



Trends-in-Medicine

April 2006

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SUMMARY

Competition has increased, but individual doctors still reported an increase in laser procedure volume, particularly for hair removal. ♦ List prices are holding fairly steady, but some behind-the-scenes deals are being cut. ♦ The various IPLs are not well differentiated. ♦ Reliant's Fraxel, Candela's GentleLase, and Rhytec's Portrait PSR³ appeared hottest, but interest is growing in endovenous ablation. ♦ There is little interest yet in cellulite treatments, such as Syneron's VelaSmooth. ♦ Home lasers are viewed as a potential adjunct profit center, not a competitive threat.

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Trends-in-Medicine

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AMERICAN SOCIETY FOR LASER MEDICINE AND SURGERY (ASLMS)

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There appeared to be a large number of doctors looking to buy at the 2006 ASLMS meeting, and each had a long and varied wish list, but many found the choices confusing and were having trouble differentiating among the various lasers. Forty-four doctors plus numerous industry officials were interviewed at the 2006 ASLMS meeting about trends in procedure volume, new products, pricing, and general business trends. Overall, procedure volume is up an average of 13% year-to-year, despite increasing competition. No products struck conference attendees as particularly exciting although interest in Reliant's Fraxel laser is increasing.

One of the challenges facing the field is the need for more randomized clinical trials. ASLMS President Dr. Roy Geronemus of New York said, "We need to have more objective evidence-based studies to demonstrate efficacy rather than anecdotal reports, particularly as there seems to be greater demand for what we are doing and an influx of vendors into the space. For the benefit of consumers and the specialty, we need to deal more with evidence-based medicine." Areas Dr. Geronemus would like to see investigated include:

- **Vascular birthmarks.** There have been advances, but there is still no cure for port wine stains.
- **Hemangiomas.** Dr. Geronemus said, "We do well with hemangiomas, but we need to do better with deeper hemangiomas, lymphangiomas, etc."
- **Pigmented lesions.** About 16% of Americans have tattoos. Current lasers can sometimes, but not always, remove them completely. Dr. Geronemus would like researchers to think about alternative ways to remove them, adding, "We can get rid of age spots on skin, and certain birthmarks, but not congenital nevi."
- **People with skin of color.** Dr. Geronemus said, "We do well, but it is riskier and sometimes we have to sacrifice efficacy because of the competition of the melanin and the laser light source itself."

To encourage independent research – studies without industry support – ASLMS is raising money to help fund that research. A silent auction at the meeting raised more than \$225,000, and that is just the beginning.

Another issue facing the specialty is training and credentialing. Dr. Geronemus said, "We want to be sure people entering the field are appropriately trained and credentialed. We need to have facility standards, standards for training, and ongoing quality control...It is much too easy on a national level for people to enter

the field without any training or credentials. These devices are very safe in *trained* hands.”

Avoiding complications and ensuring efficacy also was a topic of discussion. Doctors were urged to choose the right tool for the right patient. Dr. Rox Anderson of Massachusetts General Hospital and Harvard Medical School said, “We all cook our patients...It is important to be a gourmet chef. If you want to cook your patients well, you have to have more than one pot and pan...Don’t use phony (devices) until they are proven otherwise. (If you use things) like flashing LEDs, most cosmeceuticals, facials, and superficial microdermabrasion, cellulite vibrators, and suckers, at least play the game safely and know that you’re a faker.”

PROCEDURE VOLUME up despite increasing competition

Procedure volume is up an average of 13% year-to-year for these doctors, with the momentum expected to continue for at least the next six months.

- *New York dermatologist*: “My hair removal business is expanding, and I’m looking for something with speed and efficiency. I’d also like something to do tightening.”
- *Nebraska family doctor*: “I’m just starting in the business. There is a lot of competition, that’s for sure, but my business is slowing growing.”
- *Massachusetts dermatologist*: “Business is up 20%-25% this year. Laser volume is definitely increasing, especially for resurfacing and Fraxel.”
- *Florida dermatologist*: “I’m relatively new to this, coming from emergency medicine. I just started about three months ago, so I’m flat, but I expect to grow.”
- *California mesotherapist and surgeon*: “20% of my practice is hair rejuvenation and, yes, business is increasing.”
- *Georgia family doctor*: “I do laser procedures two half days a week and that is growing 25%. In the summer it stops because I can’t talk people out of tanning. Hair removal is growing and I’m starting to do vascular work and tattoo removal. As far as the machines go, all I have to do is prove to my practice that I can pay for them.”
- *North Carolina family doctor*: “Business has been growing, especially since I started advertising.”
- *North Carolina*: “Our hair removal business is growing 10%-30% a year, but we haven’t jumped in to skin tightening. That is an expensive leap for results that look questionable.”
- *Industry source #1*: “Ophthalmology is getting cold, cold, cold, but aesthetics is hot, hot, hot...The biggest challenge for (aesthetic) companies now is competition.”

- *Industry source #2*: “One of the ways industry is encouraging doctors to buy new lasers is by creating orphan lasers – stopping their support of existing lasers that work fine.”

The field is increasingly competitive, but doctors said it is still extremely lucrative for physicians entering the field as demand for procedures such as hair removal and facial rejuvenation increase, and as the general population ages.

- *California dermatologist/surgeon*: “Oh, yes, it’s very profitable. People don’t want to get surgery as much any more because it is so obvious. The trend is certainly toward non-ablative and minimally invasive techniques and procedures.”
- *Florida dermatologist*: “Definitely, it’s profitable although we’ve just started, and there is a lot of competition. I used to be in emergency surgery before I went into aesthetics. Of course, it will take a while.”
- *North Carolina family doctor*: “It’s very lucrative. I find a great demand for these procedures, especially since I started advertising.”
- *New Jersey family doctor*: “I was worried about getting into aesthetics, but I think it was worth it. I see so many others like me getting into it.”
- *Ohio family doctor*: “It definitely is very profitable although the number of my competitors is increasing.”
- *Ohio physician assistant*: “It takes more ramp time than the manufacturers say. Our practice is seven years old, so we expected it to take time to ramp, to raise public awareness. There is a learning curve to be time- and cost-effective.”
- *Georgia family doctor*: “Tattoo removal is going to explode. All the little girls getting their tattoos are going to find that they can’t get the jobs they want, and the removal business is going to be huge. I use the Q-switch for that, and they’re now coming out with the picosecond, and when those are available I’ll get one.”
- *MediSpa owner*: “We aren’t finding lasers as profitable as we expected. It takes work to create the business.”

LASER PRICING competitive and deals being made but not declining

Doctors offered mixed opinions on laser pricing trends. Mostly, they believe list prices are stable but deals are being made behind the scenes.

- *Maryland*: “Pricing has been stable for the last 12 months, even though there is a lot of price competition. Devices that work well and are safe and established are holding steady on prices, but new devices that are unproven will undercut.”

