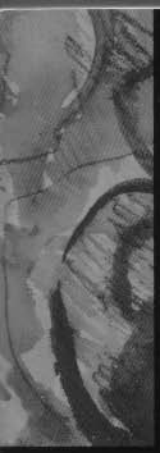

- PRACTICAL, COMPLETE, AND UP-TO-DATE
- EASY-TO-USE
- PERFECT FOR PRIMARY CARE

CURRENT

CARE OF WOMEN

Diagnosis & Treatment

Dawn Lemcke
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LANGE

Breast Augmentation & Disorders of the Augmented Breast

23

Kian J. Samimi, MD

Breast augmentation using silicone implants was first introduced in the early 1960s. Before the introduction of silicone implants, various techniques for breast reconstruction and augmentation dating back to the 19th century had yielded unpredictable results. Initial reports associating silicone implants with rheumatic disorders were published in the 1980s. In response to these reports and media publicity, the Food and Drug Administration in 1992 mandated a moratorium on the use of silicone implants. Since then, numerous studies have failed to establish a link between connective tissue disorders and silicone implants. This prompted the American College of Rheumatology to issue the following statement in 1995: "These studies provide compelling evidence that silicone implants expose patients to no demonstrable additional risk for connective tissue or rheumatic disease."

Breast implants consist of an outer shell and a filler substance. Different materials have been used for the shell in the past, but essentially all implants used in the United States over the last 10 years have silicone shells. The filler material determines the implant type. The US Food and Drug Administration (FDA) presently approves only saline implants, which have a well-documented safety record, for cosmetic augmentation. Silicone implants may be used for breast reconstruction as part of a study and are pending approval by the FDA. Other implant types (such as using organic oils as filler substance) are being evaluated but are not FDA approved.

Wolfe P: "Silicone breast implants and the risk of fibromyalgia and rheumatoid arthritis." Presented at the American College of Rheumatology, 59th National Science Meeting, San Francisco, CA, October 21-26, 1995, Arthritis and Rheumatism, 1995;38:S265.

General Considerations

Approximately 1–2 million females in the United States, 1% of the adult female population, have breast implants. The vast majority has been placed for cosmetic reasons. Surveys have shown that 90–95% of women are satisfied with the outcome.

Indications for breast implant placement include congenital causes such as Poland's syndrome (congenital absence of pectoralis major muscle and breast); acquired absence of the breast following mastectomy; and cosmetic correction of hypomastia, involution, and ptosis.

Breast implants can be placed using a variety of techniques: inframammary, periareolar, and axillary incisions are most common (Figure 23–1). Endoscopic transumbilical augmentation is less commonly used. Periareolar incisions have a slightly higher incidence of hypoesthesia of the nipple. The implants are placed subglandular (under the breast parenchyma) or submuscular (under the pectoralis muscle). While the subglandular placement was the most common with silicone implants, saline implants are most often placed in a submuscular position. The submuscular position provides an additional layer of soft tissue covering and camouflages the normal wrinkling of the implant wall, which occurs with saline implants. It also has been shown to reduce the incidence of capsular contracture (see following section on Disorders). The anesthesia ranges from local to general. Early complications including implant infection, seroma formation, and hypoesthesia or hyperesthesia at the surgical sites are rare.

Women with breast implants may have decreased milk production. A recent study suggested women who have had breast augmentation have higher incidence (64% vs 7%) of inadequate milk production than women who have not had the procedure. This was seen mostly in women with periareolar incisions. A periareolar approach may transect milk ducts and therefore is avoided by many plastic surgeons. Further, many of these women may have had augmentations for breast hypoplasia and had decreased lactation potential initially. Breast milk from women who have silicone implants does not contain increased levels of silicone.

