Trends-in-Medicine

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by Lynne Peterson

SUMMARY

Doctors see demand for cosmetic laser procedures as relatively flat in Europe, with the outlook for more of the same, but industry sources are slightly more optimistic. ♦ Hair removal/reduction is the No. 1 procedure, and use is still increasing, but there is also more interest in skin rejuvenation and tattoo removal. ♦ Home lasers for hair removal are poised to hit both the European and American markets, but doctors don't consider them very effective or much of a threat. ♦ The hottest thing right now is fractionated therapy, particularly Reliant Medical Technologies' Fraxel, though competitors are introducing their own fractionated devices. ♦ No therapy is considered effective for cellulitis. ♦ Doctors are happy with Allergan's Botox and see little reason to switch to another botulinum toxin-A, so few doctors at the meeting have switched to Ipsen/Medicis' Reloxin. However, a new head-to-head study appears to favor Reloxin, which is less expensive, and that could give Reloxin some momentum, though it isn't expected to be available in the U.S. (as Dysport) until 2008.

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1ST INTERNATIONAL CONFERENCE ON ADVANCES AND CONTROVERSIES IN LASER MEDICINE AND SURGERY

Barcelona, Spain
August 30 - September 1, 2006

Doctors from at least 46 countries, including a fairly large contingent from the U.S., attended this new European meeting on lasers in dermatology and surgery. Twenty doctors as well as officials and sales reps from nine vendors were interviewed.

European dermatologists and gynecologists at the meeting insisted that the demand for cosmetic laser procedures has been flat over the past six months, and the outlook is for demand to remain flat. U.S. doctors had a slightly more optimistic view of the future. One said, "There is room for growth for serious products and companies, but many products on the market are garbage. Doctors are finding cheaper is not necessarily better. The market for procedures is there, and people are willing to pay." Another U.S. doctor offered this suggestion, "You need to constantly re-invent yourself in your practice with technologies that work." A third U.S. doctor said, "There is growth in the non-dermatology market. A lot of primary care doctors and gynecologists are getting lasers."

Officials of companies exhibiting at the meeting had a more mixed view of demand. Compared to six months ago, five said demand is up, and three said the market is flat. However, even some of the companies that have seen growth are predicting a flattening in demand. Five predicted flat demand over the next 6-12 months, and three said sales would pick up. One had no comment. One source said Germany and France have been particularly slow, while the U.K., Spain, and Italy have been good.

Vendor Market Now and in 6-12 Months

Company	Demand vs. 6 months ago	Outlook for demand in the next 6-12 months
1	Up	Flat to down
2	Up	Up
3	Flat	Flat to slightly up
4	No comment	No comment
5	Up	Up
6	Up in the U.K.	Up
7	Flat	Flat
8	Up	Flat
9	Flat	Flat

Vendor comments included:

- "Europe is almost saturated, but it is growing. There has been a slowdown in purchases, and doctors have gotten more cautious."

- "The market is penetrated, but there is room for growth in procedures as awareness increases and more doctors and non-doctors enter the market…Patient acceptance in Europe is starting to grow, but the willingness to pay is still not quite there even though the interest is."
- "The market could pick up if there were more articles about cosmetic surgery in women's magazines. That's more helpful than advertising."
- "Spain is the best market for laser companies in Europe. It has the most potential after the U.S. and Brazil. About 1,500 lasers have been placed in Spain, half to doctors and half to aestheticians."

Sources were unable to estimate the size of the European market for cosmetic lasers, but they generally agreed that there is room for growth. Some industry sources suggested the market could be growing but appears flat to companies because there are more players sharing the pie.

Most doctors and companies don't believe that the market is fully penetrated or saturated, but many called the market "mature." They generally agreed that any growth will come from new doctors and specialties entering the field, not from expanded laser sales to dermatologists. But innovations also could spur the market.

Company sources agreed that the key buyers right now are dermatologists, aesthetic medicine doctors, aestheticians, and a few plastic surgeons. An industry source said, "The market is pretty saturated. We sell where there are no lasers yet. France and Germany are the most difficult, but Scandinavia is pretty good." Another industry source said, "Europe is pretty much saturated. It is a mature laser market. But there is room for expansion to primary care doctors in the U.K. who are looking for ways to increase their income." A third industry source said, "~40% of our sales are to dermatologists, ~25% to aesthetic medicine and plastic surgeons, and a small number are to gynecologists." A fourth industry source said, "Medical aestheticians have a lot of money to spend, and sales to them are increasing. Dermatologists also are interested."

