

# Skin Tightening

## –PART I– CUTERA & THERMAGE

By Mai Pham, Trends Editor



A few years ago, the promise of non-surgical skin tightening, often referred to as “non-surgical facelift,” was almost too good to be true. Thermage®, the leading innovator in this market space, was reportedly uncomfortable for the patient, expensive, and inconsistent in its ability to produce predictable, repeatable results. Things have changed in the last few years. Thermage has introduced new protocols and a larger treatment tip, reducing patient discomfort levels while increasing effectiveness and patient satisfaction. New technologies have been introduced, and new studies are showing demonstrable results. Non-ablative skin tightening is “in,” and with the media happily

touting this no-downtime procedure, patients willingly pay from \$2000-\$4000 for a chance to experience the fountain of youth’s latest offspring. For those of you interested in providing this procedure, we will review the available technologies and provide perspectives from leaders within the field in a series of articles.

### TECHNOLOGY

The theory behind skin tightening is simple: depositing heat into the dermis causes local injury, subsequent collagen denaturing, and over time, collagen deposition and remodeling. In short, we are heating up the dermis

to plump up collagen and induce new collagen formation. How the heat is produced depends on the technology we use. The available technologies are

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either radiofrequency (RF), light-based or a combination of both, and are summarized in Table 1 on the following page.

Technologies employing RF create a thermal injury in the target tissue as a function of the tissue’s resistance to current, a property called impedance. The electro-thermal properties of the tissue vary according to the frequency

**Table 1: Skin Tightening Technologies\***

Company	Device	Technology	FDA Clearance	FDA Indication
Alma Lasers™	Accent™	Bipolar RF or Unipolar RF	Pending	Pending
Alma Lasers™	Harmony™ ST	Near infrared light (780-1000nm)	Undefined**	Undefined**
Candela	GentleYag™	1064nm Nd:YAG laser	October 2003	Treatment of Wrinkles
Cutera®	Titan™	Infrared light (1100-1300nm)	October 2004	Provide topical heating for the purpose of elevating tissue temperature for temporary increase in local circulation where applied
Lumenis®	Aluma™	Bipolar RF with suction	October 2005	Non-invasive treatment of wrinkles and rhytids
Palomar	LuxLR Fractional™	Infrared light (825-1350 nm)	June 2005	Provide topical heating for the purpose of elevating tissue temperature for temporary increase in local circulation where applied
Syneron™	Polaris WR	Bipolar RF and 900nm diode laser	December 2003	Non-invasive Wrinkle Treatment
Thermage®	Thermacool™	Monopolar RF	November 2002	Non-invasive treatment of wrinkles and rhytids

\* FDA indications and dates were compiled from review of actual FDA 501k pre-market notifications obtained from the FDA website.

\*\* The disposition of this unit was unclear from the FDA 501k document obtained at the FDA website. Clarification was requested from the company but was not available at time of press. Further information will be disclosed in a future article.

of the current, the tissue type, and tissue temperature. Dry skin is more resistant to current than wet skin, and hot tissue is more conductive than cold tissue. A monopolar system such as Thermacool™ system by Thermage uses a single electrode with a grounding plate placed at a distance from the electrode. Energy is most concentrated at or near the tip of the electrode, decreasing with distance from the electrode. The Thermacool system can penetrate below the dermis into the subcutaneous fatty layer of tissue. A bipolar RF system

target chromophore. Cutera's Titan™ has a spectral range which targets water to produce bulk heating in the dermis at a depth of 1-3mm.<sup>ii</sup> Other technologies similarly use light to produce heat in the dermis.

## THERMAGE

In 2002, Thermage introduced a ground-breaking technology to the aesthetic market: non-invasive, non-ablative skin tightening using their radiofrequency technology. To date, more than 190,000 patients have been treated with

Thermage; and approximately 2,000 dermatologists, plastic

surgeons, and other cosmetic physicians are using the Thermage procedure worldwide. Thermage is the most widely studied skin tightening technology, with more than 20 clinical studies published in peer reviewed journals, and an equal number of

professional presentations at the ASLMS. It is the first FDA-cleared technology indicated for treating wrinkles and rhytids. It is by far the gold standard within this market.

The road to success has been somewhat difficult for Thermage. When the technology was first introduced, treatment protocols calling for high energy and a single pass were associated with much more discomfort, complications such as facial dimpling from fat loss, inconsistent patient satisfaction, and inconsistent results.

