Breast Implants: Making an Informed Decision
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More than 300,000 American women, from teenagers to retirees, receive breast implants every year, according to the American Society of Aesthetic Plastic Surgery. And yet, remarkably little is known about the long-term safety of breast implants, how long they last, or what to do when they break and leak.

One million American women had already undergone breast implant surgery before any clinical trials or epidemiologic studies were published on their safety because the implants were sold before the US Food and Drug Administration (FDA) was given the authority to regulate medical devices in 1976. After the law changed, many medical devices remained on the market as the agency slogged through an overwhelming backlog, giving priority to life-saving implants and those whose safety had been questioned most strongly.

Breast implant manufacturers were not required to submit any safety data to the US FDA until 1991, and US FDA scientists at that time were highly critical of the small samples and poorly conducted research they received. For example, McGhan (which is now part of Inamed Corp) included only 39 mastectomy patients in their reconstruction study and only 33% of their patients were evaluated even once after their initial follow-up visit. Mentor, which is now the other major manufacturer of breast implants, reported an even lower (27%) rate of follow-up for the augmentation patients in their sample. In 1992, when the US FDA decided not to approve silicone gel implants, both companies abandoned their studies. Meanwhile, several patients won multimillion dollar lawsuits against Dow Corning, the manufacturer of silicone gel, and Dow Corning then began to spend millions of dollars on research that was used as part of their legal defense to prove that their implants were not causing systemic diseases.

**LONG-TERM CLINICAL TRIALS LACKING**

Saline breast implants were approved by the US FDA in 2000, despite high complication rates, but the US FDA has never approved silicone gel breast implants. Since 1972, the latter were permitted to be sold to patients participating in clinical trials under the condition these would be limited to “reconstruction” for women with deformities or who had undergone mastectomy, or for women who needed to replace broken implants. The reality was quite different; with the US FDA’s acquiescence, “reconstruction” was very loosely defined to include women whose breasts are uneven in size or sag after breastfeeding, which probably describes most women. More than 75% of the women in these clinical trials (called “adjunct studies”) were not evaluated at the 3-year required visit. As a result, the US FDA recently concluded that the approximately 75,000 women in those trials do not provide any meaningful data.

If the adjunct studies had carefully collected data on even a random sample of those 75,000 patients, there would be 5 to 10 years of long-term safety data today. Instead, each of the companies focused their research efforts on a new “core study” of 1000 women, started several years later, and provided only 2 to 3 years of follow-up data when they again sought US FDA approval in 2005. Even after only 3 years, complication rates have been surprisingly high. Breast pain and hardness are common, but even more surprising, almost 50% of the mastectomy reconstruction patients and more than 20% of the augmentation patients required additional surgery to correct implant problems within 3 years postoperatively.

**WHAT HAPPENS WHEN SILICONE IMPLANTS BREAK AND LEAK?**

These short-term studies can’t answer the question that the US FDA considers most essential: what happens when silicone gel implants leak? US FDA scientists found that most women with silicone breast implants for 11 or more years have at least 1 broken implant, but most don’t realize it. After the implant ruptures, most of the silicone gel stays in place, but gradually silicone oil can migrate outside the breast area to the lymphatic system, and from there to other organs. US FDA scientists concluded that unless magnetic resonance imaging (MRI) is performed, neither the physician nor the patient is likely to realize when an implant has broken.

Leakage is especially important for 3 reasons: 1) leaking silicone is very difficult to remove, and the surgery can result in severe breast deformities; 2) exposure to leaking silicone is thought to be a potential cause of systemic disease; and 3) many women with leaking implants do not have their implants removed because they don’t know their implants are leaking or can’t afford explant surgery, which is rarely covered by insurance. A US FDA study found a statistically significant increase in fibromyalgia and other connective tissue diseases among women with leaking breast implants compared to women whose implants were intact. A mortality study by scientists at the National Cancer Institute compared women who had had breast implants for at least 12 years to other plastic surgery patients with similar demographic traits and health habits. They found twice as many deaths from brain...
cancer, lung cancer, and suicides in women who had breast implants. A Canadian study by epidemiologists at the British Columbia Centre of Excellence for Women's Health found that women with breast augmentation were more likely to be hospitalized and used more medical services than did comparable women without implants. Although not conclusive, these studies indicate serious reasons to be concerned about the health effects of silicone breast implants, especially when they are leaking.

