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THE NEXT
EVOLUTION
IN BODY
SCULPTING:

truSculpt[®] iD

CUTERA[®]



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THE NEXT EVOLUTION IN BODY SCULPTING

The new truSculpt iD offers personalized body contouring for faster treatment and efficacious results.

With Anne Chapas, MD; Jeffrey S. Dover, MD; Suzanne L. Kilmer, MD; E. Victor Ross, MD; and Michael T. Somenek, MD

Non-invasive body contouring is growing rapidly as an emerging number of patients seek out treatments and new and improved devices continue to come to market. According to the American Society for Plastic Surgery 2017 statistics, nonsurgical fat reduction procedures saw a 24.7 percent uptick over the previous year, and nonsurgical skin tightening procedures were up 15 percent.¹ And demand isn't likely to taper off any time soon. According to results of the 2018 American Society for Dermatologic Surgery Survey,² almost 70 percent of consumers are considering a cosmetic treatment, and excess fat on any part of the body ranks as the top concern for the sixth year in a row at 86 percent. Fifty-seven percent of consumer respondents said they are considering body sculpting treatments to achieve desired results. The body-shaping and skin tightening market is expected to expand by 14.5 percent year-over-year.³

With consumer demand high, and safe and efficacious devices on the market, offering non-surgical body sculpting treatments in practice makes sense for aesthetic physicians both in terms of the practice's bottom line and in terms of meeting patient needs.

AN EVOLUTION IN RF FAT REDUCTION

In 2018, Cutera Inc. introduced truSculpt® iD as the next evolution in body sculpting with unique hands-free capability and the ability to treat a full abdomen in as little as 15 minutes. A non-surgical body sculpting system, the



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platform uses innovative monopolar radio frequency (RF) technology to selectively target fat and therapeutically heat it until fat cells are slowly removed and excreted through the body naturally. Penetrating deep to treat the entire fat layer from skin to muscle, truSculpt iD is clinically proven for permanent fat cell destruction. With real-time temperature control working to provide consistent results, studies have shown an average fat reduction of 24 percent, with patients seeing improvements six to 12 weeks following the first treatment.⁴

This device was designed to address the voids physicians indicated existed in the body sculpting market. Physicians reported they wanted a device that could offer more consistent results after one treatment, the ability to treat larger and smaller areas simultaneously, to not be limited anatomically by where a belt or applicator could fit, or by patient's body or skin type. They also reported a desire for increased treatment speed and throughput, higher patient satisfaction, less downtime, no cold sensitivity, no need for post-treatment massage, a lighter handpiece, a smaller or portable footprint, and lower costs for consumables.⁵

truSculpt iD's design and comprehensive handpiece options offer practitioners the ability to deliver hand-held or hands-free personalized body sculpting to patients in a faster treatment time compared to other available body sculpting treatment options on the market. And, this versatile technology is able to treat various fat densities and all skin types.

"The truSculpt iD adds a new dimension to non-invasive body contouring," says Jeffrey Dover, MD, co-director of SkinCare Physicians in Chestnut Hill, MA. "The procedure is very well-tolerated with limited discomfort and can be performed quickly on a fairly large area. Six handpieces can be applied at once to treat an area such as the abdomen and flanks in a 15-minute treatment session."

San Diego laser surgeon E. Victor Ross, MD, says the concept behind truSculpt iD is that it delivers heat in a systematic, programmed, and very predictable way using radio frequency, which is not a new concept.

"The concept that is new is providing the inverse temperature gradient," he explains. "The challenge with all body contouring devices is to selectively target the fat. If the fat were on the surface that would be easy, but it is a few centimeters down depending where you are treating and the challenge has always been to selectively target fat while sparing the skin overlying it."

Radio frequency has historically been a challenge because the natural tendency is for the energy to be absorbed at the surface causing a very strong temperature rise at the surface and then less of a temperature rise in the fat, Dr. Ross says. With truSculpt iD, Cutera was able to create the

right frequency, which is 2MHz, and the right electrode configuration, to establish an inverse temperature gradient.

"In other words, the fat becomes hotter than the skin at the surface, without requiring external cooling at the surface," he explains. "Fat has a lower density and a lower specific heat, so if you put the same amount of energy in fat as you do in the dermis, the fat will get hotter and will retain the heat longer. And once you heat the fat, it does tend to stay hot. The perfusion with blood flow is poor compared to the dermis."

