Trends-in-Medicine

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by Lynne Peterson

SUMMARY

Allergan's Juvederm is off to a strong start and taking market share from Medicis's Restylane. ♦ Sales of aesthetic lasers remain strong, particularly in the non-traditional market. The bloom is off Reliant's Fraxel, which is now getting a run-for-its-money from Lumenis's ActiveFX, a fractionated CO_2 laser. ♦ Cosmetic surgeons are not very concerned about competition from home hair removal devices. ♦ Cynosure's new liposuction device, Smartlipo, didn't get a very good reception at the meeting, with some speakers calling it a fraud. ♦ The hot cellulite treatment is Alma Lasers' Accent, not Syneron's VelaSmooth. ♦ The launch of Medicis's Dysport/Reloxin may be relatively slow unless the price is dramatically lower than Allergan's Botox. ♦ Silicone breast implants are not expected to expand the overall market for breast implants, which is growing at a rate of ~10% per year. Doctors estimated 34% of their implants will be silicone this year, with cost and patient concerns the major barriers to use.

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COSMETIC SURGERY UPDATE

About 400 cosmetic surgeons – dermatologists, oral & maxillofacial surgeons, otolaryngologists, general surgeons, gynecologists, plastic and reconstructive surgeons, ophthalmologists, and other specialties – attended the American Academy of Cosmetic Surgery (AACS) meeting in Phoenix from January 24-29, 2007. The hottest topics were silicone breast implants, new dermal fillers, new technology for liposuction and cellulite, and fractionated CO_2 (ablative) lasers. Twenty-five cosmetic surgeons as well as industry experts were asked about trends in the use of these products.

What's hot? Doctors pointed to:

- **Post-bariatric surgery patients** seeking cosmetic surgery procedures. A doctor said, "They are asking for lifts, tucks, liposuction. 190,000 people had bariatric surgery with an average loss of 90 pounds, and the vast majority could benefit from skin resection surgery and liposuction. The question is whether they can afford it. They are good candidates for cosmetic surgery, and they are doing it."
- **Fractionated CO_2 lasers.**
- **Vaginal laser cosmetic surgery with a CO_2 laser.** This was a hot topic at the 1st International Conference on Advances and Controversies in Laser Medicine and Surgery in Barcelona last year, and a gynecologist/cosmetic surgeon at AACS said the procedure is continuing to gain popularity. The surgery aims to correct sequelae to the pelvic floor from pregnancy and delivery, treat urinary and fecal incontinence, repair genital prolapse, and enhance sexual gratification.

AESTHETIC LASERS AND INTENSE PULSE LIGHT (IPL) DEVICES

Despite Candela reporting a drop in its second quarter revenue, industry sources as well as physicians at AACS insisted sales of aesthetic lasers remain strong, particularly in the non-traditional market (e.g., family practice doctors). Cosmetic surgeons and industry sources also agreed that sales are still strong in the traditional dermatology market. In fact, several doctors at this meeting said they were shopping for a laser. A Candela sales rep blamed the drop in sales on a lack of new products but said he was looking forward to the new products being shown at the American Academy of Dermatology (AAD) meeting in early February 2007, "We don't have a competitive product (right now), but we are introducing four new products." A Michigan doctor said, "The market is strong, but there are a lot of players sharing the pie."

Yet, interest also is growing among non-dermatologists/plastic surgeons, which some experts estimated now comprise 75% of laser sales. Two vascular surgeons

said declining reimbursement in their field had encouraged them to switch to cosmetic surgery. A Maryland gynecologist said, "Reimbursement in traditional (gynecology) is so poor that I can't maintain a good level of medical care (in gynecology) with the staffing that is mandated by reimbursement, so I do the medi-spa three days a week so I can do gynecology two days a week." Another source, who is sponsoring a meeting in June 2007 for ~600 non-dermatologist physicians who want to get into lasers, said, "Lasers are still going strong in the traditional market, but everyone wants to get in this space." An Alma Lasers official said, "We are growing and meeting our numbers. Sales are mostly to general practitioners. The general medicine market is expanding quickly. The dermatology market is more saturated. Unless doctors have old technology, there is not much need to spend $100,000, but a lot of new people are getting into the field…Pricing is getting more competitive. Everyone is working hard to get deals, so there is more pressure on more and better technology."

