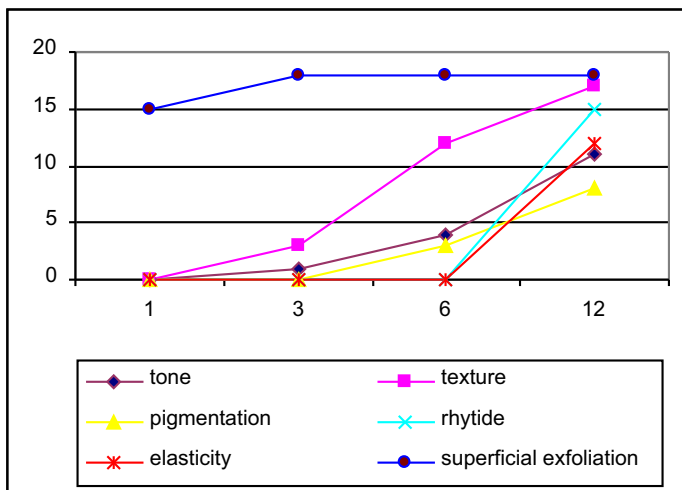
Each participant was supplied with a Princess Derma home-use microdermabrasion device and given the following instructions:

1. Wash the treatment area with soap and warm water.
2. Thoroughly dry the skin.
3. For the first two weeks, use the fine grade treatment tip in the periorbital area with the suction level on the lower (1-3) settings and the course grade tip in the rest of the treatment area.
4. After the first two weeks continue to use the fine tip for sensitive areas and the course tip for the rest and raise the suction level to the higher (4-5) settings as desired but do not exceed personal comfort level.
5. Perform 2 passes over the entire treatment area.
6. Stop treatment immediately if pain or severe redness occurs.
7. After treatment, apply an oil-free moisturizer to the entire area.

Results

Participants were evaluated at week one, three, six and twelve. At week one, Group 1 displayed minimal results in all categories while in Groups 2 and 3 (Fig. E) evaluators observed some lessening of dry, coarse skin and the

Fig. E: Clinical Observations : Groups 2 & 3



appearance of fresher skin in nearly all of the participants.

This general overall improvement in skin appearance continued to be observed in the second evaluation at week three. By week six, approximately 37% of participants in Groups 2 and 3 began to show improvement in skin tone (color) and texture. More even skin color was observed and skin began to appear firmer. Group 1 continued to lag behind and showed only mild exfoliation results. At week twelve, evaluators observed continued improvement of overall skin texture in Groups 2 and 3. There was also a marked improvement in skin elasticity in the majority of subjects and significant softening of shallow wrinkles particularly in the periorbital and perioral regions in 15 of 18 study subjects in Groups 2 and 3. The complete exfoliation of dry, photo-aged skin and the appearance of younger looking, refreshed skin was noted in all participants of Group 2 and 3 and continued mild exfoliation results were observed in Group 1.

Due to the relatively poor results observed in Group 1 (one treatment per week), it was determined that recommended frequency of treatments should be 2 to 3 times per week to achieve optimal results. All participants completed the study. Overall satisfaction was rated high with 85% of participants stating that they were satisfied with the results they were receiving (Fig. F). Mild erythema and skin tenderness that lasted from several minutes up to a few hours were noted by approximately 75% of participants.

Fig. F: Self Evaluation : Groups 2 & 3

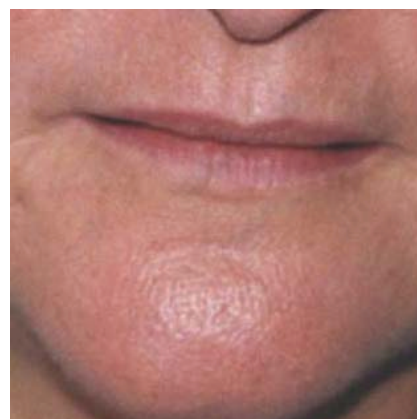
Improvement in:	Excellent	Good	Mild	None
Texture	16	1	1	0
Tone	3	11	3	1
Rhytides	1	9	6	2
Pigmentation	0	0	7	11
Vascular Lesion	0	0	0	18
Elasticity	2	13	2	1
Overall Satisfaction	3	14	1	0

21 of 27 participants stated that they would continue the treatment after the study's conclusion. Most of those who elected to discontinue treatment cited busy lifestyles as the reason.

Results: Before and After Pictures



Before



After

Before and After Pictures cont.



Before



After



Before



After

Summary

Princess Derma is a novel, home use Diamond Peel microdermabrasion device, which has the potential for satisfactory exfoliation results and improvement of fine lines and overall skin texture with repeated use. The system is easy to use and incorporates sophisticated safety mechanisms to avoid any undesirable side effects to the skin. The system can be safely used on all skin types with no lasting negative side effects.

References:

1. money.cnn.com/magazines/business2/business2_archive/2006/01/01/8368124/index.htm
 2. *ibid.*
 3. Fulton JE - Dermabrasion chemabrasion and laser abrasion - historical perspective and future trends: *dermatol surg* 1996;22:619-628
 4. For Dermabrasion reference please refer to - Yarborough GM - *derm abrasive surgery - clin dermatol* 1987; 5:75-78
 5. Fitzpatrick TB - the validity and practicality of sun reactive skin type I-VI *arc dermatol* - 1988;12:869-871.
 6. Glogau RG chemical peeling and aging skin, *journal geriatr dermatol* 1994; 2: 3035
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