# Trends-in-Medicine

January 2009

*by Lynne Peterson*


## SUMMARY

♦ **Cosmetic procedures** are down 28%, breast implants down 31%, and fillers and Allergan's Botox each down 16%. Patients are opting for less expensive, less invasive procedures than big ticket items. Doctors are optimistic that their business will rebound in late spring or summer. ♦ Cosmetic surgeons are eager to try Medicis's new toxin, **Dysport/Reloxin**, when it gets FDA approval. ♦ **Silicone breast implants** appear to have found their place, and market share is likely to remain flat over the next year. ♦ **Fat transfer** is a hot topic, but more for the face than the breast in the U.S. Stem cells for cosmetic purposes remain controversial but bear watching. ♦ Johnson & Johnson's **dermal filler**, Evolence, is getting off to a good but not spectacular start. Fillers combined with lidocaine are gaining popularity. ♦ Sales of **aesthetic lasers** have dropped significantly if not disappeared altogether, and pricing has fallen substantially. Doctors are interested in $CO_2$ fractional lasers when the economy stabilizes or improves. ♦ **Liposuction** is still popular, but many doctors are returning to traditional liposuction and using the laser lipo devices more for marketing.



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## AMERICAN ACADEMY OF COSMETIC SURGERY (AACS)

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Despite the troubled U.S. economy, attendance at the annual AACS meeting was as high this year as last year, but few of them were in a buying mood. Cosmetic surgeons come from a variety of specialties. Some do only cosmetic procedures, but most do cosmetics in addition to something else – dermatology, oral & maxillofacial surgery, otolaryngology, general surgery, gynecology, plastic and reconstructive surgery, ophthalmology, even primary care. Twenty-two cosmetic surgeons were asked about trends in the field.

There were no particularly exciting new technologies, but the products and procedures getting the most attention at AACS were:

- Fat transfer.
- $CO_2$ fractional (ablative) lasers for skin resurfacing, now being called "laser facelifts."
- Johnson & Johnson's new dermal filler, Evolence.
- Liposuction – traditional and laser.

Dr. Patrick McMenamin, 2009 president of AACS and a cosmetic surgeon with the Cosmetic Surgery Center of Sacramento, said four things have surprised him:

1. **Continuing technology explosion.** "Laser lipolysis is in its fourth generation, and we are seeing results that are remarkable."
2. **More cosmetic gynecologists.** More and more gynecologists are doing cosmetic procedures. "Now we need data, and that is happening."
3. **Less costly procedures with less downtime** like laser facelifts. "This is the most significant trend."
4. **Explosion of media marketing.** "Print advertising is down, but internet marketing is up."

### THE ECONOMY

While the current economic downturn has affected each cosmetic surgeon differently, almost no one has been unaffected. On average, cosmetic procedures are off 28%, with breast implants down 31%, and use of Allergan's Botox (botulinum toxin A) and fillers off the least (down 16%). Patients are choosing less invasive and less expensive procedures, and medi-spas reportedly are closing right and left. But even in this environment, doctors are looking to start doing new

cosmetic procedures or enter the cosmetic field for the first time. Comments included:

- *Dr. Steven Hopping, past president of AACS and director of the Center for Cosmetic Surgery in Washington DC:* "Some people are not affected, and that tends to be in the Midwest or Texas and people who are more focused on body cosmetic surgery. But on the two coasts everyone is affected, and some as much as 30%."
- *New York surgeon:* "The demand is for medically-necessary procedures – mastectomy reconstruction, etc."
- *Dr. McMenamin:* "Procedures are down across the board."
- *California:* "Diversity is helping me – I do veins, cancer surgery – insurance work – as well as cosmetic surgery."
- *South Carolina:* "There are more uninsured patients, and cosmetic surgery is down across the board. People still come for fillers and Botox who had them before, but there are fewer new patients."

**Practice changes.** In response, doctors are cutting print advertising, especially Yellow Pages advertising, as well as radio and television commercials. At the same time, many are increasing their marketing to existing patients, hoping for more word-of-mouth patients, and boosting their internet advertising. They are also putting more emphasis on their medical specialty business, and some doctors who have been doing 100% cosmetic surgery are now considering going back, in part, to their medical specialty (e.g., dermatology, ENT, gynecology, general surgery). And, in some cases, fees are being reduced.

- *New England cosmetic surgeon:* "Liposuction has fallen off the cliff. I've laid off half my staff, and I'm dropping my advertising because business is so bad that I can't afford it. When things turn around in 6-12 months, I'll advertise again. Facial fillers and Botox continue to be okay – down about 10%-15%. People will skip a meal rather than get wrinkles."
- *California #1:* "I'm doing more educational seminars to the public."

**Most Common Procedures for AACS Members in 2007**

| Number of patients | Procedure |
|---|---|
| 267,294 | Allergan's Botox |
| 156,237 | Microdermabrasion |
| 73,082 | Chemical peels |
| 68,756 | Liposuction |
| 47,998 | Sclerotherapy |
| 36,862 | Blepharoplasty |
| 34,897 | Laser resurfacing |
| 27,111 | Breast augmentation |
| 22,321 | Fat injections |
| 18,638 | Hair transplant/restoration |
| 13,948 | Facelift |
| 12,038 | Abdominoplasty |

- *Washington DC:* "We haven't laid off any staff, but we are trying to reduce overhead. I operate in my office, so if my surgeries are down, my expenses are down. What is not down are fixed costs – rent, mortgage, malpractice insurance. I shopped around for malpractice insurance and saved 30% by going with another company, Medical Protective. That was a major savings…I don't advertise, but if I did, I might do less. And I have increased my marketing somewhat – patient newsletters, interoffice things…I'm doing more liposuction and less facial stuff. Patients are looking for value right now, so I'm sure I give them value. Sometimes that means reducing my fees, especially patients with 'frequent flier' miles with me."
- *West Coast:* "A pure cosmetic surgeon can't change quickly. There may not be great demand now, but this downturn will create pent up patient demand. In December no one was going back to their primary specialty, but they are now. I've been 100% cosmetic surgery, but I'm even thinking about going back to some ENT work."
- *California #2:* "I cut my pay and kept my staff. I even gave the staff a raise. I'm doing more marketing on the internet, but I'm not doing any print, radio, or television, and I've cut my Yellow Pages advertising way back. Marketing companies say this is the time to advertise."
- *Massachusetts OB/GYN:* "I was moving more to cosmetics, but I've slowed that down now. I'm learning how to advertise smarter, not stop advertising. I'm glad I'm still doing OB/GYN."
- *Florida:* "I won't go back to internal medicine unless I go bankrupt…I haven't laid off any staff, but I'm paying more attention to marketing. The internet is doing well, and I increased my print advertising over the last three months."