Fractionated lasers. **Reliant's Fraxel** was the hot technology at the American Society for Laser Medicine and Surgery (ASLMS) meeting last year, but it is getting a run-for-its-money from **Lumenis's ActiveFX**, a fractionated CO_2 laser, and there was a bit of a buzz at the AACS meeting about ActiveFX, though Reliant reportedly is working on its own CO_2 Fraxel. None of the doctors questioned at the meeting, including many who did not already have a Fraxel, were planning to buy one. A Florida doctor explained, "I'm waiting for the new generation technology." A California doctor said, "Fraxel was a flash in the pan. There are a lot of unhappy patients even after more-than-predicted (four) treatments – even with eight treatments…I would recommend Rhytec's Portrait PSR^3 over Fraxel or a CO_2 laser." Another expert said, "We are going 'back to the future' with fractionated CO_2 lasers."

A Reliant sales rep cited several advantages to Fraxel over a fractionated CO_2 laser, including: deeper depth, a controlled spot size, non-ablative, and less social downtime.

IPLs. Many doctors already have an IPL, and few doctors at this meeting expressed any interest in buying one. One source said, "We looked at (Syneron's products), had a demonstration, and found it very powerful, but even with our experience, and a sales rep there, the patient still got burned." Another doctor said, "I wouldn't buy another IPL."

Pricing. Laser manufacturers appear to be doing a lot of "dealing" on price, but no more than in the past. A Florida doctor said, "Pricing for new lasers is all over the place." Other sources cited discounts of up to 20% off several new devices they were considering. An industry source said, "Pricing at the bottom is coming up, and at the top it is coming down, but the amount of dealing is about the same as usual."

Used lasers. Used lasers offer savings of 25%-75% off the cost of a new laser, and doctors are willing to buy them. The savings may not be quite as much when buying through a dealer specializing in pre-owned lasers vs. an eBay purchase, but those dealers often offer warranties, service, and support. A source said, "We plan to buy an IPL, and it may be a used one because we can get about a 25% discount." A Florida doctor said, "There are a lot of used lasers available because the companies hype their products and can't keep their promises. I've bought several used lasers, and I saved 50%-70%." A California doctor said, "People are buying used lasers, but you need to be laser savvy because most come without a warranty, so you need an independent servicing business. But you can save up to 75%."

An official of Sandstone Medical Technologies, a pre-owned laser dealer, said the average discount for a used laser is ~50%, and all kinds of lasers – but not IPLs – are popular. His firm provides a one-year warranty as well as factory-trained service technicians.

BOTULINUM TOXIN A

Sources said their use of **ALLERGAN'S Botox** has not plateaued; it is continuing to increase. For example, a Florida doctor said, "I do a lot of off-label use of Botox because the contouring is so phenomenal…Allergan won't list me on its Botox hyperhydrosis website because I'm not a dermatologist, but I treat a lot of patients with Botox for hyperhydrosis."

There were no experts talking at the meeting about **MEDICIS'S Dysport**, another botulinum toxin A, so there was no insight into the timeframe for FDA approval of this product. Doctors appeared mildly interested in it, but most predicted the launch will be relatively slow unless the price is dramatically lower than Botox (≥20%). Most doctors said they would try Dysport, and a few are anxious to encourage competition in the hope that competition will lower prices, but Botox's name recognition is strong, it is a tried-and-true product, and doctors will have to learn a slightly different technique with Dysport. Comments included:

- *Florida:* "I get such good, tight results with Botox that I would need an overwhelming reason to switch – not just a few dollars. If Dysport were 25% cheaper, I would use it on some patients."
- *California #1:* "I want to use Dysport as soon as it is available to give Allergan a run-for-its-money because of how they have increased prices (of Botox). I would advertise both, and see what patients will accept. Dysport will not launch as well as Botox did, but it will gain a percent of the market, depending on the patient response when we try it. If patients think they are getting equivalent results at a lower price – at least 10% lower – they will accept it."