A clinical study was designed to measure the temperature rise of 2MHz truSculpt iD RF device in the subcutaneous fat as compared to the temperature on the surface of the skin. Patients with various thicknesses of fat were treated with the handpiece placed on the surface of the skin with the set temperature at 43°C. Thermal probes measured temperature at 15mm depth below the handpiece placement, and an analytical model was used to estimate temperature in skin and fat to verify in vivo temperature measurements. Results showed fat reaches therapeutic temperature (~3-4°C increase) within four minutes, while temperature on the skin surface was maintained.

"It's a 3- to 4-degree difference over about 15 minutes, but the first 5 minutes is the critical part of this 15-minute evolution because we're trying to ramp up the temperature. The last 10 minutes is just providing for this temperature rise and keeping it stable," Dr. Ross adds. "There's evidence that if you can maintain that heat over this 10-minute period, you are able to set into motion this cascade of events that destroys the fat."

A time-temperature dependence study conducted by Stephen Ronan, MD and Cutera Clinical Research found that best results were achieved with a single treatment with 2MHz truSculpt iD to the abdomen and flanks for 10 minutes, resulting in an average approximate 24 percent fat reduction at three-month follow-up.

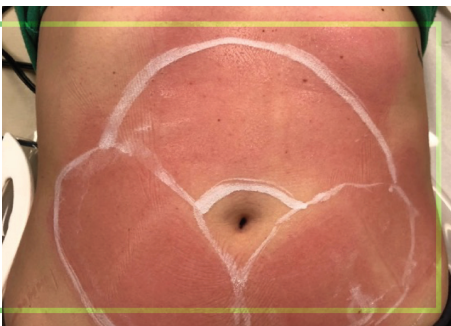
Treatment can be completed in 15 minutes—using the handpieces, therapeutic temperature >45°C in the fat can be reached in less than five minutes, then therapeutic temperature is maintained for 10 minutes in order to destroy the fat.

GAME CHANGING TECHNOLOGY

The fast treatment time and the ability to personalize treatment using one to six handpieces really makes this treatment a game changer, according to several leading aesthetic physicians who have adopted this treatment in practice.

Anne Chapas, MD, a dermatologist in New York, says she's been following this technology for a long time and is excited about the product advancements. "Cutera had a lot of a pre-

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clinical work that was published on using the radio frequency device on fat that was really exciting. Based on this work, I purchased one of their first commercial products—the truSculpt, which was a single handpiece device. I used it a lot in the practice. It had very nice, consistent results, but it was very limited in that the handpiece is about the size of a deck of cards. It's 4 by 4 centimeters, and you had to put that on each individual area for about four minutes," Dr. Chapas says. As a physician who does all of her own treatments, she explains, it was limiting to treat a larger person or to do multiple areas—the handpiece was small and most patients needed two treatments. She primarily used it on patients with small stomachs or for the bra fat area or the arms.

"With the truSculpt iD, Cutera has taken that handpiece and they've replicated it six times," she says. "You can now apply six areas onto the person at the same time (*see image above*). It treats those six areas in 15 minutes, rather than what would have been a half hour. So it's half the time and it's also a lot more comfortable. It's not hot; they're not feeling uncomfortable during the treatment." She explains that sometimes with the truSculpt 3D, because the heat was concentrated in one area, it would be a little warm and not as comfortable for some patients in certain areas.

Michael Somenek, MD, a facial plastic surgeon in Washington, DC, concurs.

In assessing non-surgical body contouring devices, Dr. Somenek compared the length of treatment times, the results, and the comfort level of the treatment. "When I looked at truSculpt iD, it met all of my requirements—it's able to cover a larger surface area than competitors' devices within a 15-minute treatment. Time is everything for people, especially in DC. Patients want to get in, get out, and potentially just go right back to work. The fact that I could offer that in a 15-minute treatment was a huge selling point," Dr. Somenek says.

He says the comfort level was also a factor and attests to it himself, since he's tried the treatment. He says the treatment feels like a hot stone massage. Another bonus is that there is no post-treatment protocol for it. "There's no massage involved like some of the other devices, which will

be a benefit to patients," he adds, noting that with CoolSculpting, patients have to undergo a massage post-treatment, which many report is uncomfortable.

