



Trends-in-Medicine

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Quick Pulse

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SILICONE BREAST IMPLANT UPDATE

To check on how quickly silicone breast implants are catching on since the FDA lifted restrictions on them in November 2006, 14 surgeons were interviewed. On average, 55% of new breast implants put in by these doctors are now silicone, and the percentage is expected to continue to increase to 60% over the next 6-12 months, reaching 76% at peak. Few women are switching out saline implants for silicone, and the new “gummy bear” implants in development are getting mixed predictions for uptake. No significant brand shifting appears to be going on, and overall implant volume is relatively flat, with no real signs that the economy is causing a decline in cosmetic procedures like this.

The FDA banned silicone implants in 1992 over health concerns – except for women who had a mastectomy, had a deformity, or needed to replace an existing implant. However, last November the FDA decided that the implants are safe and allowed Allergan and Mentor to re-introduce their new silicone breast implants for women at least 22-years-old. The FDA mandated that the companies track every implant and conduct large post-approval studies. In addition, the FDA recommended that women with the implants get regular MRIs for the rest of their lives in order to see if their implants have ruptured.

Silicone vs. Saline

Most patients are now opting for the more natural looking and feeling silicone gels. When patients do choose saline, it is primarily because of cost, though surgeons said a few patients opt for saline because they still have safety concerns about silicone.

Patients do not usually switch a saline implant for a silicone implant unless they have a problem with the saline implant, such as a rupture or wrinkling, but when they do have a problem with a saline implant, most opt for silicone. A Pennsylvania plastic surgeon said, “Few (women) are changing unless there is a problem with the implant, such as rupture, rippling, or malposition, and most women do not want to switch implants if they are not having a problem. More women are getting silicone implants, as they are more comfortable with the data and media perceptions.” An Indiana surgeon said, “If they’re switching (from saline to silicone) it’s because they’re having problems with rippling, firmness, or deflation. Patients who have switched to silicone are very happy with them. They can appreciate the difference, and I think it’s a nice improvement over saline.”

Silicone preferred:

- *California #1:* “There is a shift toward using more silicone. When I present them to my patients, I have both samples that they can see and hold and feel, and they gravitate to silicone because of the more natural feel.”

- Michigan:* “Of those patients who come in with a rupture, which occurs more than twice as often with saline, 80% are switching to silicone...Silicone has been shown to have no correlation with breast cancer or autoimmune diseases such as lupus. The silicone implants rupture less than half as often as saline implants, but if the implant were to rupture, it can go undetected. If undetected, it is possible that the silicone could leak into the breast tissue and cause scarring. However, the FDA is requiring MRIs to be done routinely every two to three years. The error rate of (the FDA study) will be close to 0%, so I see very little risk here. Thus, I see very little advantage to the saline implant. The advantage of silicone, on the other hand, is that it looks and feels much more natural. Clearly, oversized implants always look unnatural, but for the majority of patients the silicone implant will be a substantial improvement in the final result...I tell my patients that if I were to have implants, I would have the silicone implant.”
- Florida:* “Before FDA approval of silicone implants, about 90% of our breast augmentation patients were using saline-filled breast implants. The remaining 10% qualified for the FDA-approved adjunct study protocol. Today, the situation is reversed, and about 90% of our breast augmentation patients want silicone because of their more desirable feel. That is, they feel much more like a natural breast, as opposed to the feel of a saline implant. My prediction is that this trend will remain at this level, with silicone gel implants dominating the market.”
- Vermont:* “Several of my patients have had me switch their saline implants for silicone, and all have been glad that they did. They much prefer the more natural feeling of the silicone gel. Since they have experienced both saline and gel, they are in a position to have an opinion that matters...In my opinion there is no good reason (to choose saline) except that they are cheaper. I think that is a short-sighted consideration.”
- California #2:* “The silicone gel is softer, more natural, less chance of wrinkling or feeling more wrinkles, and more durable than the saline implants.”
- Colorado:* “Saline implants are cheaper, more durable, and require less maintenance. I see them for women who are really active and don’t want the headaches or expense of upkeep that the gels require...There are many restrictions or precautions associated with the new (silicone) gels: MRIs are recommended every three years, and the cost of the MRI may not be covered by the patient’s medical insurance. In addition, the manufacturers recommend that the gels be replaced every 10-15 years, which also adds up over a lifetime.”

