

Studies Validate Energy-Based Cellulite Tx

Considered by many as the next frontier in body shaping, cellulite is an incurable malady said to affect a majority of women. Through time we have witnessed the evolution of cellulite reduction treatments beginning with mechanical massage, advancing to endermologie, mesotherapy and a variety of other energy-based therapies. However, while the reduction of cellulite is hard to prove, a new device from Elemé Medical, Inc. (Merrimack, N.H.), possesses scientifically validated evidence supporting its effectiveness.

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Scientific Evidence Proves SmoothShapes Reduces Appearance of Cellulite

By Kevin A. Wilson, Contributing Editor

Cellulite most commonly affects women and is notoriously difficult to effectively treat, suggesting that a scientifically proven device would have obvious value to any aesthetic practice. According to Michael I. Kulick, M.D., D.D.S., a plastic surgeon in San Francisco, Calif., and author of a recent SmoothShapes study, SmoothShapes® XV from Elemé Medical is the first device to successfully show reduction in the appearance of cellulite under a more rigorous scientific protocol.



Michael I. Kulick, M.D., D.D.S.
Plastic Surgeon
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SmoothShapes XV attacks cellulite non-invasively by combining mechanical manipulation (vacuum suction and massaging rollers), with laser and light wavelengths (915 nm and 650 nm) in one device. Dr. Kulick explained this patented mechanism of action known as Photomology®; "There are three components to treatment with the SmoothShapes device. First is laser energy: the 650 nm wavelength transcutaneously promotes the expansion of pores in the cell membrane of adipocytes to increase permeability, whereas the 915 nm wavelength softens the fat under the skin's surface, so that it is more easily expressed by the cell and more readily removed through the lymphatic system, and thus eliminated from the body. Circulation and inflammation are also improved by the 915 nm wavelength."

"SmoothShapes' suction component is thought to stretch the fibrous septae that tether the hypodermis to the fascia

below and provide a matrix to support the surrounding fatty tissue," Dr. Kulick continued. "The uneven anatomical arrangement of this lattice is thought to be a major contributor to the appearance of cellulitic dimpling. Roller massage gently promotes the photo-thermal expression and drainage of lipid material, as well as the mechanical manipulation of the fibrous septae. In theory, SmoothShapes utilizes these three components together to maximize the effect, and results suggest that this theory is sound."

According to Bruce Katz, M.D., medical director of the Juva Skin and Laser Center in New York, N.Y., SmoothShapes represents the first truly effective technology for moderate cellulite. "We see improvement in dimpling and skin seems firmer, as well as smoother. Many of our patients have noted improvement – more than they've seen with other technologies. We usually prescribe six to eight treatments, once or twice a week, with maintenance once or twice a year. It's not a cure for major or type 3 cellulite, but people with moderate type 1 or 2 are very happy with improvement. Clinically, I'm comfortable saying we often see 60% to 70% improvement with SmoothShapes alone."



Bruce Katz, M.D.
Medical Director
Juva Skin and Laser Center
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W. Jason Martin, M.D., director of the Aspen Institute of Plastic Reconstructive Surgery in Aspen, Colo., feels the ideal candidate for SmoothShapes as a stand-alone therapy is the same as it



48 year old male after lipo sculpting of the back, flanks and abdomen

48 year old male 21 days after SmoothShapes Tx

Photos courtesy of W. Jason Martin, M.D.

"SmoothShapes represents the first truly effective technology for moderate cellulite. We see improvement in dimpling and skin seems firmer, as well as smoother."



42 year old female after lipo sculpting of the flanks and abdomen



42 year old female four days after SmoothShapes Tx

Photos courtesy of W. Jason Martin, M.D.

“The most desirable patient is healthy, active and physically fit, but has small areas of cellulite that have not improved despite healthy diet and exercise.”



