Results Mixed for Cellulite Treatment Device

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SAN DIEGO — A combination radiofrequency, infrared, and suction device has achieved mixed results in the treatment of cellulite according to two papers presented at the annual meeting of the American Academy of Cosmetic Surgery.

Twelve of 20 patients (60%) treated with the VelaSmooth device (Syneron Medical Ltd.) by Neil Sadick, M.D., eight times in 4 weeks achieved only mild improvement in cellulite, said Thomas W. Barnes, M.D., who delivered the paper for Dr. Sadick. Another seven patients (35%) were judged to have "good" improvement, and one patient had "very good" improvement.

The results were better among patients who were treated by R. Stephen Mulholland, M.D., 16 times over 8 weeks, said Dr. Barnes, who practices in Newport Beach, Calif. Two of 11 patients (18%) achieved excellent improvement in cellulite, 4 (36%) achieved very good improvement, 4 (36%) achieved good improvement, and in 1 patient (9%) the improvement was mild.

At the end of the study, none of the nine patients said that they would be willing to pay for treatment.

DR. HABBEMA

Already available in Europe and Canada, the VelaSmooth device has not yet been approved for sale in the United States. In January 2005, Syneron, based in Yokneam Illit, Israel, announced that the company would soon be applying to the Food and Drug Administration for marketing clearance in the United States.

The intense pulsed light and radiofrequency components of the device increase tissue temperature and are claimed to cause an increase in the available oxygen for fat metabolism, possibly also having an effect on adipocyte integrity.

The suction component is said to physically break down fat-cell clusters, stretch fibrous bands, and increase lymphatic drainage and evacuation of fat metabolism end products. The suction may also push adipocytes back into the subcutaneous compartment.

Dr. Barnes acknowledged receiving compensation from Syneron when speaking about the company's products, and Dr. Sadick acknowledged serving as a consultant to Syneron and other companies.

In two separate studies, Loek Habbema, M.D., of Medical Centre 't Gooi (Bussum, the Netherlands) treated a total of 17 patients with the VelaSmooth device. He stopped the first study, which included 8 patients, early because of an apparent lack of efficacy. Upon examining the device, the distributor noted inadequate suction, which necessitated repair.

Dr. Habbema then treated another nine patients, conducting a blinded study in which one of the patient's outer, inner, posterior, and anterior thighs and buttocks were treated. Each patient was treated eight times over 4 weeks, and was evaluated 5 days following the final treatment. An investigator scored the extent and intensity of the patient's cellulite.

At the end of the treatment period, the investigator found that none of the patients showed any left-right improvement. The patients themselves completed a survey, and none of the nine noticed any improvement. In addition, none said that they would be willing to pay for treatment.

Dr. Habbema, who declared that he had no financial conflicts of interest (although the VelaSmooth device was placed in his office at no charge) offered several possible explanations for the apparent lack of efficacy: The device may inherently lack efficacy; the treatment schedule may need to be changed; the device's output may need adjustment; or the indications for treatment and the patient selection criteria may need alteration.

Dr. Habbema noted that the device's user manual has changed recently. In July 2004 the manual read, "The VelaSmooth system is indicated for the treatment and reduction of cellulite, and the improvement of adipose tissue metabolism."

But in January 2005 he said he saw that a new version of the manual read, "The VelaSmooth Shaper system is indicated for temporary reduction in the appearance of cellulite, to relieve minor muscle aches and pain and for temporary improvement in the local blood circulation." ■