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Skin Deep

Do My Breast Implants Have a Warranty?

By NATASHA SINGER

A NAKED woman, her left arm strategically draped over her nipples, grins beatifically at readers in an advertisement for [cosmetic surgery](#) that equates breast implants with a more durable commodity: jewels.

“You know that feeling when you find the perfect size,” reads the copy for the Natrelle Breast Enhancement Collection that ran in the November issue of Elle magazine. “And we’re not talking diamonds.”

It is the kind of marketing analogy that gives breast implants a bad name. Diamonds, as De Beers and a James Bond novel once suggested, are meant to last forever. But breast implants often do not.

“Breast implants are not lifetime devices, and breast implantation is not necessarily a one-time surgery,” reads a warning in much smaller type on the back of the advertisement. Indeed, whether women initially underwent implant surgery for cosmetic reasons or for reconstruction after [breast cancer](#), roughly one third of patients in clinical trials had a second operation within four to five years, according to statistical tables in the ad.

Almost two decades after a national hue and cry arose after fears that leaking silicone breast implants might cause systemic disease, [breast augmentation](#) has become the country’s most popular cosmetic operation. The renaissance of breast enhancement surgery is fueled in part by the [Food and Drug Administration](#)’s decision in 2006 to approve a new generation of silicone implants, ending a 14-year moratorium on their general use.

But with such high rates of reoperation, a new debate is emerging over whether breast implants constitute the kind of annuity medicine that will entail regular surgical tuneups, exposing patients to increased medical risk and out-of-pocket expenses. At a time when manufacturers have provided the F.D.A. with clinical studies that follow patients for just a few years, there is no established medical consensus on how long implants last, leaving doctors to rely on their anecdotal experiences when discussing durability with patients.

Given the lack of such data, critics said, women may not be prepared in the long term for the ordeal or financial burden of subsequent surgery.

“Your implants may last less than 10 years or more than 10 years, but when you start having problems with them, your [health insurance](#) is unlikely to cover the [M.R.I.](#) tests or the reoperations,” said Carol Ciancutti-Leyva, the director of a 2007 anti-implant documentary called “Absolutely Safe.” “It can be a very expensive proposition, especially if you are young.”

Many women are aware that implants can break down over time, requiring replacement just like car tires. Both saline implants, made out of a saltwater solution, and silicone implants, made out of gelatinous silicone, can form minute tears in their rubbery shells, causing ruptures. In the case of such defects that require product replacement, both manufacturers, Allergan Inc. and the Mentor Corporation, offer guarantees. Mentor has a 10-year guarantee to replace implants and defray some

surgical fees; Allergan's warranty includes lifetime implant replacement and up to \$1,200 for fees for the first 10 years.

Dr. Mark L. Jewell, a plastic surgeon in Eugene, Ore., who is a past president of the American Society for Aesthetic Plastic Surgery, said he warns his patients that breast augmentation surgery automatically guarantees a second operation at some future date. He added that many patients in clinical studies had elected to have follow-up operations to change implant type, size or position.

"Women are used to having their hair or nails done on a regular basis to maintain their appearance," said Dr. Jewell, who has conducted clinical trials for both implant manufacturers and is a consultant for Allergan, the manufacturer behind the ads running in Elle. "Ultimately, breast implants may also be a matter of maintenance."

But a rupture is only one of the local complications that may engender additional surgery. Like cocoons that grow around larvae, [scar](#) tissue can form around implants; and sometimes that scar capsule hardens and squeezes the implant, causing pain and deforming breasts. And saline implants can cause visible, tactile rippling beneath the skin.

Not all doctors, however, are as forthcoming about the risk of additional surgery as Dr. Jewell.

"My plastic surgeon told me that my saline implants should last forever," said Krista Schell.

Ms. Schell, 29, who lives in Thornton, Colo., and works for the State of Colorado, said she first spent \$6,500 in 2003 on breast enhancement surgery with a doctor in California. She had a second operation with that doctor last April to replace a deflated saline implant whose collapse made her left breast look "hollow"; her implants were still under warranty, but she did have to pay for the trip to California and lost a week's pay, she said.

