Aesth Plast Surg (2010) 34:23–28
DOI 10.1007/s00266-009-9429-6

ORIGINAL ARTICLE

Breast Implant Stability in the Subfascial Plane and the New Shaped Silicone Gel Breast Implants

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Received: 20 June 2008 / Accepted: 28 August 2008 / Published online: 21 November 2009

Abstract The author presents his experience with breast augmentation using a next-generation, form-stable, anatomically shaped silicone gel breast implant. Rotation is a potential complication for anatomically shaped breast implants. Anatomically shaped saline implants have been reported to have a rotation rate as high as 14%, while lower rotation rates of 1–2.6% for anatomic cohesive gel silicone implants have been reported. Currently, these implants are limited in the United States to US FDA-approved clinical trials. The author reviews the appropriate surgical techniques to prevent rotation when using these devices. A recent innovation, placement of the superior pole of the implant underneath the superficial fascia of the pectoralis major muscle, is described. Primary and secondary breast augmentations in 241 procedures using the Allergan Style 410 implant resulted in a 0.0% rotation rate. Overall, the anatomic form-stable silicone gel breast implants, when placed subfascially, improve common complications such as capsular contracture and implant rupture with improved aesthetic outcomes and patient satisfaction.

Keywords Breast augmentation · Cohesive gel breast implant · Breast implants · Rotation · Subfascial implantation · Complications

Breast implant technology has evolved in recent years with the introduction of anatomic (or teardrop-shaped) implants. These implants, available in both saline and silicone gel forms, more closely resemble the natural shape of the breast, making them readily accepted by both patients and surgeons.

Silicone gel-filled anatomic implants such as the Style 410 implant (Allergan, Inc., Irvine, CA) and the Contour Profile Gel® (CPG™) (Mentor Corporation, Santa Barbara, CA) implant are marketed in most countries for women seeking breast augmentation, revision, or reconstruction. The Style 410 implant is a form-stable, highly cohesive, silicone gel-filled breast implant constructed with a low-diffusion silicone elastomer shell (Intrasheil™ barrier technology) [2, 31]. The Style 410 implant, which is manufactured with a Biocell® surface texture and is available in various sizes, has been available in Europe and Brazil since 1994 and in Canada for general use since 2006. A premarket approval application for the device was submitted to the US Food and Drug Administration (FDA) in 2004; its current use in the US is limited to clinical trials conducted under FDA-approved study protocols. The CPG anatomic implant is a soft cohesive silicone gel implant [5]. The differences between the CPG implant and its round counterpart are the shape, slightly more crosslinking of the gel, and the slightly more textured outer surface. The CPG implant has been available in Europe and Brazil since 2003 and in Canada since 2006. Current use in the US is limited to FDA-approved clinical trials.

Cohesive gel implants, unlike traditional silicone gel implants, are form-stable, meaning that in the unlikely event of implant rupture, the gel remains confined inside the shell. Form-stable implants are available with three different types of gels: soft cohesive (CPG), highly cohesive (Style 410), and dual-gel soft touch (Style 510). All three types of implants appear to be well accepted by patients and surgeons.

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History of Silicone Gel Implants

The history of silicone gel breast implants has been widely reported in the literature, with several advances and many setbacks [35]. In brief, the first generation of silicone gel implants (1963–1972) contained a thick outer shell filled with thick silicone gel. The second-generation implants (1972–1980) were manufactured with both a thin outer shell and a thin silicone gel. The third- (1980s), fourth-, and fifth-generation implants (1992 to present) returned to a thicker outer shell and a barrier layer that reduced the diffusion of the silicone gel through the implant shell. Third-generation implants have a smooth surface, round shape, and more viscous silicone gel. Fourth-generation implants have smooth or textured surfaces, round or anatomical shape, and more viscous (cohesive) silicone gel. Fifth-generation implants are form-stable devices filled with enhanced cohesive silicone gel and have smooth or textured surfaces and round or diverse anatomical shapes [2, 23, 29].