50 year old female before Tx



50 year old female six months after SmoothShapes Tx
Photos courtesy of Leyda Bowes, M.D.

would be for most non- or minimally invasive body contouring devices. “The most desirable patient for SmoothShapes treatment is healthy, active and physically fit, but has small areas of cellulite that have not improved despite healthy diet and exercise. In our experience, the most requested area for treatment is the bulging outer thigh, or saddle bags. Since SmoothShapes addresses localized areas of cellulite, these treatments are not as useful for the patient who has diffuse deformities or who is moderately or severely obese.”



W. Jason Martin, M.D.
Director
Aspen Institute of Plastic Surgery
Aspen, CO

“Technologies such as SmoothShapes are not about weight loss,” Dr. Katz added, “but about recontouring, smoothing out localized fatty deposits and improving the appearance of cellulite. I think most patients are sophisticated enough to understand this, but it still bears mentioning because expectations management is important with this or any other aesthetic therapy. With SmoothShapes, this is mostly confined to informing patients that it’s not a cure, or permanent and that maintenance treatments will be needed in the future.”

Leyda Bowes, M.D., director of Bowes Dermatology (Miami, Fla.), tells her patients, “Cellulite is an ongoing, active, hormonally mediated process. A one-time treatment isn’t going to get rid of it; there is no way to make it go away completely, but we can improve its appearance considerably, as well as promote the formation of a more aesthetically pleasing contour to the treatment area.” SmoothShapes offers aesthetic practices a device, “that really treats cellulite, as



Leyda Bowes, M.D.
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well as mild laxity and loss of skin toning in the abdomen, with results that last six months. We do not have any other device with which to achieve this. SmoothShapes isn’t a cure but it does represent a successful modality with predictable, reproducible results. We’ve seen improvement in all cases ranging up to 60%, or higher with continued treatment and regular maintenance. Patients are very happy with both the tolerability of treatment and the results.”

In Dr. Bowes experience, the reduction of cellulite is most often a concern for women. “While men may develop cellulite, and may, for one reason or another, seek treatment with technologies such as SmoothShapes, the overwhelming majority of patients will be women, especially if you’re looking at the therapy by itself,” she said. “Women are both more likely to have cellulite, and will have more cellulite than men. Although the full story behind the cause of cellulite is not known, this is probably due to hormonal factors, which are quite different between men and women, as well as the way fat and the supporting tissues are distributed in their bodies, which is also much different.”

According to Dr. Bowes, women are prompted to treat cellulite by psychological forces and societal values. “This is true anywhere, but especially in warmer climates where the choice of clothing is more likely to reveal areas where cellulite commonly develops in women, especially the buttocks or thighs,” she said. “Cellulite is perceived as less attractive, and as a sign of age or poor

muscle tone. Many times women will lose volume at various body locations due to age, laxity or weight loss, which exacerbates the condition." Although the development of cellulite is not so much a consequence of unhealthy living as it is genetics, the perception still drives patient decision making and will continue to do so. "There are plenty of patients who come in for SmoothShapes treatment who are in very good shape and at an ideal weight, but still have cellulite," Dr. Bowes pointed out.

When men come in for cellulite, Dr. Bowes continued, it's usually to firm up the buttocks. "We have also had success treating the abdomen with SmoothShapes after a man has lost weight, where laxity becomes more noticeable."

One key advantage to SmoothShapes treatment is that not only is it effective, it is easy and safe enough to pass on to ancillary staff, freeing the physician for other tasks. "This allows you to expand and offer additional services to patients without increasing your own personal workload," Dr. Martin advised. "In terms of capital expenditures for aesthetic medical devices, SmoothShapes has a very desirable return on investment."

Amy Kilian, L.M.T., a massage therapist and office manager at Dr. Martin's practice who regularly performs SmoothShapes therapy, described the treatment process; "You simply apply the device to the treatment area, then slowly glide it across the skin moving in the direction of lymphatic drainage. SmoothShapes can treat any area of the body that the PhotoMod hand-piece can suction onto, such as legs, back, abdomen or even the bra line. When the smaller head is introduced in the near future, we'll be better equipped to address arms and other small areas, which I find very exciting. I recommend eight sessions over a four week period for maximum

results," keeping in mind that more than two sessions per week really won't speed up or improve the overall outcome. "For patients with very pronounced or stubborn cellulite that may be slightly resistant to treatment, I've done ten sessions over five weeks, but most patients get a really good result with eight sessions," she added.