- *New York:* “There is more competition in hair removal, so pricing is down. IPL (intense pulsed light) pricing is also coming down. There is probably more downward pressure.”
 - *Ohio family doctor:* “Prices seem to be going down because there’s a lot of competition. I’ve been shopping around and some companies are offering 25% discounts – just a few companies, like Lumenis and Palomar.”
 - *Florida dermatologist:* “No – prices aren’t going down. I’m in the market, and one alternative for me is barely used equipment.”
 - *Pennsylvania family doctor:* “I’m not exactly sure, but increasing competition will drive prices down.”
 - *California dermatologist/surgeon:* “When I started out, lasers cost more, and now prices aren’t as high. There are also vendors of used lasers, which can be very useful.”
 - *New Jersey dermatologist:* “Prices have come down 10%-15% in four years. Today I can buy two of what I could buy one for four years ago.”
 - *Georgia family doctor:* “Prices aren’t going down. PRS (plastic and reconstructive surgery) machines are \$60,000 this year, and they were \$50,000 last year.”
 - *Industry source #1:* “Laser prices are going down behind the scenes. Companies are selling the same lasers this year as last year, so they are doing more discounts and deals are being cut, and I think that will continue for the next year.”
 - *Industry source #2:* “Pricing actually is going up, but not a lot. Customers don’t blink an eye at it, and they are raising their prices.”
- “There are no stand-out devices. Nothing is earth shatteringly new at this meeting.”
 - “There aren’t really any big differences among the (IPL) lasers.”
 - “They are all a little different with little tweaks. My view is a laser needs to be around a couple of years before I trust it. For hair removal I have 2 Lumenis lasers and a Cutera YAG, which I use mostly because it also has IPL, so it is multipurpose, and it can do veins.”
 - “Not enough is known yet about the Alma ST...It has a little shorter infrared device, with a very large spot size. They’re just getting going on a clinical trial.. Anecdotally, yes, you can get some very nice responses. It will probably be a viable device, but we don’t have enough actual data to say more.”
 - “There is a two-site clinical study with 46 subjects (underway with Lumenis’ Aluma)...They found that the majority of patients – >90% – were ‘satisfied’ with the treatments, where 17%-36% were ‘very satisfied’ to ‘extremely satisfied.’”
 - “For (mild-to-moderate) photodamage on the neck, hands, and arms, by far my No. 1 choice is the Fraxel. It is the only device with which you can treat aggressively off the face and get predictable results...You can use CO₂, erbium, and Rhytec, but I find I get my most predictable results – and with less downtime – using Fraxel. If there is moderate-to-severe damage, then I get the most predictable results with the least downtime with the Rhytec. If they have severe or advanced damage, then my choice is the CO₂ and erbium combined...However, I will usually mix and match, and I commonly use all three devices on the same patient. I may use Rhytec on the cheek, Fraxel on the neck and chest, and CO₂ periorbital. I try to use each when trying to get the best benefit. For acne scarring my No. 1 choice is the Fraxel. For patients who have ice pick scars or dilated pores, you can’t predict the response precisely, but a higher percentage of patients get a better result with Fraxel than any other device, and with melasma a higher percentage of patients get a higher rate of response than with other devices.”

WHAT DOCTORS ARE USING

Many doctors attributed the increase in their procedure volume to growing demand for hair removal procedures and, to a lesser degree, facial surfacing, toning, and texture. Most have multiple lasers in their practice; one doctor has 26 different lasers, and another has 35 lasers! The most popular for hair removal is Candela’s GentleYAG, and Thermage has the lead in skin tightening, but a variety of other lasers are used.

Among the comments on laser choices were:

- “I’m really impressed with the newest version of the Candela VBeam.”
- “Palomar and Lumenis are the big guys with the best quality.”
- The Cynosure laser was described as faster, with a smaller foci of injury, limited damage, less risk of epidermal injury, fewer passes, and less pain.
- “Lumenis is top of the line.”

At one session, panel members were asked what two devices they would take with them to a desert island. Some of their answers were:

- “I’d probably bring it down to two: for photodamaged patients, my Fraxel and a pulsed IPL...I wouldn’t buy another system just for collagen remodeling. We all (on the panel) studied these things alone and in combination – we all can afford to do that – and I have all the systems in my practice. I always use the one that works the best, and at the present time I like the (Candela) Smoothbeam, but if I need dermal change I’ll use Fraxel. None of these things are taken in isolation. If you have a 1064 and want to use it for photo rejuvenation, it’s okay, but to buy it alone is kind of silly.”

Key Products Doctors Were Discussing and Examining

Company	Device	Type	FDA approval	Comments
Alma	Accent	Bipolar RF (Handpieces emit in the 800-1000 nm range)	Pending for cellulite	Limited, short-term experience. Preliminary studies suggest it can produce clinically significant tightening.
Biolitec	Ceralas D15	810 nm diode laser	Skin lesions; soft tissue, fat, and muscle treatment, and dermabrasion	---
Candela	Ellipse	IPL	Skin rejuvenation of vascular and pigmented lesions	---
Candela	GentleLase	755 nm alexandrite laser	Hair removal, some pigmented lesions, leg veins and wrinkles	---
Candela	VBeam	595 nm pulsed dye laser (yellow)	Spider veins, sunspots, skin rejuvenation, facial veins and redness, rosacea, pigmented lesions, scars, hemangiomas, and warts	---
Candela	Smoothbeam	Diode laser	Acne, sebaceous hyperplasia, scars, and wrinkles	----
CoolTouch	CTEV	1320 nm laser	Varicose veins	---
Cutera	Solera Titan	Infrared light. Majority of the energy in the 1100-1300 nm range	Topical heating to elevate tissue temperature for a temporary increase in local circulation where applied	Pulse cycle averages ~6 seconds but is longer at higher fluences, limiting the number of pulses during a treatment session. No good multicenter trials. 4 passes in several treatment sessions 4-6 weeks apart
Cutera	Opus	IPL	Photorejuvenation and hair removal	---
Cynosure	Cynergy	595 nm pulse dye laser	Vascular and pigmented lesions: freckles, scars, birthmarks, spider veins, port wine stains, rosacea, etc.	---
Cynosure	Affirm	1440 nm IPL	Skin rejuvenation: wrinkles, skin texture, and discoloration	---
Diomed	EVLT	810 nm laser	Varicose veins	---
Light BioScience	GentleWaves	590 nm narrow band laser (yellow) LED	Freckles, eye wrinkles, periorbital rhytids	---
Lumenis	Aluma	RF and vacuum suction (4-28 Hg), using a modality called FACES	Fine lines and wrinkles	High patient satisfaction on upper and lower face with modest skin tightening observed.
Lumenis	LightSheer	800 nm diode laser	Hair removal	---
Lumenis	Lumenis One	IPL	Photorejuvenation and treating vascular and pigmented lesions	---
Palomar Medical Technologies	StarLux	1540 nm laser broadband IPL	Pigmented and vascular lesions, hair removal, etc.	---
Reliant	Fraxel	1550 nm laser	Wrinkles around the eye, age spots, sun spots, acne, and scars	No cooling
Rhytec	Portrait PSR ³	Plasma technology	Facial rhytids, superficial skin lesions, and actinic keratoses	---
Sciton	Contour	Er:YAG	Wrinkle reduction	---
Sciton	Image	Nd:YAG	Hair reduction, hair removal, vascular lesions	---
Syneron Medical	Aurora	RF + broad spectrum light	Skin resurfacing	---
Syneron Medical	Polaris	Bipolar RF + 900 nm diode laser	Wrinkles, leg veins, and vascular lesions	No studies proving the light/ RF combination is synergistic clinically.
Syneron Medical	VelaSmooth	RF + infrared light	Cellulite	---
Thermage	ThermaCool	Monopolar capacitive RF. Maximum fluence 225 J/cm ² , peak temperature 203 mm beneath the surface. Highest temperature 55-70° C	Skin tightening of periorbital region, full face, neck, and body	Cost of disposable products, cryogen, treatment grids, and coupling fluid. Bad early experiences with pain, subcutaneous fat atrophy, but shorter treatment cycle duration now makes it possible to treat large areas more efficiently.
VNUS Medical Technologies	Closure Plus	RF	Varicose veins	---

- “I haven’t been as successful with the (Cutera) 1064 nm laser as with the (Candela) Smoothbeam or (Cynosure) Affirm, where we’ve seen some major toning and remodeling.”