Medi-spas, which have sprung up in the U.S., also are multiplying in Europe, but they were not viewed by either doctors or industry sources as a major threat or market, respectively. In some countries lasers are not limited to physician offices, but doctors would like to do that, though few sources think those efforts will be successful. A Norwegian doctor said, "In a town of 160,000 people we have 10 medi-spas. But they don't have lasers."

In this environment, more aggressive pricing on new lasers might be expected, but European doctors said they aren't seeing much of that, though there are deals available. An industry source said, "There hasn't been more discounting than usual. People want to bargain the way they do for a car. They try to get the price down, but eventually they buy." The litigation going on among the laser companies, particularly Palomar and Candela, does not appear to be impacting either the choice of a laser or the decision to purchase a device.

According to sources, larger companies such as Johnson & Johnson or Allergan are not interested in getting into the cosmetic laser market, at least not yet.

The Fastest Growing Procedures

Skin rejuvenation procedures and tattoo removal are increasing in Europe, particularly with fractionated therapy, but laser hair removal/reduction remains the most popular laser procedure in the world, and it is also the fastest growing laser application in Europe, doctors and industry sources agreed. There is also growing awareness of vascular applications (e.g., varicose veins), though that is still a very small market. A U.S. doctor said, "I see hair removal as commoditized – 20 devices can do that." An industry source said, "Hair removal is still growing, but skin rejuvenation is picking up because it makes people feel good and is part of the 'grooming ritual.'"

Experts warned that:

- **Dark coarse hair on fair skin** is easy to treat, but there has been a lot of misuse of this technology in spas. An expert said "If you turn the energy way down, you get temporary hair removal, without permanent hair removal. That's a good way to stay in business because patients will come back 30-40 times, while they really only need about six treatments for permanent hair removal."
- When treating **fine, dark hair**, some women, especially those from the Middle East, can suffer hair ***stimulation***, regardless of whether an IPL (intense pulse light) or a laser is used.
- The FDA definition of permanent hair reduction has lead to unrealistic patient expectations because of misrepresentations in newspapers and advertisements. That definition says: *"The long-term, stable reduction in the number of hairs regrowing after a treatment regime. The number of hairs regrowing must be stable over a time greater than the duration of the complete growth cycle of hair follicles, which varies from 4-12 months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treatment area."*

Applications for IPL for hair removal – dubbed IPL photoepilation – are gaining favor because they are non-invasive, have versatility on different kinds of hair types, are easy to use, and have shown good results. Dr. Herbert Honigsmann, a dermatologist at the University of Vienna, said his study of 102 adults found very good results with IPL in about 1/3 of patients, "It is not complete hair removal in all cases, but patients are usually comfortable with the results."

Home lasers for hair removal

Home-use lasers for hair removal have not taken off in Europe, and sources were dubious that they will. However, several sources mentioned that New York-based Radiancy offers a home-use hair removal system outside the U.S. that may be coming to Europe. Radiancy's SpaTouch is a non-laser, light-based photoepilation system with FDA approval. An industry source said, "It is being sold by TV for hair removal, but don't call it a laser or light pulse. They advertise it as 'inspired by light pulse,' implying that it is a laser or light-pulse device. It won't have any impact. It's rubbish."

Experts were not particularly negative about the idea of home lasers. One said, "The results look impressive. I think they work for big hair." Another said, "The best place for hair removal is the bathroom. I think there will be a bunch of competing technologies for home use. There is one in Japan that is a small version of (Lumenis's) LightSheer diode laser…A version that looks like a razor may be more accepted.

Lasers vs. IPL for Permanent Hair Reduction

Hair type	Best option
Fine	Short pulses
Melanin	Lasers
Red hair	Yellow IPL
Dark, coarse hair on fair skin	Easiest to treat. 30% reduction typical per treatment.
Dark, coarse hair on dark skin	Long pulse Nd:Yag (1064). These patients can be very treatment resistant.
Fine, dark hair, regardless of skin type	Short pulse (1 ms) or 3rd generation IPL. Generally difficult to treat.

