MIRApeel™ System: Case Study for Trans-Epidermal Water Loss and Histology
After Microdermabrasion (MDB) and Micro-needling (MN)

Healthcare professionals have individually applied microdermabrasion (MDB),[1-3] micro-needling (MN),[4-5] and light emission diode (LED)[6-7] treatments in their skin care practices as simple, safe, versatile, user-friendly, and cost-effective procedures. The procedures are well-tolerated for cosmetic skin conditions, including photodamage,[8-9] facial rejuvenation,[10] superficial hyperpigmentation,[11] acne and inflammatory scars,[12] hypertrophic scars,[13] striae,[13-14] cellulite,[15] and alopecia[16] for all ages and ethnic groups (Fitzpatrick's Skin types IV through VI) with minimal downtime and side effects.

Recently, the MIRApeel™ device was developed to deliver both MDB and MN therapies with sequential passes with a grit handpiece that abrades the non-viable corneocytes and its bi-lipid barrier in upper levels of epidermis and with a roller handpiece covered with fine needles to penetrate the abraded stratum corneum up to a 0.25mm depth. Also, a third handpiece equipped with blue/infrared LED light is available to treat *Propionibacterium acnes* and reduce inflammation. This unique procedure provides both non-invasive exfoliation and increased skin permeability by selectively removing the stratum corneum barrier and allowing penetration of skin-specific larger molecular weight and water-soluble molecules for a transdermal passage. Although the benefits of MDB or MN procedures alone or combined with topical skin-specific products or biologic agents during the intra- and post-treatment periods have been published,[2-4,14] the recovery kinetics of the epidermal barrier system after dual treatments with abrasive removal and needle penetration have yet to be examined in more detail for the following reasons. In the first place, a slow recovery extends the time for passage of larger molecules or biologic agents to optimize therapy for desirable aesthetic results.[14,17-22] By contrast, a more rapid recovery of the skin's barriers restores earlier protective function to lower the risk for passage of allergens, cytotoxic substances or pathogens from the external environment.[23-30] Thus, the timescale of recovering skin integrity should be optimally balanced to allow a sufficient delivery period of active ingredients, but short enough to reduce exposure to noxious elements.

The purposes of this study were to: (1) determine the onset, duration, and quantity of elevated trans-epidermal water loss (TEWL) values, as an indirect measure of lipid-barrier permeability and its renewal during and after dual treatments in a patient; and (2) observe the degree of micro-histological changes by Hematoxylin and Eosin staining of the stratum corneum after microdermabrasion and micro-channels from micro-needling in intact segments of preauricular skin immediately prior to a face lift procedure in another patient.

METHODS

Devices

The microdermabrasion and micro-needling device (MIRApeel™; FDA-cleared, Class I, Königsbach-Stein, Germany) consisted of a motor unit and handpieces attached either to a disposable diamond abrader (150/180/220 grit) or a disposable needle roller (twelve 0.25mm long needles; 200-300 µm diameter). Each handpiece was attached with connecting tubing for vacuum-assistance (12 PSI) to remove debris, desquamated tissue, and fluid during wet dermabrasion and micro-needling (salicylic acid-based serum, ascorbic acid, and hyaluronic acid). The handpiece for LED light emission was not used in this case study.

The trans-epidermal device (DermaLabSkinLab Combo Module with Cortex Technology; Class I, Hadsund, Denmark) is an established device to measure TEWL. The device was calibrated by the manufacturer with a Declaration of Conformity prior to initiation of the study. The Trans-Epidermal-Water Loss Probe measured water loss through designated spot of skin with 2 sets of sensors (temperature and humidity) mounted in its diffusion chamber with a diameter of 10mm covering an area of 0.79cm^2. The water pressure measured in the open chamber was used to calculate the evaporated water over a constant skin area. The TEWL result was designated in g/m^2/h as a function of time as the mean value over the last 5 seconds. The maximum obtainable value was 250 g/m^2/h. Measurement duration could be selected for different time lengths from 1 to 250 seconds.[31]

