BREAST AUGMENTATION: NOVEL TECHNIQUES, NEW IMPLANTS, AND AN UPDATE ON COMPLICATIONS

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ABSTRACT
Breast augmentation with implants is the most common surgical aesthetic procedure performed in the United States. A number of advancements have occurred in recent years to improve implant composition and develop strategies for both predicting and optimising aesthetic outcomes. Nevertheless, complications and risks are still associated with breast implants. In this article, discussion focuses on the role of preoperative imaging, the recent developments in implant composition, the current data on complications, and risks associated with breast augmentation.

Breast augmentation is the most popular cosmetic procedure performed worldwide with over 285,000 surgeries completed in the United States during 2012. In 1895, Vincenz Czerny conducted the first attempt to augment the breast by transplanting a lipoma to the breast. Decades later in 1961, Cronin and Gerow reported on their use of the first silicone implant. Since then, implant-based approaches to augmentation with both silicone and saline filled implants have become more prevalent, with significant developments in implant shape and composition. Additionally, new research has investigated the impact of preoperative imaging on aesthetic outcomes, the psychological benefits of cosmetic surgery, and a greater awareness of possible risks.

Breast augmentation has a number of potential complications, including implant rupture, rippling and leakage, asymmetry, capsular contracture, animation deformity, seroma and haematoma formation, implant extrusion, and infection. Additionally, case reports have raised concerns that there may be serious long-term sequelae from chronic exposure to implants. Questions have also been raised as to how breast implants may alter the risks of breastfeeding and that breast cancer screening guidelines may need to be modified.

This article aims to discuss the latest research in implant-based breast augmentation, including novel preoperative imaging techniques, developments in implant shape, and recent Food and Drug Administration (FDA) approved implants. Discussion will also focus on recent findings regarding the risks associated with implants and how breast augmentation changes the approach to screening and healthcare maintenance.
Methods
A PubMed search was used to compile the references for this article. Focus was placed on articles published from 2006 to 2013, they had to be written in English, and involve humans. The key words used in search engines are listed in Table 1.

Preoperative assessment and three-dimensional imaging
In addition to explaining the risks of breast augmentation, the clinician must ensure that the patient has reasonable expectations of the aesthetic outcome and be able to guide the patient in selecting an appropriate implant. Linear measurements taken preoperatively help to estimate native breast size. However, two-dimensional assessment is limited in quantifying breast shape and volume.

Preoperative three-dimensional (3D) imaging is a new technique that can both accurately and reliably determine total breast volume, glandular distribution, breast projection, and symmetry\(^1\). Using a series of lasers to demarcate specific planes of the breast, images are compiled to generate a 3D model of breast shape, quantity breast volume, and determine spatial distribution\(^2,3\). Canfield offers the Vectra 3D imaging system (Canfield Imaging Inc, Fairfield, NJ), which uses six two-dimensional images to recreate a 3D model of the breasts with the ability to visually approximate breast appearance with a range of implants\(^4\). Crisalix also offers a 3D imaging system (Crisalix, Lausanne, Switzerland) and a virtual assistant that enables visualisation of augmentation options online\(^5\).

Using 3D imaging technology, studies have been able to objectively assess the conformation that implants assume after placement. Multiple studies have demonstrated that the ultimate projection volume of implants in vivo is 20-23% less than that purported by implant advertisements\(^6,7\). With this newfound understanding of how implants behave in vivo, 3D imaging has potentially created opportunities to individually customise breast shape and size with reliable accuracy\(^8,9\). Furthermore, the images generated by the 3D systems help a patient better predict how they will appear postoperatively, creating a more informed patient and potentially allowing for improved patient satisfaction. The significant limitation to 3D systems is their cost, making the financial implications of their use an important discussion point for patients.

Implant type
Filling: silicone versus saline
Of all breast implants placed in the United States during 2012, 62% contained silicone filling and 38% contained saline filling\(^1\). The preference of silicone over saline represents a shift from the early 1990s when a moratorium was placed on silicone implants because of a suspicion of increased risk of systemic illnesses. After returning to the market in 2006, silicone implants have gained popularity over saline implants owing to a decrease in deflation, visual irregularities, and rippling or wrinkling\(^2\). The differences between the two implants are more prominent with smaller breasts, thin skin, or when the implant is placed in the sub-glandular as opposed to sub-muscular position\(^3\).