Examining the Augmented Breast

Typically, patients are in their 30s, successful, self-confident and well informed. When examining the breast, a horizontal incision above the inframammary fold, a round incision in the outer margin of the areola, or a straight scar within the axilla can be seen. These scars

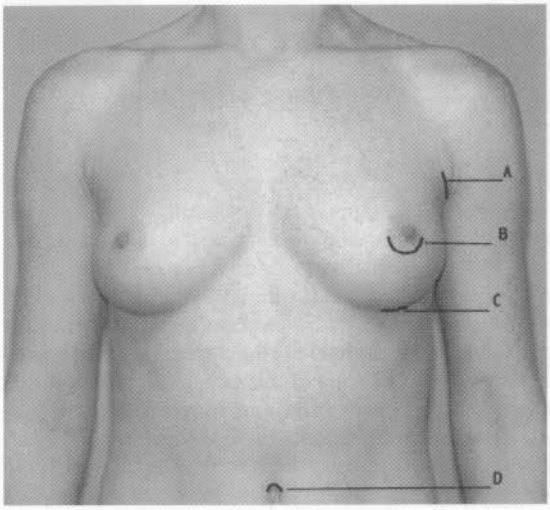


Figure 23–1. Axillary, periareolar, inframammary, and umbilical incisions for breast augmentation are marked.

tend to fade and may be barely noticeable after several years. Palpation of the augmented breast will reveal whether a silicone or saline implant has been used. A silicone implant feels very similar to breast tissue, and the presence of the implant may be noticed only on firmer palpation. Saline implants do not feel as soft as a silicone. Also, the wall of the implant may be felt along the medial and inferior border of the breast. Rippling (wrinkling) of the implant may be noted in these areas. This is a normal finding with saline implants (Figure 23–2).

Women who have breast implants should follow the same routine schedule for mammography as women who do not have implants. Mammography of the augmented breast requires special techniques and therefore should only be performed at facilities accredited by the American College of Radiologists. Only about two thirds of the breast parenchyma can be visualized using standard techniques. The Eklund displacement technique involves manually pushing the implant towards the chest wall and selectively compressing the breast. This improves the amount of breast parenchyma visualized from 56% to 64% for subglandular implants and from 75% to 85% for submuscular implants. There have been reports of implant deflation with standard mammography techniques; the risk of this should be lower with the Eklund technique.

Baker JL Jr: Classification of spherical contractures. Presented at the Aesthetic Breast Symposium, Scottsdale, Arizona, 1975.

Brinton LA et al: Characteristics of a population of women with breast implants compared with women seeking other types of plastic surgery. Plast Reconstr Surg 2000;105:919. [PMID: 10724251]

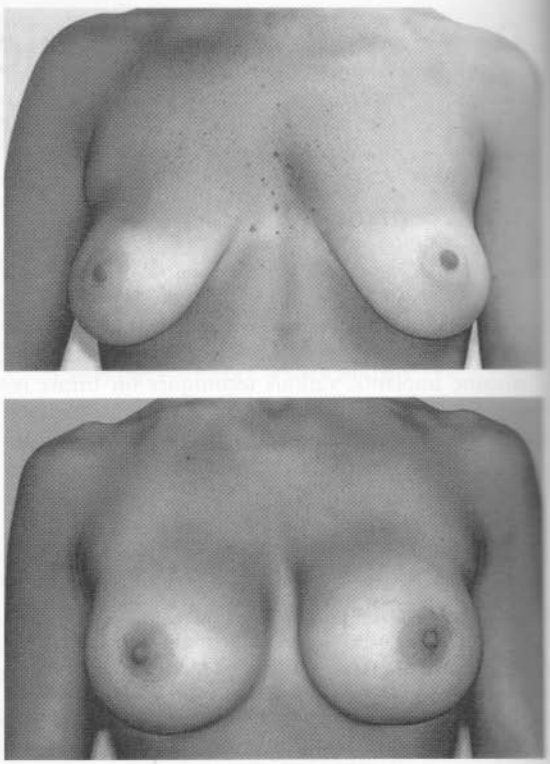


Figure 23–2. Preoperative and postoperative saline breast implant augmentation for treatment of glandular ptosis.