### HISTORY

Thermage has done much to overcome this history. To its credit, "Thermage is the only company in this space that actively monitors the side effect profile," according to Brian D. Zelickson, M.D., Associate Adjunct Professor of Dermatology at the University of Minnesota, and Director, Cosmetic Care Center. To ease patient discomfort levels and increase treatment consistency, they introduced a treatment tip three times the size of

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has two electrodes at a fixed distance which are applied to the treatment area. Energy passes between the two electrodes and is limited to the area between the electrodes.<sup>i</sup>

Light-based technologies rely on the selective absorption of light by a



Before (left) and After (right) Thermage face treatments. Results show reduction of fine lines and wrinkles, significant decrease in marionette lines, tightening of the jowls, and overall smoothing and tightening. Treatment and photos courtesy Flor Mayoral, M.D.

the old tip (3.0cm vs. 1.0cm) and a modified treatment protocol employing low energy, multiple passes, and visual observation of skin tightening. This modified protocol is currently being used to yield consistent, predictable results.

At this year's annual ASLMS meeting, summary results from a consensus survey of 14 cosmetic procedure specialists treating 5,700 patients showed an extremely high rate of efficacy. Presented by Jeffrey S. Dover, M.D., Associate Professor of Dermatology at Yale School of Medicine and Director of SkinCare Physicians of Chestnut Hill, the results showed that at 6 months post-treatment, 92% of the patients treated with the new protocols achieved



Brian D. Zelickson, M.D.



Jeffrey S. Dover, M.D.

visible tightening. The consensus also showed a significant decrease in the incidence of complications, with less than 0.02% occurrence of surface irregularities since introduction of the new treatment guidelines.<sup>iii</sup>

Positive PR on programs such as Oprah and E! Red Carpet have also helped to create new buzz around the brand as well as increased consumer demand. Earlier this year, Thermage launched a new campaign called Body by Thermage™ after receiving FDA clearance to market its procedure for off-face indications such as the abdomen, arms, and legs. In addition, they just launched Thermage Patient Builder, an online resource allowing



physicians to customize marketing materials to their practice (i.e. complete with their own practice logos and customizable marketing photos).

The success of Thermage has created a niche in the aesthetic market space for skin tightening, with other companies quick to follow. Syneron, one of Thermage's early rivals, was embroiled in a patent infringement suit with Thermage which ultimately ended in settlement. In June 2005, Thermage and Syneron granted each other a non-exclusive paid-up license under their patents in suit and related patents. In addition, Syneron paid Thermage a one-time undisclosed sum.

#### WHAT THE EXPERTS SAY

Valerie T. Stevens, M.D., Director of the Hypatia Aesthetic and Laser Clinic in Woodinville, Washington, is tremendously successful with the Thermage procedure. She now has three Thermacool units in her office, and has performed more than 4,000 procedures to date. "Treatment consistency is dependent on two main factors: patient selection and proper application of the procedure," says Stevens. Dr. Stevens employs a treatment algorithm of 600 pulses on the full face and neck using the 3.0cm tip. She performs 2 standard passes, then spends time selectively shaping and contouring the face by applying pulses to specific areas or vectors. Average treatment time is 1-2 hours, depending on the treatment area. In her experience, the ideal patient is someone in his/her 40s or 50s who does not have an extreme amount of

Product Highlights

# THERMAGE

**PROS**

- Pioneer in the field of skin tightening
- FDA cleared specifically for wrinkles and rhytids
- Only technology which is scientifically proven to heat the fibrous septae
- Backed by the most scientific evidence
- Largest provider base and number of treatments
- Generally requires a single treatment, which can be more profitable than other technologies requiring multiple treatment sessions

**CONS**

- "Per procedure" cost of disposables is high
- Some negative history to overcome surrounding side effect profile and discomfort levels

**PRICE**

- List Price: \$35-40k for the Thermacool base unit based on options
- Disposable tips range from \$99.00 to \$459.00

For Information, please visit:  
[www.thermage.com](http://www.thermage.com)



Before (left) and After (right) Thermage abdomen treatments. Results show improvement in skin texture, reduction of wrinkles, tightening of umbilicus, and overall smoothing and tightening. Treatment and photos courtesy Dennis Hammond, M.D.

loose skin, is at or near ideal body weight, and does not have a lot of sun damage, while patients with weather-beaten, cross-hatch, or criss-cross static wrinkles will not respond to any level of Thermage.