Silicone implants, however, are not without complications. They have a higher rate of capsular contracture than saline implants (13.2% versus 7.2%)\(^4\). Slow silicone leakage over time, also known as silicone bleed, has been implicated as a cause of capsular contracture. While saline implants deflate with leakage, silicone bleed does not result in volume depletion owing to the trapping of silicone in the fibrous capsule. Therefore, detection of silicone bleed is often made incidentally, making epidemiologic analysis of its occurrence difficult to ascertain\(^5\). By contrast, saline implants are known to leak in 1-7% of patients\(^6\). Newly FDA-approved high cohesive gel implants have both a thicker capsule and denser silicone filling, making...
them less likely to experience rupture or silicone bleed compared to the traditional non-cohesive implants\(^a\). This may lead to a lower capsular contracture rate among silicone implants.

The IDEAL IMPLANT\(^\text{®}\) (Ideal Implant Incorporated, Dallas, TX), a saline implant with multiple nested shells and an internal baffle structure, was developed to optimise the advantages of both silicone and saline implants\(^b\). The multiple shells, available in a single lumen with saline and a double lumen with both gel and saline, are advertised to provide better contour to the chest wall and reduce wrinkling. Although not yet FDA-approved, investigational studies suggest lower rates of capsular contracture with the IDEAL IMPLANT\(^\text{®}\), though effects on leaking and deflation remain to be demonstrated\(^c\).

**Shell: smooth versus textured**

Implant shells can be classified as either smooth or textured. Textured implants were developed to reduce rates of capsular contracture based on the hypothesis that lower rates of contracture were observed with older textured implants\(^d\). Unfortunately, multiple level one studies failed to show lower capsular contracture rates in the newer textured implants when placed sub-muscularly\(^e\). Conversely, evidence has demonstrated a decreased capsular contracture rate when textured implants are placed in the sub-glandular position compared to smooth implants\(^f\). On the other hand, textured implants in the sub-glandular position are associated with increased rates of palpability and rippling\(^g\). Therefore, the advantage of lower capsular contracture rates sub-glandularly may be offset by other adverse outcomes.

**Shape: round versus anatomical**

Both round and anatomical implants are commonly used for breast augmentation. Certain patients may be better suited for a particular shape depending on her desired breast appearance. Round implants increase fullness of the breast superiorly. They are preferable for patients who have a small breast volume and want a fuller appearance, or for those who desire breasts that look overfilled. Additionally, patients who are very active can experience implant rotation, which is inconsequential when using a round shape, but can result in significant deformity with shaped implants.

For anatomical implants, more precision is required during placement as distortions are readily apparent if the implant is slightly rotated or in the sub-glandular position\(^h\). Anatomical implants however, have more variables (width, height, and projection) that can be altered to customise breast shape for an individual\(^i\). The success of the aesthetic outcome irrespective of shape depends greatly on the development of capsular contracture, which occurs with equal frequency in both round and anatomical implants\(^j\).

For women unsure of their desired breast size or appearance, a double-lumen adjustable gel implant, available in both round and anatomical shapes, may be a preferred option given the ability to optimise for size postoperatively\(^k\).

**High cohesive implants**

The current silicone implants contain a cohesive gel that stabilises the implant shape in vivo, theoretically decreasing the likelihood of silicone bleed. However, implant rupture and subsequent leakage still occur, and can lead to capsular contracture owing to silicone exposure\(^l\).

Recently, the FDA approved a generation of updated silicone implants that contain a high cohesive gel, designed to both improve shape retention and decrease the rate of implant rupture. Anatomically shaped, the high cohesive gel implants, colloquially known as ‘gummy bear’ implants, have been shown in multiple international centres to have lower rates of silicone bleed (0.3–1.7%), capsular contracture (1.9–5.6%), and higher patient satisfaction levels compared to traditional silicone implants\(^m\). In addition, Heden et al reported a 5.3% rate of grade III capsular contracture and no cases of severe, grade IV capsular contracture in 163 patients with high cohesive implants who were followed for 8 years\(^n\).