**Purchasing plans.** None of the doctors interviewed has plans to buy any expensive equipment over the next 6-9 months, though several would like to get a $CO_2$ fractional laser later in the year if the economy starts to pick up again.

- *Washington DC:* "Some vendors have told me they are having a great year – web design firms, instrument companies, not laser companies, though."
- *California:* "I was going to get a $CO_2$ fractionated laser, and I will probably still do it in the next 12 months, but I'm not buying it now."
- *Florida:* "The companies think we are stupid with their high prices…And Cynosure has a big problem. A couple of people wanted to sell their SmartLipo to me, but the warranty is not transferable – it is a license, not a warranty." (**NOTE:** Cynosure confirmed that warranties do not transfer; new owners have to buy their own warranty for about $6,000.)

- *Ohio:* "I'm not buying any high dollar items or capital equipment, but I am interested in smaller products that I could introduce as a niche, like Johnson & Johnson's new filler, Evolence."

**Financing.** Financing has gotten more difficult over the past few months for both doctors and patients.

- *New York:* "Patients can't get credit any more. I used to do 10 liposuctions a week, and it is now down to 3-4 a week. GE's CareCredit is either turning people down or approving them for $1,000 instead of $5,000."
- *Nevada:* "Most patients pay by credit card, though some finance through CareCredit. Occasionally, we do in-house financing."
- *California #1:* "Before, a lot of patients paid by credit card, but now more pay cash or finance with CareCredit."
- *California #2:* "Patients are getting denied more – even patients who used to be approved and have good credit."
- *Florida #1:* "It used to be that 80% of procedures were paid for by credit card or financing, and financing has almost dried up."
- *Florida #2:* "The last 14 patients who applied for credit were turned down."
- *Industry #1:* "Lenders are tighter with their money, for doctors especially. I've seen a higher percentage of people buying outright rather than leasing."
- *Industry #2:* "Unless a patient has really good credit, no one is giving out money right now…Doctors are still buying with a check or leasing, but they are not financing much. Credit is tight right now."

**Outlook.** Doctors were surprisingly optimistic about 2009. Most believe the economy will get better under President Obama, perhaps as early as late spring.

- *Dr. McMenamin:* "We are all feeling the pinch but continue to be optimistic that the cosmetic surgery industry will rebound and in turn grow stronger within the next year…We are notlooking at this (downturn) as a three- to six-month phenomenon. We need a good President. The market has some basic strengths, but there are still likely to be hits from credit card debt and farm credit."
- *Dr. Hopping:* "There is still a lot of bad news coming. We are all sort of hunkering down. My anticipation is that the trend to people doing less invasive procedures, which was beginning even before the economic crisis kicked in, will continue. In a certain way, major cosmetic surgery procedures may well have peaked, and we may find people doing lesser procedures – things that let them get back to the office in one week instead of three weeks, procedures that can be done without anesthesia – 'awake anesthesia.'"
- *Florida:* "With the Obama presidency, I expect things to improve. I think things will be okay by spring or summer."
- *Midwest breast surgeon:* "I think it will be 2010 before there is any bounce back. I'm reassessing my situation weekly."
- *California:* "I'm optimistic the economy will bounce back."
- *Industry source:* "As long as people let fear dominate their mindset…I hear business is off 10%-50% for plastic surgeons."

**Industry perspective.** Many of the companies that had large booths in the past trimmed the size of their booth this year. Companies selling big ticket items generally admitted that these are tough times for them. Industry sources as well as doctors said the emphasis right now is on purchases of smaller items. Among the industry comments were:

- *Laser company #1:* "It varies by area and depends on the individual market, the patient demand – some patients are just not picking up the phone and calling – and how doctors respond to that. Some doctors retract and have a fear response, and others have the opposite response. There is one plastic surgeon (in Florida) who just got started, and he takes a contrarian view, taking this as an opportunity to expand, offering new procedures while other people are hiding, and he is very busy as a result."
- *Liposuction company:* "Prices are way down on surgeries and liposuction – invasive things. Patient Botox pricing has disintegrated to almost nothing. Everyone is using Botox parties to bring in patients. Breast augmentation is down to $4,000 in Beverly Hills (CA), and it used to be $12,000-$20,000…(Cosmetic surgery) offices are all in survival mode and trying to hang on to what they made in the past. If they bought something new, that would be better, but they aren't…2009 will be a tough year for laser sales."
- *Laser company #2:* "The concern I'm hearing is that plastic surgeons who used to be booked out 4-6 months are now booked out only 1-2 weeks, and that is making them very, very nervous about equipment purchases and leases…Prices are going down for equipment and for patients…And there is more interest in leasing. You can lease a laser, and one procedure a month almost pays for it…Medi-spas are closing, especially corporate ones."
- *Electronic medical records company:* "Doctors are tracking their own databases more for patient referrals, doing more injectables, focusing on recurring procedures, doing more internal marketing such as practice newsletters, and increasing their interest in electronic medical records (EMRs). They would like to do more patient financing, but it is harder to get patients approved."