PROTOCOL

Two adult female patients volunteered to participate in this case study. Each procedure was conducted in the operating suite of the author's surgical center in Pasadena, California. Each procedure was conducted under the ethical guiding principles of the 1975 Declaration of Helsinki. These case studies did not require IRB approval as the MIRApeel™ device is registered with the US FDA. Each patient was preoperatively informed via written consent, optional use of local anesthesia, intraoperative video recording and photography. Patients did not receive any compensation and were not financially responsible for any of the validation studies. Each patient never received muscle relaxers, filler, ablative and non-ablative procures to the proposed treatment sites within 6 months. Each patient presented with no active systemic or local infections, acne, pregnancy, autoimmune diseases, or hemorrhagic disorders. Each patient refrained from application of any topical skin care formulations, vigorous physical activities, swimming, saunas, and intake of alcoholic beverages, caffeinated drinks over a period of seventy-two hours prior to their single treatment.

TEWL STUDY Case #1: A 43-year-old patient had her face thoroughly cleansed with Cetaphil liquid soap to remove all cosmetics. Thereafter, the patient rested in the controlled environment operating room for one hour to acclimate the facial skin to the experimental ambient conditions (relative humidity, 23.8%; range, 23.3-23.9%) (room temperature, 23.4^0 C; range, 22.7-24.2^0 C) before commencing the treatments and data collection. The patient received no oral pain medication, anti-inflammatory medications, or topical analgesic gel applications during the entire procedure. In a randomized fashion, a TEWL dot site was marked on three 2x5cm treatment strips on each side of the midface to ensure that the instrument probe was positioned in the same place on each evaluation period from baseline to forty-eight hours (Figure 1).

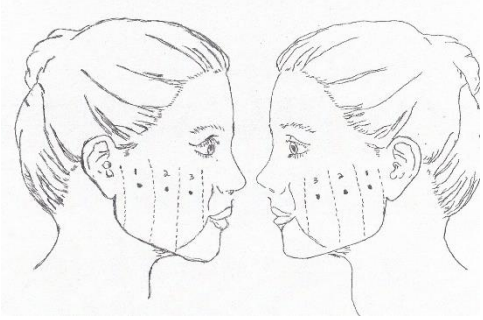

Figure 1. Diagram of six randomized treatment zones

An aesthetician provider (NK), certified for training with the MIRApeel™ device, performed the specific treatment in each strip that replicated the device's clinical treatment protocol (Table I). The investigator (GHS), experienced in the Cortex technology, performed all TEWL measurements at the same marked skin location at baseline and subsequent post-treatment intervals. The final data points were expressed as the average of five measurements per site (Table II).

Table I. Treatment Protocol

Right Mid-Face: Description of Treatments and Ingredients

1. Lateral strip (2x5cm): 220 grit wet dermabrasion (2 passes); vacuum-assistance; salicylic acid-based serum + Vitamin C with hyaluronic acid serum.

#2. Central strip (2x5cm): wet 0.25mm micro-needling on roller (2 criss-crossing passes); no vacuum assistance; Vitamin C with hyaluronic acid serum.

#3. Medial strip (2x5cm): 220 grit wet dermabrasion (2 passes); vacuum-assistance; salicylic acid-based serum + Vitamin C with hyaluronic acid serum. Wet 0.25mm microneedling on roller (2 passes); no vacuum-assistance; Vitamin C with hyaluronic acid serum.

Left Mid-Face: Description of Treatments and Ingredients

#1. Lateral strip (2x5cm): vacuum-assistance with dermabrasion probe with 0 grit (2 passes); salicylic acid-based serum + Vitamin C with hyaluronic acid serum.

#2. Central strip (2x5cm): 220 grit wet dermabrasion (2 passes); no vacuum-assistance; salicylic acid-based serum + Vitamin C with hyaluronic serum.

