

Toward a safer implant?

A firmer silicone gel may be more resistant to rupture and leaks than the controversial liquid silicone.

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There's no understating the disappointment felt by manufacturers of silicone gel breast implants, plastic surgeons - and of course many women - when the federal government voted in January to continue a 12-year-old ban on the implants.

But manufacturers have a card up their sleeve, and they plan to play it soon.

Three companies are working on a different type of silicone gel breast implant, called a cohesive gel implant, which they say is unlikely to leak or rupture. One manufacturer - Inamed - plans to file paperwork later this year seeking approval to market the product.

Although still made of silicone, the gel in the new implants has the consistency of a gummy bear candy; the gel inside traditional implants has a motor-oil feel.

Even in the event the new implants do rupture, researchers say, the silicone won't leak and migrate to other areas of the body. In its January ruling, the Food and Drug Administration had cited concerns over what happens when silicone implants rupture and this migration occurs.

"These cohesive gel implants make a lot of the questions the FDA asked irrelevant," said Dr. William P. Adams Jr., associate professor of plastic surgery at the University of Texas Southwestern Medical Center in Dallas. He is researching a cohesive gel implant made by Mentor, which may be ready to seek approval for its product by the end of next year.

"There is good data on cohesive gel implants in the United States and Europe, and everyone's hope is that these implants can be approved," Adams said.

Cohesive gel implants are also superior, compared with other types of implants, in terms of cosmetic results, some plastic surgeons say.

"Patients are dissatisfied with saline implants," said Dr. Grant Stevens, medical director of Marina Plastic Surgery Associates in Marina del Rey. "They don't like the ripples or the liquid feel. But they, and the FDA, have some concerns about liquid silicone."

The cohesive gel has a better feel and look but eliminates the question of what happens when liquid silicone migrates out of the breast, added Grant, a clinical investigator on a cohesive gel implant made by a Dallas-based company called Silimed.

The advent of the cohesive gel breast implant is the latest twist in a long saga involving breast implants, a product in which many American women are profoundly interested.

The first breast implants, containing silicone gel, were introduced in the United States in 1963 but were banned in 1992 except for use in clinical trials and by women undergoing breast reconstruction surgery. At the time, the government cited reports that the implants sometimes became hard, that they could rupture and that the gel could leak.

Some studies suggested that the implants caused autoimmune diseases such as lupus and arthritis, but a 1999 report from the Institute of Medicine found no link between the implants and those diseases.

After years of continued safety studies, a divided government advisory panel last year recommended that the FDA allow the implants back on the market for general use. That panel cited studies showing the implants did not appear to cause autoimmune disease, but the experts recommended that doctors provide patients with more information on the possible complications from implants.

However, in January the FDA decided to continue the ban, saying that manufacturers had not answered questions on why implants rupture and where the gel goes when implants leak.

American women can still obtain saline implants (and silicone gel implants under the FDA restrictions) - and they appear to be doing so in record numbers. More than 254,000 women underwent breast augmentation in 2003, a 20% increase from 2000, according to the American Society of Plastic Surgeons.

Elsewhere in the world, women rarely opt for saline implants and are increasingly choosing cohesive gel implants over free-flowing silicone gel implants, said Stevens. The cohesive gel implants now under investigation are similar to the original implants of decades ago, said Dr. Rod Rohrich, president of the American Society of Plastic Surgeons and chairman of plastic surgery at the University of Texas Southwestern Medical Center.

"When implants first came out, they were like this," said Rohrich. "But the demand was to make implants softer, so they added more oil. Now we're coming full circle with silicone implants."

One criticism of the cohesive gel implants is that they may prove to be too rigid for some women. Also, because the implants are less flexible, surgeons may need to make a slightly larger incision to place the implants into the breast, Adams said.

Capsular contracture, which sometimes occurs with other types of implants, could also occur with cohesive gel implants, experts note. That condition, in which scar tissue forms around the implant, makes the breast feel hard.

And, Adams adds, even leakage of the silicone from a cohesive gel implant, while unlikely, cannot be ruled out based on studies so far.

"Right now there is no way to say scientifically that the cohesive gel won't leak," he said. "We only have two to three years of data. In Europe and Brazil, we have 10 years of data. There are phenomenal results. The patients are happier, and there are less complications. But you need to [study] implants up to 15 to 20 years to see what happens when the shell loses its integrity."

The lack of long-term data is what concerns some consumer activists.

"Without long-term studies, we won't know whether this cohesive gel is any better than what has been presented before," said Sybil Niden Goldrich, executive director of the Command Trust Network, a consumer group that has criticized the safety of implants. Even hard silicone may break down and migrate, she says.

Goldrich and other consumer activists continue to question the overall safety of any type of silicone implant, noting a recent study that found high concentrations of platinum in a small sample of women who got silicone implants. Platinum can cause nerve damage.

And, she says, a harder gel implant may obscure mammograms.

Adams, however, says that studies in women with implants have found that breast tumors can still be detected with mammography, although additional pictures of the breast may need to be taken. That shouldn't change just because the silicone gel is thicker, he added.

It's likely that implant makers will seek FDA approval of both cohesive gel implants and the traditional liquid silicone gel implant; implant manufacturers say they are working with the FDA to resolve the agency's questions about traditional silicone gel implants, experts say. But which type of implant may be approved first - or ever - is guesswork.

"There is politicization to this whole issue," said Stevens. "It's absurd. We're the only industrialized country in the world that has kept the moratorium on silicone gel breast implants in place."