- *Laser company #3:* "Doctors are looking for less expensive lasers with high efficacy but fewer bells and whistles…Two years ago doctors bought the whole suite; now, they are buying 1 or 2 handpieces. Plastic surgeons and dermatologists are the strongest market right now. Doctors are still shopping. The majority of customers lease, which is not a change, but the problem is qualification. A lot of lenders have made leasing more difficult. Doctors are holding onto cash now, not spending, just waiting, but I'm still seeing sales."
- *Laser company #4:* "We are seeing more sales of additional handpieces than new devices. There has been no change in the split between leasing and purchases."
- *Instrument vendor:* "Business is off 28% nationally for the doctors we do business with. I don't expect an upturn until 2010, but it may stabilize by July 2009."

**AACS survey.** AACS conducted an Economic Impact Survey in fall 2008, and the results from the 242 responders were released at the AACS annual meeting. From this survey, it is clear that cosmetic surgeons were hit early and hard by the economic downturn, and from interviews at AACS it is obvious that things have only gotten worse. Yet, cosmetic surgeons remain optimistic about the future.

**AACS 2008 Economic Impact Survey**

| % Impacted | Impact |
|---|---|
| 96% | Concerned about the economic downturn |
| 79% | Already affected |
| 71% | More patients choosing non-surgical procedures, such as fillers or Allergan's Botox |
| 82% | Patients choosing less expensive procedures |
| 51% | Increased marketing efforts |
| 39% | Seeing more patients from their original specialty (e.g., dermatology, general surgery, obstetrics/gynecology) |
| 30% | Laid off employees |
| 34% | Amount that patient volume has declined |
| 33% | Amount that gross billings have declined |
| 11% | "Very confident" that practice volume would fully rebound in the next year |
| 42% | "Somewhat confident" that practice volume would fully rebound in the next year |
| 42% | Optimistic about the U.S. economy rebounding within the next year |

## BOTULINUM TOXINS

While Allergan's Botox procedures are holding up better than more expensive procedures, they are still off 15%-20%. Patients are stretching the time between injections by 1-2 months (from 3 times a year to twice a year), and they are watching how much they spend. Yet, doctors are optimistic that Botox use will not decline further. In this environment, it surprised doctors that Allergan raised prices again this month. Comments included:

- *Midwest doctor:* "I can't increase my price, but Allergan raised my cost of Botox."
- *Ohio:* "Patients are still getting Botox, but they are getting less, setting a dollar limit – 'What can I get for $300?' And they are extending the time between treatments."
- *Midwest:* "Patients are showing up, but less often, and they are buying less…Frugal is the new chic. But I think we've hit bottom. I don't expect Botox demand to go down further."
- *California:* "The price is going down for patients. When the market contracts, people try to get other business by lowering the price of Botox to get people in the office."

### MEDICIS's Reloxin/Dysport

Botox pricing is making cosmetic surgeons more receptive to another botulinum toxin A – Medicis's Reloxin, which is awaiting FDA approval. All doctors questioned said they plan to try Reloxin, especially if it is cheaper than Botox.

- "I will try Reloxin. I expect that if the price is equal to or less than Botox, we'll all go to it. Patients will accept a cheaper substitute. They would be happy with a generic Botox if they saved money. The advantage of Reloxin is that it is competition for Botox, and it may reduce the price. The disadvantage is it is not a known commodity in the U.S. But Allergan has alienated U.S. physicians."
- "Some patients will want Reloxin because it is the newest thing."
- "To get people to change from Botox to Reloxin will take at least a 20% price difference. The price discount has to be substantial because patients ask for Botox by name. We may offer both."

**Botulinum Toxins Approved or in Development**

| Company | Product | Type | Status |
|---|---|---|---|
| Allergan | Botox | A | Approved |
| Solstice Neurosciences | Myobloc | B | Approved |
| **In development** | | | |
| Ipsen/Medicis | Reloxin/Dysport | A | Submitted to FDA |
| Medy-Tox | Neuronox | A | Just bought by unnamed European company |
| Lanzhou Biologic Products | Esthetox | A | Chinese |
| Johnson & Johnson/Mentor | PurTox | A | Phase III just completed |
| Merz | Xeomin (NT-201) | A | Just started Phase III |
| Revance | Revance | A, topical | Trials ongoing |

- "Even a 10% price difference would make a difference."
- "I will definitely use Reloxin. If it works the same, it will catch on. It isn't just a price issue. But to get patients to use Reloxin, doctors need to explain to patients why they should try it."
- "Reloxin has been on the market in Europe longer than Botox, and it may well be less expensive to us and then to the patient. There are some indications the onset of action is faster and that the effect is a little more profound, and there is a lesser suggestion that perhaps it has longer duration. But people are less sure of that. I absolutely will try it. Botox has had a monopoly for a long time."
- "Botox has the name, but the media will write about Reloxin as 'the new Botox,' and people will ask for it. We don't have to promote it; the media will promote it, and the company will promote it."
- "I'll try Reloxin, but you need a higher dose for the same efficacy, and so cost will be an issue. I'll probably pit Reloxin and Botox against each other and find the cheapest."
- "Name recognition is a big help to Allergan, but people are not stupid. If there is no price difference, patients will choose the brand name. But if there is a price difference, patients will try Reloxin. Patients are price sensitive. And there will be a lot of media coverage of a new botulinum toxin, so patients will ask about Reloxin."

While Reloxin is expected to be cheaper than Botox, doctors need to learn to use it differently. It diffuses different and is diluted differently, so it has to be injected with a different technique. A Midwest doctor said, "Diffusion is an issue, and doctors will need instruction in technique and dilution." Another doctor said, "I think there is some evidence Reloxin diffuses a little more, so we have to re-learn injection techniques and be more cautious about our doses. Unit conversion will be a problem…I went to a meeting, and I'm still confused…That will be the big chore for Medicis – to make sure they are showing doctors how to use this properly or people will go right back to Botox." Dr. Gary Monheit from the University of Alabama, Birmingham, said, "I don't think we should use the word diffusion. We are talking about spread, and that is a factor of how hard you push the syringe, the dilution, and where we put it. With Reloxin the rate of spread is the same and only depends on the injection technique…We must learn to think in Reloxin units."