Lasers and IPLs for Permanent Hair Reduction

Laser wavelength	Efficacy
694 nm	Highest risk in darker phenotypes.
755 nm	Higher safety in Types 2 and 4. Works well on fine and lighter brown terminal hair.
800-810 nm	Highly effective for dark terminal hair.
940 nm	More comfortable than 810 nm with equal efficacy, especially for patients of color.
Nd:Yag	Only good for individuals with Type 5 and 6 pigment.
1064 nm	Excellent for dark-skinned people.
IPL 590-1200 nm	Safe for phototypes 1-4 with the right filters. Large spot sizes enable rapid treatment. Works somewhat better on lighter brown or blond hair.

Study of 755 nm Laser for Permanent Hair Reduction

Hair location	Efficacy	Average number of treatments	Average follow-up
Overall	89%	3.0	3.4 years
Face	82%	4.0	N/A
Axilla	95%	3.0	3.4 years
Bikinis	93%	3.0	3.3 years
Legs	92%	3.0	3.3 years
Back	89%	2.0	3.5 years

Initially, you plug it in, but it will become battery operated. Home-use lasers won't put us out of business. There are a fair number of people who want it done professionally." A U.K. doctor said, "We shouldn't endorse and encourage home laser removal devices. And we should define laserceuticals vs. real medical devices that need to be under medical supervision."

Palomar and Gillette are collaborating on a home-use hair removal laser for the U.S. market, but it is still awaiting FDA approval. Sources didn't really know what the hold-up is. One expert said, "The FDA wants to make it safe for everyone. They want it to be safe even if it's misused…So, they want more safety data." Another doctor speculated, "The issue is it doesn't work, and there is a risk with it even in a spa without a doctor."

THE HOTTEST TECHNOLOGY: FRACTIONATED THERAPY

RELIANT TECHNOLOGIES' Fraxel was just as hot a topic at this meeting as it was at the American Society for Laser Medicine and Surgery meeting in April. Doctors and industry sources alike pointed to Fraxel as the technology to watch. A Swiss doctor said, "Fraxel is why I'm here (at the meeting)."

Fraxel is a mid-infrared laser (1550 nm) 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 usually treated with 8-12 passes of 125-250 microthermal zones/cm^2 to give a final density of 2,000-3,000 microthermal zones/cm^2, which translates to ~20% of the skin's surface being treated. Patients often have 4-5 sessions spaced one to three weeks apart.

Fraxel is FDA approved for facial rejuvenation, melasma, surgical scars, acne, periorbital wrinkles, photocoagulation of pigmented lesions, 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 the face, on the neck, chest, arms, and hands. The procedure can be done by a doctor or a nurse.

Comments about Fraxel included:

- *Dr. Robert Adrian of the Center for Laser Surgery in Washington DC:* "I like the versatility…What's nice about Fraxel is you can treat all skin types. I have a hard time with Asian patients with the CO_2 laser. Fraxel is very, very effective in treating melasma. You won't cure melasma; it is a genetic disease, and if the patients go back in the sun, they will get the melasma back again… And the melasma occurs in the same area with the same individual every time. I believe these (melasma) are genetically determined conditions in individuals who are susceptible, but patients are very, very happy (with Fraxel treatment)…Acne itself can go away with Fraxel treatment, but I'm not sure this should be a first-line treatment. People notice a reduction in pore size. If we can prove

this occurs, I think it will be a home run. It is not a home run with Fraxel, but you are beyond first base…I'm not as impressed as some others with the effects on stretch marks, but there is an effect…Does Fraxel benefit 100% of patients? Probably not."

- *Dr. R. Rox Anderson of Boston:* "I really like this device for treating regions where CO_2 and peels are a little more treacherous. It's the first laser I've encountered where I feel comfortable treating melasma because the risk of hyperpigmentation is quite low…It is not a cure for melasma but shuttles a lot of the pigment out and gives patients an improvement. About half the women experience long-term benefit and the other half recur."
- *Spain:* "I bought a Fraxel in December 2005…It is most important to inform patients that this is not a CO_2 laser…Patients need to know what to expect…If the patient can tolerate the pain, you can get good results (with Fraxel). The procedure is very safe, with minimal side effects and minimal time for recuperation, and patients can use makeup or shave the day after. There is pain for 1-2 hours, and edema for two days."
- *Norway:* "I only have a CO_2 laser, but I'm considering a Fraxel. I don't like IPL. My volume has been flat, but it may pick up if I get a Fraxel because it will do things that can't be treated with the other lasers, especially acne and melasma."

Other fractionated therapies

Fraxel was the first fractionated therapy, but there are now several competitors. A Reliant official said his company isn't worried about the competition, "We will always be two years ahead of them. We have a strong R&D department."