In an upcoming presentation of a recent multi-center study with SmoothShapes, a regimen of eight, 30 minute treatments, twice per week, was used to treat an entire thigh. For the 72 patients completing both one and three month follow-up, average circumference reduction was 3.5 cm and 2.9 cm respectively (statistically significant, $p < 0.001$, Student's t-test), between three thigh measurements (upper, mid and lower) compared to those taken before the first treatment session.

Results with Dr. Kulick's investigation were also impressive. In his study¹, 20 women (aged 25 to 45 years) with mild-to-moderate cellulite of the lateral thigh underwent a regimen of eight, 15 minute treatments, twice per week, at maximum energy settings, with medium suction increased to tolerance. Over-the-counter compression garments were worn for one day post treatment. The primary outcome measurement included changes in surface height and volume via analysis with the VECTRA three-dimensional camera system from Canfield Scientific, Inc. (Fairfield, N.J.)

"The VECTRA system captures a three-dimensional image of the leg in a manner that removes the effects that light has on the topography of the skin surface, which is important because lighting has a major impact on how cellulite looks in a photograph," Dr. Kulick said. "Tattoos were placed on each patient's thigh outside the treatment zone, which helped us align the images properly from each post treatment time period to minimize



37 year old male before Tx



37 year old male six months after SmoothShapes Tx

Photos courtesy of Leyda Bowes, M.D.



Before Tx



After SmoothShapes Tx

Photos courtesy of Kenneth Beer, M.D.

"In general, patients with more pronounced cellulite had greater visible and measurable benefit."



This is a close up of the right lateral thigh. The view is what a person with cellulite sees when they turn their head to the right and look down on their right thigh.



This six month after picture shows significant improvement in the surface contour.

Photos courtesy of Michael I. Kulick, M.D., D.D.S., from the SmoothShapes study *Evaluation of a Non-Invasive, Dual-Wavelength Laser-Suction and Massage Device for the Regional Treatment of Cellulite*

variability between pictures and improve the accuracy of the comparisons. Also, software within the VECTRA system generates numerical values that quantify changes in surface height and volume; this cannot be manipulated by the operator. VECTRA analysis is what made the study unique and the successful results distinctive." Data for measurements were taken at one, three and six months after the final treatment.

Furthermore, no complications were reported; 17 subjects (all women, average age 37 years) had complete data for the analysis phase of the study. As Dr. Kulick reported, "In general, patients with more pronounced cellulite had greater visible and measurable benefit." All but one patient felt they still saw contour improvements at the six month endpoint, and the majority stated they'd recommend the treatment to a friend. "This is despite all but one patient reporting discomfort at the first treatment. Less discomfort was reported following initial treatments, but it did not require any topical anesthetics or oral medication."

"The real significance of this trial," Dr. Kulick elaborated, "is that while other studies with this device have shown circumferential improvement in the thigh size, this study only treated a small area, approximately 8" x 15" (20.3 cm x 38.1 cm). Within the treatment area, there was an elevation of the skin depressions as well as flattening of adjacent bulges. The results lasted for six months after the eighth treatment with no maintenance treatments in between." This skin contour improvement was much more obvious when comparing the standardized VECTRA system images than with normal digital photography."

Both Dr. Katz and Dr. Martin believe that SmoothShapes will prove to be a valuable adjunct to liposuction procedures as

more physicians learn firsthand how it enhances the experience and outcomes. According to Dr. Katz, "We'll typically use it after laser-assisted liposuction, starting at about two weeks post treatment. We know that in people with a decent amount of cellulite before liposuction, we're not going to have a significant impact on cellulite with liposuction alone. We'll tell them we can take away the fat deposits and we can tighten the skin, but the cellulite isn't going to necessarily improve, which prompts them to ask what else we can do. We explain that with SmoothShapes as an adjunctive therapy, we can reduce the appearance of cellulite and perhaps improve the total outcome as well. That's our approach. We believe it reduces post treatment swelling and bruising, as well as cellulite that wouldn't be improved through liposuction alone. I also think it helps improve drainage and reduce inflammation to help maximize improvement from liposuction."