- *Oregon:* "I'd initially order a lot of Dysport to help lower the Botox price, but for me to continue to use Dysport, the price needs to be 20% lower."
- *California #2:* "Medicis will push hard, but the problem is the rare patient who gets flu-like symptoms with the current Botox. The new one has a higher protein level, so I think it will increase the flu-like symptoms…I'll try Dysport, but I won't make a wholesale switch."

MENTOR'S PurTox is a third botulinum toxin A in development. Phase III trials are expected to start this year.

CELLULITE

Cellulite Therapies

Therapy	Comments
Massage	Short-term results but usually no long-term results.
Mesotherapy	Still quite controversial.
Bipolar RF	Shown to work but requires multiple (6-16 biweekly) treatments, with fairly small results.
Unipolar diffuse RF	Painless, simple, some erythema but no blistering or scarring. Doesn't work on fat but good for skin tightening. May have synergistic effect with other cellulite treatments.
Focused ultrasound	Not yet FDA approved. Non-invasive, non-thermal effect. Is not a weight loss technique. Good patient satisfaction.

There were no new data at the meeting on **SYNERON'S VelaSmooth** for cellulite, but a sales rep said a "white paper" will be presented on it next week at the American Academy of Dermatology meeting in Washington DC. Doctors questioned about it were very skeptical. A New York doctor said, "VelaSmooth is bipolar, but it is not as good as Alma's RF system. The VelaSmooth issue is the results are modest, and it requires so many treatments (twice a week for 16 weeks)."

However, there was some excitement at the meeting over **ALMA LASERS' Accent,** a combination unipolar and bipolar RF system for cellulite treatment. This is not yet FDA approved, but the company is hoping to have FDA approval in time for the American Academy of Dermatology meeting in early February 2007. Accent is a non-pulse, continuous energy machine that costs about $100,000 fully loaded, which an Alma sales rep said is $50,000 less than a Palomar StarLux. Accent also was touted as fast, efficient, and energy efficient. A user said, "I have one, and I've gotten excellent pre- and post-procedure results. I've seen dramatic improvement. And there are no disposables."

DERMAL FILLERS

ALLERGAN'S Juvederm, a new hyaluronic acid dermal filler, is off to a strong start. It already accounts for an average of 13% of these doctors filler use, and that is expected to almost triple this year, at the expense of both **MEDICIS'S Restylane** and **BIOFORM MEDICAL'S Radiesse**. A West Coast doctor said, "Medicis is arrogant. I get bills before I even get the product, so I'll use Juvederm and drop Restylane." Another doctor said, "Juvederm is interesting, and I'm trained to use it, but I'm not totally sold that it will replaced (Medicis's) Restylane and (Allergan's) Captique."

On December 28, 2006, the FDA approved Radiesse for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in HIV patients, but many doctors said they are using it off-label for other purposes. A California doctor said, "Radiesse lasts up to 18 months, and I can use it lots of places."

In the U.S. there are two Juvederms – Juvederm Ultra, which is the thin formulation, and Juvederm Ultra Plus, which is a little thicker. Each has its proponents, and many doctors are stocking both, but few believe there is a need for a whole repertoire of one brand. In Canada and Europe, there are several other forms of Juvederm – Juvederm 18, 24, 30, 24HV (high viscosity), and 30HV – but U.S. doctors said they could not imagine stocking all of these in their offices. One expert suggested, "Find which fillers give consistent results in your hands, and use one or two – a fine line and a deeper line filler." Another doctor said, "I have a tool box with six different fillers, including Restylane and the two Juvederms."