Noteworthy is Dr. Steven's experience with Thermage on the body. Body by Thermage currently represents 50% of her skin tightening caseload. She will be sharing her body protocols, many of which have been adopted by Thermage, in upcoming workshops throughout the U.S. Dr. Steven's advice for readers interested in skin tightening: "Get a Thermage. Don't be fooled by wanna be's. Go to a conference to get adequate training and do not delegate to improperly



Michael S. Kaminer, M.D.

trained personnel."

The doctors at SkinCare Physicians of Chestnut Hill have had the Thermacool unit in their office since it was first developed in 2000. I

interviewed Dr. Dover and one of his partners, Michael S. Kaminer, M.D., Assistant Clinical Professor of Dermatology at Yale School of Medicine. Dr. Kaminer performed the second Thermage procedure in the world prior to FDA clearance. Both doctors

remarked on dramatic improvements in Thermage since the early days. "We can now predict the outcome of the procedure based on immediate skin tightening during treatment on the first half of the face. Using low energy, multiple passes, and an endpoint of



Before (left) and After (right) Thermage arm treatments. Results show significant reduction in loose skin and wrinkles, smoother skin texture and tone, and reduction of crepiness. Treatment and photos courtesy Martin Safko, M.D.

visible tightening, Thermage is effective in 92% of cases," says Dr. Dover. Furthermore, "Within the last 15 months, there have been no reported side effects anywhere. Depressions in the skin associated with high doses of energy per pulse have been 100% eliminated. The side effect profile has dropped to zero," says Dr. Kaminer.

While efficacy is increasing, pain is decreasing. Consensus data from Dr. Dover's presentation, referenced earlier in this article, show that complaints of patient discomfort have decreased to 5%. "We are no longer pushing the envelope of pain. On a pain scale of 0-4, the treatment is generally done at a "2," with the patient reporting that they feel warmth and a little pinching," says Dr. Kaminer. Both doctors stress the importance of patient selection. "The best patient is intelligent and nice, understands the risks and benefits, has reasonable expectations, and *doesn't expect the results of a facelift*," says Dr. Dover. When asked about other skin tightening technologies, Dr. Kaminer, who is on the editorial board of several peer-reviewed journals, says that there is very little real data. "We are beginning to see some papers coming through, but it is hard to say what these technologies do without some real scientific evidence." His advice to our readers is this: "Do you have patients who would be interested in skin tightening? If so, the choices are limited. Thermage is backed by scientific evidence. When evaluating the technologies, ask yourself: If I gave this to them for free, would they do it? If the answer is yes, then it is just a matter of what to charge."

## CUTERA

Cutera's Titan™ is Thermage's closest rival in the skin tightening space. Instead of radiofrequency, the Titan uses light energy in the 1100 to 1800nm range to target intracellular water, which creates a bulk heating effect in the dermis. The differences do not end with the technology. Titan is reportedly less painful than the Thermage procedure and is usually done in a series of 2-3 treatments. The actual procedure is significantly different than Thermage. During the Thermage procedure, an ink grid is laid onto the patient's face and cryogen spray cools the epidermis, while a coupling gel and disposable tip provide volumetric heating of the dermis and subcutaneous tissue. The Titan procedure is similar to other light-based procedures, where colorless gel is applied to the face and a sapphire cooling tip cools the epidermis during each pulse. The

Titan can be purchased as a stand-alone unit or purchased as an add-on to Cutera's XEO platform, where it can be used in combination with IPL or laser therapies for full facial rejuvenation. It is interesting to note that when asked about the number of installations in the U.S., Cutera informed me that the Titan systems are used throughout the U.S. and the world, but did not provide specific data. FDA clearance for skin tightening and/or wrinkles and rhytids is still pending. Currently, the Titan is FDA cleared for topical heating (see Table 1 on previous page).

Cutera has been amazingly successful at creating interest in the Titan with PR which gets straight to the consumer. Titan has been featured in more than 12 women's magazines, including *New Beauty*, *Harper's Bazaar*, *InStyle*, and *Marie Claire*. They have also been featured on popular TV shows such as *The View*, *Access Hollywood*, *Good Morning America*, and *Extreme Makeover*.