Dr. Martin also regularly uses SmoothShapes in conjunction with assisted liposuction procedures. "I do such a large volume of laser and ultrasound-assisted lipolysis cases that frankly, I use SmoothShapes more often as an adjunct to those procedures than as a stand-alone treatment," he explained. "Initially I pre-treat the surgical area with SmoothShapes to raise the temperature of tissue and prime the area for treatment. This makes it easier to perform these types of liposuction procedures and improves the skin tightening outcome. It also seems to make the overall procedure more tolerable for patients."

"Immediately following the procedure, I perform another SmoothShapes treatment to speed drainage of the residual infusion fluid to the lymph node beds and out of the treatment area," he continued. "This helps minimize potential irregularities or small areas of hardness

that may develop independent of the quality of your technique." Over the next few weeks, Dr. Martin's patients will undergo an additional eight to ten treatments to decrease swelling and promote drainage, enhancing the final result. "This technique dramatically reduces post-procedure swelling and bruising, and in my experience reduces recovery time by several days in most patients."

"From start to finish, what I consistently see is an improvement in the overall patient experience with laser or ultrasound-assisted liposuction procedures that are combined with SmoothShapes treatments," Dr. Martin concluded. "Patients really appreciate the way SmoothShapes helps them relax and focus on healing, promotes a quicker recovery and improves their surgical outcome. Patients who are eager to share their experience and show their results are one of the best assets an aesthetic practice can have. In the end no patient desires prolonged pain or downtime after cosmetic procedures. The addition of these treatments to our pre- and post-procedure protocol helps us provide our patients with a speedy and relatively pain free recovery."

Dr. Bowes also uses SmoothShapes as an adjunct to cryolipolysis, another emerging non-invasive technique for body sculpting. "With cryolipolysis the thickness of the fatty layer will be reduced, and then we use eight sessions of SmoothShapes to improve the tone of the skin after treatment. It may also help improve lymphatic drainage, which may enhance the overall result, but we don't have any scientific evidence of that yet."

Dr. Martin is eagerly awaiting the introduction of a new treatment head for SmoothShapes. "I see this as the only non-invasive device on the market that's truly effective for reduction of both cellulite and post-operative bruising and swelling.



The SmoothShapes device was able to elevate depressions as well as flatten areas within the treatment zone, which translated into an overall improvement in surface contour based on the VECTRA system. After superimposing the zone of analysis from the pre to the six month after image, the picture on the right shows varying colors within the analysis zone. The color bar scale defines the change in contour height - the darkest red area represents a flattening of skin surface height by 2.8 mm and the darkest blue area reflects an elevation of 1 mm. The dynamic improvement in contour is illustrated by labeling the pre-treatment image on the left - A-D. Looking at the six month image on the right, the depression to the right of "A" is elevated as indicated by the light blue color while being surrounded by skin that is green in color reflecting a flattening. The area to the right of "B" was flattened by the treatment. The depression to the right of "C" was elevated and its surrounding area flattened as depicted by the green color. The same kind of elevation and flattening in close approximation can be seen to the right of "D."

Photos courtesy of Michael I. Kulick, M.D., D.D.S., from the SmoothShapes study *Evaluation of a Non-Invasive, Dual-Wavelength Laser-Suction and Massage Device for the Regional Treatment of Cellulite*

The future addition of new smaller and more powerful treatment heads will further transform this modality, especially for areas such as the arm and neck."

"It's very exciting to be able to impact cellulite like we do with SmoothShapes," said Dr. Katz. "A lot of people in this field, such as myself, would put cellulite as one of the last frontiers left to realistically explore. This could be a home run because 80% of women have cellulite, and the other 20% think they do. Anyone can see what that could mean for aesthetic practices." ■

1. Kulick M. Evaluation of a noninvasive, dual-wavelength laser-suction and massage device for the regional treatment of cellulite. *Plast Reconstr Surg.* 2010 Jun;125(6):1788-96

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