Juvederm was described as fairly comparable to Restylane. A Florida doctor said, "Restylane was my No. 1 filler because it is bio-identical, degradable, and doesn't interfere with the natural aging process, but with the introduction of Juvederm, my Restylane use will go down…I don't know if Juvederm lasts longer than Restylane, but Juvederm is a smoother injection and causes less post-procedural redness and swelling."

Dermal Filler Use by These Sources

Company	Product	Type	Use as a percentage of all filler use	
			Today	In 6-12 months
Allergan	Juvederm	Hyaluronic acid	13%	38%
Medicis	Restylane	Hyaluronic acid	39%	22%
BioForm Medical	Radiesse	Calcium hydroxylapatite	32%	21%
Sanofi-Aventis	Sculptra	Poly-L-lactic acid, synthetic, biocompatible	6%	8%
Allergan	Captique	Hyaluronic acid	6%	2%
Artes Medical	ArteFill	PMMA microspheres in a bovine collagen gel	0	1%
Others, including Allergan's CosmoPlast and CosmoDerm, etc.		Collagen, silicone, etc.	4%	8%

However, one expert predicted that when Restylane Perlane is approved, Medicis will take back some of the market share Restylane is losing to Juvederm. A Pennsylvania doctor said, "Juvederm and Restylane are variations on the same theme… I'll use a lot of Juvederm until Perlane is approved, and then I will compare Juvederm and that…Perlane will directly compete with Juvederm Ultra Plus, but there are no side-by-side comparisons yet."

Dr. Helga Van den Elzen of the Netherlands, who has used injectables more than 8,000 times, reviewed some of the issues with dermal fillers. She emphasized that it is important to base the choice of a filler on the desired results.

JOHNSON & JOHNSON recently purchased Colbar, an Israeli company, with a dermal filler, Evolence, that has a C.E. Mark and is available in Europe, but almost no U.S. cosmetic surgeons were aware of either the company or the filler. Colbar (J&J) was a high level (platinum) sponsor of the AACS meeting, and the Colbar name was on a lot of signage, but that's all that was on the signs: "Colbar LifeScience" – no mention of J&J or Evolence. Evolence, a long-lasting (8-12 months) ribosome-linked collagen filler, reportedly is the first in a "family" of fillers J&J is planning. Evolence is currently in clinical trials. An investigator said it is "smooth to inject."

MENTOR'S Puragen. This double-cross-linked hyaluronic acid filler is already approved in Canada. A Mentor official said it lasts "at least as long" as Restylane, but the company hopes the FDA will grant it a label for 9 or 12 month duration of action. The FDA submission should be completed by summer 2007, and the company is looking for approval by the end of 2007.

HAIR REMOVAL

Hair removal remains a mainstay of many cosmetic surgery practices. One source said, "Hair removal is increasing. That is a major, major area. And we can train a technician to do that at $75-$125 per treatment, and then offer patients a package."

Three companies have home use hair removal devices on the horizon, but they are aimed totally at the consumer market, and even sales reps from the two companies represented at the meeting didn't know much about their own product.

- **PALOMAR'S device,** which will be sold by Gillette. The Palomar sales rep said he didn't know anything about this and hasn't even seen it, but insisted it would be handled entirely as a consumer product. He thought Gillette was currently doing or planning some test marketing. Asked about the impact on cosmetic surgeons, he suggested it might actually have the effect of increasing their hair removal business, the way home teeth whitening products at first threatened dentists but turned out to boost in-office teeth whitening.

- **RADIANCY'S NoNo.** The company is trying to carefully separate its consumer products like NoNo and its professional products, and the professional sales reps have not been trained or briefed on NoNo. A sales rep said the product will not be launched at the American Academy of Dermatology meeting, and he thought it would be marketed through TV infomercials and perhaps a high-end department store, not to doctors.

However, Radiancy has a professional, handheld acne (and perhaps photorejuvenation) device designed to be used by consumers under the direction of a doctor, and it may be shown at AAD. It is designed for cosmetic surgeons to sell to their patients who would use it for touch-ups. The sales rep said, "It will be a culture change for doctors to embrace the consumer products."

