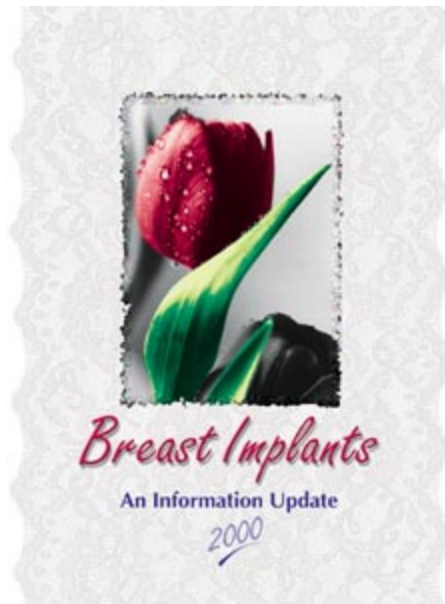


BREAST IMPLANT RISKS

BREAST IMPLANT RISKS



November 2000

The Institute of Medicine's (IOM) 1999 study of silicone breast implant safety found that local complications with silicone breast implants were the primary safety issue, that they have not been well studied, and that information on these complications is crucial for women deciding whether or not they want breast implant surgery.¹

There are risks or complications associated with any surgical procedure, such as the effects of anesthesia, infection, swelling, redness, bleeding, and there are complications specific to breast implants. These complications and others are described below.

1. CAPSULAR CONTRACTURE

Capsular contracture occurs when the scar tissue or capsule that normally forms around the implant tightens and squeezes the implant. There are four grades of capsular contracture: Baker Grades I – IV.

The Baker grading is as follows

Grade I - breast normally soft and looks natural

Grade II - breast little firm and looks normal

Grade III - breast firm and looks abnormal (visible distortion)

Grade IV - breast hard, painful and looks abnormal (greater distortion)

Correction of capsular contracture ranges from surgical removal of the implant capsule tissue to removal (and possible replacement) of the implant itself. Capsular contracture may happen again after this additional surgery.

Photograph 1 below shows Grade IV capsular contracture in right breast of a 29-year-old woman seven years after subglandular (on top of the muscle and under the breast glands) placement of 560cc silicone gel-filled breast implants.²

Photograph 1



¹Safety of Silicone Breast Implants. Institute of Medicine; National Academy Press, Washington, D.C. 2000. (IOM Report)

²All photographs courtesy of Walter Peters, Ph.D., M.D., F.R.C.S.C., University of Toronto

2. DEFLATION or RUPTURE

When silicone gel-filled implants rupture, some women may notice decreased breast size, hard knots, uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation. Other women may unknowingly experience a rupture without any symptoms (i.e., “silent rupture”). Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant. Silicone gel may escape from the fibrotic capsule around the implant, may migrate away from the breast, and may cause lumps called granulomas to form in the breast, chest wall, armpit, arm, or abdomen. Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues.

When saline-filled breast implants deflate, the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or progressively over a period of days, months, or years and is noticed by loss of size or shape of the implant. Additional surgery is needed to remove deflated implants.

For silicone gel and saline-filled implants, some causes of rupture or deflation include:

- damage by surgical instruments during surgery
- overfilling or underfilling of saline (only) implant
- capsular contracture
- manually squeezing the breast to break the hard capsule
- trauma, injury, or intense physical manipulation
- excessive compression during mammographic imaging
- placement through the belly button
- normal aging of the implant
- unknown/unexplained reasons

Photograph 2 below shows a 30-year-old woman’s left saline-filled breast implant deflation. The suspected cause was the leaf-valve design of the implant, which is no longer being used by manufacturers.

Photograph 2



3. ADDITIONAL SURGERY & REMOVAL WITHOUT REPLACEMENT

Women with breast implants may need additional surgery at some point to replace or remove her implant(s) due to problems such as deflation, capsular contracture, infection, shifting, and calcium deposits. Women who do not have their implants replaced may have cosmetically undesirable dimpling, puckering of the breast following removal of the implant, or other unsatisfactory cosmetic outcomes.