Brand Preference

Surgeons said that patients do not request a specific manufacturer, and the products and prices are comparable. Physicians reported no significant brand shift, saying that their choice of manufacturer is usually based on their relationship with the company and its sales representatives.

- “I use Mentor because I like their service, and long ago the local McGhan (Allergan) guy was a turkey. The products are pretty equivalent.”
- “We use Mentor for both silicone and saline. We expect to stay with Mentor, as the company is very service-driven.”
- “I use Mentor just because of the sales rep; I have known her personally for years. One day recently I did four patients with new or replacement implants: one was an Inamed (Allergan) saline, two were Mentor saline, and one was a Mentor gel...McGhan (Allergan) has a great warranty. With Mentor, you have to pay a bit extra for the better warranty. McGhan also has some great statistics in terms of rupture rates, etc.”

Market Outlook

Doctors said that while more and more women are choosing silicone, it is at the expense of saline, and their overall implant volume is only expected to increase an average 3% in 2007 vs. 2006.

There were no signs that the current housing crisis or other economic factors are dampening demand for breast augmentation. A California surgeon said, “The economy is improving, and patients are having more plastic surgery than ever before.”

Saline preferred:

- Florida:* “Saline does retain a few positive attributes: It is adjustable and can be placed through a smaller incision, and it is easy to tell if it ever leaks, as the deflation becomes obvious in a shorter time. The implants are also less expensive. For some women, these factors are important and this determines their selection.”
- Oregon:* “Choosing saline over silicone is a price choice...Some think there is a safety issue as well.”
- Massachusetts:* “Women choose saline because of the cost and also MRI follow-up costs. Also, some women are concerned about safety.”

Market Share Predictions

Implants	Use now	Use expected in 6-12 months	Share eventually expected
Total silicone implants	55%	60%	76%
Allergan	36%	44%	---
Mentor	19%	16%	---
Total saline implants	45%	40%	24%
Allergan	21%	23%	---
Mentor	24%	17%	---

Comments included:

- *Michigan*: “The number has stayed constant, but it might have increased if the Michigan economy were better.”
- *Florida*: “The total number of breast augmentation surgeries we do continues to increase each year by 5%-10%, but the number of saline implants used has certainly dropped significantly in our practice.”
- *Oregon*: “Volume is down a bit lately – maybe the economy or end of summer – who knows.”
- *Colorado*: “Implants are becoming much more accepted or even de rigueur for a certain class of women. It’s just part of looking your best.”
- *Indiana*: “Volume is consistent. I haven’t noticed a huge increase or huge decrease. This is a typically busier time for breast surgery, after school has started. August and September are typically dead.”

On average, silicone implants now account for 55% of procedures for these doctors, and that is expected to increase over the next 6-12 months to 60%. In time, silicone implants are expected to peak at about 76% market share.

Price

Prices remain unchanged for silicone implants. They’re still usually \$1,000 more than saline implants. A California cosmetic surgeon said, “Silicone is \$1,000 more than saline, and that’s not too onerous. Cost is rarely a factor. It might be a consideration in fewer than 10% of patients.” An Indiana surgeon said, “People have been accepting of the additional cost.” A Colorado doctor added, “With replacement every 10-15 years, over a lifetime gels can be a lot more expensive... Right now, the McGhan implants are a bit more expensive than the Mentor implants, and this is a procedure that is very cost sensitive. A lot of doctors buy the implants themselves, so the cheaper they can get them, the more money they make on the markup. I personally have been surprised that McGhan hasn’t started some sort of price war to really lower prices, but so far the two are very close in price.”