- **SPECTRAGENICS' device.** This is not yet FDA approved, and there was no information on it at the meeting, and doctors were unaware of it.

Comparison of Some Less Common Dermal Fillers

Company	Product	Duration	Disadvantages/complications	Best indications	Physician comments
Artes Medical	ArteFill	N/A	N/A	Small corrections, wrinkles and folds	None
Polymekon Research	Bio-Alcamid	N/A	Active inflammation, granulomas, and migration.	N/A	"It can react even after a year."
DermaTech	Dermalive/ Dermadeep	N/A	Very reactive; granulomas with necrosis.	N/A	"A European doctor who did a lot of this says it should be banned, so don't use it."
BioForm Medical	Radiesse	6-8 months	Submucosal "nodules," bruising, redness, swelling, pain, tenderness, itching.	Lower 1/3 of face	"The company discourages use in lips, but doctors are using it there."
Sanofi-Aventis	Sculptra	18-24 months	Inflammatory reactions if injected too superficially; granulomas; painful unless mixed with lidocaine, and multiple treatments (2-3) needed.	Tear trough, acne scars, volumetric filling, hand rejuvenation	"This is the one product that has changed my practice."

Cosmetic surgeons were not very concerned about competition from home hair removal devices. Comments included:

- Asked if these devices can be both effective and safe, a Florida doctor said, "There is effective, and there is safe... Some consumers will buy them and use them, and they will find they don't work. Probably there will be no noticeable impact on cosmetic surgeons."
- "I wouldn't mind if home devices do hurt hair removal. It is the bane of my existence. I hate hair removal. My nurses do it all. Patient expectations are just too high. A patient complains at least once a week."

LIPOSUCTION

Liposuction is a popular procedure with patients, and demand is growing, but traditional devices remain the mainstay for performing these procedures. One new product got panned, while another was well received.

CYNOSURE'S Smartlipo, a new liposuction device, didn't get a very good reception at the meeting. It is a 1064 nm Nd:YAG laser. Dr. Neil Sadick gave a talk about Smartlipo, calling it a major advance because it also produces skin tightening. He said, "It is particularly effective in areas of skin laxity – e.g., the neck, arms, and thighs." An Oregon doctor said, "I'm getting Smartlipo. It works well. People really like it. It is especially good for the neck." A California doctor said, "I'm getting Smartlipo, and I think it will work. I like the efficacy and tailor-ability. Patients have routinely asked for it for the last three months."

Cynosure's signage announces: "*Where art and science meet*." But sources criticized Cynosure for promoting Smartlipo before there is science (or studies) to back it up. Dr. Edward Lack, the president of AACS, said, "Cynosure is making claims they can't substantiate. I'm not saying it is a bad machine, just 'Buyer Beware'…They are reshaping the past and packaging it in a new $90,000 box." Another prominent cosmetic surgeon described Smartlipo as "a total fraud," adding, "We tested it and proved it does nothing."

A third expert said, "A doctor who bought one said it doesn't work but that it is paying for itself as a marketing tool to bring patients into the office for other procedures. Another doctor said a colleague recently got a Smartlipo but isn't sure yet what he thinks about it. A California cosmetic surgeon said, "Cynosure is spending a lot of time, money, and effort to promote it without a lot of clinical data…Doctors are presenting it with little clinical experience." A Michigan doctor said, "It is gimmicky, but it may help marketing and have some benefit for patients in the long run. There has been a lot of hype preceding the science."

Cynosure will bring a machine to a doctor's office for a demonstration but will not let doctors keep it for 30, 60, or 90 days for a trial. The device costs about $94,000 plus disposable fibers which cost $500 and can be used, on average, for five procedures.

Smartlipo is not designed to treat all liposuction patients. A Cynosure official said doctors will still want to use a traditional liposuction system as well, "Doctors may do 60%-80% of large patients with standard liposuction equipment, and this is for the balance of patients. We are not selling it to anyone who doesn't already have liposuction experience… FDA approval is for use with aspiration, but it is up to the doctors whether they aspirate or not. No suction device comes with Smartlipo. It is up to the doctor to provide suction."