**Comparison of Botox and Reloxin**

| Measurement | Botox | Reloxin |
|---|---|---|
| Response time | 5-7 days | 2-4 days |
| Diffusion/spread | --- | Slightly more |
| Duration of effect | --- | May be slightly longer |
| Potency | Same | Same but units different |
| Immunogenicity | --- | Less protein load |
| Dilution | 1-1.5 cc | 2.5 cc |

### REVANCE's Revance, a topical toxin

There is also a topical botulinum toxin A in development, Revance's Revance. It is applied in a paste of Cetaphil cream. In the first study in 2007 on 12 patients, it was applied to crow's feet areas, resulting in a 65% decrease in wrinkles at 4 weeks. There were "almost no adverse events." Dr. Monheit said, "We definitely see an effect…Revance is also in trials on the forehead and for hyperhydrosis (excessive sweating)…You will apply this in the office. This is not something you can prescribe for patients to use at home…I don't think this will have an effect in deeper muscles, such as the forehead, but a lot of patients are totally needle phobic, and this is a way of bringing them in (to the office). It is definitely much nicer for the palms, soles, and axilla. There is a 90% responder rate in these (hyperhydrosis) trials so far. There is a noticeable effect on control of acne and size of pores with injectable toxin. If we could use this for acne control, it would be great."

Doctors liked the idea of a topical toxin, but few were aware of Revance. One doctor said, "It is an interesting concept. I'll believe it when I see it."

## BREAST IMPLANTS

Breast implant volume is down an average of 31% for the doctors questioned at AACS, and they are hopeful that this is the bottom and that volume will remain stable for the next 3-12 months. A Texas doctor was more optimistic than that, saying, "In 6-12 months, demand will increase and be above where we were."

Silicone implants represent an average of 26% of these doctors' implants. There are some doctors who have gone almost entirely to silicone, but others who still use it for <5% of patients. Penetration has been slow due to both cost and continued patient fears about the safety of silicone, they said. Silicone use was predicted to increase very little over the next 1-3 years, with silicone estimated to comprise an average of 28% of their implants in 12 months. Comments included:

- "I spend a lot of time educating patients about silicone."
- "Price is an issue with silicone implants, but there also hasn't been enough advertising."
- "I offer silicone implants, but most women reject them because of the cost of the initial surgery plus the follow-up care, MRI, and the suggestion they need to be replaced at 10 years."
- "I'm doing mostly silicone now. It was surprising. I expected a small shift to silicone, but it has been dramatic."
- "Some patients still have an unrealistic phobia about silicone."

Most surgeons remain loyal to one brand or another – Johnson & Johnson/Mentor or Allergan/McGhan. None indicated they have recently changed brands, and none plans to switch.

**Stable-form implants**

Allergan and Mentor both have stable-form silicone implants – also referred to as "gummy bear" implants because of the texture – in development, Allergan's Model 410 and Johnson & Johnson/Mentor's Contour Profile Gel (CPG). Doctors continue to predict that these implants will be for a niche population, perhaps 10%-15% of total implants. A Midwest surgeon said, "They are harder to put in and require a bigger incision. I have a wait and see attitude, though. In a very competitive environment, where someone is trying to distinguish himself, they will be used for marketing."

## EYELASHES

### ALLERGAN's Latisse (bimataprost ophthalmic solution 0.03%)

At AACS last year, cosmetic surgeons heard about an off-label, topical use for Allergan's Lumigan, a glaucoma medication, to lengthen eyelashes. Allergan acted quickly to reformulate Lumigan into an eyelash-specific product and received FDA approval for Latisse in December 2008. The company plans to launch it later this month.

Eyelash growth is a known side effect of Lumigan, and cosmetic surgeons and ophthalmologists have been writing prescriptions for it. They instructed patients to dip an eyeliner brush into the Lumigan and then paint it on the eyelid at the base of the lashes, repeating the treatment daily or less often as needed. A 2.5 ml vial of Lumigan typically lasted about a month, at a cost of ~$100. Eyelashes were reported to begin growing in as quickly as two days, but Allergan is warning that it can take up to a month to see the results.

Doctors at AACS were aware of the imminent launch of Latisse, and most expect to prescribe it. Several commented that they have had success with ProCyte's Neova eyelash enhancer and/or Jan Marini's Revitalash, and a new product that works should be well received by patients. Revitalash was ordered off the market by the FDA because it contained naturally-occurring bimataprost. One doctor said Neova is the No. 1 selling product in his practice.

The biggest advantage to Latisse: it really does work, and the effect is real and far better than mascara alone. And it is "medically proven" while other products say only "gives the appearance of." The biggest disadvantage is not the occasional iris color change but the cost. One expert said she has heard that Latisse can cause some facial fat loss and said that needs to be watched. Although Allergan hasn't announced the cost, it is expected to be the same as Lumigan – ~$100 a month.

On average, doctors estimated that 71% of their patients would be candidates for Latisse, and 38% would try it. Comments included:

- *Washington DC:* "It works. I'll prescribe it. All my patients are candidates, and the market is huge."
- *Florida:* "I definitely will prescribe it…The disadvantage is the cost and the time for an effect to show. The advantage is beauty."
- *Ohio:* "I will prescribe it if patients ask for it."
- *California:* "I'll prescribe it because we used Revitalash, and the results were outstanding. How many patients use it will depend on the price."

## FAT GRAFTING/TRANSFER

Fat grafting – particularly in the face – was attracting a lot of attention at AACS, and some experts predicted it will decrease the use of other dermal fillers. In Europe, fat grafting is being done in the breast for both cosmetic and reconstructive purposes, but the lectures at AACS were restricted to the face. Dr. Mark Berman, a Santa Monica CA cosmetic and breast surgeon and president-elect of AACS, lectured on facial fat grafting, commenting, "I don't see an old person anymore; I see a fat-challenged person." Another surgeon said, "I limit fat transfer to facial procedures." A Florida cosmetic surgeon said, "The next step for me is fat transfer for breast, buttocks, and facial augmentation." Dr. Suzan Obagi of the University of Pennsylvania Medical Center in Pittsburgh also uses fat transfer on the face. She said, "I only use Sculptra if I can't get fat. You have to do multiple Sculptra injections, and it doesn't last as long as fat. I can be more artistic with fat, and I don't see nodules with fat."

