Choice between silicone, saline implants is still not easy to make

by R.J. Ignelzi

After 14 years, women who want to surgically add more curves to their figures again have a choice: saline or silicone.

However, those who opt for the newly approved silicone breast implants may find their choice is padded in confusion, frustration and added costs.

Recently, the Food and Drug Administration lifted its ban on silicone gel implants, dismissing concerns about harmful effects from leaks as unsupported by extensive testing. But the agency, along with manufacturers of the implants, urged women to undergo a special magnetic resonance imaging (MRI) every couple of years "over a woman's lifetime" to detect ruptures. The series of MRIs could cost women $10,000 in the first 10 years, on top of the costs of the original cosmetic surgery, usually $5,000 to $8,000.

RESEARCH FIRST - Kristin Brackenmyre, who recently had breast augmentation surgery, runs along a pier in San Diego. CNS Photo by John Gastaldo.If any break in the implant's seal is detected, "the implant should be removed and replaced, if needed," the FDA says and tells women to expect at least one additional surgery to remove or replace faulty implants. No such recommendations are made for saline breast implants.

Because breast augmentation is a cosmetic procedure, medical insurance does not pay for the original surgery, testing or repeat surgeries.

"What was a relatively inexpensive way for a young lady to feel better about herself can now become very expensive," says Dr. Richard Bodor, chief of plastic surgery at the VA Medical Center in San Diego and an assistant professor of plastic surgery at the University of California San Diego School of Medicine.

Breast augmentation is one of the top three cosmetic surgeries for women. Nearly 300,000 women got breast implants in 2005 in the United States, according to the American Society of Plastic Surgeons.

The FDA had banned silicone gel implants for cosmetic use in 1992, amid worries that the devices were rupturing and the leaking silicone caused or contributed to autoimmune disorders, including lupus, multiple sclerosis and rheumatoid arthritis. The silicone gel moratorium never applied, however, to women getting reconstructive surgery after cancer.

For the past 14 years, most women who wanted breast enhancement used implants filled with saline, which is

less popular than silicone because it doesn't look and feel as much like natural breast tissue.

The FDA doesn't recommend regular testing to detect leaks in the saline implants because if one breaks, a woman knows it. A leak in a saline implant causes it to noticeably deflate as the salt water is absorbed into the body. The broken implant is then surgically removed and a new one inserted.

When a silicone gel implant breaks, nobody may know. Called a "silent rupture," it can go unnoticed, because the cohesive gel usually stays within the capsule of scar tissue that forms around the implant. The fear is that the gel may migrate to other parts of the chest or underarm area. Only a special breast coil MRI can adequately detect small breaks or tears in the implant.

Despite rupture risks, some plastic surgeons have never had concerns about the safety of silicone implants.

"I never doubted that silicone was a problem. I personally did around 125 pairs of silicone implants a year for eight years (before the 1992 ban), and never saw any problems that had to do with cancer or immune or arthritis problems," says Dr. Michael Roark, plastic surgeon at the La Jolla Cosmetic Surgery Centre.

Dr. Ross Rudolph, a Scripps Clinic plastic surgeon, says the concern over silicone implants "never made a lot of sense to me." He notes that silicone was considered safe enough to be used for reconstructive surgery, and that the outer envelope of saline implants is made out of silicone.

"A lot of the negative press (about silicone implants) wasn't really fed by science. It was fed more by fear," Bodor says. "I think most doctors will probably recommend what the FDA recommends ... but I think it's best to base this surveillance on a less dogmatic and a more individualized program."

Some plastic surgeons, however, aren't convinced that the MRIs are necessary.

"As a matter of practicality, I won't push anyone to get MRIs. There's no science in that. It's simply an outgrowth of the restrictions of the FDA," Roark says. "Why do we have to do this now after 40 years of augmentations? I am certain that is just a political maneuver. The only reason someone would do MRIs without any medical indication is (because of) fear."

Some consumer health groups like the National Research Center for Women and Families in Washington, D.C., warn that not following the FDA's MRI recommendation could be dangerous.

"Getting silicone breast implants (without the MRIs to detect ruptures) has greater risks than sky diving," says Diana Zuckerman, president of the nonprofit research and education organization.

"The thing that's so dangerous about silicone breast implants is that things can seem absolutely fine. But in time, they can break inside the body and might leak," she says. "We don't actually know what those (leakage) risks are. But, we do know that two-thirds of the time, you can't detect a rupture (without an MRI)."

Because there's no way to enforce FDA recommendations, she believes most women won't follow through, either because they can't afford it or because they don't think there's anything wrong.

"Right now, I think the biggest issue for women making a decision about silicone breast implants is 'Can I afford an additional $10,000 to $20,000 (for MRIs and possible replacement surgeries) over the next few years?' " Zuckerman says.

The FDA will continue its review of the silicone implants, requiring the manufacturers to study their effects on 43,000 women for 10 years after surgery.

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