Cunningham BL, Lokeh A, Gutowski KA: Saline-filled breast implant safety and efficacy: a multicenter retrospective review. Plast Reconstr Surg 2000;105:2143. [PMID: 10839417]

Eklund GW et al: Improve imaging of the augmented breast. AJR Am J Roentgenol 1988;151:469. [PMID: 3261503]

Hurst NM: Lactation after augmentation mammoplasty. Obstet Gynecol 1996;87:30. [PMID: 8532261]

Silverstein MJ, Handel N, Gamagami P: The effect of silicone gelfilled implants on mammography. Cancer 1991;68 (5 Suppl):1159. [PMID: 1913498]

DISORDERS

Capsular Contracture

ESSENTIALS OF DIAGNOSIS

- *Increasing firmness and deformity of the augmented breast.*

General Considerations

The incidence varies according to the different implant types and placement techniques. Any implanted foreign body will induce an inflammatory reaction, which results in a fibrous capsule or scar. The degree of capsule formation is variable and unpredictable. The newer saline implants with a textured surface have a drastically lower incidence of capsular contracture than silicone implants. The incidence according to the implant manufacturer is between 5% and 20%. The Saline Prospective Study found a 9% incidence of Baker grade III or IV contractures (see following Diagnosis section) at 3 years.

Clinical Findings

On examination, firmness of the implant is noted. There may be a palpable capsule surrounding the implant. The breast has an unnatural appearance, frequently with upward displacement of the implant and descent of the breast parenchyma over the implant (Figure 23–3). Firmness of the underlying implant differentiates this from the natural ptosis of the breast tissue, which occurs with age. The patient complains of increasing firmness, implant displacement and, in the later stages, breast pain. Implants in place for more than 10 years may have palpable calcifications in the capsule. These are also seen on mammogram.

Diagnosis

The Baker classification is used to grade the degree of firmness:

Grade I: No palpable capsule
Grade II: Minimal firmness
Grade III: Moderate firmness
Grade IV: Severe contracture

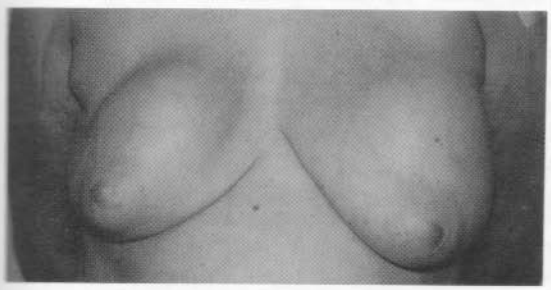


Figure 23–3. Capsular contracture is evident in the right breast.

In essence, grades I and II are considered normal and acceptable results. The examining physician notices a grade III capsular contracture with a palpable capsule surrounding the implant more often than the patient. Because the hardening occurs slowly, the patient may not be aware of an existing grade II or grade III contracture. Implant malpositioning or deformity and increasing pain are signs of a grade IV contracture. The amount of breast tissue visualized on mammography decreases with increasing capsular contracture.

Treatment

Intervention is indicated for grade III or IV contractures. Closed capsulectomy by forcefully manipulating the breast and capsule has been largely abandoned because of possible implant rupture. Surgically incising or completely excising the capsule is the treatment of choice. Because implants with a textured surface seem to reduce the risk of capsular contracture, smooth-walled implants should be replaced with textured implants. The patient may still develop a significant capsular contracture and ultimately require removal of the implants. At present, there are no medical treatments for the prevention or treatment of capsular contracture. Massage and displacement exercises of the augmented breast help prevent the development of capsular contracture. In these exercises the implant is pushed forcibly around the pocket to prevent formation of a tight capsule. These need to be performed daily for years after augmentation because the onset of contractures may be late.

Baker JL Jr: Classification of spherical contractures. Presented at the Aesthetic Breast Symposium, Scottsdale, Arizona, 1975.

Handel N et al: Factors affecting mammographic visualization of the breast after augmentation mammaplasty. JAMA 1992; 268:1913. [PMID: 1404718]

Implant Leak

ESSENTIALS OF DIAGNOSIS

- *Sudden or gradual volume loss of implant.*
- *Evidence of leak by ultrasonography or magnetic resonance imaging (MRI).*

Clinical Findings

Risk factors for an implant leak include implant older than 10 years, attempts at manipulation of capsule (closed capsulotomy), and iatrogenic (such as biopsy, needle localization, aspiration, mammogram).