Reliant speakers emphasized the difference between Fraxel and these competitors, explaining that Fraxel is a robotic scanning device, and the others use a stamping technology which fires a laser beam through a lens (e.g., a microarray crystal), which disperses the beam. Reliant speakers insisted scanning is better than stamping. Not surprisingly, competitors with stamp devices claim they are either equivalent or superior. A speaker insisted, "They are not the same." Another speaker said, "Stamping fractals seem to work as well, but they are probably not as convenient to use."

Cost may become a differentiator. The disposable tip for Fraxel costs about $400 and can be used for 4-5 treatments, or about $80-$100 per treatment. In comparison, the disposable for Cynosure's Affirm costs about $500, but it can be used for 10 treatments, or about $50 per treatment.

CYNOSURE'S Affirm, a 1440 nm fractional laser. A company source said this is the second fractionated therapy on the European market, and it sells for slightly less than Fraxel, ~€95,000. He said the advantages are that no dye or anesthesia is needed, it is less painful than Fraxel, and has similar results. It requires no gel and has direct air cooling while Fraxel requires a separate air cooler. It also has IPL included. A speaker said, "This is very similar to what we see with Fraxel. It is air cooled, and you don't have to use a gel or water on the skin…There is similar epidermal damage as with the 1550 (Fraxel) laser. There is redness and swelling lasting 12 hours to 5 days, like other fractionated devices…There is average discomfort. It is not comfortable but not unbearable, and we don't typically use anesthesia…It takes about 15 minutes to do a full face…It is relatively painless and economical for patients."

LUMENIS'S Active FX

This is a fractionated CO_2 for resurfacing. A sales rep said, "This has all the advantages of traditional resurfacing in terms of results but without the long down time. Down time is now 3-5 days."

PALOMAR MEDICAL TECHNOLOGIES' LuxIR (StarLux handpiece)

Palomar was noticeably absent from the meeting, and there were few talks about its products. Industry sources offered several possible reasons for this:

- The company has a small presence in Spain.
- The company has a small presence in Europe.
- It was a new meeting, and the timing didn't work for the company.

How do the Palomar and Cutera devices compare? A Cutera sales rep said, "Our device is more reliable, has a better wave shape, and better pulse-to-energy control, and the handpiece energy is consistent from the first to the last shot with no difference in fluence." There were no Palomar officials there to respond, but a doctor with a Palomar StarLux said, "StarLux is good for intermediate doctors, and they have a version of Fraxel."

Questions and answers about fractionated therapy and Fraxel

Could other wavelengths be fractionated and delivered by this methodology? Dr. Anderson suggested that microspots of UVB could be used for psoriasis, or a CO_2 light could be used to make deep laser channels in subcutaneous fat.

Is there any tightening with fractionated therapy? Dr. Anderson said, "Yes, there is delayed tightening. Remodeling seems to take three months." Dr. Adrian agreed, "We are seeing tightening."

What are the pitfalls of fractionated therapies? Dr. Anderson said, "Bulk heating. It is possible to burn your patients. That is avoidable by air-cooling and proper treatment technique. You also have to avoid unrealistic expectations. It is generally less effective than laser resurfacing, but the trade off in down time is usually what

people are interested in. The side effects are erythema, HSV reaction, and PIH (post-inflammatory hyperpigmentation), though I have yet to see PIH."

Are there other uses for fractionated therapies? A speaker suggested that fractionation could be used for drug delivery, "To deliver drugs accurately to skin, you don't need to drill holes…An Australian company has been working for eight years on delivering insulin this way. The fact that it hasn't come to market probably means there are some technical issues…but whether it is a 1550 nm laser or a CO_2 laser, there would be a massive increase in absorption capability." Another speaker said CO_2 lasers work for cancer prophylaxis but fractionated therapies do not. Reliant is investigating the use of Fraxel at other wavelengths for other purposes, including drug delivery and treating skin cancer. Dr. Adrian thinks those applications offer some exciting possibilities, but neither he nor the company would explain the research any further.

Reliant also is working on a CO_2 at 10,600 nm, and an expert said that would be good for skin tightening.

How long does a Fraxel treatment last? Dr. Adrian said, "Serious fractional resurfacing has gone on only for the last two years. I've seen patients coming back after a year, and they still have effects, but patients will come back for continued maintenance. You can set up maintenance treatments, and I'm not sure from a business or economic sense that you want a single treatment. Do you want Restylane (Medicis) to last three years? We would like all the fillers to last longer than they do, but something in the middle of the road. I believe people will come back for further Fraxel treatments, not just touch-ups – because that means they don't pay you. I would say Fraxel lasts longer than 18-19 months."