In 1992, amid concerns of safety and effectiveness, the FDA issued a moratorium on the use of silicone gel implants. A report issued in 2000 by the Institute of Medicine found no convincing evidence of connective tissue disease, neurologic disease, breast cancer, or cancer treatment interference in silicone gel breast implant patients, which were the specific concerns that led to the ban [21]. Thus, in 2006, the moratorium was lifted after the FDA accepted the vast body of scientific evidence supporting the performance and safety of these prosthetics [24].

The fifth-generation, form-stable, highly cohesive silicone gel implants such as the Style 410 and newer dual-gel Style 510 implants, which are available outside the US, are a significant improvement over earlier generations [2, 31]. Breast implant manufacturers continue to research and make advances in implant technology and design resulting in lower complication rates, better aesthetic outcomes, and more consistent results. Surgeons can maximize the likelihood of good aesthetic results by focusing on implant selection and surgical technique.

This review of breast implants discusses the aesthetic benefits of anatomic silicone gel implants, focusing on design elements that help to prevent or reduce the complications of breast implants, especially the issue of implant rotation. In addition, the placement of the implant in the subfascial plane rather than in the submuscular or subglandular plane to more effectively stabilize the implant and prevent implant rotation or contouring distortion is discussed.

Rotation of Breast Implants

Round implants were the standard breast implant until the introduction of anatomic implants. Rotation was not a problem with round implants because their symmetrical shape did not allow them to appear malpositioned [3]. However, when anatomic saline or silicone gel implants rotate, they can appear misshaped, which falls into the category of implant malposition [3, 8].

Several clinical studies specifically have evaluated the incidence of rotation of the different types of anatomic implants. Tebbetts [32] reported that no rotation occurred after 5 years among 609 primary augmentation patients with anatomic saline implants with adequate fill (McGhan style 468). Adequate fill of any breast implant, irrespective of shell characteristics, shape, or filler material (saline or silicone), is important to prevent shell wrinkling, folding, or collapse. Any of these consequences could potentially shorten the life of the implant and require reoperation. In addition, adequate fill produces an increased firmness of the breast.

In a retrospective study of mostly Mentor implants, Baeke [3] reported that anatomic saline implants had a 14% rotation rate and stated that the nipple-areola complex is often the telltale visual sign of implant rotation. When the fuller lower pole of the implant rotates 90° medially on the z axis, the nipple-areola complex shifts, pointing laterally. If the implant spins 180°, the nipple-areola complex will point down.

In a German trial among 132 women who received a total of 240 implants within 3 years, one case of implant rotation/mobility occurred following primary augmentation, three cases occurred after secondary augmentation, and two cases occurred after immediate reconstruction following mastectomy with Style 410 cohesive silicone gel implants [19].

A prospective, randomized, controlled, double-blind Swedish study of 80 women (Style 410 implants, $n = 40$; Eurosilicone Vertex implants, $n = 40$) reported a 5% rotation rate after 4-6 years (median = 5 years). Both types of implants produced similar instances of rotation [26].

An exemption study required by the FDA for premarketing approval of the Style 410 implant in the United States is ongoing. In this prospective, nonrandomized, 10-year study, 48 plastic surgeons in the US used the highly cohesive anatomic silicone gel Style 410 implant. After a 3-year follow-up of 941 women, 2.6% of primary augmentations, 4.7% of augmentation revision surgeries, 4.9% of primary reconstruction surgeries, and 3.0% of revision reconstruction surgeries resulted in implant malposition [5]. In contrast, no rotations were reported in a large Canadian retrospective study using the Style 410 implant in 235 implantations in 117 women [8]. After 4 years of follow-up, implant malpositions occurred in less than 1% (3/885) of the 467 patients receiving Style 410 implants [5].

Hedén [17] reported nine implant malpositions (1.1%) after seven Swedish plastic surgeons implanted 1676 Style 410 implants for mostly primary augmentation (6 for

reconstruction after cancer resection; 6 for congenital breast deformities) in 823 women.