Dr. Hopping said that at the International Master Course on Aging Skin (IMCAS) meeting held in Paris, January 8-11, 2009, experts were reporting on the use of fat injections rather than implants after mastectomy, and they said that 6-12 months later the skin looked normal, even after radiation burns, "Fat grafting was a big deal at IMCAS." A breast surgeon warned that using fat in lieu of synthetic implants is a time consuming (2-3 hour) procedure and extremely laborious, adding, "Most of us need a ***lot*** of scientific data before we jump on that." Dr. Berman said, "I don't use fat for breasts except for breast defects. The breast procedure takes a long time (1.5-2+ hours). Breast implants are easier, safer, and more predictable. Fat is great as a ***supplement***." Dr. Obagi added, "It is just being reported that an irradiated breast is softened with fat. That is a field to watch."

At its booth at AACS, Wells Johnson Medical Supplies was advertising an American Academy of Cosmetic Physicians course in breast fat transfer – Advanced Awake Liposculpture with Fat Transfer – to be held in Jupiter FL on February 21-22, 2009. Wells Johnson is creating a machine to harvest ***and store*** fat and stem cells for patients and doctors. (Please see **www.cosmeticphysicians.org/course_information_29.html**)

*Are the benefits with fat grafting due to a stem cell effect?* Perhaps. The question is whether the stem cells in harvested fat are sufficient or whether additional stem cells should be harvested and added to the fat grafts, and companies are

working on stem cell harvesting techniques. Some AACS experts insisted that the stem cells in autologous fat transfers are sufficient, and additional stem cell supplementation is not necessary, but this is still an open question – and probably an opportunity for stem cell companies. Dr. Hopping said, "Even if fat doesn't survive when injected in the face, if the skin looks better...It (the fat) does something salutary for the skin…With the new administration (President Obama), stem cells will be a bigger deal here (in the U.S.)…A number of American doctors are going to Europe to learn this…It will be huge." Dr. Berman said, "Stem cells are too controversial. Most of us in the trenches are going with the tried and true." Dr. Obagi said, "The problem is injection fat subcutaneously alone doesn't do much. You need the surrounding complex, the right environment. But purifying stem cells out of fat is not the solution."

Some American doctors are already advertising stem cell breast augmentation without either silicone or saline implants. However, AACS experts said they believe this is premature. Dr. Hopping said, "The hype is way ahead of the reality… Stem cells will catch on because we are an industry that likes to be on the cutting edge, and a lot of people will jump on the bandwagon even before there is real good science behind it… All of us know fat helps in a number of ways. Yes, it fills the face, but it also seems to help the skin…Is it the stem cell? We don't know." Dr. Berman said he is using fat transfers for breast rippling but not augmentation.

Cytori Therapeutics' Celution System isolates stem cells and concentrates them, so they can infuse them back into the patient – or stored for later use. It was approved in Japan in October 2007. An expert at AACS said, "There is a little bit of a leap that you need this $100,000 system just to add stem cells to your fat that supposedly is the source of the stem cells …Where people are using it now is to increase the survivability of fat…In the breast, there is a concern, a suggestion, that stem cells – if injected into cancer – can make cancer cells more prolific…If that is true, we have to be very, very certain that injecting fat and/or stem cells is safe…This is a ***big red flag*** and has to be answered first. Fat injection for breast augmentation is experimental…in this country…It is exciting. It may well be the future…and it also may be hype at this point…We will know in a year or two." Another expert said, "Cytori's system is promising, but the problem is we know we can collect and harvest stem cells, but cosmetic surgeons don't have as much use for them as other physicians (e.g., orthopedic surgeons). In fact, there may be some value, but if you get good results with fat, do you really need more stem cells? This needs university-level research."

*Does frozen fat work better?* That is another unknown at this point. Some doctors insist that frozen fat seems to "take" better, but others said they haven't seen any difference in the results between frozen and fresh fat.

*Are necrotic cysts a concern?* An expert said the risk is both theoretical and real. And the necrotic cysts can make cancer detection more difficult. Dr. Berman said, "Any fat transfer is technique-sensitive. What doesn't vascularize dies (necroses)." Dr. Obagi said, "Yes, you can get necrotic cysts if you put too much fat in one focal spot. It has nothing to do with the total amount of fat, just how much you put in each pass (the surface area)."

## FILLERS

Filler procedures are holding up better than many other cosmetic procedures, but they are also down an average of 16% over the past few months. Patients are going longer between treatments, though. However, doctors are optimistic that filler use will not decline further.

- *Dr. Hopping:* "I think filler use will come up a little as surgeries go down."
- *Ohio:* "Patients are still getting fillers, but they are setting a dollar limit…And they are extending the time between procedures."

Apparently, filler sales are not off enough to encourage the filler vendors to lower prices. However, there are some promotions going on, discounts for big volume users to keep the orders up. A California doctor said, "Both (Medicis') Restylane and (Allergan's) Juvederm are offering 2 for 1 specials. And there is a $100 rebate on the package." A Midwest doctor said, "Both Allergan and Medicis are doing some discounting. And (Anika Therapeutics') Elevess use is up significantly because it has lidocaine in it and because a syringe is $99 vs. $200 for Juvederm."

A number of fillers are already on the market from which doctors can choose, and more are coming, and even more are on the horizon. Dr. Monheit said, "I'm becoming less aggressive in treating patients because they are coming in earlier (with less damage)."

Most of these fillers are only FDA-approved for nasolabial folds, so much of how they are used is off-label. A speaker commented, "I don't think many of us put that in our consent forms, but that's the way it is."

An expert said Restylane, Perlane, and Juvederm can be used "somewhat interchangeably." However, two experts – one of whom made the comments from the podium – complained about problems with the Juvederm injector "blowing the needle." One said, "It happens with 1 in 4 syringes. I am so angry and frustrated that I encourage patients to go to Restylane."