As high cohesive implants are anatomical in shape, aesthetic concerns owing to implant malposition have been reported, but at relatively low rates (less than 26%)\(^o\). High cohesive implants have been found to rotate less often than other anatomical implants and significantly less than round implants, which can rotate in as many as 41% of patients\(^p\). Though only recently FDA-approved in the United States, high cohesive implants will likely increase in prevalence in the upcoming years.

**Surgical incision**

The incision selected for breast augmentation must provide adequate access for implant placement and haemostasis while being strategically located to hide the resulting scar. Incision size depends on both location and type of implant, with saline implants generally requiring the
smallest incision followed by smooth, and then textured implants requiring progressively larger incisions. As far as incision location, an inframammary approach is used in 90% of breast augmentation cases because of the ability to conceal the incision under the breast. Many surgeons prefer the inframammary or periareolar incision because of the ease of accessing the implant pocket. In thin patients, the breast may be insufficiently sized to obscure an inframammary scar. Additionally, Stutman et al. showed in a cohort of 619 patients that those who had inframammary incisions were more likely to undergo reoperation for asymmetry, ptosis, or implant change. The periareolar approach also has its limitations, including poor scar formation, higher capsular contracture rates, and greater risk of desensitisation of the nipple areolar complex. A smaller areola may also limit the access that can be achieved through a periareolar incision making the approach less ideal.

Many patients request either transaxillary or transumbilical incisions owing to the inconspicuous nature of the scar. While aesthetically appealing, the challenge of accessing the appropriate space leads to less precision in implant placement, increased risk of infection and capsular contracture, and greater risk for damage to surrounding tissues. Additionally, the transumbilical approach requires an inflatable implant, limiting the implant choice to saline. To strive to reduce the length of an incision and to ease implant placement, a newly-developed funnel from Keller Medical Inc. has been developed called the Keller Funnel™ (Keller Medical Inc., Stuart, FL).

Implant placement
Breast implants are either placed deep to the pectoralis muscle or superficial to musculature and under the mammary gland. A sub-muscular approach has the advantage of lower capsular contracture rates, but can result in a second breast contour or 'double-bubble' deformity in patients who have breast ptosis. Additionally, many patients can experience breast distortion or 'animation deformity' during contraction of the pectoralis muscle after implantation. Implants that are placed more superficially in the sub-glandular position avoid the double-bubble and animation deformity effects. However, if a patient does not have enough breast fullness superiorly, a sub-glandular implant is more likely to be palpable or show visible irregularities. Subglandular implants can also have reduced stability, increasing the risk of rotation and extrusion below the inframammary fold. A subfascial implantation decreases the risk of both animation deformity and implant instability, allowing for better preservation of the inframammary fold and prevention of visible irregularities or rippling. A total sub-muscular position, in which the serratus fascia is elevated as part of the implant pocket, requires dissection of an unnatural plane, which poses more operative challenges with minimal benefits and is thus infrequently used.

A newer, ‘dual-plane’ approach places the superior portion of the implant sub-muscularly with the inferior aspect remaining in a sub-glandular position. The traditional sub-muscular approach often leaves a small portion of the inferior aspect of the implant in a sub-glandular position; however, the demarcation is much less significant than in the dual-plane approach. The dual-plane technique retains the advantages of both sub-muscular and sub-glandular implants, including less implant palpability and capsular contracture as well as a more natural breast shape. Critics of the dual plane technique comment that it may lead to an increase in animation deformities and a visual muscle retraction. With varying degrees of sub-muscular versus sub-glandular coverage possible, dual-plane breast augmentation is becoming a more popular and attractive option for implant placement.

Complications
Seroma and haematoma
Common complications in any surgery where a cavity is created include haematoma (collection of blood) and seroma (collection of serous fluid). Both can cause localised swelling and pain. The rate of haematoma formation has been reported to range from between 0.9% and 3%. Ultrasound is often used as to not damage the implant during needle aspiration.

