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CLINICAL ROUNDTABLE SUPPLEMENT



By Kevin A. Wilson, Contributing Editor

As CoolSculpting® by ZELTIQ® (Pleasanton, Calif.) continues to take the aesthetic market by storm, it also evolves as as a functional technology platform. Considered a natural evolution of this body contouring modality, the company has unveiled new protocols using additional treatment applicators that can, over time, non-invasively provide results approaching those seen with liposuction.



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"By simply performing numerous applications (called cycles) in a short period of time, we can achieve significantly greater reductions, even in larger patients."

Essentially, CoolSculpting is controlled induction of cold panniculitis, according to Jeffrey Dover, M.D., medical director of SkinCare Physicians (Chestnut Hill, Mass.). "The dermatology community has known for decades that when exposed to extreme cold, subcutaneous fat becomes inflamed, which leads to apoptosis of affected adipocytes. R. Rox Anderson, M.D., and Dieter Manstein, M.D., Ph.D., at the Wellman Center for Photomedicine at Massachusetts General Hospital in Boston – a teaching affiliate of Harvard Medical School – grasped this phenomenon, and with the help of others, determined how to harness it for aesthetic purposes."

With CoolSculpting, tissue is drawn into the applicator and then cooled rapidly to a level that doesn't injure skin, but causes inflammation in the fatty tissue beneath, making the treatment fat-selective as well as non-invasive. As the body removes the dead cells and their contents naturally, unwanted fat is reduced, providing visible results over a few months. "Fat freezes at a warmer temperature than the epidermis, dermis and surrounding tissue. The mild to moderate subcutaneous inflammation is usually painless, and because the effect causes the gradual release of fat there's no perceptible rise in blood lipid levels," Dr. Dover explained. "The downside has been that we are limited by how much tissue can be drawn into a single applicator; therefore, only so much area can be affected in one treatment."

New protocols, collectively known as Treatment to Transformation™ (T2T), involve the use of additional applicators in a single treatment, as well as multiple sessions to achieve the patient's desired aesthetic outcome over time. "By simply performing numerous applications (called cycles) in a short period of time, we can achieve significantly greater reductions, even in larger patients," reported dermatologist Suzanne L. Kilmer, M.D., director of the Laser and Skin Surgery Center of Northern California (Sacramento, Calif.), who performed the first CoolSculpting treatment on a human during initial clinical trials. "Our ability to transform the silhouette has increased and patient satisfaction has improved with it, as long as we are careful with patient selection. For me, the natural look of the result is astounding, without the laxity and lumpiness often associated with liposuction."

The quest to sculpt a more pleasing shape has historically been a top aesthetic concern, and the emergence of new devices has stimulated market growth considerably. Medical Insight's current Body Shaping and Skin Tightening market study projects overall market expansion of almost 13% per year through 2016 owing to the strong acceptance of emerging technologies. This will translate into billions of dollars in treatment fees for aesthetic practitioners worldwide. "CoolSculpting is unique in the market as the only cooling technology FDA cleared for non-surgical, non-invasive long lasting fat reduction in the anterior abdomen and flanks," said Dr. Manstein. "There is significant potential for growth in this market, especially with a device of this nature, because it provides exactly what everybody is looking for: localized fat reduction that is virtually painless during treatment, but delivers potentially dramatic outcomes without surgery. It's exciting for both physicians and patients."

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Dr. Dover likens the body sculpting market to that of facial injectables as they emerged decades ago and changed the face of aesthetic medicine. "What we're doing is shaping a new market," he explained. "There is a huge pool of potential patients completely uninterested in liposuction, but definitely interested in lasting fat reduction without surgical intervention, which until recently was not possible."

**Editor's Note:** In the following clinical roundtable, six top aesthetic physicians and one physician assistant share their knowledge and clinical experience with CoolSculpting. Collectively, these individuals have dozens of years of experience in the field, including a thorough understanding of the modality being discussed.

# What has actually changed between the original CoolSculpting device and the newest iteration?

**Dr. Dover** – The device itself has not changed, the applicators have. We have the original CoolCore, which is small and curved, and we also still have the larger CoolMax. We've added CoolCurve+, which fits beautifully on and around the curves of the body, and CoolFit, which is flat and perfect for vertical fat in areas such as the abdomen. We also have the T2T protocols, which are an extension of what we called DualSculpting™, the use of two devices at the same time versus just one. We choose the proper applicators – one per device – and place them on the peaks of the fat bulge. Then we treat. Thus, with two systems we can do six treatments in three hours.