Hair removal

Comments included:

- “We use Candela for hair removal. We grew up with Candela. They emerged on top and kept coming up with improvements. They keep upgrading and have excellent customer service.”
- “I’m getting my first hair removal laser, and I’m getting the Palomar StarLux. It covers a good spectrum, has good fluence, and I can use it for photo discoloration. And I like the handpiece aspect...But they all work the same.”
- “There are so many lasers for hair removal, and a lot do a fairly good job. Candela’s GentleLase is very popular. I also like (Lumenis’) LightSheer. For skin tightening, Thermage has the lead, with Palomar and Cutera years behind, though their clinical studies show promise.”
- *Warning about the dangers of Q-switched lasers near the eye:* “All the hair removal lasers are devices made to destroy pigmented objects at great depth, and when you take a good look at the eye with lasers, the highest concentration of melanin is in the eye right there. All the hair removal lasers have been made to destroy melanin pigmentation of depths of a centimeter. You can get uveal tract entry, and there have been cases of anterior chamber injury due to IPLs and lasers. (With the Q-switched lasers) there are absolutely eye hazards...The highest number of laser-induced blindness is Q-switched YAG, so it is particularly an eye killer.”

Skin tightening

The various non-invasive skin tightening devices on the market fall into three categories:

- **Monopolar radiofrequency (RF)** for deep dermal tissue tightening, which is not accomplished with Nd:YAG or Er:YAG lasers. Thermage’s ThermoCool was the first out of the box.
- **RF plus laser.**
- **RF + IR.** Syneron has the only combination system currently on the market, but another is coming soon.

Skin Tightening Lasers

Device	Characteristics	Mechanism
CO ₂ and Er:YAG lasers	Ablative lasers	Superficial ablation-wound healing heating in depth
Cutera’s Xeo (Nd:YAG)	1064 nm laser	Dermal heating
Cutera’s Titan	IPL – longer wavelengths	Superficial heating
Palomar’s Polaris	Low energy bipolar RF	Superficial heating
Reliant’s Fraxel	Non-ablative laser	Microthermal zones of injury
Rhytec’s Portrait PSR ³	Plasma	---
Thermage’s ThermoCool	High energy monopolar RF	Volumetric heating

Dr. Brian Biesman of Vanderbilt University said, “The key to success, when using these technologies – thermal treatment of the upper and lower face and neck, Botox (Allergan, botulinum toxin A), Restylane (Medicis) – is that we get the best results when we combine skin rejuvenation with other minimally invasive or non-invasive treatments.”

He said unresolved issues include:

- Multiple sessions vs. single and how many?
- Treatment over fillers?
- After initial session is complete, when should additional sessions be offered?
- Who are the best and worst candidates?
- What adjunctive treatments should be offered simultaneously and can surgery be performed simultaneously, i.e. forehead, eyelids, and lower facial skin tightening?

Dr. Ken Arndt, a former ASLMS president, said, “The most common problem with tissue tightening is that it doesn’t work.” He said that he treated 10 patients with monopolar RF (Thermage’s ThermoCool) on one side of their faces to tighten skin, and he found a 4.3 mm brow elevation in the mid-pupillary brow and a 22% decrease in mean surface area in the jowls, and that may have convinced him ThermoCool works. He also think Palomar’s Polaris works, “I think it’s legitimate. There are three studies to date that show some degree of wrinkle reduction, but none has shown skin tightening, so there is still a lack of evidence.” As for Cutera’s Titan, Dr. Arndt said that there are no published data that show the Titan results in tissue tightening, adding, “It can be uncomfortable, and there is a potential for burn. If the patient backs away, the skin may be inadequately cooled.” As for the millisecond Nd:YAG, he treated seven patients on one side with 50 ms 1064 nm Nd:YAG with DCD and with monopolar RF on the other side, “The biggest complication was the difficulty in perceiving improvement.”

Dr. Robert Adrian of the Center for Laser Surgery in Washington DC expressed some skepticism about photographs of ThermoCool patients. He said, “Those pictures are taken immediately after the patient sits up, but when you follow them, there are not impressive results in many cases...People continue to market procedures to patients, bypassing unbiased physician research. I can say that, although I’ve used a tissue tightening device for more than two years, I haven’t seen a single case in which I could clearly say that I saw clearly identifiable significant clinical results...I stay away from tissue tightening because only 50% get a clearly identifiable result, and most back away from that.”

Dr. Eliot Battle of Cultura Cosmetic Medical Spa in Washington DC joined the chorus that said that tissue tightening results are not what the device companies claim. He said, “The results aren’t the results that companies are claiming, but there are some results...”

If you don't have the efficacy, boy, you'd better be safe." Of the four tissue-tightening devices available, he said that Palomar Polaris gave the most superficial, marginal results. He said that he sees some results with Cutera's Titan, but "nothing competes with CO₂ or surgery, but we're seeing results lasting months and months and months...It does work, but it's not 100% consistent. The problem is the very large handpiece with very small flat blades, and it's very hard to see if you're confluent with the patient." As for Lumenis' Aluma, he said, "It has a different approach – sucking up the skin and shooting sideways. What makes it unique is that I can do periorbital – I can treat eyelids, upper and lower."

Ablative lasers are not dead – yet

Dr. Christopher Zachary, chairman of the department of dermatology at the University of California, Irvine, insisted there continues to be a role for ablative resurfacing even in the new era of non-ablative therapies. He said, "There is still a place for your ablative laser; don't throw it out. There is also a place for your dermablator; don't throw it out. Some of the non-ablative (therapies) aren't as good as they're cracked up to be...One of the reasons some of us switched from CO₂ to Er:YAG was hypopigmentation. There was 15%-20% hypopigmentation with CO₂, and with Er:YAG there was <5% hypopigmentation. Of course, serious treatments can have serious problems. When you ablate the surface of the skin with a CO₂ laser, you're not really vaporizing the tissue. It sits there until you wipe it off, and CO₂ isn't good at vaporizing tissue after you've taken away the epidermis. With the Er:YAG lasers, particularly at the neck, we often go there with intraepidermal vaporization...If we're going to do these treatments, we have to learn how to use topical and intralesional nerve blocks...We have heard about delayed healing and problems with healing, especially with the Er:YAG, so aggressive resurfacing has its price."

Dr. Zachary said that a lot of doctors are doing micro laser peels (MLPs) using an Er:YAG laser intraepidermal peel. It has some upper dermal heat deposition, similar to plasma resurfacing. He said, "I'd use the Zimmer forced air cooling system; it's a very superficial peel – 10 microns – and it's very similar to plasma resurfacing. So don't throw away your Er:YAG laser...Don't throw away your devices. Yes, they have to go through healing for a week or two. Yes, they're out of circulation for a week, but, by Jove, it still works."

Ablative resurfacing, Dr. Zachary said, is very unforgiving, but he cited several positives: "Among its advantages is that it does have significant visual endpoints. I can tell a patient who has significant lines on the upper lip and around the eyes, that if they want to get a specific endpoint, the only way I can do that is with a CO₂ laser. I can do 70% improvement predictably with CO₂, but I can't predict that with any other technology. And CO₂ has visual endpoints during the process, where you do see if you're getting there or not. It has significant tightening advantages and ablative advantages in taking care of precise lines. I find it most useful in upper lip and the periorbital area and also for treatment of rhinophyma."