Suzanne Kilmer, MD, Founder of the Laser and Skin Surgery Center of Northern California and Clinical Professor at the University of California, who has been involved in the research studies for truSculpt iD, agrees.

"Short treatment time is a benefit not only for the patient, but to the practice's bottom line as well. Longer treatments cost the practice more. If a patient is in an exam room for a lengthy treatment, it means fewer patients can be treated in a day. It means higher costs to pay a registered nurse or physician extender to do the treatment. It means a car is taking up a spot in your parking lot," Dr. Kilmer says. "Treatment time is an important consideration."

Dr. Kilmer also finds the versatility of the six handpieces a significant benefit. It allows for use of the truSculpt iD to treat multiple body areas simultaneously and to treat varying body types.

The physicians also agree that the fact that the device is hands-free is a significant benefit. While a staff member needs to be nearby, Dr. Chapas says treatment is not physically wearing on the treating physician or staff member.

Dr. Somenek also says it's important to consider staff logistics as well. "There's not a lot of work that the staff has to do during and even after the treatment, which expedites and enhances the entire patient experience."

Dr. Dover concurs with the fact that the device is user-friendly: "At SkinCare Physicians all the body contouring procedures are done by registered nurses. The truSculpt iD takes a skill set which has been easily learned by our designated registered nurses."

THE PATIENT EXPERIENCE

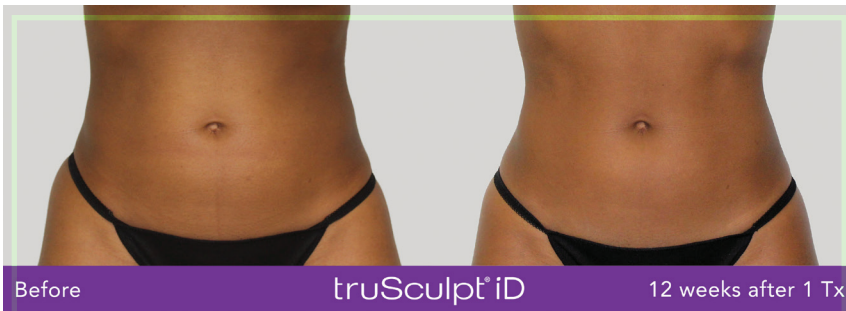
The expected treatment time is about 15 minutes per area treated, and the entire appointment should be about 30 minutes for the patient. Patients do not have to do anything before the treatment. Multiple areas can be treated simultaneously.

Handpieces are applied using a double-sided adhesive film or decal. Once the handpieces are secured, they are then wrapped in place. "You place the decal on the patient, put the handpieces in each individual area, then you wrap it around, and just keep it in place for the 15-minute treatment. It's very easy. And wherever you can place the decal, you can treat," Dr. Chapas explains.

Unlike with other RF devices and with truSculpt iD's

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Photos courtesy of Dr. Somenek



Photos courtesy of Michael Somenek, M.D.

FACE + BODY AESTHETIC SOLUTIONS by CUTERA

Photos courtesy of Dr. Kilmer



Photo Courtesy of Dr. Kilmer

FACE + BODY AESTHETIC SOLUTIONS by CUTERA



Before



After

25% Fat Reduction

predecessor, the handpieces stay in one place—there's no moving them around.

"I think having the handpieces placed in one position for 15 minutes offers a more predictable, reproducible temperature gradient, which is really what you want to have in any of these devices. You want it to work the same way for most patients," Dr. Ross adds.

To determine the ideal handpiece separation for adequate treatment effectiveness, Cutera conducted a study with five patients who each received one treatment with truSculpt iD

(43.5 and 44° C for 15-minute treatments) using two handpieces on abdomen placed either 1 or 1.5cm apart. Using thermal probes, the temperature was measured 15mm beneath the handpiece gap during treatment and an analytical model estimated temperature in skin and fat to verify in vivo temperature measurements. The study found fat reaches therapeutic temperature with handpieces placed 1 and 1.5cm apart, and the skin surface between gaps is 7°C cooler than fat beneath. The thermal model showed therapeutic heating 0.5cm beyond electrode edge, leading to the conclusion that placing the handpieces no greater than a 0.75cm gap is ideal to provide therapeutic treatment between the handpieces. All six handpieces can potentially treat 298cm² surface area in a single treatment.