Where does Fraxel fit in with IPL (intense pulse light)? Dr. Adrian said, "I have four IPL machines, and I use them, so Fraxel doesn't discourage use of IPL. I use them differently. IPL is a good, safe technology, but IPL can't do what Fraxel can do for me on a consistent basis. I use IPL for relatively young people with relatively simple photo damage, some pigmented patients, and some telangia."

How soon can a fractionated treatment be repeated? Dr. Anderson said, "Dermal healing occurs in about a week, so you can repeat in about a week." Another doctor said you can re-treat with the Zimmer SmartCool at 4-6 weeks.

What is the optimal spot size for fractionation? Dr. Anderson said, "There is a fundamental limitation…You can't make the spot smaller than several times the wavelength, which is a few microns…These spots are already close to the limit. I think it would be very interesting to make nanoholes instead of microholes…The advantage of microspots is that you can sort of get away with murder." Dr. Christopher Zachary of the University of California, Irvine, said, "Spot size is incredibly important…We've done studies, which we are submitting for publication but as you broaden the beam diameter, the tissue effect is much more superficial. I haven't used the device by Lumenis with a type of fractionated CO_2, but I like the idea. It's a great idea, and other companies should consider producing them…But the problem is that spot size is probably way too wide to get the fractionated delivery with nice depth and a cylindrical result…You are inducing 3-D instead of 2-D change; you lose the Z factor if the spot is too wide."

Is a Fraxel treatment painful? Yes, said Dr. Anderson, "Most cutaneous pain is in the epidermis, and if you are treating a more dermal problem, the Fraxel device – and probably other devices – can be set with a higher pulse and lower density, which is better for the patient." A Spanish doctor said, "It's more painful with higher energy." Dr. Henry Chan of Hong Kong said, "For Asians we halve the density. I still use a fairly high level, but I increase the number of sessions." Dr. Adrian added, "Pain is related to heat load in the skin. I think when someone says a particular machine is less painful, it is heat related…And no pain, no gain. If it's a painless procedure, you may not really be doing anything. Pain is part of the process…Fraxel is not a painless procedure; most painful is the forehead."

Is there pain with Palomar's LuxIR? An expert said, "I treat the face with the 10 mm spot size, 50% overlap, and approximately three passes, without any anesthetic, and it is extremely well-tolerated. If you ask patients who had other procedures, they would say it feels like an IPL treatment."

Ablative Lasers

Ablative resurfacing remains the "gold standard," but newer technologies are gaining popularity. Dr. Adrian said an ideal resurfacing treatment should:

- Have reproducible results.
- Have a minimal risk of infection, scarring, or PIH.
- Leave skin natural, smoother, and more even-textured.
- Treat all skin types and anywhere on the body.
- Have a short application time.
- Be an easy treatment technique. He described Fraxel as "easily learned by nurses and technicians."
- Be well-tolerated by patients. He said Fraxel pain lasts 3-6 days, depending on how aggressive the doctor is, with many patients back in makeup the next day.
- Make post-procedure patient management easy.

However, ablative procedures have lost popularity, and non-ablative treatment options have grown. The question is how good the results of those procedures are. A common way of judging results is to use before and after photographs. Dr. Daisy Kopera of Austria presented a study which found that

photos simply are not reliable in determining the effect of a non-ablative treatment on wrinkles.

Using a 1450 diode laser, Dr. Kopera studied nine female patients with periorbital wrinkles. Each got three treatments at three-week intervals, and all were carefully photographed. All (100%) of the patients were very satisfied with the results, but Dr. Kopera said, "In my opinion, the results were not very convincing. So, I asked 25 independent dermatologists to rate the 22 pairs of before and after pictures, a total of 550 ratings: 57% thought the post-treatment photos were better, and 42.5% thought the pre-treatment photos were better. Clinical photography is really not the right tool to give an objective judgment…Non-ablative methods are popular because they are convenient, but the effect may be rather discreet, and there is an inconsistency in objective professionals ratings and patient self-assessments…Patients think that if they do something costly to their face, it must be improved…I question whether clinical photography is at all a proper tool for judgment."