Current controversies with fillers include:

- **Bioactivity** – stretching, bruising, incorporation into the dermal matrix. There is a lot of research being done looking at all this.
- Whether **natural products** are better than synthetic products.

- **Placement complications** (papules, nodules) vs. true hypersensitivity reactions (granulomas).
- **Duration of activity**.
- **Biofilm-related infections**. Biofilms tend to form around permanent implants, and when a filler is injected nearby, it can trigger a fulminant infection. The problem for cosmetic surgeons is that patients do not always tell them they had an implant.

What's new in soft tissue augmentation in 2009:

- **Volumization** – a 3-D approach to facial rejuvenation.
- **Off face rejuvenations** – hands, neck, decollete, cellulite/ post-liposuction defect repair, and even earlobe augmentation.
- **Combination treatments** – filler + intense pulse light (IPL), laser, radiofrequency, or toxin.

**Current Soft Tissue Dermal Fillers**

| Company | Product | Duration | Source/type | Comments |
|---|---|---|---|---|
| **Collagen** | | | | |
| Allergan | Zyderm, Zyplast | Short-acting | Bovine collagen + lidocaine | There are rumors that Allergan is running out of bovine collagen and will not produce these in the future |
| Allergan | Cosmoderm, Cosmoplast | Short-acting | Human collagen + lidocaine | --- |
| Artes Medical * | ArteFill | Long-acting to permanent | 20% PMMA | Will another company bring this product back? |
| Johnson & Johnson | Evolence | Immediate | Porcine | Good for deep lines and wrinkles. Can't be used in lips or high up on the face |
| **Hyaluronic acids (HAs)** | | | | |
| Allergan | Juvederm Ultra, Juvederm Ultra Plus | Intermediate | HA gel | Very nice for lips |
| Anika Therapeutics | Elevess | Intermediate | HA + lidocaine | Was first HA/lidocaine combination approved in U.S. |
| Johnson & Johnson/ Mentor | Prevelle Silk | Short (~2 months) | HA + lidocaine | Like Allergan's Captique with lidocaine. Very soft but doesn't last long |
| Medicis | Perlane | Intermediate | HA | Good for severe nasolabial folds |
| Medicis | Restylane | Intermediate | Non-animal stabilized HA | Sometimes called the "gold standard," with durable, natural results |
| Medicis | Restylane Subcutaneous | N/A | HA | Difficult to inject. May not come to U.S. |
| **Others** | | | | |
| Alcon | Silikon 1000 | Permanent | Pure silicone | Not approved for cosmetic use, but used off-label |
| BioForm Medical | Radiesse | Long-acting but not permanent (6-8 months) | Calcium-based microspheres suspended in water-based gel | More scaffolding so good for localized volumization |
| Sanofi-Aventis | Sculptra | Intermediate (18-24 months) | PLLA | Makes the texture of the skin smoother but takes 3-5 months before seeing results |
| --- | Autologous fat | Intermediate to long-acting | Live adipocytes | Increasing in popularity |

* The company has gone bankrupt, and the product is no longer being sold.

**Fillers in Development or Available in Europe but Not the U.S.**

| Company | Product | Comments |
|---|---|---|
| Bluemedica | Dermalive | Expert recommended against use. |
| Contura International | Aquimid | A permanent hydrogel gel deep filler that is not degradable. Highly elastic, uses 27 g needle. No allergy testing needed. Comes ready to use, stored at room temperature. From Mexico. Problematic because it is a "biofilm breeder" so requires very sterile environment. (complete sterile prep). Complications have been infections. |
| Corneal/Allergan | Voluma | An HA with deeper structural filling. Large particle size, high viscosity. Requires 21 g needle and deep injection. Approved in Europe and Canada. |
| Genzyme | Dermal Gel Extra | Very stiff injectable that may last 2 years. |
| Johnson & Johnson | Evolence Breeze | Will be able to be used in lips and higher face. 27 g needle. |
| Merz | Belotera | Similar to Juvederm but stiffer, a little more robust, good for nasolabial folds. |
| N/A | Bioblue | A polyvinyl alcohol approved in Canada. Not expected to come to the U.S. |
| Stiefel | Atlean | Tricalcium phosphate particles (Beta-TCP) suspended in a hyaluronic acid gel. Approved in Europe. |
| TBMC Aesthetics | Matridex | Has dextran. Expert recommended against use. |
| Uroplasty BV | Bioplastique | Basically "plexiglass." Expert recommended against use. |

- **Lidocaine addition** – doctors often add lidocaine to Sculptra and Radiesse. The problem with doctors adding lidocaine to an HA is the consistency of the combined product can vary.
- **Lidocaine supplementation** – currently Anika Therapeutics' Elevess and Johnson & Johnson/Mentor's Prevelle combine lidocaine and a filler, but Juvederm Ultra Plus and a Restylane + lidocaine are expected to be available soon in the U.S. The biggest problem with HA fillers has been pain, and combining a filler with lidocaine is designed to address this.

Combination lidocaine/filler products are viewed by cosmetic surgeons as important, not just a marketing gimmick, but they are mostly replacements for non-lidocaine products rather than important market expanders. Most sources have already started using Elevess and/or Prevelle, and all plan to try Juvederm Ultra Plus and Restylane with lidocaine. Juvaderm Ultra Plus has been submitted to the FDA for approval, but the Restylane lidocaine product is still being tested. Comments included:

- *Mid-Atlantic:* "The lidocaine combinations will be important because, from a doctor's point of view, they will be easier to inject and more comfortable for patients. Anything we can do to make it a nicer experience is helpful. A lot of us are already adding lidocaine, and it seems to help the (filler) flow. I've had (a combination lidocaine) personally, and it is a non-event. It will be good for needle-phobic patients. But how widely they are used will depend on the pricing."
- *Midwest:* "Lidocaine combinations are a big deal to doctors."
- *West Coast:* "The jury is still out. There haven't been any meaningful randomized clinical trials in large population groups, only company-sponsored, small studies. It needs to be out before we can see if there is a clear advantage. I will try it and see and talk to my colleagues."
- *South Carolina:* "I've been blocking everyone, so there is no need to use lidocaine. I'm not likely to change to a lidocaine combination unless it has a longer lasting effect."