#3. Medial strip (2x5cm): 220 grit wet dermabrasion (2 passes); vacuum-assistance; salicylic acid-based serum + Vitamin C with hyaluronic acid serum. Wet 0.25mm microneedling on roller (2 criss-crossing passes); no vacuum; Vitamin C with hyaluronic acid serum. Repeat wet 0.25mm micro-needling (2 criss-crossing passes); no vacuum-assistamce,

Table II. Transepidermal Water Loss Measurements ($g/m^2/h$) after Various Treatment Modalities over Time

	Left Mid-Face #1	Left Mid-Face #2	Right Mid-Face #1	Right Mid-Face #2	Right Mid-Face #3	Left Mid-Face #3
	Dermabrasion Probe (0 grit) (2 passes) *Vacuum* *(Salicylic Acid) (Vit C with HA)*	**Dermabrasion (2 passes) No Vacuum** *(Salicylic Acid) (Vit C with HA)*	**Dermabrasion (2 passes) Vacuum** *(Salicylic Acid) (Vit C with HA)*	**Dermabrasion Probe (0 grit) (2 passes) Roller MN (2 passes) No Vacuum** (Vit C with *HA)*	**Dermabrasion (2 passes) Vacuum** *(Salicylic Acid) (Vit C with HA)* **Roller MN (x1) (2 passes) No Vacuum** *(Vit C with HA)*	**Dermabrasion (2 passes) Vacuum** (*Salicylic Acid) (Vit C with HA)* **Roller MN x2 (2 passes) No Vacuum** (Vi*t C with HA)*
Baseline	11.9 ± 0.2	12.2 ± 0.4	11.0 ± 0.6	12.2 ± 1.0	13.4 ± 2.7	15.6 ± 0.1
Post 1hr	12.2 ± 0.4	18.6 ± 1.0	31.4 ± 0.5	17.4 ± 0.2	29.1 ± 0.6	34.5 ± 0.5
Post 2hr	11.3 ± 0.5	19.1 ± 0.5	28.8 ± 0.4	17.5 ± 0.4	24.8 ± 0.9	34.5 ± 0.5
Post 3hr	11.1 ± 1.2	18.2 ± 1.2	29.2 ± 1.8	17.7 ± 0.2	25.2 ± 1.3	33.9 ± 2.4
Post 4hr	11.8 ± 0.5	18.7 ± 0.1	30.5 ± 0.5	16.2 ± 2.4	25.3 ± 1.9	44.7 ± 1.1
Post 5hr	12.6 ± 0.4	19.5 ± 0.5	26.4 ± 0.8	13.2 ± 2.3	26.0 ± 1.7	36.1 ± 0.6
Post 18hr	12.0 ± 0.5	12.1 ± 0.8	25.0 ± 0.5	12.9 ± 0.2	25.2 ± 1.2	26.1 ± 3.6
Post 24hr	12.1 ± 0.6	12.2 ± 0.7	15.7 ± 0.5	11.1 ± 0.4	20.8 ± 0.4	21.2 ± 0.7
Post 48hr	9.6 ± 0.4	11.6 ± 0.6	15.5 ± 0.9	11.3 ± 0.8	20.7 ± 2.0	21.8 ± 0.9

Histology Study Case #2: A 69 year-old healthy patient treated both sides of her marked preauricular skin with the MIRApeel™ device in the morning prior to her consented face lift procedure. The same aesthetician provider (NK) performed three specific randomized treatments in each strip without the use of any topical or local anesthetic solution (Figures 2-3). After completion of the MIRApeel™ procedure, the entire face was prepped with betadine solution and draped for the surgical procedure. Local anesthesia (4cc lidocaine HCL 0.5% and epinephrine 1:200,000; 2cc sodium bicarbonate USP, 8.4%) was delivered 1cm outside the periphery of the marked ellipse of preauricular skin, limiting its infiltration into the treated area. After removal of the skin, each 1x2cm segments was excised and immediately immersed in individually numbered vials containing a 10% formalin and transported to an out-sourced hospital pathology department for sectioning (μm), staining (Hematoxylin & Eosin), and interpretation. The pathologist was blinded to the type of treatment to remove bias in determining epidermal, dermal changes, and needle- penetration depths. The face lift procedure was completed under local anesthesia.