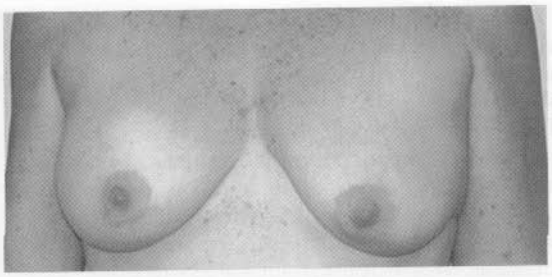


Figure 23–4. Deflated saline implant is easily recognized in the left breast.

A. Symptoms and Signs

Patients will notice a loss of breast volume. The rate of deflation can be very slow; ultimately, breast asymmetry will develop (Figure 23–4). Frequently, the initial complaint will be a misfitting bra or clothing. A burning sensation may be reported.

B. Imaging Studies

Routine screening mammograms may suggest a rupture if disruption of the implant wall is seen. Calcifications are not a sign of rupture. Mammograms alone are inadequate to work-up a suspected leak or smaller rupture. Sensitivity is low, especially with the more common intracapsular rupture. Ultrasonography is the most practical tool in the work-up of a suspected implant rupture. A sensitivity of 70% and specificity of 85% have been reported. These results are highly operator dependent. The most accurate tool is MRI with specificity reaching 100%. The accuracy can be improved by the use of breast surface coils. The high cost of MRI limits its use. The algorithm in Figure 23–5 can help the clinician work-up a suspected leak or rupture.

Diagnosis

A fully deflated implant is easily recognized, while a slow leak may be difficult to detect initially. Leaking saline implants will usually lose most of their volume within a few weeks. A small tear may stop leaking when the implant loses some saline and the pressure within decreases. The patient almost always notices the volume loss, so she is aware of the leak when she seeks medical attention. No diagnostic tests beyond a physical examination are necessary. Breast asymmetry and marked wrinkling of the implant wall are noted (Figure 23–4). There are no systemic or local adverse reactions associated with a saline leak.