Dr. Richard Fitzpatrick, director of cosmetic dermatology at La Jolla Cosmetic Surgery Centre, said that he uses CO₂ resurfacing, Fraxel, and Rhytec in his practice. He said that ablative resurfacing is still the gold standard, but ablative techniques have several problems, including:

- Unforgiving system.
- Pain, oozing, and prolonged erythema.
- Risk of infection and scarring.
- Re-Epi- α [follicles] lead to downtime.
- Can leave an unnatural skin sheen.
- Avoid certain skin surfaces or there will be scarring.
- Pigmentary problems.

Advantages and Disadvantages of CO₂ Skin Resurfacing

Advantages	Disadvantages
Visual endpoints	Downtime (2 weeks)
Predictable results	Healing time (3 months)
More defined goals	Inherent risk: dyschromia, prolonged healing, and scarring

THE ATTENTION-GETTERS

Almost any session where different lasers were compared drew a crowd. Doctors clearly wanted to hear what the experts thought about the various products, and which they preferred. Many doctors were shopping for new machines, particularly Candela's new generation VBeam and Reliant Technologies' Fraxel laser, about which there was quite a buzz. A Midwestern dermatologist said, "We heard about the Fraxel last year. There's been success with it, and now we want it." Another source said, "We are seeing more subtle changes with newer lasers – not dramatic results."

Another continuing trend is any non-ablative, minimally invasive procedure.

- *Florida*: "Non-ablative therapies are definitely the trend. We do non-surgical procedures like spider veins, Botox, hair removal, microdermabrasion."
- *Massachusetts*: "Patients want maximum safety and very little downtime. That's the trend."
- *Ohio*: "Patients want Botox and Restylane, and now they've started to ask for Fraxel."

CANDELA'S GentleLase and GentleYAG

Doctors really liked Candela's GentleLase and GentleYAG lasers for hair removal. A New England doctor said, "We have five lasers for hair removal, but the Candela GentleLase gets 90% of the use."

RELIANT'S Fraxel

This laser created the biggest stir at the conference, and it was on many doctors' wish lists. The Fraxel is a mid-infrared laser that propels thermal energy through microscopic sites

deep in the dermis without removing the top layer of skin. Side effects are minimal – typically redness and some swelling. Patients are typically treated with 8-12 passes of 125-250 microthermal zones/cm² to give a final density of 2,000-3,000 microthermal zones/cm², which translates to ~20% of the skin's surface being treated. Patients typically have four or five sessions spaced one to three weeks apart.

The Fraxel is used for facial rejuvenation, melasma, surgical scars, hypopigmentation, mild rhytids, and acne scarring. Side effects are minimal, including redness for several days and mild-to-moderate edema. The laser is also being used off-face, including the neck, chest, arms, and hands. Doctors said the only thing that makes them hesitate is the high price – ~\$100,000.

ASLMS President Dr. Geronemus said, “(The Fraxel is) a well-tolerated treatment with mild pain. Discomfort can be eased with a topical anesthetic. It shows effective collagen shrinkage. As for short-term side effects, we see edema and erythema, and we put those patients on a short course of prednisone. We get some itching and pruritis, but no scarring and no hypopigmentation... We also use an air cooling device, using forced air cooling, and that minimizes discomfort.”

Dr. Geronemus said Fraxel is the “treatment of choice” for acne scarring: “The scars are significantly better. This is a gradual response. We do see some short-term edema, but over the long-term collagen formation occurs, and there is a longer term benefit... What we found looking at 60 acne scars was an average quantitative improvement of 50%... We haven't looked at long-term data over a large significant number of patients, but we have found in other technologies, such as the Q-switched YAG laser, that there was a long-term benefit and continued healing over time after the last treatment session. I don't know if we'll see it with Fraxel; time will tell. One of the nice things about using Fraxel was that we can treat beyond the face and do neck, arms, and hands.” In a preliminary study, with 18 of 20 female completers, the result was: “The striae aren't gone, but they are much softer and better.”

Other comments about Fraxel included:

- *Illinois*: “The Fraxel has quick effect and no downtime.”
- *Massachusetts dermatologist*: “I use a lot of Fraxel, with good results. It's great for melasma and acne. Patients are demanding very little downtime.”

Fraxel Compared to Other Techniques

Indication	Ablative	Non-Ablative	Fraxel
Dyschromia	Yes	Yes	Yes
Tone	Yes	Yes	Yes
Mild rhytids	Yes	No	Yes
Deep rhytids	Yes	No	Yes and no
Laxity	Yes	No	Yes and no
Acne scars	Yes	Yes	Yes

- *Texas*: “The Fraxel is very good, but it is also very expensive. The technology is cool.”
- *Georgia*: “I like the Fraxel laser but it costs \$100,000. I'm excited about it because it's better for face and skin.”
- *North Carolina*: “The most exciting thing here is the Fraxel laser treatment. I'm typical in that I follow something for a few years before I make a decision to get the device. Non-ablative is definitely the trend now, and Fraxel is a happy medium. There's no downtime, little pain during the procedure, and no liniments to apply.”
- *Ohio*: “Fraxel is still the big thing this year. Last year it was a buzz, and this year it's a bigger buzz. It does what it says it's going to do, but it also has a steep learning curve.”
- *California*: “You are always going to get improvement in color, texture, and fine lines. There is also nice tightening with Fraxel. It's not predictable, but you can get significant tightening with it. Even with moderate-to-severe photodamage, with Fraxel you can get a really good response. You can get the neck to match the face by using the Fraxel on the neck and chest. And it's the ice pick scars and dilated pores that do so well with Fraxel. There's an individual wound-healing response, and not everybody is going to get that, but there is a larger probability of improving acne scars with Fraxel than with any other technology.”

Two companies are working on competing products: Palomar (LuxIR, a handpiece for StarLux), and Iridex (ScanLight).

RHYTEC'S Portrait PSR³ Plasma Technology

While not on the top of physicians' wish lists, doctors were interested in the company's plasma skin resurfacing system which, compared to the Fraxel, appears to give more dramatic results. However, patients need as many as three days of post-operative healing time after treatment. Doctors also talked about the possibilities of using this device off-face, especially for the neck, chest, and hands.

The device is a non-contact plasma device that works by millisecond pulses of nitrogen plasma to create thermal damage, but leaving the epidermis intact. It uses one to four joules, with a repetition rate of 1-4 Hz. It heats up the area with an inner zone and outer zone. Dr. Suzanne Kilmer, director of the Laser & Skin Surgery Center of Northern California, said that skin regeneration is seen in a few days with ongoing reduction of elastosis and continued neocollagenesis persisting a year after treatment.

Other comments about Portrait PSR³ included:

- *Texas surgeon*: “Plasma is new to me, and it sounds like cool technology, but I need to know more about it.”
- *Georgia*: “I'm interested in the Rhytec plasma device. It's appealing because it's resurfacing without downtime

of a peel or dermabrasion, and there's no weeping or infection. There are results in seven to 12 days and the skin is soft. It's also nice on hands. It's not a laser, and so it's safer around the eyes."

