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System that enhances dermal permeability shows early promise even in heavy molecule delivery

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NATIONAL REPORT ► A transdermal delivery system that combines dermabrasion and iontophoresis (Transderm Ionto; Mattioli Engineering Corp.) could revolutionize delivery of many dermatologic treatments, experts say. However, they add, first it must overcome technical and commercial hurdles.

SKIN SUPER BOWL “If one could deliver Botox [botulinum toxin A;

Allergan] fast enough and without needles, that’s like winning the Super Bowl” of dermatologic applications, says Michael H. Gold, M.D., medical director at Gold Skin Care Center, Advanced Aesthetics Medi Spa, The Laser and Rejuvenation Center, and the Tennessee Clinical Research Center, and clinical assistant professor, Division of Dermatology,



Dr. Gold

Vanderbilt University School of Medicine and School of Nursing, Nashville. “The Transderm Ionto System is the only transdermal delivery device that’s Food And Drug Administration [FDA] approved as an alternative to injections,” and the only such device that can deliver heavy molecules such as botulinum toxin and hyaluronic acid, Lindsey Donlan,



Mattioli's U.S. sales and marketing manager, tells *Cosmetic Surgery Times*.

That's important because "Some of the proteins and peptides that are on the horizon for anti-aging, as well as genetically engineered products, are fairly big, clunky molecules," adds David H. McDaniel, M.D., director of the Laser Skin & Vein Center of Virginia in Virginia Beach, Va. He states that if one can enhance the skin's permeability, "One can deliver larger proteins that won't go in" without injections.

The system uses a proprietary process called dermoelectroporation, a combination of iontophoresis and electroporation that directly follows microdermabrasion, Ms. Donlan says. "The solution flows from our Super Precision Liquid Dispenser (PLD) onto one of two separate probes"— the Ionto, a square probe containing nine electrodes used for larger body areas, or the smaller circular Ionto Lips, she explains.

"When the probe is on," adds Ms. Donlan, "the electrical pulses drive



Dr. McDaniel

the solution into the skin. Since we do microdermabrasion prior, there's about a five times greater delivery rate of the solution" versus topicals.

"That's probably the maximum one could get" with an ideally formulated solution, says Alan Cross, Ph.D., president of Cosmetic Technologies, a medical products distributorship based in Montpelier, France. Nevertheless, he says, "One of the advantages of a system like this is that it could provide a more even distribution of botulinum toxin into the skin" than injections do.

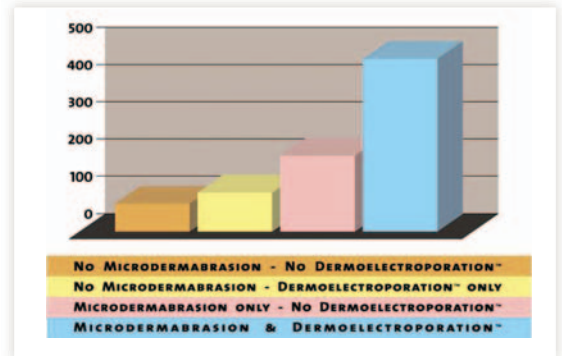
JUST THE START? Dr. Gold says the device's ability to deliver needle-free lidocaine in 10 or 15 minutes inspired him to wonder what else the technology could do.

Recent research suggests the system works for botulinum toxin delivery in hyperhidrosis patients (Cavallini et al. 2007 [poster]). In this study, researchers treated six female patients with mild dermabrasion on treatment areas and control areas, then with botulinum toxin A applied via pulsed current iontophoresis for 10 minutes. They compared results of minor tests taken before treatment and two weeks afterward and found significant decreases in patients' axillary perspiration. Moreover, the authors write that histologic testing showed "The toxin was

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localized in association with striated skeletal muscles below the deep dermis," while hematoxylin-eosin testing revealed no significant alteration to treated skin.