Photograph 3 below shows the same 29-year-old woman in Photograph 1 one year after removal of her silicone gel-filled breast implants without replacement. Patients with large implants, particularly those inserted subglandularly (on top of the muscle and under the breast glands), may have a major cosmetic deformity if they choose not to replace them or to undergo additional reconstructive surgery.

Photograph 3



4. PAIN

Women may feel pain of varying degrees and lengths of time following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. You should tell your doctor if you have pain.

5. DISSATISFACTION WITH COSMETIC RESULTS

Dissatisfying results such as wrinkling, uneven sizes, implant shifting, incorrect size, unanticipated shape, ability to feel implant, scar deformity, irregular or raised scarring, and/or sloshing may occur. Careful surgical planning and technique can reduce but not always prevent such results. For saline-filled implants with valves, you may be able to feel the valves. Repeated surgeries to improve the appearance of the breasts and/or to remove ruptured or deflated prostheses may result in an unsatisfactory cosmetic outcome.

6. INFECTION

Infection can occur with any surgery and at any time. Most infections appear within a few days to weeks after the -surgery. Infections with an implant present are harder to treat than infections in normal body tissues because infection may not respond to antibiotics. The implant may have to be removed and replaced after the infection is gone.

7. HEMATOMA/SEROMA

Hematoma is a collection of blood inside a body cavity and a seroma is a collection of the watery portion of the blood around the implant or around healing. A small scar can form or a rupture may occur if the implant is damaged during draining the incision. Post-operative hematoma and seroma may contribute to infection or capsular contracture. Swelling, pain, and bruising may result. A hematoma usually occurs soon after surgery but may occur at any time or after injury to the breast. While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can form or a rupture may occur if the implant is damaged during draining.

8. CHANGES IN NIPPLE AND BREAST SENSATION

Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense to no feeling in the nipple or breast after surgery. Changes in feeling can be temporary or permanent and may affect sexual response or the ability to nurse a baby.

9. CALCIUM DEPOSITS IN TISSUE AROUND IMPLANT

Calcium deposits can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery to biopsy or remove the implant to distinguish these deposits from cancer. Calcium deposits may be felt as modules or bumps under the skin around the implant.

10. DELAYED WOUND HEALING

In some cases, the incision site fails to heal normally or takes longer to heal.

11. EXTRUSION

Unstable or weakened tissue covering and/or interruption of wound healing may result in extrusion, (when the breast implant comes through the skin). Surgery needed to correct this can result in unacceptable scarring or breast tissue loss.

12. NECROSIS

Necrosis, the formation of dead tissue around the implant, may prevent wound healing and require surgical correction and/or implant removal. A permanent scar may form.

13. TISSUE ATROPHY/CHEST WALL DEFORMITY

Pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement

14. INTERFERENCE WITH MAMMOGRAPHY

Interference with mammography due to breast implants may delay or hinder the early detection of breast cancer either by hiding suspicious wounds, injuries, or tumors or by making it more difficult to include them in the image. Implants increase the difficulty of both taking and reading mammograms. Women who undergo reconstruction and have some breast tissue remaining must continue to have mammography of that breast, as well as of the other breast, to detect breast cancer. Mammography requires breast compression (hard pressure) that could contribute to implant rupture. When making appointments, women with implants should tell the scheduler that they have breast implants. Before mammography, women should also tell the radiologic technologist about their implants. The technologist will then take extra care during compression to reduce the risk of implant rupture. The technologist will also use the special displacement views to see as much as possible of the breast tissue.

15. UNEXPECTED MILK PRODUCTION AND LEAKAGE

Following breast implant surgery, your body may begin to produce milk. This production may cease spontaneously or after medication is given to stop milk production. In other cases, removal of the implant(s) may be needed.

Please refer to our breast implant consumer handbook entitled, "Breast Implants – An Information Update – 2000" for a more detailed description of these risks, as well as a description of other illnesses that women believe are related to their implants. The handbook is available through our FDA website at:

<http://www.FDA.gov/CDRH/breastimplants/>.