- *North Carolina:* "My opinion is that it's limited. I was excited when I first saw it, but I didn't realize that a day or two later you still get sloughing and redness and up to a week of downtime, so I don't need to use it to replace my Er:YAG."
- "One of the differences between Rhytec and Fraxel is that Rhytec is a heating device, so you're heating down to 500 microns, but you're heating the entire surface of the skin, so because of that uniform heating, you're getting more significant skin tightening, so I really like the Rhytec around the eyes. You get nice improvements in crow's feet, tightening of the upper lids, and only one week of downtime. But it takes three to four months to get to this point; you don't even see it in a month, and it is because of the collagen formation...I think (using the Portrait PSR³ for perioral rhytids) it's the heating effect that does it, and the improvement around the eyes is remarkable. I don't see it with anything else. You're peeling away the epidermis, but you're heating the collagen down to 500 microns uniformly across the skin."

Dr. Kilmer said, "I've been doing the clinical trials for this plasma device, mainly in ablative mode...All this starts within a few days – new collagen formation. One of the beauties of this is that you can go from a lighter treatment to a higher level...When I do (CO₂) resurfacing, I tell patients, 'You're going to look like a tomato.' This isn't as bad. At about Day 3-5, you'll get a browned skin that starts peeling off, sloughing skin, but by Day 10 there's new skin surface...I don't think it's as good as the Fraxel for acne scars, but this is all single treatment."

Dr. Kilmer said that she evaluated the device using a second pass with a new narrow nozzle as an adjunct to the standard nozzle. Twelve patients were recruited and given a topical anesthetic. Biopsies were taken pre-treatment and at Day 90, and those results are pending. Patients were treated with a single pass with standard nozzle on full face, and the deeper rhytids were then treated with a second pass with the narrow nozzle. Ten patients completed 90 days of follow-up. Dr. Kilmer said, "The patients were pretty satisfied and there was 60% improvement on their grading. There was improvement in wrinkling, but not in deep lines. The conclusion is that multi-pass with higher energies gets much better results." She added that she usually does two to three passes per patient. She also said that she used the device at lower energies (in the 1-2 J range) off-face and on the chest. Dr. Kilmer said that it takes about 15 minutes to do a full face using the device, and it leaves the epidermis intact and with no pain. However, she said that "It does hurt when you're doing it, so we typically give a shot of (Roche's) Toradol, or valium, and numbing cream. The redness fades much more quickly and there isn't the duration nor extreme that you get with more ablative

modes, and patients are happy...I don't think it will be as effective as CO₂, but it is a nice middle ground. Portrait PSR³ is a nice middle ground; there isn't as much tightening, but it is more tolerable."

She concluded that the Rhytec device has:

- Rapid treatment paradigm.
- No vaporization or carbonization of SC/epidermis.
- Treatment-induced erythema fades quickly.
- Rapid recovery phase with majority of patients reepithelialized by Day 7.
- Bronzed skin post-treatment that acts as a natural dressing.
- Consistent patient satisfaction levels.
- Shown a trend for continuing improvement beyond 90 days.
- Mean wrinkle severity rating reduced by 19% (from 5.3 to 4.3).
- Results that are superior to TCA peel/single pass Er:YAG in terms of healing and collagen remodeling

Patient Questionnaires from the Double Pass, Narrow Nozzle Study

Measurement	Day 30	Day 90
Average Improvement Scale 0-100%	58.13% (range 15%-100%)	60% (range 35%-100%)
Average Smoothness 0=very rough, uneven 10=very smooth	5.94 (range 1.5-9)	8.11 (range 5.5-10)
Average Satisfaction 0=no satisfaction 10=total satisfaction	6.31 (range 0.5-10)	7.11 (range 3.5-10)
Patients who would recommend the therapy	70%	80%

PALOMAR MEDICAL TECHNOLOGIES' StarLux

Doctors were fairly interested in Palomar's StarLux system, which uses a "laser-in-a-box" concept, with the most interest coming from those doctors entering the market for the first time as well as family doctors. The system has one base unit to which handpieces are attached. The various color-coded laser, intense pulsed light (IPL), and infrared (IR) handpieces filter light according to the desired treatment. The newest attachments are: the LuxIR fractional IR handpiece, for skin tightening (not yet FDA-approved); the Lux1540 fractional laser handpiece for fractional skin resurfacing and wrinkle reduction (also awaiting FDA approval); and the Lux1064 Nd:YAG laser handpiece for leg veins, wrinkle reduction, vascular, and other treatments.

Family physicians and doctors entering the aesthetic market were most interested in the system for a variety of reasons: flexibility, ease of use, a small footprint, cost compared to the cost of multiple devices, and the benefits of one service contract. One family doctor said, "There are too many choices

here; it's mind-boggling. This system offers everything on one platform, and that's attractive." However, experienced physicians said they would rather keep their armamentaria of lasers. They also said that the fractionated handpiece wasn't as good as the Fraxel laser.

Advantages and Disadvantages of StarLux

Advantages	Disadvantages
Multiple applications in one box	May include unneeded applications
Good cooling with sapphire tip	Green laser spot size small
Unlikely to cause blisters	Yellow laser too large for face
One service contract for different applications	
Strong patents	

Sources generally agreed that StarLux has not differentiated itself well – except that it offers multiple options in one machine. A doctor said, "Palomar is not differentiated from the others." Another doctor said, "(Palomar's) StarLux and (Reliant's) Fraxel are equivalent, but there are more data on Fraxel." A New Jersey doctor said, "StarLux is not different from the others." A fourth doctor said, "I advise new IPL users to buy second-hand. After they learn it, my taste is Lumenis; it's the most versatile."

Among the comments about Palomar and StarLux were:

- *New York dermatologist*: "I'm very interested in this and might buy it."
- *California surgeon*: "It's part of a new phenomenon – a lot of applications in one box, and that may include applications that you may not really need."
- *Massachusetts dermatologist/surgeon*: "I think that having to put a bunch of different things in one machine might be difficult. It's hard for one system to do everything, and it ends up being a master of none."
- *Pennsylvania family doctor*: "I bought it and I think I got a good deal – \$170,000 for essentially four lasers. We looked at used lasers and they were more expensive than the combos. The service contract also looks good. We wanted to get into hair removal, and this will do it."
- *Maryland dermatologist*: "Palomar has really developed the best cooling for patient comfort. The sapphire tip is the most comfortable, the safest, and the least likely to cause blisters...But the disadvantages are that the spot size on the green laser is small, and the yellow is too large for the face."
- *California surgeon*: "It looks great...I think the idea of having a single power source and plug-in applications is good. And the first year you can change anything out. That's a great level of service."
- *Georgia family doctor*: "There's nothing on it that I don't already have, except for the fractional handpiece, but I wouldn't buy it for that."

- *Illinois dermatologist*: "I understand the concept, but we have so many lasers already, we don't need a laser in a box. That's for general practitioners."
- *North Carolina family doctor*: "Palomar piqued my interest. From what I've read, it has probably the best IPL units on the market and has invested the most time and R&D and effort to make a quality product. The sapphire tip for cooling is impressive. I'm pleased with the hair removal and comfort level, so it's a very attractive device and is actually cheaper because there is one service contract...(As for what happens if it breaks) I'm told they are table top units and replacements are shipped overnight."
- *Louisiana*: "I have StarLux for hair removal, and I just got their skin tightening (device). Palomar has a reputation for building safe, effective equipment, and the platform lets you add on in the future. The technology is evolving, so we need to be flexible."
- *New York dermatologist*: "I'm impressed with the cooling system in the tip of the Palomar Lux1540. If I buy it, I'll use it for tightening, hair removal, and rosacea."