"In 15 minutes, we can use all six handpieces to treat a fairly large area," says Dr. Dover. "The treatments are adjusted and customized to each individual patient and each area treated, but it's important to remember that the treatment of six areas only lasts 15 minutes." He says that

truSculpt iD treatments are well-tolerated and results seem very similar to those achieved with CoolSculpting and with SculpSure.

In the trials to assess the safety and efficacy of truSculpt iD, after one treatment, average fat reduction varied from nine to 36 percent for an average fat reduction of 23.5 percent in the abdomen and 23 percent reduction in the flanks as measured by Ultrasound. Peak fat disruption was observed at 30 days, and inflammatory resolution observed 90 days post-treatment. Patients rated the procedure as comfortable with little to no pain.

Physicians using this device in practice have seen similar results.

Dr. Somenek says his patients start to see results as early as around six to eight weeks, but he has patients wait 12 weeks to realize the full benefits because the studies demonstrated that the difference from going from six to 12 weeks is almost double the improvement. He waits 12 weeks before taking the after photos, final measurements, and assessments.

Post-treatment, there is no downtime and patients can resume normal activities immediately. Describing his own personal experience with treating his abdomen, Dr. Somenek says his skin was red for about 45 minutes following treatment, but that he otherwise felt nothing and

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In addition to breakdown of fat in the abdomen and flank, truSculpt iD can be used to heat tissue in other areas including upper arms, back, and inner, outer, and back of thighs.

Dr. Kilmer, one of the investigators who completed a truSculpt iD upper arm feasibility study with favorable results, also treated her own arms and saw results of treatment within six weeks. She says she is very satisfied with her treatment results.

Dr. Somenek, another investigator who completed a truSculpt iD feasibility study that included upper arms, also experienced efficacious results, particularly with improvement to the shape and some skin tightening. "Although skin tightening is not the indication for this device, the technology is the technology. It's radio frequency and radio frequency heats tissue. I use other radio frequency devices specifically for skin tightening, so it's not a far stretch with clinical data to think that this device can potentially provide some element of skin tightening, as well," he says. But as with other areas, treatment is comfortable, there is no downtime, and minimal side effects.

was able to go to the gym and attend a fitness class later in the evening. "My skin looked totally normal, it felt normal. I didn't have any numbness or tingling, and I literally felt nothing the next day. There wasn't any soreness. It's a very comfortable treatment," he says.

To date, the treatment protocol has been for one treatment and patients and physicians report satisfaction. Dr. Chapas, who is investigating the potential benefits of a second treatment—of 12 patients that she treated in trial, she has now retreated eight and is waiting to see the results. She says she expects the second treatment will result in an even greater fat reduction.

PATIENT SELECTION AND MANAGEMENT

The ideal patient for truSculpt iD is similar to other non-invasive body contouring devices, the physicians all agree. It's not a weight-loss program, but a treatment to reduce localized areas of fat, such as on the abdomen and flanks. The device is designed to treat both large and small body types, as well as all skin types and even skin with laxity.

"This technology is very adaptable to patients of all different sizes and for all different body areas since you're not trying to squeeze them into a certain handpiece," says Dr. Chapas, adding that it's also an excellent option for patients who want to treat multiple areas.

Dr. Dover also notes that the truSculpt iD offers rapid, well-tolerated treatments for a variety of areas from large areas with significant fullness to small customized areas with little excess fat.

"We have used it to treat localized areas of excess fat in the love handles and on the belly in individuals who were otherwise not ideal candidates for other non-invasive body contouring treatments. For example, women who are at or very close to their ideal body weight with relatively flat abdomens with localized small areas of fat have done very well with truSculpt iD," Dr. Dover says.

This treatment is ideal for patients looking for body contouring—someone who has been working out and has some stubborn areas that they're looking to contour or refine, Dr. Somenek says. And, he adds, it's also an ideal treatment for patients who have had body contouring, liposuction, and other types of treatments who are either not satisfied with or still have some contouring they want to address post-surgically.

Drs. Dover and Kilmer also note a benefit to treating patients with truSculpt iD in conjunction with other treatments, such as CoolSculpting, to fine-tune results.

"We like to use truSculpt iD for small areas of fat reduction, in patients who have already had excellent results from CoolSculpting who are left with small localized areas

of fat, which are not amenable to further CoolSculpting, and for individuals where the CoolSculpting handpieces can't achieve enough suction to be usable in certain areas," Dr. Dover explains.