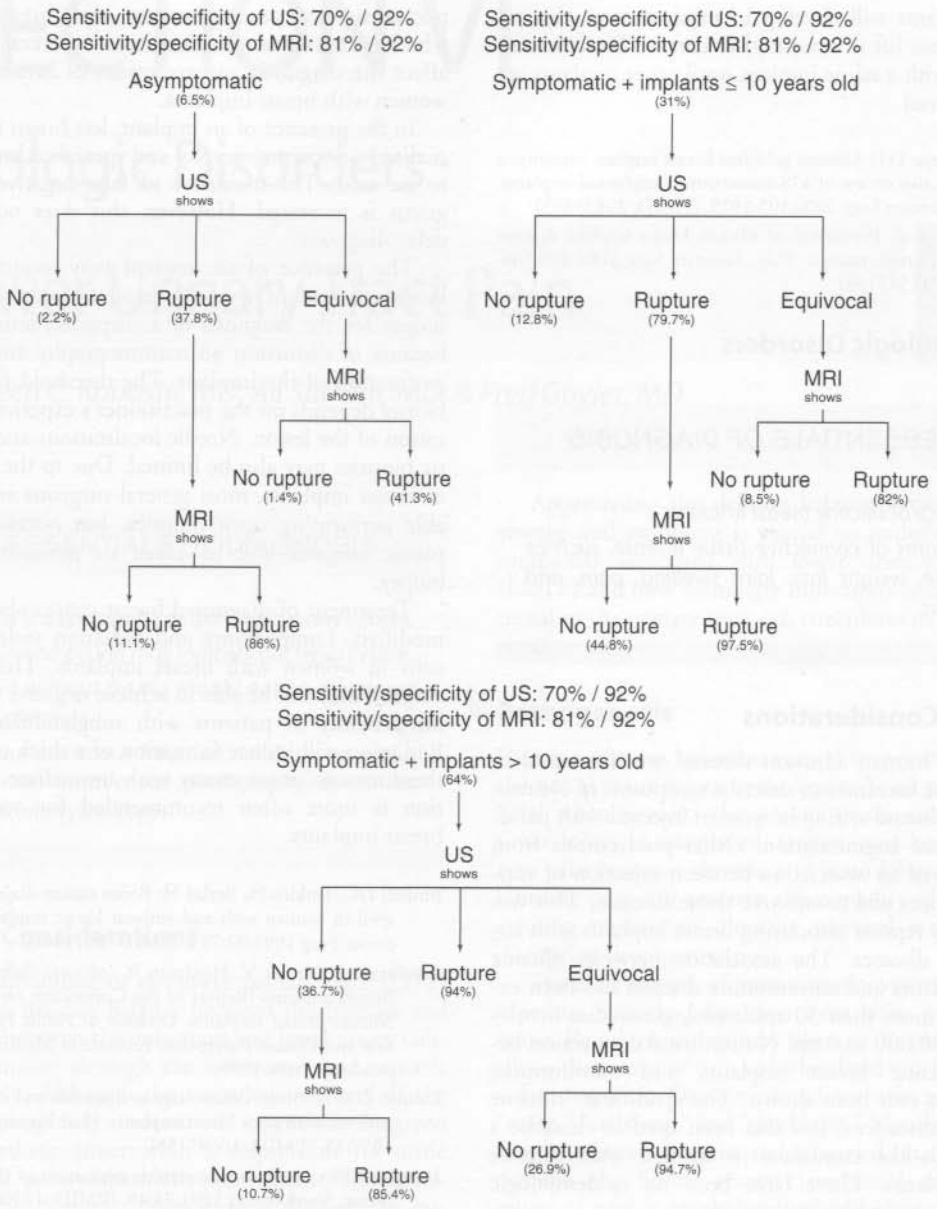
Silicone implants have a very slow rate of deflation. All silicone implants allow for diffusion of silicone oil and this process is called **"bleed." Bleed** is normal and should not cause a noticeable change in implant volume. A **leak** results from a small hole in the implant wall and a thin coating of silicone is deposited around the implant. Again, examination will be normal. A major tear is considered a **rupture.** A significant portion of the gel is outside of the implant. The silicone is not absorbed. It is contained in the capsule and therefore does not cause a loss of breast volume. Physical examination may reveal an area of induration or an irregular capsule, although the examination is frequently normal. Even when **extrusion** of silicone occurs into the adjacent soft tissues through a tear in the capsule, the examination may be normal. Extracapsular extrusion of silicone is the only instance in which adverse reactions may occur. An inflammatory reaction to the extruded silicone may manifest as an induration, erythema, or necrosis of the overlying skin. There are reports of silicone migration into the axilla and subsequent neurologic symptoms. Enlarged axillary nodes have been biopsied and found to contain silicone. These are isolated, rare reports and seem to be associated with the use of a certain type of low viscosity silicone in the late 1970s. No association between silicone implant rupture and rheumatologic disorders has been established.

The only common findings on examination associated with silicone implant rupture are breast asymmetry and capsular contracture.

Treatment

Surgical removal of the ruptured or leaking implant is the appropriate therapy for both saline and silicone implants. Any deflated saline implant should be removed. If the patient wishes to have the implant replaced, this should not be delayed beyond 4 weeks because the skin envelope may contract. Older saline implants do not have to be routinely exchanged as a leak is easily diagnosed and causes no adverse reactions.

Any silicone implant, which has signs of a leak or rupture, should be removed. As the incidence of implant failure increases significantly with age, silicone implants older than 10 years with a suspected leak should also be removed. Ultrasonography may be used in the work-up. Although MRI is more accurate, its use should be reserved for patients who are reluctant to have an older implant removed. The patient has to decide whether she wants to have the implants replaced during the same surgery. Frequently, patients (especially older women) do not want to have the implants replaced. It is important for the physician to inform the woman that she will not regain the preimplant shape of her breast. Atrophy of the breast parenchyma occurs naturally with age and seems to be accelerated with breast implants. Marked ptosis following removal of



US, ultrasonography;
MRI, magnetic resonance imaging

Figure 23–5. Algorithm illustrating the work-up of silicone implant rupture. (Data from Chung KC, Greenfield ML, Walters M: Decision-analysis methodology in the work-up of women with suspected silicone breast implant rupture. Plast Reconstr Surg 1998;102:689.)

breast implants will develop in most women; this requires a breast lift (mastopexy) to correct. Replacement should be with a saline implant until other implants are FDA approved.