In addition, the soft cohesive anatomic silicone gel implants (CPG) had no rotation reported in 25 reconstruction and 10 augmentation cases followed for about 2 years [14]. A recent study reported rotation rates of 1.1, 2.3, 2.5, and 1.5% in primary augmentation ($n = 551$), augmentation revision ($n = 146$), primary reconstruction ($n = 251$), and revision reconstruction ($n = 69$) cohorts, respectively, at 2-year follow-up [12].

Causes of Implant Rotation

One theory about the cause of implant rotation is the lack of development of a connective tissue adhesion layer (or stable interface) between the implant and the capsule, thus allowing the implant to move freely in the pocket [16].

Because of its cohesive gel, the anatomic implant maintains its shape and is less likely to fold or collapse, especially in the upper pole of the breast. Implant shape is maintained whether the implant is inserted correctly or is slightly rotated or upside down. A report of 132 cases of primary augmentation found that a surgical pocket that is too large can lead to implant rotation, which occurred in 6/132 cases, and a surgical pocket that is too narrow and too high can lead to upper-pole fullness (10/132) because the gel does not sink [19].

Other factors that contribute to the possibility of implant rotation have been hypothesized in the literature. Capsular fluid, which may persist for weeks following submuscular augmentation mammaplasty, may be a cause of implant rotation; this can be circumvented by routinely using small suction drains postoperatively [3, 7]. Double capsules [27], capsule within a capsule [11], periprosthetic mesh, and prosthetic massage [28] also have been reported as possible contributors to implant rotation. An implant placed in the submuscular plane is susceptible to the dynamic action of the muscle, which may induce the implant to move laterally or vertically.

Implant Design to Prevent Rotation

Texturing of the implant with larger pore sizes encourages the development of a stable interface between the implant and the capsule, thus forming a connective tissue adhesion layer. In one study [13], surface texturing with Biocell, which is used in the Style 410 implant, showed a "mirror image" interface and full integration, as detected by scanning electron microscopy on explanted human capsules and implants. The authors concluded that the adhesive effect of the Biocell texture of the Style 410 implant may have a positive impact on implant stabilization in primary reconstruction and secondary corrections of asymmetry or bad position [13].

A group of 114 patients who received a total of 228 Style 410 implants for cosmetic augmentation were followed clinically and by ultrasonography to detect the development of a stabilizing implant-capsule interface. Two cases (0.9%) of implant rotation were detected ultrasonographically. Ultrasonography demonstrated a stable interface in 171 cases (75%), while palpation alone was able to detect the interface in only 145 cases (64%). Four cases (1.7%) were rated false positive using palpation alone compared with ultrasonography. Based on this study, ultrasonography is recommended as an additional step in routine clinical follow-up [16].

Surgical Techniques to Prevent Rotation

Surgical technique may influence the probability of implant rotation. In breast augmentation, pocket plane selection is a major influential factor in the dynamics between the implant and soft tissue following surgery. Precise pocket dissection is essential to encourage a tight fit of the implant to enhance adhesion [1].

In reoperation following the rotation of an implant, a partial capsulectomy should be performed to reposition the implant and thus enhance prosthetic adherence. Inserting the new anatomic implant into the old capsule could result in a lack of adherence and possibly a rotational relapse [28].

Placement of the implant in the submuscular and subglandular positions leads to a higher incidence of rotation. Of 41 cases of breast augmentation revision, 5 cases of rotation occurred when these positions were used [28].

Subfascial Plane

A relatively new implant position involves the subfascial plane, which is gaining popularity because of its low incidences of both implant rotation and capsular contracture [15]. The subfascial plane provides a stronger supporting system for an implant's superior pole. This surgical technique offers more accurate control of breast shape and inframammary fold position. It also provides a more rapid postoperative recovery compared with other techniques and avoids distortion when the pectoral muscle is contracted [15].

In this technique the implant is placed in the subfascia position on the superior half (particularly the upper pole). The dissected anterior-pectoral fascia with the curve limit of the upper pole fits to the upper curved edge of the implant, creating a muscle-fascia system that surrounds and adheres to the implant (Fig. 1).