Palomar is attempting to compete with Fraxel with its LuxIR handpiece, but it doesn't yet have FDA approval for soft tissue coagulation, skin resurfacing, wrinkles, and pigmented lesions. However, the company is expecting soft tissue approval soon and was telling doctors it expects to be able to deliver systems by early summer 2006.

Dr. Christine Dierickx, a visiting scientist at Harvard Medical School and director of the Skin and Laser Center in Belgium, discussed off-label use of Palomar's StarLux with the LuxIR fractional handpiece, for skin tightening. She said the preliminary results are promising and that it efficiently heated islands with a minimized risk of tissue bulk damage, lower patient discomfort, and fewer side effects (than other available devices).

Dr. Brian Zelickson, medical director of the Abbott Northwestern Hospital Laser Center in Minneapolis, compared the Palomar StarLux 1540 fractional device and Reliant's Fraxel for treatment of photodamaged skin in six women.

Comparison of StarLux and Fraxel

Measurement	StarLux	Fraxel
Number of passes	2	8
Energy/microbeam	15/30	8-10
Total microcolumn density	800 cm ²	2,000 cm ²
Mode	Stamped	Scanned beam
Energy	1.5 kJ	2.9 kJ
Pain	Similar	
Pigmentation (self-evaluation)	Early-on similar but better at 3 months with Fraxel	

Dr. Robert Weiss, a professor at Johns Hopkins University School of Medicine and director of the Maryland Laser, Skin, and Vein Institute of Baltimore, described a pilot study in four patients of Palomar's LuxIR fractional infrared light for skin tightening. He reported the results were fluence dependent, with people treated below 50J non-responders. The best responses were in people with thin skin. He believes that patients will need more than three treatments, adding, "We've used Fraxel for two years...but we will try Palomar. It takes longer to see results – when I see patients after 4-6 Fraxel treatments, they look a lot better than just before the fourth – so we prepare patients that it will take time...Deep heating is underwhelming in the pictures, though you see some change...It is very different from seeing the patient in front of you...It is taking 3 dimensions and putting it in 2 dimensions. Two dimensions doesn't do the results justice." Another expert added, "Is it (the result) underwhelming at times? Certainly. But that is something that patients appreciate."

Palomar sued Cutera for patent infringement, and the case goes to trial on May 30, 2006. If Palomar wins, Cutera could be liable for triple damages for selling a patent-infringing product. Doctors could not predict who will win, but they were generally not very worried about the outcome. One said, "Palomar's patents are very strong, and it will affect the entire industry if they win, but it only means that other companies will have to pay them a royalty."

ENDOVENOUS ABLATION – slowly catching on

Doctors questioned about endovenous ablation offered these comments:

- *Canada*: "The companies are really trying to get lasers for deep veins, but sclerotherapy is still better. It is a lot more technically difficult to do injections, and we have nurses who do sclerotherapy."
- *Sweden*: "I'm going to start doing varicose veins with a Palomar laser. I've been doing injections, and injections are very cost effective. The laser is expensive, it hurts, and it takes time, so I will use the laser only for small veins."
- *North Carolina*: "Sclerotherapy is still the gold standard for reticular and spider veins, and it is less painful than a laser."
- "The laser is effective and has a place for the patient who is needle-phobic or has tiny veins. I'm very impressed with endovenous ablation, but you need to be skilled to do it, but it will decrease significantly the need for vein stripping."
- *Massachusetts*: "Endovenous ablation is not new but it is catching on. There is not much excuse (any longer) for stripping. It is not replacing sclerotherapy, but it is replacing stripping...I don't do it, but my colleague (partner) does it under ultrasound visualization, and it is not difficult."

A session on endovenous ablation was well-attended, but few doctors in the audience were doing it yet. Several experts described their experiences with endovenous ablation for varicose veins instead of surgically stripping them. They predicted endovenous ablation will catch on and even expand outside of varicose leg veins – but probably not until there is good five-year data.

Dr. Weiss said, "There are ways to enhance stripping, but this is such an easy technique and highly successful that I would predict stripping will go by the wayside." In his practice, he uses three different endovenous devices:

- **RF** e.g., (VNUS Medical Technologies' Closure Plus catheter), which uses heat to contract the vein wall collagen. He said, "We still use this occasionally."
- **810 nm laser** (e.g., Diomed's EVLT or Biolitec's Ceralas D15), which deposits thermal energy in the blood and venous tissues. Dr. Weiss described this as "boiling blood" that distributes heat to the vein wall. He said, "The problem is that, depending on the amount of hemoglobin in the vein, you have to do just the right amount of tumescence, and sometimes you come across areas where there is more blood than others, so you can get a little more bruising and pain afterwards...We see less branch occurrences (with the 810)...and we find we are getting into veins we never could get into before."
- **1320 nm laser** (e.g. CoolTouch's CTEV), which heats water in the vein wall to heat-shrink the vein wall.

Results at 4 Years

Measurement	Patency	Expectations for patency at 5 years
1320 nm laser	96%	95% - 96%
RF	90%	85% - 88%
810 nm laser	72%	75%
Ligation/stripping (in literature)	60%	---

Dr. Gilly Munavalli of Charlotte NC said he started doing endovenous ablations about three years ago and has evaluated all of the different technologies. His choice: a 1320 nm laser with an automated pull-back device, the Closure device. He said, "The 1320 is more flexible, saves time and expense on my part, and the new sapphire fiber has a spacer tip for increased protection and is even more flexible."

Dr. Neil Sadick of Sadick Aesthetic Surgery & Dermatology in New York warned that to do this procedure well, doctors need to learn duplex ultrasound. He uses ultrasound-guided EVLT, explaining, "One of the pitfalls is tortuosity of the greater saphenous vein or accessory veins." He said he is now looking at doing hand veins and other veins and predicted, "I think you will see more non-leg vein use of this technology... We found if you are treating hands, you need to put multiple catheters in all segments of the veins at the same time, so you don't get movement of the blood."

Dr. Sadick's Results with Diomed's EVLT

Follow-up period	Number of patients	Recurrence rate
4 years	3	0
3 years	29	3.4%
Ecchymosis	58	61.7%
Delayed pain/cramping	39	41.5%
Nerve injury	4	4.3%
Hyperpigmentation	1	1.1%
Parathesias	0	0
Skin burns	0	0
Edema	5	5.3%

WHAT WASN'T HOT

Cellulite. Several laser companies were citing cellulite therapy as a hot new area. An industry source said, "Cellulite is hot in Europe, and people are starting to ask about it here." Another industry source said, "Cellulite is the start of body-shaping, which is the next big wave. MediSpas are the key customers now, but doctor interest will grow."

However, most U.S. doctors expressed little interest in cellulite treatment with current devices. Asked about this apparent disconnect between what industry is saying and physician reactions, an expert said doctors will become more interested in cellulite treatments as the therapies get better. A doctor said, "The results with cellulite are not dramatic or as consistent as they could or should be, but that will get better, and the devices will get better over the next year or two." A California doctor said, "Doctors aren't interested in cellulite because nothing does well. Everything is temporary (one month). New technology has the potential to more permanently target cellulite. If it works, then use will increase...(Syneron's) VelaSmooth is a temporary fix. Thermage is more potentially permanent, but they need to maximize the technology. Next year there should be more stuff on cellulite. Everyone wants it, but they are not sold on the technology yet." A North Carolina doctor said, "I'm interested in cellulite and looking at devices, but the science is not there yet. If there were, that would be big!" Another source said, "The buzz at this meeting is that there is no buzz. Fraxel is hot, but it isn't new. So, I think companies are trying to drum up cellulite as a new interest area." A fifth source said, "It is questionable how well they work, but two or three new technologies are coming out for reducing fat, and if fat is reduced, that would affect cellulite."