Infection risk
Higher rates of infection are observed with transaxillary approaches for breast augmentation, owing to the increased implant manipulation required for placement. In addition to causing morbidity and potential implant loss, even mild infection can trigger capsular contracture, resulting in poor long-term aesthetic outcomes. The Keller funnel™, which allows implant placement...
because a smaller incision, has been shown to reduce bacterial inoculation and thus likely infection in a cadaveric study, where the device reduced contact between the implant and patient’s skin by up to 27-fold. Irrigation of the implant pocket with an antibiotic lavage prior to implant placement statistically reduces the risk of infection. Additionally, anecdotal reports have suggested that using a transparent adhesive film dressing to cover the peri- incisional skin and nipple prior to implant placement may reduce the rates of infection. Regarding systemic antibiotics, a recent meta-analysis revealed inconsistent reports of an association between preoperative antibiotic dosing and infection rate. As a result, no consistent recommendation is currently available regarding the role of systemic antibiotic administration in breast augmentation.

**Capsular contracture**

Capsular contracture of the breast is defined as constriction of the fibrous capsule surrounding an implant, resulting in painful, palpable and visible irregularities of the breast. The hypothesis of capsular contracture centralises around inflammatory factors that are acutely protective, but can promote the growth of contractile cells with more chronic exposure. Graded from I to IV in severity using Baker’s scale, capsular contracture is one of the most common and disfiguring complications of breast augmentation. Multiple surgical steps can be taken to prevent the development of capsular contracture, namely limiting handling of the implant, irrigation of the breast pocket with antibiotic solution, and sub-muscular implant placement. However, once capsular contracture has developed, definitive treatment involves removal of the implant, with less aggressive approaches including capsulotomy, capsulectomy, capsule expansion, and revision with acellular dermal matrix. Non-surgical options for reducing contracture and pain including capsule massage, ultrasound therapy, and pulsed electromagnetic field therapy, have all shown variable success. More recent studies looking at the role of leukotriene inhibitors in increasing capsule compliance appear promising and consistent with the theory that capsular contracture is modulated by immunologic factors.

**Lymphoma**

First described in case reports in the 1990s, the literature shows a possible association between both saline and silicone implants, particularly textured salt-treated implants, and the development of anaplastic large cell lymphoma (ALCL), a rare form of non-Hodgkin’s lymphoma. Though breast implants and ALCL have been linked, no causation has been established owing to the exceedingly low rate of ALCL in the breast, estimated to be approximately 3 in 100 million women per year. It has been hypothesised that implant shell composition triggers pathogenesis of the condition; however, both implant type and characteristics are largely under-reported in clinical studies. The most common presentation of ALCL is a late periprosthetic seroma developing months to years after implantation with malignant cells visible on cytology. Treatment of ALCL involves removal of the implant and capsule with no current consensus on the role of chemotherapy or radiation therapy.

**Systemic diseases**

Though a moratorium was placed on silicone implants from 1992 to 2006 because of suspicions of increased risk of systemic illness, a number of studies have failed to show any correlation between the use of silicone implants and rheumatologic diseases. Furthermore, a 2001 study by Fryzek et al examining 1369 women who underwent breast augmentation found no consistency in either the types of symptoms reported or their time of onset after surgery. However, recent immunologic research has identified pro-inflammatory proteins that adhere to the surface of silicone implants causing significant capsular fibrosis, possibly triggering autoimmune conditions in predisposed individuals. Further research is needed to determine if, or whether, a correlation exists between these proteins and systemic disease. Nevertheless, a full personal and family history of autoimmune disease should be accounted for from each patient during evaluation for breast augmentation.

**Nipple desensitisation**

Reduced sensation or pain of the nipple and areola are common complaints after breast augmentation, with 26.7% of 121 women surveyed in a recent study reporting dissatisfaction with sensory changes after augmentation.

