

Novel radiofrequency-based treatment achieves skin tightening with minimal discomfort

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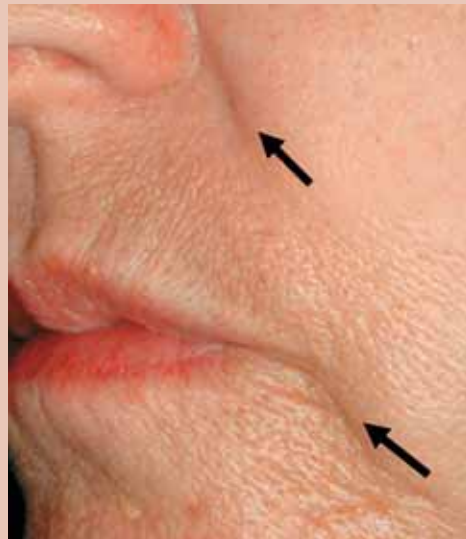
National report — Functional aspiration controlled electrothermal stimulation (FACES) appears to be a safe, effective, and very well-tolerated modality for non-ablative treatment of facial rhytids and improvement of skin texture, reports Michael H. Gold, M.D.

The procedures were performed without any anesthesia and yet were regarded by the majority of patients as pain-free or associated with only slight to moderate discomfort.

The technology used for the procedure (Aluma, Lumenis) is awaiting marketing clearance from the Food and Drug Administration. It integrates radiofrequency dermal heating with suction to help enhance the specificity of energy delivery. In FACES, the skin is aspirated with vacuum into a specially designed hand piece where it is held between two parallel electrodes and treated with a radio frequency current, explains Dr. Gold, founder and medical director, Tennessee Clinical Research Center, Nashville, Tenn.

The study

Dr. Gold and Mitchel P. Goldman, M.D., are the investigators in a two-center, pilot study evaluating the safety and



Perioral facial region in woman aged 61 years. Photos were taken before treatment, and six months after start of treatment (end-trial) with the FACES modality. Wrinkles are progressively reduced with no adverse effects.

Photos: Michael H. Gold, M.D.

efficacy of FACES for non-ablative rejuvenation of periorbital and perioral rhytids. The ongoing trial enrolled 46 subjects (mean age 52 years), of whom 36 completed the planned course of eight treatments. Follow-up visits are scheduled for one, three and six months after the final treatment, and so far 34 patients have been evaluated at one month and 19 at three months.

The procedures were performed without any anesthesia and yet were regarded by the majority of patients as pain-free or associated with only slight to moderate discomfort. Investigator-rated elastosis scores showed onset of reduction in the appearance of upper and lower face wrinkles as early as after the first treatment with continued gradual improvement over time. Those observations were corroborated by investigator visual analogue score evaluations of improvement and by high

patient satisfaction ratings, Dr. Gold reports.

“The preliminary efficacy data are very encouraging and the ability to achieve tissue tightening while minimizing treatment-related discomfort represents a particular advance considering that pain is a significant feature of radiofrequency-based and many other non-ablative facial rejuvenation procedures,” he says.

Analyses of treatment-related pain showed discomfort, if it occurred, appeared to lessen over time. After the first treatment, 19 percent of patients indicated the procedure was pain-free while 33 percent said they experienced moderate pain. After the eighth treatment, 43 percent of patients indicated experiencing no pain and only 11 percent said they had moderate pain. No patients considered the procedure intolerable at any session.

Efficacy ratings

Efficacy ratings were made separately for the upper and lower face in recognition of their physiological differences. The Fitzpatrick Classification of Wrinkling and Degree of Elastosis was used to assign an elastosis score at baseline and at each subsequent visit. Mean scores at study entry were 4.50 for the upper face and 4.13 for the lower face. Those scores were reduced to 4.30 and 3.98, respectively, after just the first treatment, fell to 2.74 and 2.56, respectively, at the one-month post-treatment follow-up, and declined further to 2.37 and 2.32, respectively, at the three-month post-treatment visit.

"Analyses of the changes from baseline in elastosis score at each visit showed there were similar and statistically significant improvements for the lower and upper face at each visit," Dr. Gold observes.

Study evaluation

A visual analogue scale was used as a complementary tool to evaluate efficacy. Prior to treatments five and eight and at the post-treatment follow-up visits, improvement was rated using a

10-point scale (0 = none, 10 = complete). Mean VAS scores for the upper and lower face were about 2 at the fifth treatment session and continued to increase, more than doubling to reach scores of 4.35 and 4.24, respectively, at three months post-treatment.

"The gradual but progressive improvement observed in the elastosis scores and visual analogue scale ratings are consistent with the relatively slow process of collagen reformation in skin that has been delicately triggered but not extensively traumatized," Dr. Gold says.

Patient satisfaction ratings were obtained at the same visits when the VAS scores were collected using a five-point scale (1 = not satisfied, 5 = extremely satisfied). At each assessment, more than 90 percent of patients were satisfied, while 17 to 36 percent of patients at each visit indicated being very or extremely satisfied.

"We found no correlation between patient satisfaction and reported levels of treatment discomfort, suggesting that clinical improvement was the main determinant of patient approval," Dr. Gold says.

Adverse event rates low

In 327 treatments, there were 30 "related" adverse events, all of which were mild or moderate in severity. Burns/blistering were most common (14 events) followed by erythema (eight events). All of the local adverse events resolved or improved with no or minimal intervention.

"The adverse events occurring in this trial are probably associated with a learning curve, and we expect as users gain more experience with this modality and the treatment parameters are refined, their frequency will become even lower," Dr. Gold says.

As performed in this study, the procedure used adjustable suction in the range of 4 to 28 Hg, radio frequency energy ranging from 2 to 10 watts, and treatment times lasting from one to six seconds. Expanded investigations will include larger patient groups and evaluate the effects of alternative treatment parameters. **DT**

Disclosure: Dr. Gold and Dr. Goldman are consultants, perform research, and lecture for Lumenis. Dr. Gold also owns stock in the company.

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