SOUND SURGICAL TECHNOLOGIES' Vaser. In contrast to Cynosure, Sound Surgical will let doctors try out this device for about 45 days for a fee of $2,000 and no disposable charge. If the doctor decides to buy it, the price is $12,000 plus a disposable fee of $395 per procedure. A sales rep said, "98% of doctors who try Vaser, buy it."

Comparison of Smartlipo and Vaser. Cynosure was emphasizing that this is not a cost-effective option for high- or even medium-volume doctors, and they might be right, but the upfront costs are less with Vaser, and the Vaser system includes infusion and suction equipment, which the doctor has to get separately with Smartlipo. Smartlipo also reportedly has a smaller cannula, and can be used in the neck, where a Cynosure sales rep said Vaser should never be used.

MEDI-SPAS

Some states, such as Arizona and Texas, require certification training for physicians, nurses, laser technicians, aestheticians, and medical spa personnel who operate lasers, IPL, radiofrequency or other thermal devices. Cosmetic surgeons said they believe laws such as these are a good idea and a positive step and should be expanded to other states. Neither doctors nor industry sources believe tech certification would have a chilling effect on the industry. A California doctor said, "Certification is a ***good*** thing because a physician is often not present in a medi-spa." An industry source said, "We already have a certification law in Arizona, and it is proving very difficult to enforce. It certainly hasn't slowed down sales."

Comparison of Estimated 5-Year Cost of Smartlipo vs. Vaser

Product	Initial cost	Per procedure fee	Low volume center (40 procedures/year)	Medium volume center (100 procedures/year)	High volume center (150 procedures/year)
Smartlipo	$94,000	$500 for 5 procedures ($100 per procedure)	$114,000	$144,000	$169,000
Vaser	$12,000	$395 per procedure	$91,000	$209,500	$308,250

SILICONE BREAST IMPLANTS

In November 2006, the FDA approved the return of silicone breast implants to the U.S. market. Doctors insisted they did not have a list of patients waiting for the silicone implants, and most do ***not*** believe that silicone breast implants will expand the overall market for breast implants. However, as long as the economy is doing well, ***total*** breast implant procedures in 2007 are expected to be about 5%-10% higher than in 2006 due to more publicity about, and acceptance of, cosmetic procedures in general. Among comments about this were:

- *New York:* "There is no increased interest in silicone breast implants. The market expansion will be in (saline) revisions, not silicone. Patients with unsatisfactory saline results almost always switch to silicone."
- *California #1:* "Breast augmentation is now high on women's list of things to do."
- *California #2:* "There is no increase in patients due to silicone implants, but the patients who do come in are delighted that we can offer silicone."
- *Oklahoma:* "Silicone is not a market expander."

The choice of silicone implant – **ALLERGAN'S Inamed** or **MENTOR'S MemoryGel** – will have more to do with prior relationships than anything else, doctors insisted. They described the Mentor and Allergan implants as very comparable. A source said, "We have an agreement with Allergan on pricing – a volume discount – so that is motivating us."

Doctors estimated that in 2007 an average of 34% of their patients will get silicone breast implants and 66% will get saline implants. There was a big variation from doctor to doctor, with some expecting 75%-80% of their implant use to be silicone, and a few saying it will only be 10% for this year, though increasing in later years. An industry source predicted that only 25%-30% of implants will be silicone this year because of the cost and the paperwork. He said that about 25% of implants now are silicone, and he did not believe that this would grow much in 2007. A California doctor said, "Probably 85% of my implants will be silicone this year. The only patients who will get saline will be those who still feel prejudiced against silicone based on rumors or stories about older silicone gels that have been off the market since about 1990…The high profile saline implants work well, but they don't look as natural, and they feel harder." Another doctor said, "I'll recommend silicone to all my patients, but I expect 75% of them to accept it." A speaker said that 40% of his saline patients have called or come back to ask for silicone, but he estimated that only 50% of his patients will get silicone breast implants in 2007.