**Breastfeeding**

Many women who undergo breast augmentation during their reproductive years raise
> concerns that breast implants may affect their future ability to lactate. Desensitisation of the nipple areolar complex can result in a poor sucking reflex culminating in decreased milk letdown. Additionally, complications such as infection or capsular contracture can potentially lead to further operations with additional risks of damaging the mammary gland. Although trauma to the breast and desensitisation of the nipple areolar complex can be minimised with good surgical technique, 10% of patients who undergo breast augmentation are still likely to have lactation insufficiency compared to those without implants. Regarding the safety of breast milk, studies examining women with and without implants have found no difference in silicone levels. Furthermore, women those who have undergone breast augmentation have statistically less silicone in their breast milk compared to over-the-counter formulas.

Patient satisfaction

When surveying patients, multiple studies found that 99% of women were extremely satisfied 1 month after augmentation and that 95% maintained this high satisfaction after 6 years. Satisfaction rates were based on self-assessment of attractiveness, psychosocial wellbeing, and sexual function.

Though breast augmentation successfully achieves the goal of improving patient satisfaction, multiple studies have found an almost three-fold increase in suicide rates among women who have undergone breast augmentation compared to non-augmented women. Risk increases in women over the age of 40 years at the time of surgery or who have had implants for a longer period of time. Though no precise cause-and-effect relationship has been established, the increased prevalence of pre-existing psychological disturbances among women who pursue breast augmentation, inappropriate expectations for quality of life after augmentation, and failure of psychosocial coping mechanisms in the event of postoperative complications have all been considered as possible causes. More recently however, Kalaaji et al found a 6% rate of depression in a study of 121 augmented women compared to a 7-17% reported for the general population in Norway. Although depression and suicide risk are relatively rare outcomes after breast augmentation, a patient’s psychosocial status and psychiatric history must be seriously evaluated during their initial consultation with the surgeon.

Screening

Breast augmentation does not increase the risk of developing breast cancer but does obscure portions of the breast from view on mammographic screening. This is especially true in the case of silicone implants, which are relatively radiopaque, and in cases of capsular contracture owing to the increased fibrous tissue. Greater sub-muscular or subfascial as opposed to sub-glandular coverage of an implant helps reduce obstruction of the breast parenchyma on mammography.

Magnetic resonance imaging (MRI) of the breast is able to accurately and reliably detect a breast mass in the presence of an implant. For women who have undergone breast augmentation, current guidelines recommend an initial MRI at 3 years, followed by a screening every 2 years thereafter. In addition to cancer surveillance, this regimen has the added benefit of assessing for subclinical implant rupture. The expense of MRI however, raises questions for whether other imaging techniques such as ultrasound or standard mammography should be used, particularly for patients younger than the appropriate age for breast cancer screening. While other screening mechanisms are being investigated, MRI currently remains the gold standard for breast cancer screening after breast augmentation.

Conclusion

Multiple evidence-based studies have found implants to be a safe and effective approach to breast augmentation. Although the most commonly performed aesthetic procedure, breast augmentation still presents with its limitations and complications. Novel techniques in planning for augmentation and updates to implant structure have helped to minimise adverse outcomes. For patients who desire augmentation but wish to avoid implant-based procedures, recent developments in autologous fat injection after external tissue expansion appear promising. Nevertheless, with newfound research and understanding of the challenges associated with breast implantation, clinicians are better equipped to appropriately counsel patients, thereby increasing the likelihood of improved patient satisfaction.

Key points

- Preoperative three-dimensional imaging is a new technique that can help determine total breast volume, glandular distribution, breast projection, and symmetry, aiding a patient to better predict how they will appear postoperatively.
- The recently FDA approved generation of high cohesive gel implants are designed to both improve shape retention and decrease the rate of implant rupture.
- The high cohesive gel implants, or ‘gummy bear’ implants, have been shown to have lower rates of silicone bleed, decrease capsular contracture, and result in higher patient satisfaction levels compared to traditional silicone implants.
- Though breast implants and ALCL have been linked, no causation has been established to the low rate of ALCL in the breast. The most common presentation of ALCL is a late peri-prosthetic seroma with malignant cells on pathology which develop months to years after implantation.
- When surveying patients, multiple studies found that 99% of women were extremely satisfied 1 month after augmentation and that 95% maintained this high satisfaction after 6 years.

Declaration of interest

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