#### How does the research and data associated with CoolSculpting verify its efficacy?

**Dr. Manstein** – Beginning with our proof-of-concept porcine animal studies through today, we have a growing body of device specific literature that includes more than 20 peer-reviewed papers and abstracts that have firmly established CoolSculpting's effectiveness and safety. Time has borne out the results of our original studies that showed an average of 25% fat reduction per treated area with a single cycle. CoolSculpting is safe enough that one may theoretically undergo multiple treatments over time. As well, we have not noted any rebound effects or redistribution of adipose tissue, even with larger amounts being treated at one time. If a patient gains some weight, the general localized effect persists and remains natural looking.

**Dr. Dover** – As far as persistence goes, we're seeing what amounts to a long lasting result. Once fat is gone, it's gone. There is no reason to expect differently as time passes, which is reflected in the FDA clearance. Patient satisfaction is easily 90% to 95%.

## What do the histologies reveal?

**Dr. Manstein** – Post treatment biopsy of abdominoplasty patients shows no visible effect immediately after treatment, but within a few days we see inflammation begin to set in, and with staining we observe evidence of apoptosis. This builds over a few more weeks and then it levels off at two to three months.



Before Tx



Two months after one CoolSculpting Tx on patient's left side



Two years after one CoolSculpting Tx on patient's left side (+10 pounds)

Photos courtesy of Eric Bernstein, M.D.



Before Tx



Eight weeks after CoolSculpting Tx (—6 pounds)
Photos courtesy of Leyda E. Bowes, M.D.



Before Tx



16 weeks after CoolSculpting (no weight change)
Photos courtesy of John B. Fasano, M.D.

"CoolSculpting is so safe that most of the time patients can be left alone during the session. As well, there are no real in-office, pre or post treatment procedures to be concerned with."

**A. Jay Burns, M.D.** – The results of clinical trials continue to instill confidence in the validity of the technology. Ultrasound imaging shows clouds of dead fat cells and you can't fake that. Although CoolSculpting isn't designed to compete with liposuction, the safety profile allows us to treat aggressively and now we're achieving a much more impressive and predictable result non-invasively.

What would you say are the main points that make CoolSculpting stand out, especially since the development of the T2T protocols?

**Dr. Burns** – Plenty of companies claim to achieve non-invasive fat reduction. CoolSculpting actually delivers, and does so in a tolerable and reliable fashion. It's almost too good to be true.

**Dr. Manstein** – One contributing factor is the difference between apoptosis induced by CoolSculpting, versus heat-based methods that cause fat cell necrosis. Additionally, with CoolSculpting, we have fewer instances of fibrosis.

**Leyda E. Bowes, M.D.** – CoolSculpting is so safe that most of the time patients can be left alone during the session. I'm a full time dermatologist and mother, so when I undergo CoolSculpting it's an opportunity for much needed "me" time. As well, there are no real in-office, pre or post treatment procedures to be concerned with, such as administration (and removal) of numbing cream, which adds to treatment time. Also, there's no need for patients to wear compression garments as they would need with liposuction.

**Dr. Dover** – The fact is, most patients coming in for CoolSculpting would never consider liposuction. Statistics demonstrate that liposuction is among the most commonly performed aesthetic surgical procedures in the nation, but not when compared to the total population, for this very reason. As a non-surgical approach to body contouring, CoolSculpting offers a new paradigm that can include a much larger potential patient population.

How has T2T become a core concept contributing to the success of CoolSculpting?

**Dr. Kilmer** – Originally we saw encouraging and significant outcomes with one or two cycles. With T2T we perform more cycles in a short period of time and can do additional treatments eight weeks later to continue and improve results. The applicators help us better treat different areas effectively. The result of multiple applications provides that 'wow' factor, which we first saw with our employees, who were delighted. Now, patients are thrilled, which is a word one must be careful using in this business. Therefore, it is especially important to match patient expectations with what can be achieved realistically.

How important is expectations management in achieving patient satisfaction with CoolSculpting?

**Dr. Kilmer** – The success of any modality in aesthetic medicine does hinge on expectations management in some way; CoolSculpting is no exception. The difference is that we know what we can reliably deliver in terms of outcomes and we know it will be a virtually painless treatment. This is an ideal setup for

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satisfaction as long as we place the applicators correctly and don't oversell. There may be some discomfort afterward but it's minimal and certainly much less than one would see with heat-based modalities.

**Laura Pietrzak, PA-C** – I believe that setting the right patient expectations from the start is the most important towards overall patient satisfaction. My patients understand that results are not immediate – it can take three to four months to see the final outcome. They also know from the beginning that multiple treatments are recommended. We carefully choose before and after pictures that show realistic results in regular patients, not idealized or glamorized photos but ones that reflect what can truly be expected and accomplished.