A huge segment of the population has cellulite. Dr. Tina Alster of Washington DC said, "85% of post-pubertal women have it, and the other 15% think they have it." Current treatments include:

- Topical creams (most if not all are incapable of significant absorption).
- Diet and exercise.
- Liposuction (often worsens lumpy skin appearance).

- External massage (temporary results on the surface).
- Surgical subcision (invasive).
- Mesotherapy (largely unstudied).

CYNOSURE'S TriActive. A study found this device, which is not yet FDA approved for cellulite reduction, produced a 21% overall improvement, but clinical improvement wasn't sustained even at the four-week follow-up. Dr. Alster concluded that combination therapy (e.g., RF/IR light/mechanical) can significantly improve cellulite and reduce thigh circumference, and additional studies are warranted to determine optimal treatment intervals and a maintenance schedule.

LED therapy. Doctors also generally dismissed LED therapy.

- *Florida:* "My personal experience (with LED) is minimal; I hear that it is excellent for acne because it shrinks the sebaceous gland."
- *North Carolina:* "I heard one of the speakers give the advice that you should never buy anything with blinking LEDs, meaning that it's all smoke and mirrors."

SYNERON MEDICAL'S VelaSmooth. Doctors were particularly unimpressed with Syneron's VelaSmooth device for the treatment of cellulite. VelaSmooth has mechanical rollers that knead the skin, and suction creates negative pressure, dilating blood vessels. IR light heats tissue up to 5 mm depth, and RF heats tissue to a depth of 5-15 mm. Treatment indications include cellulite, non-proprietary fat distribution, and post-liposuction non-uniformity of adipose tissue.

Most sources insisted it doesn't work:

- *Florida:* "Cellulite machines have less than stellar performance. In other words, they don't work."
- *Pennsylvania:* "I'm not impressed at all."
- *Massachusetts:* "I haven't been impressed with it yet, and my wife is waiting for something to come along that works!"

Dr. Alster described a 20-patient study with VelaSmooth that found that 90% had subjective improvement, 17/18 patients would undergo treatment of the contralateral thigh, and side effects were transient erythema and bruising (two patients). She said, "In my practice I kept the device that was on loan to me for the course of the study (a VelaSmooth). I purchased it. I tell people they will likely need eight treatments twice weekly for four weeks."

SYNERON'S Polaris, a combined RF/light-based technology. Although doctors were interested in combined therapy, they were uncertain about the efficacy of combined RF/light therapy for photoaged skin, for hair removal, leg vein removal, acne scarring, skin rejuvenation, and wrinkle reduction compared to other lasers. Although there is minimal

downtime involved, the therapy generally needs more treatments and doesn't work as well as conventional methods, and it is considered downright ineffective for wrinkles and acne scars.

Polaris has different modules – one for treating vascular lesions, another for wrinkle reduction, etc. The modules differ in the application tip design, sequence of firing the laser, RF generator, and pulse profile. An expert said, "This is a neat idea, and we are going to see papers...talking about the clinical effects. The paper we have yet to see is where you turn off the RF and use light alone, then turn light off and use RF alone, then use both together. Investigators are apparently getting good results with this technique, although it's a difficult approach to use because it's so new. I was at a disadvantage using the Syneron device because I was used to using Cutera and Thermage. It's just different, and I would have had an easier time starting off if I hadn't been used to something else."

The Polaris device has been used internationally reportedly with good success for both treatment of vascular lesions and tissue tightening. An expert said, "Polaris is generally used to provide a series of treatments to accomplish desired endpoints. While some investigators feel strongly that the combination of light and RF energy produce a synergistic effect clinically, this has not yet been confirmed in an objective study. I am told that such studies are currently underway...A side-by-side comparison of the bipolar and unipolar devices has not been performed. Additional clinical evaluations are currently underway in the U.S."

Comments about this technology included:

- *Florida dermatologist*: "Hypothetically, you should get better results with combined RF/light technology, but in actuality, though, do you get it? The jury is still out."
- *Massachusetts surgeon*: "A bunch of companies are working on RF combined with light therapy to get better effect and less pain, and it may work. I think that Cynosure and Palomar are working on it. The combinations are fascinating, but we need to see the numbers."
- *Pennsylvania family doctor*: "We decided not to try RF/light based. It's not that effective, and it just doesn't seem to work."

THERMAGE. Some doctors said they got good results with Thermage, while others said the results ranged from non-existent to good. The most difficult thing to do, they said, is to tell a prospective patient that Thermage may not work at all, and it is still impossible to predict for whom the device will give results. Just a few months ago, it appeared that interest in Thermage was fading, but it has picked up again with the new model.

Vanderbilt's Dr. Biesman said there were some problems with Thermage's device: "As everyone knows, treatments were

very slow, with a 6-second treatment cycle. It was very painful, unpredictable, and there were cases of subcutaneous fat atrophy because of overheating of the tissue...Thermage improved its tip design, and the 'fast tip' became available. The cycle time (increased), and tips went from 1.5 to 3 cm². Simultaneously, clinicians...started to use multiple passes at lower energy and found the number of complications reduced dramatically, and patient tolerance went up substantially."

Ideal candidates for ThermoCool are typically aged 35-55, and Dr. Biesman, who typically doesn't use any anesthesia with ThermoCool, warned not to expect the same results as with a surgical procedure. He said, "You can see some modest tightening, but not home runs. You can get results. There are treatments being done off the face – belly and arms – but they don't have results as impressive as with the face."

A major drawback to Thermage, according to Dr. Biesman, is the cost of disposable products required for each treatment. The treatment tips and the return pads that complete the RF circuit are single use only. Cryogen, treatment grids, and coupling fluid are also required, bringing the cost of performing a ThermoCool treatment to nearly \$800.

Comments about Thermage included:

- *California #1*: "It works sometimes, and sometimes it doesn't work at all. I think that techniques are improving, however, and we may see better results in the coming years."
- *Florida*: "I use Thermage for some patients. For some, it has little effect, for some it has poor effect, and for some it has just OK effect. It is painful, and I've had a few bad results. There have been no definitive studies yet, and more time is needed to perfect this device."
- *California #2*: "We are impressed with Thermage and have been having some success with it."
- *Massachusetts*: "Thermage is OK, but it's hit or miss. When it doesn't work, it's not fun at all."
- *Texas*: "Nothing helps with skin laxity yet. Thermage seems to have the efficacy though, and it works somewhat – again, with the maturing of the technology we will know the people for whom it's going to work."
- *North Carolina*: "RF is in its own niche. Thermage is the first RF device for skin tightening and I still think it's probably the best – you get more volumetric heating compared to some of the other sources. As far as infrared, some of the bipolar RF doesn't penetrate as deeply and as efficaciously but Thermage is the better choice. I've been using it for one and a half years with overall good results. I wish it could be more predictable, but that's an issue with skin tightening. It's good if plastic surgery isn't an option and you want to do something now. I see 75% to 80% results, some see immediate tightening and for some it takes three months before I see changes."

- *Texas surgeon:* “I think Thermage does make a case for minimal changes if you don’t want surgery, and you want a reduction in wrinkles, compared to creases. A lot of doctors are going into it.”