CO_2 lasers

Experts insisted that the CO_2 laser isn't dead. A Spanish doctor commented, "I think the CO_2 laser is good enough." An Italian doctor said, "Usually I'm able to combine the CO_2 with surgery, and the patient has down time anyway, so they are willing to accept it." Dr. Arielle Kauvar of NYU Medical Center added, "I think both CO_2 and erbium are very much alive…Nothing can replace this procedure in the appropriate patient."

Should patients get antibiotics as a prophylactic before a CO_2 laser treatment? Experts generally said no. One explained, "In burns you don't give antibiotics because the question of whether it will be colonized by bacteria is obvious …You can't keep it bacteria-free. Will you have an infection or not? It doesn't depend on what chemicals you put on the burns, but the immune resistance of the patient and how clean you keep the burn. If you give prophylaxis, that influences the flora. It means you will select the most antibiotic-resistant pathogens, and that is why I oppose using any topical antibiotics. I give one shot of IV antibiotics, which has to do with surgical prophylaxis, and that has been proven effective if given at least a half hour before the surgical procedure."

What about combining an erbium laser and a CO_2 laser? Dr. Katharina Russe-Wilflingseder of Austria said a key disadvantage of the CO_2 laser is pigmentary changes, but when combining the CO_2 with an erbium, there are no pigmentary changes, "You get better results, better patient satisfaction, less down time, and fewer side effects…I think that combination treatment is an aggressive ablative procedure with severe and long lasting down time, with a risk of side effects, but you need only one treatment and only one down time."

Erbium lasers

What's the role for the erbium laser? Dr. Albert Nemeth of Clearwater FL has two erbium lasers – a WaveLight and a Fotona Skinlight – and he said the erbium laser is good for acne, "Our patients re-endothelialize in a mean of 6.4 days. Despite rather aggressive treatment, there is rapid erythema dissipation after Day 2, and 80%-90% of erythema is gone in a week – and you can hang your hat on that!...I tell patients they will need filler as well as laser. While you are able to smooth out the edges of tissue loss (with the laser), there are still areas that benefit from tissue augmentation…No one has an issue going back to work the next day…It's a delightful, quick (12 minute) procedure where you won't have to explain that the algorithm just changed again, as with **THERMAGE**." He said 83% of the patients he treats with this laser are females.

Should you treat the entire face or just parts? Dr. Russe-Wilflingseder recommended treating the entire face, not just zones. She said, "Select patients according to skin type and conditions."

LASERS IN GYNECOLOGIC SURGERY

Vaginal laser surgery

Dr. Jack Pardo of the Clinica Las Condes in Chile, discussed what he called a growing field – vaginal laser surgery with a CO_2 laser. In the U.S. Dr. David Matlock introduced and trademarked the name **Laser Vaginal Rejuvenation (LVR)**. The surgery, which has been a hot topic in many women's magazines, aims to correct sequelae to the pelvic floor from pregnancy and delivery, treat urinary and fecal incontinence, repair genital prolapse, and enhance sexual gratification.

The goals of LVR are:

- Shortening the functional length of the elevator ani muscle.
- Improving vaginal control.
- Diminishing the external and internal diameter of the vagina.
- Reinforce the perineal body.
- Embellishment of the perineum.

The procedure is minimally invasive, improves surgical accuracy, causes minimal bleeding and minimal post-surgical pain, and leaves "invisible" scars. Dr. Pardo uses a 1064 diode laser, but he said the choice of laser is not the most important thing.

Dr. Pardo said the surgery must be done by people skilled in uro-gynecology. He added, "Plastic surgeons want to do it, but they can't do it well."

Another procedure Dr. Matlock has trademarked is called **Designer Laser Vaginoplasty (DLV)**. This is his name for the aesthetic surgical enhancement of the vulvar structures, labia minora, labia majora, mons pubis, perineum, introitus,

and hymen. Other, non-trademark names include: laser labioplasty, laser perineoplasty, laser hymenoplasty, and labia majora laser lifting.

According to Dr. Pardo, a surprising number of women have a vaginal problem they would like resolved with one of these surgeries. He said a 2004 survey of 10 women (university students and professionals) found that 90.5% believe their vagina is wide compared with its pre-delivery status, and 100% said they would be interested in laser vaginal rejuvenation surgery with a narrowing of the vagina. He said, "There are a lot of advertisements on genitals…And many women see that they don't have the genitals they see on the screen…so there is an aesthetic issue. Plus there are injuries from skiing and horse riding. Imagine the shame of some girls who have to take a shower in school and have big labia majora."