Collis N, Sharpe DT: Silicone gel-filled breast implant integrity: a retrospective review of 478 consecutively explanted implants. Plast Reconstr Surg 2000;105:1979. [PMID: 10839395]

Holmich LR et al: Prevalence of silicone breast implant rupture among Danish women. Plast Reconstr Surg 2001;108:848. [PMID: 11547138]

Rheumatologic Disorders

ESSENTIALS OF DIAGNOSIS

- *Presence of silicone breast implants.*
- *Symptoms of connective tissue disease, such as malaise, weight loss, joint swelling, pain, and stiffness.*

General Considerations

The term "human adjuvant disease" was first used in the Japanese literature to describe symptoms of connective tissue disease arising in women injected with paraffin for breast augmentation. Other publications from Japan showed an association between injection of various substances and connective tissue diseases. This was followed by reports associating breast implants with autoimmune diseases. The association between silicone breast implants and autoimmune diseases has been examined in more than 30 epidemiologic studies involving over 500,000 women. No statistical connection between silicone breast implants and autoimmune diseases has ever been shown. The syndrome "silicone associated disorders" has also been used to describe a fibromyalgia-like condition in women with silicone breast implants. There have been no epidemiologic studies to support this association.

As mentioned above, all silicone gel implants "bleed" and a small amount of silicone is deposited outside of the implant. This results in elevated blood and tissue silicone levels. This may induce an immune response. There have been no laboratory or epidemiologic data linking this immune response to an immune disease.

Carcinogenesis

No study has credibly found an association of breast implants and breast cancer. Recent epidemiologic studies have not demonstrated any delay in diagnosis or poorer survival among women with breast implants who have breast cancer. Despite this, several issues may affect the diagnosis and treatment of breast cancer in women with breast implants.

In the presence of an implant, less breast tissue is visualized on mammography and special techniques have to be used. The incidence of false-negative mammograms is increased. However, this does not seem to delay diagnosis.

The presence of an implant may require an open biopsy instead of a needle aspiration or core needle biopsy for the diagnosis of a suspected lesion. This is because of distortion on mammography and potential perforation of the implant. The threshold for an open biopsy depends on the practitioner's experience and location of the lesion. Needle localizations and stereotactic biopsies may also be limited. Due to the prevalence of breast implants, most general surgeons are comfortable performing open biopsies, but occasionally, the plastic surgeon will be asked to perform the open biopsy.

Treatment of diagnosed breast cancer also has to be modified. Lumpectomy and radiation yields poor results in women with breast implants. The oncologic surgeon may not be able to achieve negative margins on lumpectomy in patients with subglandular implants. Radiation will induce formation of a thick capsule. For these reasons, mastectomy with immediate reconstruction is more often recommended for women with breast implants.

Birdsell DC, Jenkins H, Berkel H: Breast cancer diagnosis and survival in women with and without breast implants. Plast Reconstr Surg 1993;92:795. [PMID: 8415960]

Bondurant S, Ernster V, Herdman R, (editors): Safety of Silicone Breast Implants (Report of the Committee on the Safety of Silicone Breast Implants, Division of Public Health Promotion and Disease Prevention, Institute of Medicine). National Academy Press, 1999.

Deapen D et al: Breast cancer stage at diagnosis and survival among patients with prior breast implants. Plast Reconstr Surg 2000; 105:535. [PMID: 10697158]

Douglas KP et al: Roentgenographic evaluation of the augmented breast. South Med J 1991;84:49. [PMID: 1846050]

Handel N et al: Breast conservation therapy after augmentation mammaplasty: is it appropriate? Plast Reconstr Surg 1996;98: 1216. [PMID: 8942907]

Hoshaw SJ et al: Breast implants and cancer: causation, delayed detection, and survival. Plast Reconstr Surg 2001;107:1393. [PMID: 11335807]

Leibman AJ, Kruse BD: Imaging of breast cancer after augmentation mammoplasty. Ann Plast Surg 1993;30:111. [PMID: 8387738]

Silverstein MJ et al: Breast cancer diagnosis and prognosis in women following augmentation with silicone gelfilled prostheses. Eur J Cancer 1992;28:635. [PMID: 1591087]