Joseph Niamtu III, DMD, a cosmetic surgeon from Richmond VA, advised doctors just getting started with fillers that:

- The technique used is far more important than the filler used.
- They should use what works best in their hands.
- They should be conservative, use "appetizer size" portions at first.
- The procedure should be painless for the patient.

### JOHNSON & JOHNSON's Evolence

As the newest HA filler on the market, Evolence was in the spotlight at AACS. Evolence requires no refrigeration and no skin testing, and it lasts a little longer than other fillers (9-12 months). It requires a 30 gauge needle and isn't for fine lines, but Evolence Breeze is on the horizon, and it is designed for fine-to-moderate wrinkles. Speakers all had nice things to say about Evolence, though so far it hasn't gained any widespread use. One speaker asked his audience how many doctors had tried it, and no one raised a hand.

Dr. Monheit offered some tips on using Evolence:

- Do not refrigerate it; it clumps when cold.
- Roll the syringe in your hands to warm the product slightly before injection.
- Use it immediately after assembling the syringe and needle.
- Inject at a slow and steady pace.
- Massage immediately after injection. He said, "It cements up quickly, and if you are not careful, you can get nodules, so it is very important to massage quickly."
- Don't inject superficially into the epidermis.
- Do ***not*** use it in the lips.

Among user comments were:

- "It is a very nice appearing filler…The flow characteristics are quite good. This is excellent for nasolabial folds…It has a little more structural integrity than HAs, and patients can sometimes palpate it for the first couple of weeks, but that is not a bad thing."
- "Evolence is a wonderful product."
- "I like it, and patients like it."
- "It is smooth, like injecting the old collagen, which was always easy to inject. There is less bruising with Evolence and more rapid onset. It is good for lip lines. But it isn't lasting longer than Restylane and Juvederm…In a year it could take 20% of the market."
- *Dr. Monheit:* "The way I like to inject it is to get a female-to-female adapter and put 1 cc of lidocaine in it because it doesn't come with lidocaine. But the company can't tell you this…Evolence injects very much like Zyplast, smooth and easy, with a 27 gauge needle. The durability is at least a year and in some patients a little longer…One downside is that it is not malleable after about five minutes, so you have to be sure to massage it within 10 seconds of injection."

### What's on the horizon?

New techniques, more HAs, fat transfer, and stem cells all look promising. Dr. Monheit said that at the IMCAS there were 140 booths, and every one had a different filler.

*Will it be difficult for the newer filler products, especially combination products, to get through the FDA?* Dr. Hopping said, "I would expect another advisory panel or a task force because of the three new products coming. They will need some guidelines. I think the FDA is raising the bar."

## LASER FACELIFTS

This is a new term for laser skin resurfacing. Dr. Robert Shumway of San Diego said the results are excellent, and there is a relatively low incidence of complications, but patient selection is important, and care should be taken not to "over-peel" the skin. He presented a retrospective chart review from 1995-2008 of 100 consecutive $CO_2$ laser facelifts.

A Midwest doctor said, Lifestyle Lift, a franchise face rejuvenation business that has grown to more than 80 doctors, is hurting his business. "Their TV commercials are spectacular," he said.

**Lasers for Rejuvenation**

| Company | First generation laser | Second generation laser |
|---|---|---|
| Reliant/Thermage | Fraxel Restore | Fraxel Repair |
| Cynosure | Affirm 1440 nm $CO_2$ | --- |
| Palomar | Lux 1440 nm $CO_2$ | --- |
| Palomar | Lux 1549 nm $CO_2$ | --- |
| Cutera | --- | Pearl Fractional YSGG |
| Alma | --- | Pixel 2940 Er:YAG |
| Deka Lasers | --- | SmartXide DOT $CO_2$ |
| Sciton | --- | ProFractional 2940 Er:YAG |
| Lumenis | --- | FX $CO_2$ Deep Fx |

### CYNOSURE's Affirm $CO_2$ fractionated laser

Dr. Jan Zemplenyi of Bellvue WA cited several reasons for doctors to consider an Affirm $CO_2$ fractionated laser:

- R&D and customer service by Cynosure.
- Local repair service.
- Competitively priced.
- Only single scanner head needed.
- Cutting handle available.
- Micro-ablative, standard, and cutting modes.
- No consumables.
- Full-line of other lasers available.

### ELEME MEDICAL's SmoothShapes

This private, New Hampshire-based company has been selling lasers for about 3 years. SmoothShapes incorporates a 2-wavelength laser (915 nm and 650 nm) to shrink fat cells and give skin tightening and long-term (>13 months) cellulite reduction. It is FDA-approved for cellulite reduction. So far, "a couple hundred" have been sold in the U.S. at a price of ~$70,000. A sales rep said, "In the current economic environment, lower-cost, non-invasive body contouring has picked up quite a bit."

Eleme also offers a laser-assisted liposuction machine, SmoothLipo.

### LASERING USA's Mixto SX

Lasering USA, a privately-held U.S company, started selling its $CO_2$ fractional laser in the U.S. in the summer of 2008. The company's Mixto is a 10,600 nm laser manufactured in Italy that has FDA-approval for resurfacing and soft tissue incision/excision ablation and coagulation. So far, more than 50 have been sold or leased in the U.S. The company's timing may not be great, but it hopes that its low price (~$80,000), a requirement for fewer procedures (1-3 visits compared to 4-6 visits for its competitors), and no disposable costs will appeal to plastic surgeons, dermatologists, etc.