The procedure is somewhat controversial. Dr. Pardo said, "To talk about this in a Catholic society like Chile – at a major hospital clinic – was sort of a revolution. This is a very important change…The beginning was very complicated. The director told me everyone was against the narrowing of the vagina for women to feel orgasm…They had no problem with Viagra (Pfizer, sildenafil), though." However, Dr. Pardo convinced his hospital to allow the surgery, and he said the results have been excellent.

Over the past three years, Dr. Pardo has done vulvovaginal laser surgery on 322 patients with >600 surgeries, including: colpoperineoplasty for classic genital prolapse, colpoperineoplasty in vaginal amplitude, labioplasty, and correction of labia majora. He said patients have been very satisfied with the results, and 100% of the male partners were very satisfied with the surgery.

Who are these patients? Dr. Pardo said, in his experience, the patients have come to the clinic spontaneously because they read or heard about the surgery and knew his clinic did it. This surgery is also being done in Korea, France, Switzerland, and the U.S. He estimated that 67 centers worldwide do this kind of surgery today. Dr. Pardo said more than 10,000 American women have already had this surgery, and he called it the fastest growing plastic surgery.

OTHER LASER NEWS

LUMENIS

Several doctors complained that Lumenis is not supporting their older but quite effective Lumenis lasers, making them somewhat wary of whether other laser companies will continue to support their products.

LYNTON LASERS' Lumina

This established U.K. laser company may enter the U.S. market in about a year, and its technology is interesting. It has a multi-platform laser that combines different technology: active Q-switch, IPL, and long-pulse laser – and plans for a stamped fractionated add-on in the future. The company expects to finish its FDA 510(k) application this year, and is starting to talk to potential U.S. distributors. The price is expected to be comparable to Palomar's StarLux. An official said, "In the U.K., we have a short-term rental option that is applied to the purchase price. It is not a lease." A 650 nm laser is standard but 585 nm, 650 nm, 755 nm, and 1064 nm are available.

Photodynamic Therapy (PDT)

While interest in PDT to treat cancer is increasing somewhat, it has not caught on for hair removal. An expert said, "In oncology, it was done on the worse patient load, where surgeons got tired of surgery, and the photosensitizers used were totally different. The issue that was never solved was margin delineation and how to target that." Another expert said, "A pilot trial of PDT + ALA (aminolevulinic acid) worked better than the ruby laser. But it is not easy…It is tedious and expensive, but it removes 100% of antigen follicles. PDT might now be viable and maybe we should look at it again."

INTENSE PULSE LIGHT (IPL)

There was not a lot of news about IPLs at this meeting, but a few interesting points were made, including:

- *U.S. doctor:* "I think IPL has plateaued. You can't squeeze more blood out of that turnip." He commented – and several other sources agreed with him – "If I were starting out today, I would probably chose a Fraxel over IPL."
- *Industry source:* He said a Chinese IPL has gotten a C.E. Mark and sells for ~€12,000. He commented, "People are price driven, and there is a lot of lack of technical background. The challenge in Europe is educating the doctors…Many doctors don't know what the shape of the wave (pulse) means, and price is the No. 1 issue."
- *Panamanian doctor:* "I would like an IPL before a Fraxel because I can do more with it, including hair removal. And I like the handpiece and multiple lights with (Palomar's) StarLux."
- *Czech doctor:* "I would never buy an IPL again. I use it as an alterative and in my spas and small clinics where doctors are not in the clinic all day."
- *Industry official:* "100% of the population may be candidates for hair removal. Skin rejuvenation is growing from a low point. The results were very soft, and not many people are willing to pay for what doesn't work."

RADIOFREQUENCY SYSTEMS

THERMAGE

Thermage did not exhibit at the meeting, and there was little discussion of this technology. Some experts suggested it has fallen into disfavor lately because of a lack of a noticeable effect and the patient pain factor. One said, "Thermage has

had some dubious results, and the company has made comments that are suspect." A U.S. doctor said, "I stopped Thermage because I couldn't get results after 150 patients."

SYNERON'S VelaSmooth

Doctors expressed little interest in Syneron's VelaSmooth for treating cellulite, and few believe it is effective. A Norwegian doctor was typical, saying, "Nothing works for cellulite." A U.S. doctor said, "Most available devices don't work very well." A Czech doctor said, "None of them work, but home cellulite devices will be big." A doctor from Dubai said, "I don't believe it works."