Cohesive Implants

Cohesive, or “gummy bear” implants, are a form-stable implant made of high-strength gel with the consistency of dense Jell-O inside a new shell container. Silicone gel implants don’t leak when cut or punctured, and neither do cohesive silicone implants. Both are more solid than a liquid,

Advantages and Disadvantages of Cohesive Breast Implants

Advantages	Disadvantages
Shape stable	Longer scar
Natural, teardrop shape	Relative hardness
Few or no folds and rippling	Unpredictable movement
No leaking	Higher cost
Less capsular contracture (theoretically)	

but cohesive implants are designed to be longer lasting than gel implants, which are longer lasting than saline implants. These are not yet approved by the FDA.

Surgeons were mixed on their opinion about these devices, with half saying they want to “wait and see” until after they are approved. Some said it will be a niche product, but just as many were fairly upbeat about the implants, including a California doctor who said he has implanted more of them than any other surgeon in the country. He called them “a superior product with a good safety profile.”

Other comments included:

- *Michigan*: “The upside is that if they rupture, there will be no risk of them leaking into breast tissue. However, the risk of this occurring, given the FDA protocol, seems negligible. The downside is that they may feel more rigid. Mentor, for example, has had a cohesive gel on the market (in Europe) for some time now, and they are so firm that no one utilizes them. Allergan of course attests to their softness, but we will have to see what the patients think of them after they are on the market. If they are everything that Allergan says they are, then they may overtake the current silicone gel market.”
- *Florida #1*: “It’s hard to know how they will be accepted in the North American market. Certainly, everyone likes the idea of potentially limiting any migration of the gel in case of an extra-capsular leak, but patients don’t seem to like the idea of trading that feature for excessive firmness of the breast. Also, most American surgeons favor round, smooth implants, so the idea of a textured teardrop gel implant that requires a more complex selection algorithm and an even larger incision may have a hard time catching on.”
- *Colorado*: “Gummy bears are too hard! What’s the point? You want implants to feel soft and natural – well, not always. Some ladies do like the you-can-eat-off-of-them look – but for most the softer the better.”
- *Oregon*: “The current gels are cohesive, but the gummy bear types aren’t out yet. I think they will be just a niche. They stand up too much and are more for reconstruction, I think.”
- *Pennsylvania*: “It’s a new version of silicone implants. I don’t feel they are any more or less safe than current silicone implants.”
- *Indiana*: “They’re going to be a niche market. There are a few patients who are exceedingly thin who have rippling even when using gel and submuscular; they will be candidates. But those products require a substantial incision, and not a lot of patients will accept that. My saline incision is 3 cm, gel is 4 cm, and gummy bears will be 6-8 cm incisions... And they are pretty firm, so they won’t appeal to patients other than those who don’t mind having breasts that have that ‘my breasts don’t move’ look. So, there may not be that big an audience.”

- *Florida #2*: “Firmer may be a niche use as in recurrent capsular contracture.”
- *California #1*: “They are a superior product with a good safety profile.”
- *California #2*: “The reports I’ve gotten are that they are good and beneficial. They supposedly don’t have any leakage or rupture problems, and the only disadvantage is that they need a larger incision. From what I’ve been told, they do soften up as they become warm...but they’re still not going to be quite as soft as the ones that are available. Why choose them? They are form stable – a teardrop shape – that can be anatomically shaped, and, in certain patients, it would appear to provide benefit aesthetically, with nicer gradation from the upper chest into the breast. Form stable – you don’t have to put them under the muscle. However, that raises questions. Putting implants on top of the muscle supposedly gives a higher percentage of capsular contracture compared to going underneath the muscle. If you have a thin patient who seems to be an ideal candidate, would that increase her potential for capsular contracture or not? We don’t know that. The other advantages are that you don’t have to worry about the small but definite percentage of leakage or rupture with silicone gels that are now available. Even if they rupture, the silicone isn’t going to go anywhere. It could be a niche product, or it could be the next big thing, depending on how it’s marketed. I think it will be expensive, maybe twice or even three times the price of gels.”