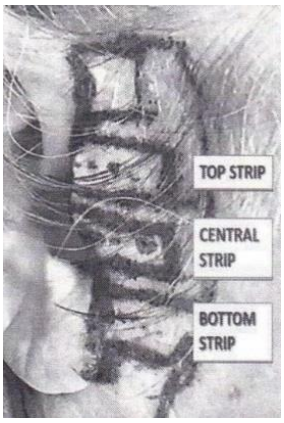

Figure 2.

Right Top Strip:
dermabrasion (180 grit) (1 pass); no vacuum; salicylic acid serum
dermabrasion (180 grit) (1 pass); no vacuum; Vit C with hyaluronic acid
Right Central Strip:
dermabrasion (180 grit) (1 pass); vacuum; salicylic acid serum
dermabrasion (180 grit); (1 pass); vacuum; Vit C with hyaluronic acid
roller MN x1; (2 passes); no vacuum; Vit C with hyaluronic acid
Right Bottom Strip:
dermabrasion (0 grit) (1 pass); vacuum; salicylic acid serum
dermabrasion (0 grit) (1 pass)/ vacuum; Vit C with hyaluronic acid
Unlabeled Top Square: control untreated skin

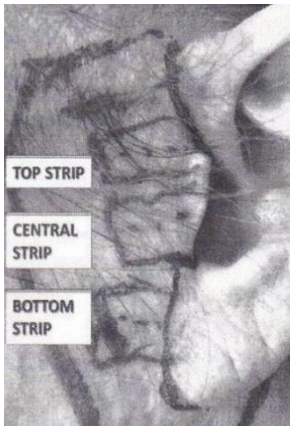

Figure 3.

Left Top Strip:
dermabrasion (180 grit) (1 pass); vacuum; salicylic acid serum
dermabrasion (180 grit) (1 pass); vacuum; Vit C with hyaluronic acid
Left Central Strip:
dermabrasion (180 grit) (1 pass); vacuum; salicylic acid serum
dermabrasion (180 grit) (1 pass); vacuum; Vit C with hyaluronic acid;
roller MN x2; (2 passes); no vacuum; Vit C with hyaluronic acid
Left Bottom Strip:
dermabrasion (0 grit); 1 pass); vacuum; salicylic acid
serum dermabrasion (0 grit); (1 pass) vacuum; Vit C with hyaluronic acid
roller MN (2 passes); vacuum; Vit C with hyaluronic acid

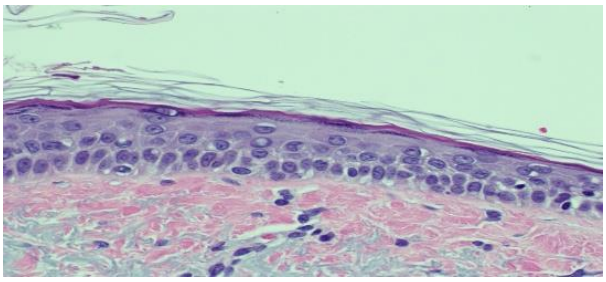

Figure 4. Control showing fully intact stratum corneum and stratum granulosum; no spongiosis or intercellular edema (400x).

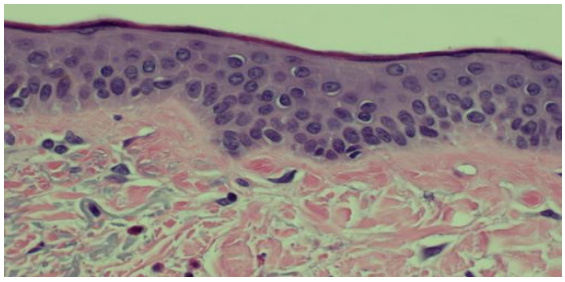

Figure 5. Right Top Strip: dermabrasion (180 grit), 2 passes, no vacuum; complete removal stratum corneum, mild changes stratum granulosum, no spongiosis or intercellular edema (400x).