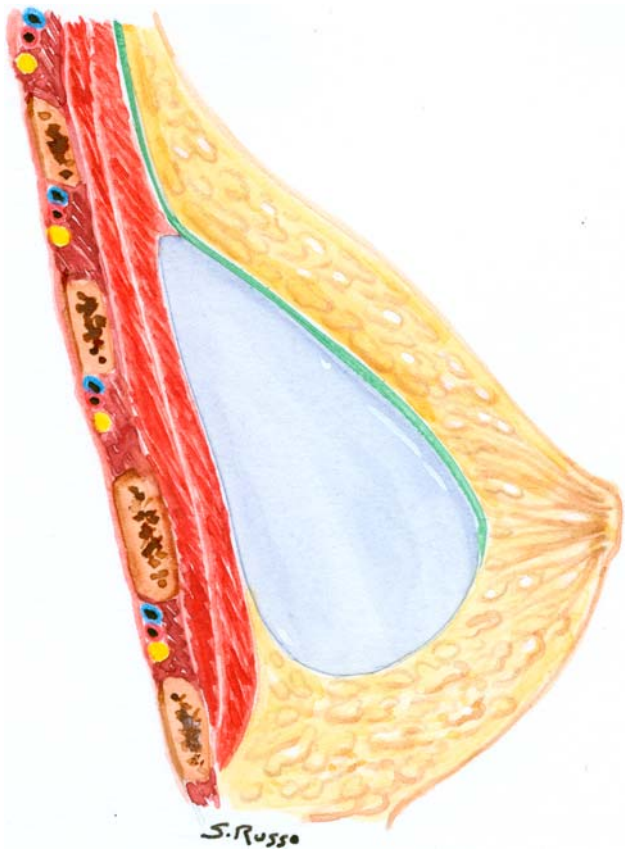

Fig. 1 Placement of the implant in the subfascial plane. The anterior wall of the implant's pocket consists of pectoral fascia, breast parenchyma, subcutaneous tissue, and skin. The stronger supporting system that results from placing the implant under the fascia tends to keep the implant's upper third from altering its shape and position over time [15]

This author has had remarkable success with placing the highly cohesive anatomic Style 410 implant in the subfascial position (Fig. 2). Recently, he has been using this same position with the Style 510 implant. The newest dual-gel Style 510 implants have a concave posterior that conforms and adheres better to the chest wall. In addition, the edging of the Style 510 implant makes this device easier to control during insertion.

For exact implant adaptation and to ensure implant stability, it is important to create a tight pocket. This can be accomplished by using the exact dimensions of the implant's height and width, which helps to avoid implant movement and/or rotation. The skin envelope should be adjusted to the implant size. If an implant has insufficient volume compared with the quantity of skin available, rotation will occur more frequently. If necessary, the skin may be adjusted with vertical or periareolar resections in order to achieve an appropriate match between the implant and pocket volume. The Style 410 or 510 implant can achieve excellent results without the submuscular placement often customary for older-style round implants. An aspirator drain should be inserted for at least 5 days to avoid liquid collection (seroma or hematoma) and induce the adherence of scar tissue to the implant. Immobilization with an occlusive curative and adhesive bandage should be used for 5 days to facilitate cicatrization around the implant as well as to maintain its ideal positioning.

In the unlikely event that implant exchange is required, a capsulectomy must be performed and internal sutures used to readapt the pocket dimensions to the new implant, following the procedures described above.

It is important to advise patients to curtail certain activities for a period of time following implantation to minimize the risk of implant rotation and other complications (Table 1).

Although a direct comparison of subfascial placement with submuscular and subglandular placements has not been undertaken, anatomic implant rotation using the latter two surgical techniques has been reported in the literature. In this author's earlier report of 241 primary and secondary breast augmentation procedures using highly cohesive, textured, anatomic silicone gel implants (Style 410), no incidences of rotation occurred using the subfascial plane surgical technique [15]. Thus, use of this technique combined with a tight pocket results in a stable implant.

Other Complications

In addition to implant rotation, other postoperative local complications of concern to surgeons are capsular contracture and rupture. The overall complication rate is lowest for highly cohesive silicone gel implants compared with implants filled with silicone or silicone and saline [22].