However, Alastair Carruthers, M.D., says the hyperhidrosis study is "inaccurate insofar as it says they did a preliminary minor test for quantitative evaluation of patient sweating. Minor's test is actually a qualitative evaluation. One problem with this poster is that there's no gravimetric assessment," which is the



Microdermabrasion coupled with electrical pulses serve to increase delivery rate of solutions through the skin, say the device's developers.

Chart credit: Mattioli Engineering Corp.

accepted way of testing such treatments. He is president of the American Society for Dermatologic Surgery.

He adds, "The results this poster shows have already been demonstrated with other systems. We need more evidence to demonstrate clinical relevance."

The system's early potential is "fascinating," counters Dr. Gold, who at press time was trying to create a multicenter U.S. clinical trial to confirm and expand on the above research. However, he says moving the idea forward domestically will require FDA oversight and a corporate sponsor, which Dr. Gold says he's "working feverishly" to land. At press time, adds Ms. Donlan, about 100 U.S. physicians were using the system.

"Getting 10 or 20 needles in one's palm or soles hurts," notes Dr. Gold. "If I can do it with current and it's not that painful, it's a home run. It behooves somebody to want to study this."

UNDOCUMENTED BENEFITS "The principle of enhancing the skin's permeability to selectively deliver topical agents is a very sound one," and the physics behind modalities including ultrasound, iontophoresis and electroporation are well defined, says



Dr. McDaniel. However, he says, “What hasn’t been well documented in peer-reviewed clinical studies are the benefits” such technologies deliver clinically, along with ideal techniques, parameters and preparations.



Dr. Carruthers

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VIRGINIA BEACH, VA.

Dr. McDaniel says that since he began studying the enhancement of skin permeability more than 10 years ago, “I always thought one of the key factors would be specially formulating the products — considering the additives, preservatives” and ingredients that might not pose problems in existing topicals but

could cause irritation or other adverse effects when delivered transdermally. “Off-the-shelf products aren’t formulated for that purpose,” he notes.

Fortunately, adds Dr. McDaniel, sound research in this regard “may finally be on the horizon. The other very interesting [possibility] involves delivering products over large areas.”

Even fairly needle-phobic patients have accepted Botox injections because “the results are so great,” notes Dr. McDaniel. Therefore, he says the transdermal system is “probably of greater value in some ways for things we cannot do now” by injection, such as treatments for cellulite, full-face wrinkles and photoaging.

Similarly, he says that for stretch marks, current topical treatments deliver limited results, while Fraxel (Reliant Technologies) is effective but uncomfortable and costly for large areas. “If a patient could come in for something that felt like a massage or a slight tingling” and was safe, reasonably priced and effective for stretch marks or other large-area treatments, the treatment would carry broad appeal, says Dr. McDaniel.

DUAL ADVANTAGE The technology also could prove useful for botulinum toxin treatments of glabellar lines, Dr. Gold says. In this case, he states, “not only would patients get the benefit of the Botox, but they’d get microdermabrasion at the same time.”

Conversely, Ms. Donlan reports that a small test conducted by George A. Farber, Sr., M.D., Kenner, La., shows that the Transderm Ionto System is effective for delivering Clobex (clobetasol propionate; Galderma) for treatment of chronic plaque-type psoriasis and lichen planus.

Regarding Mattioli’s competitors, Dr. Cross says the Transcutaneous Meso-dermic Therapy/TMT System (Mesoesthetic) uses a proprietary process called electrophoroporation in conjunction with treatment kits specially formulated for the device. The recently introduced Perfectionist Power Correcting Patch (Estée Lauder) represents the first home-use iontophoresis product, Dr. McDaniel adds.

“It’s a very exciting, very young field,” he says. Once objective clinical research begins to document benefits and establish appropriate indications and parameters, “Then we’ll see this really take off.” ◀

Disclosures

Drs. Gold, McDaniel and Carruthers report no relevant financial interests. Dr. Cross is a distributor of Mesoesthetic products.

Reference

Cavallini M, et al. Pulsed current iontophoresis of type A botulinum toxin for treatment of focal hyperhidrosis. Presented at 31st Hawaii Dermatology Seminar, March 3-9, 2007, Maui. [poster]

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