Doctors offered several reasons why they won't switch completely to silicone immediately:

- **Cost.** An Allergan official said silicone implants cost about $1,000 more per patient than saline, but doctors said the price difference is $1,500-$2,000 more with silicone.
- **Fear.** Some women are still afraid of silicone. A West Coast doctor said, "People still have the idea that silicone can be associated with complications that don't occur with saline, and it is up to Allergan to convince us to promote their product." Another West Coast doctor said, "I'll use silicone for less than 20% of patients the first year, but I'm kind of conservative and not convinced personally that they aren't associated with autoimmune diseases." An Oklahoma doctor said, "There are still a lot of patients who don't know silicone is approved, and some have reservations. Younger patients don't have reservations, but they don't have the money."
- **Experience.** Some doctors have never used silicone implants because they started practice after silicone was taken off the market and do not do reconstructions. Others have had good results with saline and plan to use silicone only in women who insist on silicone. A New Jersey doctor said, "I'll only do about 10% silicone this year because I've never done them, and I have to learn a new technique, but the numbers will go up because women will demand them."
- **Procedural techniques.** Some surgeons have adopted techniques that do not lend themselves to use of silicone breast implants, which require a larger incision (about 5 cm) than for saline implants. One surgeon, for example, said, "I'm still geared to saline implants because I use an intra-areolar approach, which is easier with saline implants, but I may use silicone implants for patients with a lack of supportive tissue to cover the implant." A California surgeon said, "I do transumbilical breast augmentation, so I'll stay 90% saline this year. I'm surprised I don't get more requests for silicone. I'm surprised at the percent of patients who want saline for the first time; most patients still ask for saline."

However, the one thing that is ***not*** expected to negatively impact use of silicone breast implants – or the choice of a particular brand – is the requirement that most patients enter a trial or a registry. The Allergan program is voluntary, though a company official indicted that if enough patients are enrolled voluntarily, then it will become mandatory. Mentor is requiring that all patients getting its MemoryGel implants be enrolled in either the clinical trial or a registry. A Mentor official explained, "Why the mandatory Mentor model? To ensure that the study is completed." A speaker added, "There is a movement afoot among legislators to again have silicone (implants) taken off the market. Some of the liberal, tree-hugger-type people want these taken off the market. So, I think it is important to get this study done."

All the doctors questioned insisted that the difference in the two programs will not influence the choice of implant, and most said they plan to put all patients in a trial whether required or not.

Comments included:

- *New England:* "The trials will have no impact on the choice of implant. We put all patients in a trial or registry."
- *California:* "Women are not deterred by these studies. The requirements are not onerous. I thought the main barrier would be the MRI at three years and then every two years after that, but they are not required, only recommended…And many people believe the requirement will be lessened because it is a significant cost for patients ($800-$1,200) that won't be covered by insurance."
- *Oklahoma:* "The MRIs are not a deterrent because they are not mandatory."

FDA approval requires:

- Device tracking (a registry).
- Physician certification. A Mentor official said >350 physicians have already been approved.
- IRB approval for sites. A Mentor official said 550 facilities have been approved, with >400 waiting for national IRB approval, and >200 waiting for local IRB review.
- Signed informed patient consent.
- A 10-year post-approval study by each company to begin by February 15, 2007. Mentor's study, MGPAS, will enroll 41,900 MemoryGel patients and 1,000 saline patients. The first patients have already been enrolled. A Mentor official estimated that if every surgeon enrolled 15 patients, the company would meet the trial goals.

Both Allergan and Mentor put on special sessions on silicone breast implants. Allergan's session, attended by about 40 cosmetic surgeons, offered doctors an opportunity to meet the FDA requirements for silicone breast implant certification. Mentor did not offer an on-site certification course – their session, attended by about 15 doctors, was more informational – but doctors can take the approximately one hour course on the web for free. Both companies warned doctors that after February 15, 2007, they will no longer be able to ship them silicone breast implants until and unless they complete certification.