This treatment is also not limited by a patient's BMI, and both smaller and larger patients can see good results with the truSculpt iD.

"In the ultrasound studies and in practice, we've seen an average of 24 percent reduction in the fat pad. On the surface you would think thinner people would respond better, but we've seen with some patients with a larger fat burden, not someone who's obese but someone who just has a larger fat pad, more of a response in photographs because 24 percent of that fat pad is going away," says Dr. Somenek. "We've also treated people who are fit and have stubborn areas and are just looking for additional contouring and we've seen great results with that as well."

Although surgery remains the gold standard for a more definitive treatment, Dr. Somenek notes not everyone has the downtime or financial means to opt for surgery.

"For those patients, this is a great alternative because it's able to offer them some type of refinement to the area that they're worried about, in a single 15-minute treatment. They could go to the gym later that day. They could go right back to work after their lunch break. That's attractive to people—they can potentially get a treatment that really doesn't affect any aspect of their life," he offers.

It really comes down to expectation management when patients are considering a surgical vs. non-surgical solution. Dr. Somenek says patients need to know this is going to offer a percentage of a surgical result and if that statistic resonates with them, this may be the right choice. But patients also need to understand that this treatment will only be successful for those who have a healthy lifestyle in terms of diet and exercise. It's not a quick fix.

Dr. Kilmer also notes that a potential advantage to truSculpt iD versus surgery is that she has seen some skin retraction with treatment. "With liposuction, significantly more fat can be removed at one time, but liposuction does not typically address skin laxity—it needs to be performed with a tummy tuck or other treatments in order to achieve skin retraction," Dr. Kilmer says.

Dr. Chapas says she has also seen early signs of skin retraction post-treatment and is optimistic about the potential for this technology to be studied and indicated for skin tightening. "This could be the first hands-free skin tightening. That's the holy grail right now," Dr. Chapas notes. "Everything we have for skin tightening requires us to be physically doing the energy treatment. A hands-free option would be very exciting."

THE RIGHT CHOICE FOR AESTHETIC PRACTICES

With so many devices and treatment options on the market, making the right purchasing choice is important. Dr. Ross says the most important considerations are purchase price and consumable costs, reliability, service, and efficacy. It's essential that you know the device works well—especially when you're talking about devices for treatments like body sculpting where patients don't see results for a few months vs. a device to treat a brown spot or broken blood vessel where you see results in a week or less. You need to have the confidence that patients will see results so you can start using and marketing the device as quickly as possible, even before you can show successful examples of patients you've treated.

It has to be predictable, work predictably well, be reasonably easy for staff to use, be able to treat something that's a common problem, have a small footprint, and be ergonomically easy to move around.

"The truSculpt iD meets a lot of criteria that I have," Dr. Ross says, adding that while he has only used the device for a short amount of time in his practice and doesn't yet have a reference for long-term results, the science behind the device and its operation are sound.

"If you appropriately promote the device, like anything that you have within your practice, and you do two to four treatments a week on patients, you should be able to pay that device off within six to nine months and realize a return on your investment," says Dr. Somenek.

And, again, the short treatment time offers a significant potential benefit over other non-invasive body contouring devices that offer similar efficacy.

"It's really able to treat the same surface area as most of the other non-invasive body contouring devices in a fraction of the time. The same surface area that you would have to spend 90 minutes treating with CoolSculpting, you could treat in 15 minutes with truSculpt iD. With SculpSure, you can treat the same surface area in 50 minutes. And UltraShape Power can treat the same surface area in 32 minutes, but it takes three treatments, so about 90 minutes," explains Dr. Somenek. "If somebody told me that they could treat the same area in a 15-minute treatment of what I would have to spend 90 minutes or two hours doing, I would easily take the 15-minute treatment, hands down." ■

1. <https://www.surgery.org/sites/default/files/ASAPS-Stats2017.pdf>

2. <https://www.asds.net/Medical-Professionals/Practice-Resources/ASDS-Consumer-Survey-on-Cosmetic-Dermatologic-Procedures>

3. http://miinews.com/wp-content/uploads/2017/04/BodyShap-SkinTight-ExecSummary_071817.pdf

4. Amy Taub, MD ASDS 2017 Poster Presentation.

5. Survey data on file with Cutera, Inc.

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