Last November, Ms. Schell had a third operation, which cost \$6,000, this time with a surgeon in Denver who removed both implants as well as extensive scar tissue, she said. She also lost two weeks' wages because she had to take time off, she said. The implants had also caused rippling, a lump around one nipple and pain. "If you look at the negatives, you would talk yourself out of getting implants," Ms. Schell said.

Doctors nationwide performed about 329,000 breast augmentations in 2006, up from about 291,000 in 2005, according to a survey of doctors from the American Society of Plastic Surgeons. But medical experts said they could not determine exactly how long breast implants may last.

"The short answer is, we don't know specifically how long implants last," said Stephen Li, the president of a medical device testing company in Sarasota, Fla. Dr. Li, who has served on three of the F.D.A.'s panels that reviewed implant safety, voted to approve silicone implants. He said manufacturers' data suggested the implants should last at least a decade. "The current implants are no worse than before and ought to be better, based on the clinical and laboratory data, which is the only way you could rationalize approving a device that you have only three or four years of data for."

As a condition of approval, the F.D.A. asked silicone implant makers to follow their existing study groups for 10 years total and to enroll 80,000 new patients in a database. Both companies also developed extensive informed-consent processes.

Caroline Van Hove, the vice president of corporate communications for Allergan, wrote in an e-mail message that after a patient goes over a detailed checklist of implant information with her surgeon, she signs a consent form acknowledging her understanding of the risks of the surgery.

Although the number of reoperations may seem high — about a third of patients in an Allergan study had a second operation within four years of their initial surgery — Ms. Van Hove said that less than a

third of the follow-up operations involved implant removal. Patients also counted as reoperations if they had surgery to reposition their implants or had biopsies, she wrote. In the same study, even though 28 percent of silicone implant patients needed a second operation within six years, 95 percent of patients were satisfied.

But Eugene Goldberg, a biomaterials professor at the [University of Florida](#), Gainesville, said the F.D.A. should have required longer-term studies before it approved these devices. Research conducted by hip replacement manufacturers, for example, makes it clear that such artificial joints last roughly 10 to 12 years, he said.

“But with breast implants, informed consent is much more fuzzy because each doctor has his own perspective on how long they last, making it difficult for patients to realistically calculate the risks and benefits,” Dr. Goldberg said. He has testified as an expert witness for both plaintiffs and defendants in implant litigation cases and teaches a course in which he uses breast implants as a case study of a badly engineered medical device.

Dr. Linda Huang, a plastic surgeon in Denver, tells patients that their implants should be removed after 10 to 15 years. She said she had removed implants from more than 1,000 patients. She charges about \$7,000 for breast augmentation; roughly \$5,000 to remove implants; roughly \$7,500 to replace old implants; and roughly \$9,000 for surgery in which she removes implants and performs a breast lift using the patient’s own tissue. “If they would rather spend their money on a trip to Paris than on me, then I recommend they do not have breast augmentation to begin with,” she said.

Surgeons said that implant replacement can be a straightforward operation. But explantation surgery, in which a surgeon removes implants for good along with scar tissue, can be more complicated, particularly for older silicone models.

“If the envelope has broken down and the silicone has leaked out, you are trying to get out all of that goo,” said Dr. Susan E. Kolb, a plastic surgeon in Atlanta who performs three to five explantation surgeries a week. To remove scar tissue, which can adhere to muscles and to the fibrous tissue covering the ribs, some doctors mistakenly remove too much muscle or breast tissue, which can cause chest deformities, she said.

Given the impermanent nature of breast augmentation, it is perhaps fitting that a different ad in the January issue of *Elle* puts implants on par with a more short-lived purchase: footwear.

“You know that feeling when you find the perfect pair,” reads the ad copy running underneath a photo of another naked, contented-looking woman. “And we are not talking shoes.”

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