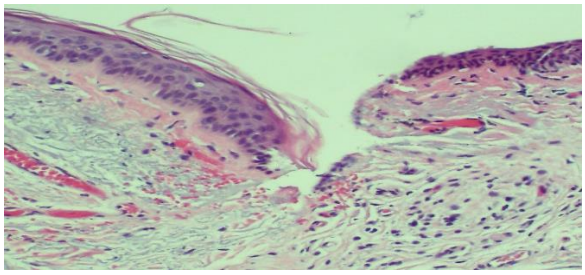

Figure 6. Right Central Strip: 2 dermabrasions (180 grit), 1 pass each, vacuum; 1 MN 2 criss-cross passes; complete removal stratum corneum and most of stratum granulosum, mild spongiosis and intercellular edema; sharp microcleft from needle insertion (100x).

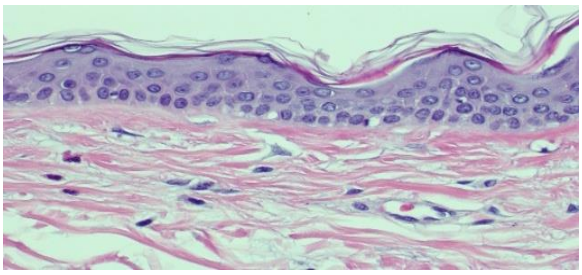

Figure 7. Right Bottom Strip: dermabrasion probe (0 grit), 2 passes, vacuum; completely intact stratum corneum and stratum granulosum; mild spongiosis and intercellular edema (100x).

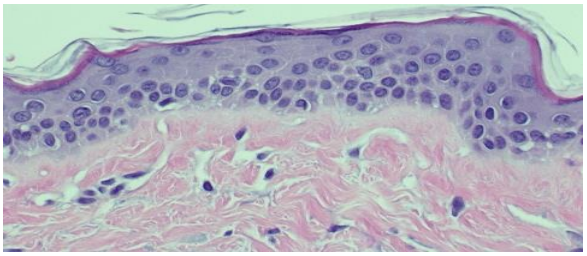

Figure 8. Left Top Strip: dermabrasion (180 grit), 2 passes, vacuum; complete shredding of stratum corneum and segments of stratum granulosum, moderate spongiosis with intercellular edema (400x).

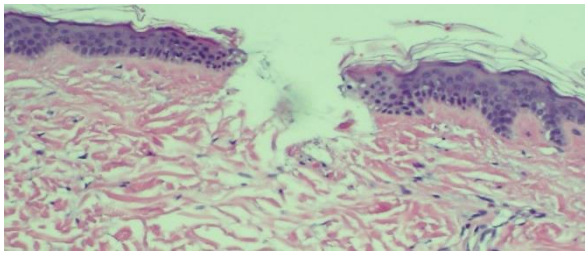

Figure 9. Left Central Strip: dermabrasion (180 grit) 2 passes, vacuum; roller MN x2, 2 criss-cross passes; vacuum; shredding of stratum corneum and parts of statum granulosum, moderate spongiosis with intercellular edema, cleft from MN needle (100x).

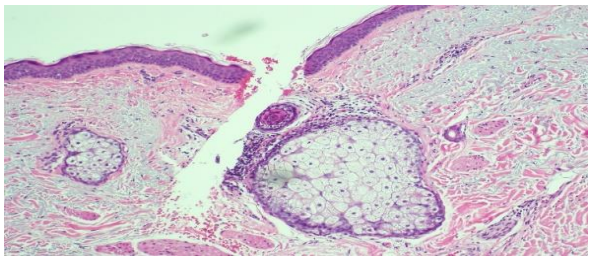

Figure 10. Left Bottom Strip: dermabrasion probe (0 grit); 2 passes, vacuum; roller MN 2 criss-cross passes, **vacuum**; intact stratum corneum and stratum granulosum (100x).

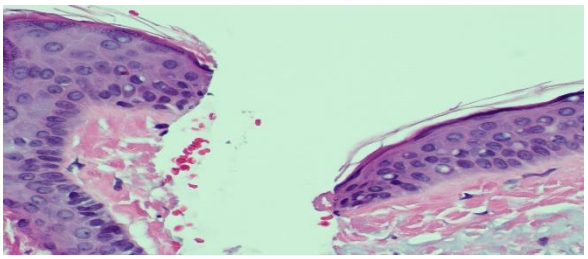

Figure 11. Left Bottom Strip: Higher magnification of another section next to that shown in Figure 10 with micro-cleft; no spongiosis or intercellular edema (400x).