What about the procedure itself? What steps do you take to ensure the best treatment and outcomes from CoolSculpting?

Ms. Pietrzak – The T2T concept really encapsulates my technique with CoolSculpting. In my capacity, I work with Grant Stevens, M.D., an early adopter of the technology, and am one of the first to perform T2T on a large scale in practice. I have probably performed more cycles of CoolSculpting than anyone else in the world. So I can say with authority that a complete, 360° assessment is the key to approaching the high expectations of patients. One must look at the whole body and the orientation of fatty deposits, not just as a series of bulges to be reduced. Setting expectations requires me to educate patients properly as well, explaining how much one can expect with one series of sessions versus additional applications, and how the results mature over time.

### What can patients expect as far as treatment tolerability?

**Dr. Dover** – As the applicator draws in the tissue and treatment begins, there is a squeezing sensation that some find uncomfortable at first, but just when the patient begins to wonder if it's going to be intolerable, the treatment area becomes numb and the procedure is much more comfortable. After, there may be some easily managed discomfort and tenderness, which resolves within a few days. Patients may feel numbness or tingling for a few weeks, but that also resolves quickly. Bruising is uncommon.

**Grant Stevens, M.D.** – I was the first patient in my practice. It may seem in some way uncomfortable during the first five minutes and we take care to stay with patients in the early period, but soon afterward you don't feel anything. People fall asleep. I am a pretty healthy person and I take care of myself, but after a short while my pants were practically falling off and I didn't have to make lifestyle changes. That's a powerful example for my patients.

#### In your opinion, and/or experience, is there an art to CoolSculpting?

**Ms. Pietrzak** – When it comes to CoolSculpting, it very much is an art – technique matters. As a community, we're used to looking at the problem as generalized debulking instead of sculpting. Now, with the many different applicators available and the ability to perform multiple treatments in a single session, we



Before Tx



Eight weeks after first CoolSculpting Tx



Nine weeks after second CoolSculpting Tx (no weight change)
Photos courtesy of Edward Becker, M.D.



Before Tx



Four weeks after second CoolSculpting Tx (no weight change) Photos courtesy of Kathleen Welsh, M.D.



Before Tx



Two months after CoolSculpting Tx (no weight change)
Photos courtesy of Kathleen Welsh, M.D.

"Our data shows that two-thirds of our CoolSculpting patients over the first three years were new to the practice. Of those, two-thirds had no previous experience with aesthetic medicine and close to half remained in the practice and underwent other treatments we offer."

can approach the problem differently and allow for more individualized sculpting. This means a customized treatment plan and result for every body. We have patients return eight weeks after their session, reassess the results of each series of applications, and modify the treatment plan accordingly until the transformation has taken place. Then it's up to the patient to maintain their result with a healthy lifestyle. The art is in how we modify the plan between sessions to maximize debulking as well as customized shaping.

**Dr. Kilmer** – Patient assessment is much easier than it used to be in that we can treat larger patients than we would have tried in the past, thanks to T2T. Multiple cycles and additional sessions over time can visibly recontour the subset of patients in whom single cycles would show little observable effect. In fact, with small areas it is important that there be enough fat to pinch into the applicator or treatment won't work, and for larger areas it's performing enough cycles in the right places to get that 'wow' effect.

# How important is patient selection with CoolSculpting?

**Dr. Burns** – We can treat larger patients than we would have in the past now that we have T2T, but there are specific populations we should not treat. Patients with thick, doughy fat tend to be poor candidates. Patients or body regions with more fibrous adipose tissue don't respond well. Also, visceral fat can't be treated so the standard 'beer belly' patient isn't a good fit for CoolSculpting.

#### How does CoolSculpting impact the practice?

**Dr. Stevens** – The results alone make a compelling case for the adoption of CoolSculpting, but on the business side our data shows that two-thirds of our CoolSculpting patients over the first three years were new to the practice. Of those, two-thirds had no previous experience with aesthetic medicine and close to half remained in the practice and underwent other treatments we offer. So there is the initial infusion of revenue, and a secondary infusion from those who return and pursue additional treatments beyond CoolSculpting.

Furthermore, they send their friends – most notably, men. Our practice echoes the national breakdown of aesthetic patients by gender, about 87% to 13% women to men, respectively, but in 2012, 42% of our CoolSculpting patients were male. Once we break the ice with this traditionally reserved population, men return to enjoy other treatments they would have otherwise been unlikely to consider. As to our growth, we've purchased additional devices each year and we've grown about 300% annually over the last three years. We're on track to double again in 2013.