### WHAT THE EXPERTS SAY

Javier Ruiz-Esparza, M.D., Associate Clinical Professor of Medicine /Dermatology at University of California, San Diego, developed a procedure called Thermalift™ using Thermage's Thermacool unit, and is one of the first people in the world to use the Thermacool device for cosmetic purposes. Dr. Ruiz-Esparza has had the



Javier Ruiz-Esparza, M.D.

Titan in his office 18 months and loves the device. He has consulted for Cutera to develop protocols for tightening of the face and neck, and is currently an avid speaker on the Titan device. "The key to consistency is doing it right. Follow appropriate

and paid approximately \$80,000 for the stand-alone unit about a year ago. She has had incredible results with the

Titan and is happy with the choice she made. Her sentiments echoed Dr. Ruiz-Esparza regarding the importance of technique. "I spend considerable time consulting with every patient to create a custom facial treatment map," she says. Her protocol consists of a single pass over the

entire treatment area followed by later passes tailored to get the most pull per pulse. "The pulses must be placed precisely next to each other along the vector where you can get the most pull." She recently completed a study of 19 patients where all patients saw

improvement after a single session. The paper has been submitted for publication and is awaiting acceptance at this time.

Amy Forman

Taub, M.D., Medical Director, Advanced Dermatology, SKINQRI and Skinfo, and Clinical Instructor, Northwestern University Dept. of Dermatology, has four different skin tightening technologies in her office:

Thermage, Titan, Polaris WR, and Alma Lasers' Accent. She has found a niche for each product line in her office. She charges the same amount for a single Thermage procedure as she does for 2 Titan procedures. "We position the devices differently



Lisa S. Bunin, M.D.

technique." He says that he performs every single procedure himself, and achieves a consistency of about 95%. "I like the Titan because I can do the procedure painlessly, and it is a lot less expensive to operate than the Thermage. Halfway through the procedure, I will stop and show the patients half of their face so they can see the difference for themselves."

Lisa S. Bunin, M.D., an Oculoplastic Surgeon in Allentown, PA, says she found the Titan by herself

*"I've found that the Titan is better for thinner skin with more skin laxity, less subcutaneous laxity, whereas the Thermage is better for people with significant jowling, thicker skin and sebaceous glands, like men."*

— Amy Forman Taub, M.D.

### Product Highlights

## TITAN

### PROS

- Can be used in combination therapy with the Cutera Xeo platform for full facial rejuvenation
- Less painful than radiofrequency (Thermage)
- Lower relative cost of disposables
- No reported side effects

### CONS

- Pending FDA cleared for skin tightening
- Limited scientific data
- Requires more than one session

### PRICE

- Titan: base unit price = \$85,000
- Titan: as an add-on to the XEO = \$40K – \$43,500 depending on the handpiece (Titan S, Titan V or Titan XL)

For Information, please visit:  
[www.cutera.com](http://www.cutera.com)



Female patient lower face and neck Before (left) and After (right) 2 treatments with Titan – 1 month apart and 3 months post. Treatment #1 - 35-36 J, 235 pulses. Treatment #2 - 34 J, 243 pulses. 5 passes for both treatments. Treatment and photos courtesy Amy Forman Taub, M.D.

without pitting them against each other," she says. "I've found that the Titan is better for thinner skin with more skin laxity, less subcutaneous laxity, whereas the Thermage is better for people with significant jowling, thicker skin and sebaceous glands, like men." Dr. Taub already owned the Thermage when she acquired the Titan. "The Titan is a patient pleaser. We did some informal split face procedures in the office comparing the Titan and Thermage and found the Titan to be slightly less painful." She reports good results with both devices for tightening of the arms, abs, and legs. The life of the Titan handpiece must be factored into the cost of operating the Titan, since it is only good for about 10,000 shots.



Amy Forman Taub, M.D.

"Titan's disposable cost works out to be about \$70 per procedure, which is significantly less than the disposable cost for Thermage. For a 30-day period, we keep about \$10,000 in inventory of Thermage tips." Ironically, because she charges the same for both procedures, the Thermage procedure is slightly more profitable because it is limited to one session. As with the Thermage, "There are 10% of patients who do not respond." To get the best possible results, Dr. Taub gives the following advice to our readers: "You have to know and understand the 3-dimensional aesthetics of the face, learn how to manipulate tissue laxity vectors and do not use a cookbook approach." **TATI**

**Disclaimer:**

*The opinions expressed in this article are based on the author's independent research. This author has no financial interest and has not received any form of compensation from the companies mentioned in this article.*

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