Despite the clear evidence that clinical examinations are not accurately detecting rupture or leakage of silicone gel breast implants, neither plastic surgeons nor the US FDA have proactively warned implant patients about the need for MRIs. In fact, no information about silicone leakage or the importance of MRIs is published on the Web sites of either of the plastic surgery medical societies. Their collaborative Web site on breast implants describes the use of MRIs to detect leakage, but makes no recommendations about regular screening.

## Promoting Ideal Breasts

Rather than warn about risks, most of the information from manufacturers and plastic surgeons seems to be focused on reassuring patients that implants are safe. Overall, controversy is dismissed, complications are barely mentioned, and the benefits to quality of life are exaggerated. Breast enlargement is offered on the installment plan, and mastectomy patients are encouraged to have reconstructive surgery on breasts lost to cancer and augmentation in their healthy breasts so that they will match the reconstructed breasts. Promotional materials do not mention that breast implants interfere with mammograms, despite recent research indicating 55% of breast tumors were hidden by implants.

Problems with mammography were not an issue when most women getting breast implants were in their teens and 20s, but as those women have aged and as a growing number of baby boomers are undergoing augmentation in their 40s and 50s, it has become more important. In addition, US FDA scientists recently reported that mammograms can cause older implants to break and leak.

## Myths and Realities of Research on Implant Safety

Despite the growing number of studies indicating problems with implants, numerous medical journal articles have concluded that implants are safe. Most of these studies were funded by Dow Corning and received considerable press coverage. Unfortunately, almost all are poorly designed, including women with implants for just a few days or months, using inappropriate comparison groups, and relying on inadequate outcome measures. For example, many of the studies compare women with breast implants to women with breast reduction surgery, and the results indicate problems with both types of surgery. However, because women considering breast augmentation are not considering breast reduction as an alternative surgery, a more appropriate comparison sample for augmentation patients would be women who are matched on age, race, and health habits, but who did not undergo augmentation. Similarly, the study design combination of including women with implants for a short period of time and using hospitalization as the only health outcome measure maximizes the likelihood of finding no significant differences in safety between women with and without breast implants. A review of these methodological shortcomings suggests that the studies were designed to prove safety, rather than study whether implants are safe. Even when their results include statistically significant increases in chronic breast pain or autoimmune symptoms, such as those found by Breiting et al, the researchers tend to ignore those findings in their conclusions and abstracts, and instead conclude that breast implants are safe. After agreeing to a $3.2 billion settlement with implant patients, Dow Corning continues to claim that their breast implants did not cause illness and that their studies support their claim.

As is the case with antidepressants, cyclooxygenase-2 inhibitors, hormone therapy, and so many other products, it often takes years before the risk information comes to light. However, we already know this: silicone implants usually break during the first 15 years. The cost of augmentation surgery, $4000 to $7000, is a fraction of the uninsured implant expenses over a lifetime, including regular MRIs, reoperations to correct problems, and surgery to remove broken implants. Do the benefits outweigh these risks and costs? Data from implant makers indicate that patients report lower self-esteem and quality of life on most objective measure 2 years after implant.

Implant manufacturers claim that their newest implant styles, made from a more cohesive silicone gel, are less likely to leak and are therefore safer. They have applied to the US FDA for approval of these implants, which they nicknamed “gummy bear implants.” However, in the meanwhile, the companies are pressuring the US FDA to approve their older implant models, which have been shown to break and leak inside a woman’s body. Why not abandon efforts to obtain US FDA approval for their older models and just focus on the styles that they claim are safer? Nobody knows. And, are these new implants really safer? Will the gel that looks so thick on a doctor’s desk look just as cohesive after 10 years in a woman’s body? We don’t know the answer to that question either because there are no published clinical trials of the safety of these implants for even 3 or 4 years, although they have been sold in Europe for long enough to do such studies.

Internists and other physicians who treat women considering implants or who already have implants need research-based information. More than 2 million American women currently have breast implants. These women need knowledgeable doctors to help them decide what to do when implants break and leak, symptoms appear, and other problems arise. And, they need doctors to tell them what the best research shows when they ask, “Are silicone gel breast implants really safe?”
References