**Laser Facelift Results**

| Measurement | Complete rhytidectomy with full face $CO_2$ laser resurfacing | Complete rhytidectomy using $CO_2$ laser incisions with "under-the-skin flap" laser dermal tightening | Partial rhytidectomy with dermal flap tightening and full face $CO_2$ laser skin resurfacing | Partial rhytidectomy with partial face $CO_2$ laser resurfacing |
|---|---|---|---|---|
| **Efficacy** | | | | |
| Patient satisfaction score | Highest | High | Very good | Good to very good |
| Cosmetic improvement | Most dramatic | --- | --- | --- |
| **Complications** | | | | |
| Complications | 6% | 2% | 4% | 2% |
| Hematoma | 1 | 0 | 0 | 0 |
| Persistent erythema | 1 | 0 | 0 | 0 |
| Hypopigmentation | 1 | 0 | 1 | 0 |
| Hyperpigmentation | 1 | 1 | 1 (persistent) | 1 |
| Other | 1 yeast infection | 1 hypertrophic incisional scar | 1 bacterial skin infection<br>1 temporary sensory nerve parathesia | 1 acne skin infection |

*How does Lasering's Mixto compare to other $CO_2$ lasers?* Mixto uses continuous wave energy, which a company official described as "an old-fashioned concept delivered in a new way, so it delivers more heat to the dermis." Other $CO_2$ lasers generally use pulsed energy. Instead of a sequential pattern, Mixto uses a quadrant scanning method, which the company claims maximizes the time for the skin to cool between adjacent laser exposures. The company is selling through independent sales reps, with ~15 reps so far.

### LUTRONIC's eCO2

The Lutronic sales rep said the three-year warranty, $89,000 price tag, company longevity, name, and financial soundness plus the lack of disposables continue to make this laser attractive, even in a stressed market. Lutronic also was highlighting its new laser lipo machine, AccuSculpt, and the Spectra VRM III for tattoo removal and acne treatment, while admitting the Mosaic Erbium fractionated laser is not a big seller.

## LIPOSUCTION

Liposuction demand is off, but it is still an important procedure for many cosmetic surgeons. Several doctors commented that they are doing more traditional liposuction, even when they have a laser lipo machine available in their office, but the laser lipo machine is important for marketing. Comments included:

- *New England:* "I have a lipo laser (Cynosure's SmartLipo). It's good for marketing. I use it occasionally, but mostly I do plain old tumescent liposuction under a local anesthetic…I plan to start marketing lipo sculpting to fit individuals who want better definition – a High-Def Lipo."
- *Nevada primary care doctor:* "I bought a laser lipo (SmartLipo) in August 2008, and I was pleasantly surprised to be really busy in November and December, and January looks okay, so my liposuction procedures are holding up unusually well. I had a consultant come in in January 2007. She suggested I do my cosmetic consultations in a nicer environment, so I made a patient-friendly consultation room with leather chairs and a waterfall. The laser lipo also helped because before we got it we were losing patients who called and hung up when we said we didn't have it…I bought it because patients specifically asked for that."

**Laser Liposuction Systems**

| Company | Product | Wavelength |
|---|---|---|
| Cynosure | SmartLipo | 1064 nm |
| Syneron | LipoLite | 1064 nm |
| CoolTouch | CoolLipo | 1320 nm |
| Palomar | SlimLipo | 920 nm + 975 nm |
| Sciton | ProLipo | 1064 nm |
| Cynosure | MPX | 1064 nm + 1320 nm |

- *California:* "I have a lipo laser, but I mostly do tumescent liposuction."
- *Florida:* "Liposuction is hanging in. That is my main business, but it is off 30% year-to-year."

One thing that has helped traditional liposuction is KMI's Mangubat disrupter, which doctors said cuts their procedure time considerably. KMI officials said this has been a very popular tool.

### ECLIPSEMED's Body-Jet, a water-jet assisted liposuction

Dr. Robert Troell of Las Vegas told doctors that the risk of lidocaine toxicity is less with this approach, swelling is less than suction-assisted liposuction, fat cell injury/disruption is minimal, there is less post-operative pain, and surgery time is reduced. He predicted, "In a couple of years, this will be the standard-of-care (for fat harvesting). This technique is far superior to anything out there."

*Asked if there are any body parts on which it can't be done,* Dr. Troell said, "The neck because there generally isn't much fat there, so the advantage is not as much as there is in the body area."

## OBESITY

Very, very few of the doctors at this meeting do gastric bypass or banding.

- *New York general surgeon with a focus on bariatric surgery:* "I'm thinking of getting into cosmetic surgery for post-bariatric patients, but I'm not buying anything this year, certainly no lasers. I used to do Allergan's LapBand, but I quit last year because of malpractice insurance issues. I stopped all new bariatric surgery. I hope to start again by summer 2009…Gastric sleeve and staples have had no impact on banding. Twenty percent of sleeve patients have post-op nausea that can last months or years, and that discourages patients from that procedure."
- *California surgeon:* "LapBand use started decreasing last year. It takes six months for the slowdown to show up because of insurance pre-approval, so the slowdown is just starting to be felt…I only use the Allergan LapBand because the design is better…The gastric sleeve is not covered by insurance, so it has had no impact on bands – yet. It could if insurance companies get on board."

## TOPICAL ANESTHETICS

During AACS – but not at the meeting – the FDA issued a Public Health Advisory alerting consumers, patients, and healthcare providers about potentially serious and life-threatening side effects from the improper use of topical anesthetics – both over-the-counter (OTC) and prescription – that contain anesthetic drugs such as lidocaine, tetracaine,

benzocaine, and prilocaine in a cream, ointment, or gel. The FDA warned that these drugs, when applied to the skin surface, can be absorbed into the blood stream, potentially causing irregular heartbeat, seizures, breathing difficulties, coma, or even death.

The FDA said that two women have died from topical anesthetics used before laser hair removal, and the Agency is worried that similar side effects could occur when topical anesthetics are used during other procedures, including mammography. The FDA warned against:

- Heavy application of topical anesthetics over large areas of skin.
- Formulations that are stronger or more concentrated than necessary.
- Applying them to irritated or broken skin.
- Wrapping the treated skin with plastic wrap or other dressings.
- Applying heat from a heating pad to skin treated with these products.