Implant pricing. Breast implant pricing is relatively stable, and no big differences were reported between Mentor and Allergan implants. Silicone implants have not led – at least yet – to a decline in the price of saline implants. Sources insisted that Allergan is not officially bundling the sale of breast implants with Botox and/or Juvederm, but several said that Allergan is offering volume discounts on implants, and others said they get free Botox or Juvederm with some orders.

Among the comments on this were:

- "I get 20 packages of Juvederm free because I use a lot of Botox. Allergan doesn't technically bundle things, but they throw in free things."
- "When Juvederm was launched, preference on availability went to heavy Juvederm users."
- "Allergan is offering volume discounts on implants, Juvederm, and Botox, and year-end bargains for Botox, but there is no bundled price."
- "There are no deals with Allergan; they don't have to deal."
- Another source said Mentor also is getting into product bundling.

A West Coast doctor said pricing for patients could start to come down: "The number of qualified and trained surgeons doing implants is up, and that may lower the price to the consumer."

Supply. Doctors reported no supply constraints of either saline or silicone implants.

Form-stable implants. Allergan and Mentor both have form-stable silicone implants – also referred to as gummy bear implants because of the texture – in development. Sources predicted that they would both be approved by the FDA at the same time, even though Allergan's Model 410 implant was submitted ahead of the Mentor gummy bear implant, Contour Profile Gel (CPG). Doctors also predicted that these implants will be for a niche population, perhaps 10%-15% of total implants. Among the comments on these implants were:

- *New England:* "The advantages of these implants are strictly theoretical. They will probably be easier to take out, which could make a big different for revisions, and they may decrease the need for revisions/replacements. Use may be more patient-driven than physician-driven."
- *California #1:* "Both doctors and patients will drive use of these implants, but they will only account for about 5%-10% of all implants."
- *California #2:* "These implants may be more resistant to formation of capsular contraction, but that is still being evaluated. And women with ptotic breasts may be better fitted on top of the muscle, and a form-stable implant may work better in them…They will cost more, and bigger incisions will be needed. So doctors will have to recommend them…but manufacturers will promote them to the public."

MISCELLANEOUS

ZARS PHARMA'S S-Caine Peel (7% lidocaine and 7% tetracaine). S-Caine Peel was approved by the FDA in July 2006 as a topical local anesthetic peel to anesthetize skin before dermatological procedures. It is applied to the skin as a cream but forms a pliable peel when exposed to air. It is applied for 20-30 minutes prior to aesthetic procedures such as dermal fillers or facial laser ablation and 60 minutes prior to procedures such as laser-assisted tattoo removal.

There was little interest among doctors at AACS in this product. They insisted that the waiting time with the S-Caine Peel would not be an issue. As a Michigan doctor pointed out, the patient would just wait in his "numbing room," so it would not slow down his patient flow. Doctors also didn't have any real concerns about mixing an anesthetic and a filler, though some were dubious that they would mix well, and an expert said, "You might not get even dispersion. I'm not sure lidocaine will mix well with hyaluronic acid. I'm not a big fan of mixing things in sterile syringes."

For other sources, the issue was mostly a lack of any perceived need for this product.

IRIDEX. Most sources had no explanation for Iridex's purchase of Laserscope's aesthetic laser business. The Laserscope lasers, including the 1064 nm Gemini, are good lasers, but sales had been falling recently, and nothing new was on the horizon. An Iridex sales manager said Iridex is giving the business what it needs – more investment in research & development and more focus on aesthetic products. He said, "At Laserscope we were on the back burner, no R&D, only crumbs for the last three years."

Fibrin sealants. These cosmetic surgeons rarely use tissue sealants. They pointed out that tissue sealants are a good adjunct in areas that are amenable, such as the abdomen, but they said the breast is not an ideal area for these products.

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