The Baker classification of capsular contracture is the most popular and practical method of assessing clinical breast firmness following augmentation mammaplasty and thus determining outcome. Classifications range from Baker class I to IV. A soft visible implant (class IB), an implant with mild firmness (class II), and an implant with moderate firmness (class III) are considered good or excellent outcomes. Only a Baker class IV classification, which defines an excessively firm and symptomatic breast with poor aesthetic result, would be considered a poor outcome [30].

Several animal studies have examined the effects of implant surfaces on overall soft tissue contracture around the implanted prosthesis. In these studies and in human studies, capsular contracture was less of a concern with the newest generation of refined textured surface implants [4, 6, 9, 10].

Capsular contracture rates reported in several large studies of anatomic implants [17, 33, 34] ranged from a low of 0.5% to a high of 5.0%, with most cases classified as

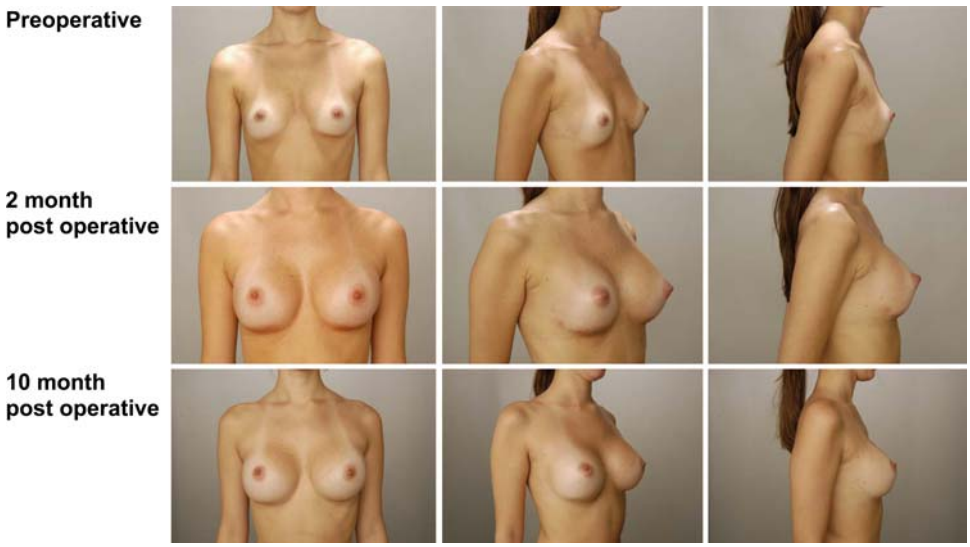

Fig. 2 Ten month follow-up of a patient with Allergan style 410 implanted in the subfacialplane

Table 1 Postimplant patient instructions to minimize rotation risk

- Do not bathe or allow the drain/bandage to become wet for 5 days
- Avoid breast massage for 30 days
- Do not lie on the implant (ventral or lateral decubitus position) for 2 months
- Do not engage in strenuous activities (e.g., skiing, tennis, swimming, pectoral weight-lifting workouts) for 2 months

Baker class I to III. Capsular contracture rates also were low in the author's previously published study [15], suggesting that implant placement in the subfascial plane does not compromise capsular contracture rates.

Implant rupture has been identified in the literature as an issue for silicone gel implants. Magnetic resonance imaging is the most accurate way to detect a possible implant rupture and is recommended by the implant manufacturers [20, 25]. Rupture rates with the first third generations of silicone gel implants were 8%, as reported in a study by Hedén et al. [18], while rupture rates with anatomic implants are shown to be low, ranging from less than 1.0–2.2% [31].

Conclusion

The latest fourth- and fifth-generation, form-stable, cohesive, silicone gel breast implants offer plastic surgeons another option to improve both surgical and aesthetic outcomes, thus meeting patient expectations and increasing patient satisfaction. Highly cohesive, Biocell-textured Style 410 and Style 510 silicone gel implants offer optimal aesthetic outcomes in breast augmentation. When implanted in the subfascial plane, these prostheses are stable, resulting in low rotation rates (<1%) over the long-term.

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