**Dr. Bowes** – I had originally trained to do liposuction as a dermatologist, but I found it impractical because as I grew my practice there just didn't seem to be room for it. CoolSculpting allowed me to enter the body contouring arena without taking too much time and energy away from things I was succeeding with, and it has become my number one revenue generator. If you consider all the income produced, including complementary and/or other treatments (aesthetic and

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medical) that CoolSculpting patients undergo, this may be responsible for 50% of my income right now.

**Ms. Pietrzak** – In our practice, we can have up to four devices in one room, so I can perform up to four applications in a single hour. That's a lot of revenue per hour for something requiring minimal supervision that is operator-independent. In the beginning, a patient received an average of 2.8 cycles per visit, now we're up to 5.2.

<u>In light of the current industry trends and climate, why is it a good time to offer CoolSculpting treatments?</u>

**Dr. Stevens** – People want body contouring without discomfort, risk or anesthesia, without needing to miss work or play time, and they want results. CoolSculpting provides all of these, and with T2T we can, over a period of months of performing numerous cycles, achieve results very similar to those seen with liposuction, without the hassles. The cost is about the same when you consider liposuction versus several months of regular CoolSculpting sessions, but the outcomes are more natural looking and were achieved non-invasively with minimal discomfort or inconvenience. The truth is, the number of people who want body sculpting far outweighs the amount of people actually willing to undergo liposuction and pay the big cost up front along with lost income due to downtime; endure the procedure and downtime; or accept the risk that goes with any invasive surgery. The cost of CoolSculpting is spread out over time, you don't lose income, treatment is extremely tolerable and there is no downtime.

**Dr. Bowes** – Also, ZELTIQ makes it attractive to buy additional devices by reducing the price after you purchase your first one. So not only does the price go down, you've already established a patient base from which to build, so growth can be rapid as your marketing efforts and word-of-mouth take hold. We had a very positive experience using a single machine originally; we did treatments ourselves and achieved nice results. After about 18 months we obtained a second device, did some internal and external marketing, and things skyrocketed. Now we have six devices, with three RNs specializing in CoolSculpting in addition to myself. It is so safe and simple to use that it can be easily delegated. Once you've placed the applicators and started the first few minutes of treatment, you can leave patients virtually unattended.

Our CoolSculpting patients often undergo complementary treatments, such as injectables, during the treatment or on the same day. We structure other promotional packages together with CoolSculpting, saving patients both time and money.

Can you share any tips for maximizing the patient experience?

**Ms. Pietrzak** – We maximize the patient experience by treating each patient like a VIP. We have a concierge who spends eight to ten minutes on the phone with new patients to help avoid phone wait times. We also have a person dedicated to handling CoolSculpting patients, to address their questions ahead of time and help them feel comfortable.



Before Tx



One year after first CoolSculpting Tx



Two years after second CoolSculpting Tx (no weight change)
Photos courtesy of Grant Stevens, M.D.

"I see continued growth as more and more physicians adopt this technology. Also, new applicators and protocols will likely be developed to further expand the utility of CoolSculpting."

The consultative assessment is thorough and makes them feel confident that I am aware of and working toward their goals as well. Through proper patient selection, setting realistic expectations and determining individualized treatment plans, we can maximize the entire experience. We also offer concurrent procedures such as neuromodulators or dermal fillers to help maximize a patient's valuable time.

**Dr. Bowes** – The comfort of CoolSculpting allows patients to relax, and we promote this by offering a television and movies, as well as WiFi in all rooms. We pamper them with robes, slippers and remote wireless headphones. We offer refreshments and some eat lunch or dinner as they may be staying for a few hours. While we want to convey that it is a medical procedure, pampering is an excellent and relatively inexpensive way to add value for patients, who may return for numerous sessions on their way to transformation, and will hopefully refer their friends.

**Dr. Dover** – While it is important to note that CoolSculpting – and any other aesthetic body contouring modality for that matter – should not be viewed as a weight loss treatment, the dramatic results tend to motivate patients to move toward a healthier lifestyle. We offer nutritional counseling to help patients harness this motivation.

#### What do you expect for the future of CoolSculpting?

**Dr. Burns** – I see continued growth as more and more physicians adopt this technology. Also, new applicators and protocols will likely be developed to further expand the utility of CoolSculpting. There is always room for improvement but right now, it seems to have hit its stride.



Before Tx and 12 weeks after second CoolSculpting Tx (no weight change) Photos courtesy of Flor A. Mayoral, M.D.



Before Tx



Two months after one CoolSculpting Tx Photos courtesy of of Grant Stevens, M.D.