

ULTRASOUND ENHANCED SKIN REJUVENATION TECHNOLOGY EMERGES

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Consumer interest in no-recovery or non-surgical skin rejuvenation is at an all time high and climbing rapidly. However, the degree of improvement from procedures such as fruit acid peels, topical home therapy and traditional microdermabrasion often fall short of providing strong patient satisfaction or enduring results.

RECENT SIGNIFICANT new advances in microdermabrasion technology used in combination with specially formulated topical agents have improved clinical results. This has been demonstrated in four separate controlled and blinded studies performed at our center. Measures of patient satisfaction additionally have confirmed that the patient also observes and values this difference in clinical results compared to traditional devices.

In addition to the well-known skin polishing and smoothing effects, microdermabrasion transiently increases the permeability of the skin to most topically applied agents. This effect can be harnessed to enhance the delivery into the skin of a wide variety of topical anti-aging cosmeceutical agents. Recent clinical trials using controlled objective measurements comparing the new positive pressure salt microdermabrasion devices with the leading brands of both physician and esthetician negative pressure (vacuum) aluminum oxide microdermabraders found that the positive pressure salt microdermabrasion devices were superior in all measured parameters including indicators of increased skin permeability.

THE USE OF low intensity ultrasonic "micro-massage" following salt microdermabrasion further enhances these effects of microdermabrasion. This too has been demonstrated in controlled clinical trials, and again patient satisfaction is increased with this combination. This combination of new positive pressure microdermabrasion with scientifically designed topical skin care formulations followed by gentle 3 MHz ultrasonic micro-massage has proven to be a safe and highly effective means of providing "no-recovery" anti-aging skin rejuvenation.

THE TECHNOLOGIES

Microdermabrasion technology is well described elsewhere. The basic principle is to produce partial

removal of the skin's outer protective layer – the stratum corneum. One may imagine the analogy of a brick and mortar wall representing the stratum corneum. Microdermabrasion essentially removes some of the top layers of the bricks and mortar. The new positive pressure salt microdermabrader removes "more layers of bricks" than the leading competing vacuum devices.

The use of ultrasound technology to enhance the delivery of topically applied drugs has been well documented. This process is termed phonophoresis (also sometimes called sonophoresis in the literature). The ultrasound handpiece produces wavefronts of sonic waves that then impact the skin surface. These sound waves create an effect on the skin termed cavitation, which produces an "air bubble" like effect in the lipid bilayer of the stratum corneum (that is within the "mortar" that seals the epithelial cell "bricks"). This results in an expansion of the space between the bricks for a short time allowing increased permeability of the skin.

ULTRASONIC ENERGY is released in the form of cavitation and also produces a thermal or heating effect. Various factors determine the amount of energy delivered and thus the degree of clinical effect (both useful and harmful). The primary parameter to consider for this application is the frequency (expressed in MegaHertz /MHz or KiloHertz /KHz). The sound waves also may be emitted continuously or in pulses. The energy delivered is usually expressed in watts. These are the three most important parameters for skin treatment.

The ultrasound delivery device consists of a handheld transducer sound head and a control panel to select the operating parameters. Sound waves may be emitted in a focused or collimated beam and may have a "servo feedback loop" design to control energy and to prevent operation if the sound head is not in proper contact with an absorbing medium. Most devices use a "coupling agent" to facilitate contact with the skin. A common agent is the familiar ultrasound gel. Without a feedback feature, the sound head may be rapidly damaged if turned on without an absorbing target or gel.

Generally speaking, the *depth of penetration* of the sonic wavefront depends primarily on the frequency. Units

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providing 1 MHz are currently the most common in clinical use. Ultrasound is only approved at present for providing deep heat/massage and increasing blood flow. These 1 MHz units are widely used for sports medicine and physical therapy. Also more recently, they have been used in conjunction with liposuction and cellulite treatment (the latter is currently a less well established and proven application). The 3 MHz units are also available commercially, but on a more limited basis.

3 MHz VERSUS 1 MHz

The decision to recommend use of 3 MHz over 1 MHz for ultrasound delivery systems *was made with great care by the authors*. In clinical studies, no advantage could be demonstrated for the 1 MHz frequency over the 3 MHz using a leading unit. Additionally, no efficacy or safety benefits of a 1 MHz collimated ultrasound system were noted, as compared with either 1 or 3 MHz non-



Courtesy of S.L. Michlovitz

collimated units, when tested for skin permeability and skin irritation. Thus the authors believe that the "deposition of energy profile" for 3 MHz provides a dramatically better safety situation for superficial skin micro massage. The use of the pulsed mode (rather than continuous) of operation is also favored for both efficacy and safety issues. Unlike microdermabraders, which are Class I devices, ultrasound units are considered by the FDA to be Class II devices and as such can only be sold to a licensed physician.

SAFETY ISSUES

There is a concern about the potential for serious

adverse events with the misuse of 1 MHz ultrasound units for these new skin rejuvenation applications. These units are widely available and the authors have a concern that these new techniques will be utilized with the 1 MHz units. Some commercially available units offer both 1 and 3 MHz combined in a single ultrasound unit. Care should be taken to ensure that *only* the 3 MHz unit is utilized for skin rejuvenation in order to exercise maximum safety. Special care should be exercised to avoid crossing the bony orbital rim. A heightened awareness should be used and note that not all ultrasound units have the same safety features: they may not be designed, configured or tested for these new applications.

CONCLUSION

Based on the scientific studies conducted to date, the best application of these combined technologies for optimal skin rejuvenation results is to utilize positive pressure salt microdermabrasion at parameters that aggressively remove a portion of the stratum corneum without producing bleeding or skin abrasion. Specially formulated products designed to minimize adverse effects can then be applied. Ultrasonic micro massage may then be performed followed by use of appropriate environmental barrier topicals including a broad-spectrum sunscreen.

PATENTS

The process of using microdermabrasion and specially formulated topical cosmeceutical products followed by ultrasound is a process covered by U.S. patent # 6,030,374 issued on February 29, 2000. The patent holder is David H. McDaniel, M.D. The claim for this process is licensed exclusively to IntegreMed, LLC. Additional U.S. and foreign patents related to this process are also pending.

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