Complications

Microdermabrasion and micro-needling to preauricular skin produced transient minor erythema, swelling or discomfort during different procedures with or without the use of vacuum and topical cosmeceutical sera.

Discussion

A primary function of skin is to provide a renewable structural and functional barrier from external biological, physical, and chemical hazards from damaging our delicate internal ecosystem. The permeable barrier is primarily located to the outer layer of the stratum corneum and consists of nonviable corneocytes, cross-linking proteins, and a lipid-enriched bi-layered matrix.32 After disruption of the lipid barrier through the compromised stratum corneum, the lamellar bodies within keratinocytes in the stratum granulosum and stratum spinosum begin to secrete phospholipids, glucosylceramide, sphingomyelin, and cholesterol that become ceramides, cholesterol, and free fatty acids in the lipid matrix.33

Previous studies have investigated the recovery of the stratum corneum, stratum granulosum and its lipid barrier after disruption by dermabrasion and micro-needling to achieve epidermal and dermal therapeutic effects. After microdermabrasion, human skin has been shown to recover its barrier between 1 and 2 days, as determined by TEWL. 19-20 The length and quality of recovery are affected by the degree of skin aging at treatment, aggressiveness of the dermabrasion material (grit), and the provider's protocol on number, vectors, and skin pressure during passes. On the other hand, compromise of the barrier by puncture with number of microneedles in human skin was shown to recover within 1-2 hours, as measured by electrical resistance.22 In a split-face study,34 barrier recovery by TEWL measurement after 0.5mm micro-needling (12 needles, 200-300µm in diameter, three

gliding passes) vs 0.5mm micro-needling-RF (49 needles; 200-300µm in diameter; 3 stamping passes; 1MHz, total RF energy up to 78.4J/cm2, level 2 monopolar; 50ms and 12 W) was similar with average mean TEWL values returning to baseline in 1 to 3 hours. However, a depth-penetration comparison of TEWL recoveries after 1.5mm micro-needling vs 1.5 micro-needling-RF exhibited both higher TEWL values and slower recovery up to 48 hour than observed with 0.5mm MN/MNRF needling. The more dramatic barrier effects of increased permeability observed after microdermabrasion may be related to its removal of larger levels of tissue, whereas micro-needling makes multiple narrow clefts (i.e., without removing tissue).

The MIRApeel™ device combines the advantages of both microdermabrasion and microneedling treatments, offering a comprehensive approach to skin rejuvenation. After removing the stratum corneum barrier through MDB, the device creates an ideal environment for subsequent MN treatment to further increase skin permeability. This greater permeability appears to be a safe in producing minimal and reversible injury to the lipid barrier for a more effective delivery of active ingredients and skin-specific products. This investigation attempts to correlate functional and histological changes after single or combined usage of MDB and MN. It is reassuring to observe that two passes of the vacuum probe without grit in the presence of salicylic acid and Vitamin C with hyaluronic acid (nourisher serum) demonstrated no elevation of TEWL values from baseline to 48 hours (Left Mid-Face #1) with histology demonstrating a complete intact stratum corneum and stratum granulosum (Figure 7). These normal histological findings were comparable to those observed in the control non-treated skin (Figure 4). Furthermore, it could be surmised that the action of the applied topical cosmeceuticals did not alter the integrity of the lipid barrier system. When the dermabrasion probe was attached to its 220 grit abrader and passed two times without vacuum-assistance in the presence of the applied serums (salicylic acid, Vitamin C and hyaluronic acid), however, there was only a modest increase in permeability up to 1-5 hours before returning to baseline values (Left Mid-Face #2) with histology showing complete removal of the stratum corneum, mild changes to the stratum granulosum, and no spongiosis or intracellular edema (Figure 5). These findings suggest that dermabrasion without vacuum results in a broad removal of the stratum corneum allowing increased water loss by TEWL measurements. After 18 hours, the lipid layer appears to have functionally recovered. When vacuum-assistance accompanied dermabrasion (2 passes) in the presence of the cosmeceutical sera, a greater elevation of TEWL values was observed at 1 hour and lasted up to 48 hours (Right Mid-Face #1) with histopathology displaying complete shredding stratum corneum and sections of the stratum granulosum with observable moderate spongiosis and intercellular edema (Figure 8). Vacuum's negative pressure was postulated to draw the skin closer to the abrader surface for more efficient abrasion and that this action might be responsible for a greater and longer duration of water loss by TEWL measurements.