IPL DEVICES

IPL is broad-spectrum light made up of multiple wavelengths, with a filter used to restrict bandwidth for different applications: shorter wavelengths are used for pigment spots, and longer wavelengths smooth the skin. IPL is used for hyperpigmentation, telangiectasia, rosacea, collagen production, fine lines, scars, spider veins, age spots, wrinkles, hair removal, and photorejuvenation. Doctors agreed that both Candela and Cutera make good products, but Lumenis was cited as the gold standard, and new IPL equipment from Candela and Cutera were just not making a huge impact.

CANDELA. Doctors generally said that other products, such as Nd:YAG lasers, are more effective at hair removal than IPL, which often results in an unacceptable amount of hair regrowth. Candela’s new Ellipse Flex IPL system treats sun-damaged skin to reduce pigment and vascular disturbances by specifically heating targeted structures in the skin. The new “flexible” IPL, which received FDA approval in December, 2005, includes a Programmable Pulse Mode with individual programmable settings for each patient.

CURELIGHT. The company doesn’t sell an IPL or an LED but a high intensity plasma light. CureLight used to manufacture for Lumenis, but that contract was cancelled, and CureLight added a red light and started selling its devices itself (directly in the U.S. and through distributors worldwide). The company reportedly has a strong presence in Japan and China.

CUTERA. Cutera’s LP 560 IPL system is for facial rejuvenation and treatment of pigmented skin problems. A California doctor said, “I can only do one full facial per day because it takes so long (1-5 hours), and I’m too tired after that to do more.”

Cutera’s Titan skin-tightening device uses infrared light energy to produce dermal heating. Most of the energy is emitted in the 1100-1300 nm range, and the thermal profile of Titan was described as “similar to that of the Thermage ThermaCool.” Approximately four passes are typically recommended in a given anatomic region during a single treatment session, and several treatment sessions, spaced ~4-6 weeks apart, were recommended. Similar to the Syneron Polaris and in contrast to the ThermaCool, operation of the Titan does not require disposables although the treatment head needs to be replaced periodically (the initial recommendation as after 10,000 pulses). An expert said, “I did find fantastic results. That is the exception rather than the rule.”

Among the comments on IPL devices in general and Cutera and Candela products in particular were:

- *Canadian dermatologist:* “IPLs don’t do anything for wrinkles.”
- *Ohio:* “IPL devices are cheaper and definitely can do a lot of functions, but I do laser for pain control, pigment, facial rejuvenation, and, most commonly, for acne and rosacea.”
- *Massachusetts family doctor:* “I’d rather use my own focus. I’d rather have individual wavelength lasers than the IPLs.”
- *Nebraska:* “I looked at Cutera and for sure am getting the Nd:YAG laser and the IPL addition. I first got interested in the cosmetic field with a Cutera workshop and I’m impressed with the company and I like the backup help. And they do an upgrade of 100% on previous purchases, and you can decide in a year. I do basic hair removal and veins and now I can do skin rejuvenation. Hair removal and veins are your base. That keeps the laser busy all year long.”
- *Massachusetts dermatologist/surgeon:* “IPLs are more unpredictable than lasers. I’d rather use VBeam or Fraxel for resurfacing.”
- *Massachusetts surgeon:* “IPLs are getting there, and a lot of people here are interested in it, but we have to look at the numbers. One thing in their favor is that they’re a lot easier to use than lasers.”
- *New Jersey:* “Candela and Cutera are both very good. I already have one, and it’s hard to say what to get now. In the end, it’s what you can afford.”
- *Texas:* “I use other lasers for hair removal, I have an individual standalone piece. Candela is doing well, as more and more consumers want to do something to rejuvenate their skin.”
- *Georgia:* “I don’t know much about the IPLs, but I think I have everything that I need, except that I’d like to get the Fraxel.”

SAFETY ISSUES – no new problems

Doctors said there are no new safety issues, although several mentioned that one of the conference speakers talked about the dangers of using lasers for hair removal around the eyes. Most said that experience and technique can prevent most problems. As one speaker put it, “We all burn our patients. The question is whether you’re going to be a hamburger flipper or a gourmet chef.”

Other comments included:

- *Georgia:* “Experience is the key.”

- *Ohio*: “If you get it wrong, that’s a problem. There can be scarring, but those who know how to use the lasers are very successful.”
- *California*: “Using lasers can be very dangerous, and I think it’s a problem when you can get hair removal at the mall, and someone who isn’t a doctor is performing the procedure. There are a lot of safety concerns there.”
- *Texas*: “There aren’t any new safety issues; most people in the business are aware of any problems, and the rest get education.”
- *North Carolina*: “There are always some blisters and burns. That’s unavoidable. It’s important to manage patient expectations.”

However, one source suggested the safety of lasers isn’t an issue but the problem is the potential for aerosolized human pathogens. He contended, “All lasers should have a vacuum system – a smoke evacuator – to pull off fumes.”

MISCELLANEOUS

Regulatory Issues. Experts insisted that they do not believe the FDA will issue regulations on MediSpas. Rather, they see states taking more initiative in issuing regulations that affect MediSpas. A source said, “It’s more on a state-by-state basis.” ASLMS past president Dr. Arndt said, “No, the FDA is not going to issue regulations, but I wish they would. There is an enormous concern with the practice of medicine by non-physicians. Anyone can buy a lot of the equipment here, especially light sources, and a lot of treatments are being given by junior high school graduates, so ASLMS is working on training and credentialing...There is legislation in various states on non-physician practice of medicine – whether a physician should be required to be on site.”

Home lasers. Palomar officials said their home device, which is being developed with Gillette, is expected to be introduced by the end of 2006. Syneron reportedly is working with Johnson & Johnson, but Syneron officials would not discuss their home laser program. SpectraGenics also reportedly has a home health device that is pretty far along.

Sources were not very concerned about the idea of home hair removal devices since the companies planning them have said they will be sold through doctors and MediSpas, not at retail stores. Rather, they saw them as a potential revenue source for their practice – and perhaps a lead-in for their services. ASLMS President Geronemus said, “Hair removal procedures are increasing, and that will continue. The next area in hair removal will be home products. That is part of the future.” Another doctor said, “I’ve seen a prototype for a temporary hair removal device, and it looks like it works. I’ll sell it in my office. Permanent hair energy is five times more, but home devices are an advance over depilatories.” A Midwest doctor said, “Home lasers are a great idea. They won’t be as

effective as what we do, so they are not a threat. Hair is a commodity.”

A home version of Light BioScience’s GentleWaves LED reportedly also is in development. An expert said, it has the same energy as the professional version, but the professional version is full-face, and the home version is just for around the eyes.

LITT (laser induced or laser interstitial thermal therapy).

This was described as a promising treatment for colorectal liver metastases or for head and neck cancer. Mostly this is done by radiation oncologists, but interventional radiologists are starting to get into it. LITT is a minimally invasive technique whereby optical energy is deposited into a solid tumor through implanted optical fibers, to heat the tissue above 55° C, which results in thermal coagulative necrosis. The limitation of LITT include: damage to the laser tip, charring and tissue impedance, and a heat sink effect.

Laser treatment of hemorrhoids. A doctor described how he used an 810 nm diode laser to treat hemorrhoids with very dramatic results. Morbidity was 6.06% (2 cases) – one due to bleeding that required an X suture to control hemostasis, and another patient with cold sweating and hypotension attributed to a vasovagal reflex.

Dental lasers. Last year, Syneron invested in a dental laser company, with plans for FDA approval later this year. A Syneron official said the company is keeping dental separate from aesthetics. ♦