A Syneron source claimed that they've sold 200 VelaSmooths in Spain – 65% to beauticians and 35% to doctors, primarily dermatologists. The source insisted VelaSmooth produces good results but takes 10-12 treatments to do that.

ULTRASHAPE'S Countour

A few doctors said this non-invasive ultrasound device, which is not yet FDA-approved, bears watching. It reportedly is in Phase III trials in the U.S. This Israeli company says the device focuses therapeutic ultrasound on fat cells without damaging neighboring tissue and calls it a "walk-in, walk-out" procedure. The company claims that >14,000 treatments have been done in 100 clinics in 35 countries. A U.S. expert said, "Ultrasound is in development, but it looks pretty disappointing because it is focused deeper. I think RF (radiofrequency) potentially could be better. Thermage is working on that. I'm not very impressed with it either, but it is better."

FILLERS

Most doctors are using Medicis' Restylane. A Czech doctor said, "Restylane is the leader because it has a longer tradition. And I think it gives better results, though I can't show it. Dermatologists tend to prefer Restylane. But there is really very little difference between Restylane and Allergan's Juvederm. Using the product for the right indication is more important…I personally use a little more Restylane, but Juvederm is cheaper."

Sources were generally unfamiliar with the new filler, Evolence, that Johnson & Johnson got with its recent purchase of ColBar. An Austrian doctor said, "I'm very, very scared because Juvederm says it is safe, and it isn't. We see side effects."

BOTULINUM TOXIN

Allergan's Botox (botulinum toxin-A) has been the only FDA-approved botulinum toxin in the U.S., but Ipsen/Medicis' Reloxin/Dysport (also botulinum toxin-A) could be on the U.S. market in 2008. The data have been locked in the pivotal U.S. trial, with an expected FDA submission in October 2007.

Even though Reloxin is already available in Europe and elsewhere, very few non-U.S. doctors questioned about it are using it yet. Most doctors were interested in hearing about Reloxin, but few saw much reason to change. A Spanish doctor said he was unaware of the product. A Mexican doctor said, "Why change when Botox works?" A Czech doctor said, "I educate other doctors about Reloxin for Ipsen. If they learned with Botox, it is hard to explain the conversion to Reloxin, but I teach them how to work with Reloxin…The results are about the same, but you need a little different technique. Reloxin has better results, diffuses more, and is cheaper, but there is a higher risk of side effects. Botox is more precise, but you need more volume, so it is more expensive." A Swiss doctor said, "Botox is No. 1 because we have long experience with it, and there is no reason to change. Fifty francs more or less is not enough to make me change. And the conversion (formula) is an issue." An Austrian rheumatologist said, "I like Reloxin better. It is easier to handle, and it gives a more natural effect."

New data were presented at the meeting on Reloxin in the treatment of hyperfunctional facial lines by Dr. Adrian. This was a blinded, bilateral, 20-week, 2-physician, comparison study of 24 patients done in Germany, using photographic and EMG comparisons. The study was sponsored by the two doctors, not a pharmaceutical company. Patients could not have had any botulinum toxin in the previous six months. Identical volumes of solution were administered to six facial sites on each patient in the trial. Follow-up was on Days 3, 7, 2 weeks, 4 weeks, 8 weeks, and 10 weeks, with photos at each visit. The photos were then read by an independent reader.

The results have not been fully analyzed, but Dr. Adrian said the preliminary results suggest: "At the very least, clearly, and unequivocally, Dysport is at least as effective as Botox...Those of you who chose to use one or the other, forget the myths that we have from marketing and sales tactics. Pay attention to the neurology literature. Use a bottle of each, and see what your patients think." Dr. Adrian wouldn't say where the final results will be presented.

Botox comes in 100 U vials, and Reloxin comes in 500 U vials, and each must be diluted with saline. Converting from use of Botox to Reloxin means adjusting the dilution so the volume remains constant. The conversion isn't complicated, but it makes it harder to switch back and forth from one to the other. In addition, Dr. Adrian says there is a little difference in technique in using the two products, which also has to be taken into account.

Dr. Adrian is a big fan of Reloxin/Dysport. He said he believes 2.5 U per 0.1 cc is the best dilution, but he uses 3.0 per 0.1 cc because "patients like it better." He believes Reloxin lasts longer and is less expensive, and he called it a myth that Reloxin diffuses more than Botox. He said, "It is clear Dysport is a better product, but Allergan marketing has been strong. Medicis will change that."

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