In contrast, micro-needling was not performed in the presence of vacuum and delivers fractional penetration of needles without removing any tissue. Thus, when 2 passes of micro-needling were done without vacuum nor pretreatment by microdermabrasion, a small elevation of TEWL values for a short duration was measured up to 4 hours returning to baseline values within 5 hours (Right Mid-Face #2) with a histopathology displaying an intact stratum corneum and the presence of the micro-cleft (Figure 10). A higher magnification of another section adjacent to that shown in Figure 10 demonstrated the microchannel, but additionally the absence of spongiosis and intercellular edema (Figure 11). However, combined usage of 2 nonvacuum-assisted microdermabrasions (1 pass each) and 1 micro-needling (2 passes) produced very high TEWL values for extended periods of time up to 48 hours duration (Right Mid-Face #3), with histopathology showing complete denudation of the stratum corneum and most of

the stratum granulosum with mild spongiosis and intercellular edema and a microchannel from needle penetration (Figure 6). The largest and most prolonged TEWL values beyond 48 hours were observed, however, with the combination of 2 vacuum-assisted microdermabrasions (1 pass each) and 2 sessions of micro-needling (Left Mid-face #3) with shedding of the stratum corneum and stratum granulosum with moderate spongiosis and intercellular edema including a single micro-cleft from needling (Figure 9).

The results from this case study underscore the importance of understanding the occurrence and duration of functional and structural changes after combined microdermabrasion and micro-needling and the introduction of non-irritating cosmeceuticals during and after the procedure. It is assumed that the application of previously used skin products on compromised skin during the initial 24- to 48-hour recovery period may increase the opportunity for infection, scar formation, hyperpigmentation, skin inflammation, allergic reactions and skin irritations.23-28 The optimal balance of skin permeability and barrier recovery is essential for achieving safe and effective aesthetic outcomes.

In conclusion, the use of the novel MIRApeel™ device appears to deliver safe and effective skin treatments that creates a therapeutic window for the delivery of active ingredients that can enhance the overall efficacy of treatment. Larger trials will be needed to confirm the findings in this case study.

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Abstract

Background: Microdermabrasion (MDB) and microneedling (MN) on facial skin result in skin rejuvenation and skin exposure to pathogens and cosmeceutical skin products.
Objective: The aims were to determine time-dependent injury and repair of trans-epidermal water loss (TEWL) and associated histological changes due to treatments.
Method: MDB and MN procedures were performed on strips on each side of a patient's midface. TEWL measurements were recorded at baseline and intervals up to 48 hours with a calibrated DermaLab Cortex device (Hadsund, Denmark). Similar treatments were performed on preauricular skin strips from a patient before facelifting for immediate histological changes by H & E stains.
Results: Changes in TEWL measurements were negligible when a vacuum probe without an abrader surface was passed over a skin strip. DMB (220 grit) resulted with higher and prolonged TEWL values in the presence of vacuum than no vacuum. MN produced similar TEWL values to those obtained after MDB without vacuum. TEWL values were the highest and longest in duration after combination vacuum-MDB with 2 sessions of MN than after 1 MN session and vacuum-MDB. Histologic changes of the protective skin layers explained the changes in TEWL values after treatments.
Conclusions:

MDB and MN devices are effective and safe and require further investigation for optimal treatment parameters and protocols.

Level of Evidence: 3

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