# Textured-Surface Saline-Filled Silicone Breast Implants for Augmentation Mammaplasty

**Scott L. Spear, M.D., Mohamed Elmaraghy, M.D., and Christopher Hess, M.D.**

*Washington, D.C.*

The earliest silicone breast implants were smooth-surface, silicone rubber devices filled with either silicone gel or saline. Because of persistent problems with capsular contracture, polyurethane-covered silicone implants were developed as an alternative. Particularly in the short run, these alternatives proved highly successful at reducing the incidence of capsular contracture. By 1990, polyurethane-covered implants were rapidly becoming the preferred implant choice of many plastic surgeons, but for legal, regulatory, financial, and safety reasons they were withdrawn from the market by Bristol-Myers in 1991. Meanwhile, during the late 1980s, surface texturing and improved materials became available on other silicone breast implants and expanders. Most studies suggest that textured-surface silicone gel–filled implants, saline-filled implants, and tissue expanders have less frequent capsular contracture than their smooth-surface counterparts. (*Plast. Reconstr. Surg.* 105: 1542, 2000.)

Textured-surface, saline-filled silicone implants are one of several options available today for breast augmentation. Understanding their appropriate use requires a review of the history of breast implant development, including the development of textured surfaces.[1–40] The literature on this subject can be confusing; thus, it is important to make certain distinctions clear from the outset. Tissue expanders are different devices than implants and behave differently than implants. Data relevant to tissue expanders are not necessarily true for implants and vice versa.[18] Similarly, silicone gel–filled breast implants are different devices than saline-filled implants.[3,4] The evidence regarding textured, silicone gel–filled implants is not necessarily relevant to saline-filled devices. Finally, for reasons that are not well understood, animal research of breast implants has been a poor predictor of clinical outcomes.[12,18,26]

The evaluation of breast implants necessarily covers two areas: safety and efficacy. Safety issues include but are not necessarily limited to toxicity, immunogenicity, teratogenicity, carcinogenicity, and potential interference with mammography. Efficacy issues include but are not necessarily limited to risks of capsular contracture, deflation, palpability, and rippling. The distinction between textured and smooth saline devices is largely one of efficacy, although there is some evidence that there may be more particulate silicone shed from the surface of textured implants than smooth ones.[39] The medical significance of such shedding is unclear.

The early history of silicone breast implants involved the use of saline-filled or silicone gel–filled devices with smooth silicone surfaces. Although both of those implant types were substantial improvements over earlier options such as Ivalon sponges, they too ultimately suffered from a significant risk of capsular contracture.[1–4,13–16] For reasons of efficacy, silicone gel implants were more popular than saline-filled implants from the beginning. Thus, much of the early literature and clinical energy surrounding silicone implants dealt with silicone gel implants and potential for their capsular contracture, including its cause and avoidance. Factors implicated in the development of capsular contracture included surgical technique, bleeding, subclinical infection, patient sensitivity, soft-tissue environment, and even silicone itself. Some of the most common strategies used in an attempt to defeat capsular contracture included systemic antibiotics, local antibiotics, steroid solution irrigations, intraluminal steroids, submuscular placement, low-bleed silicone elastomer shells, underfilled implants, double-lumen implants, and saline-filled implants.

The nearly universal experience by plastic surgeons that early-generation, smooth, silicone gel–filled breast implants placed in the subglandular plane had a significant risk of developing capsular contracture led, in part, to the development of the polyurethane-covered silicone gel–filled breast implant (Fig. 1).[1,5–7,9–11] Although there were more than one type and manufacturer of polyurethane-covered implants and although they have always been associated with nagging questions
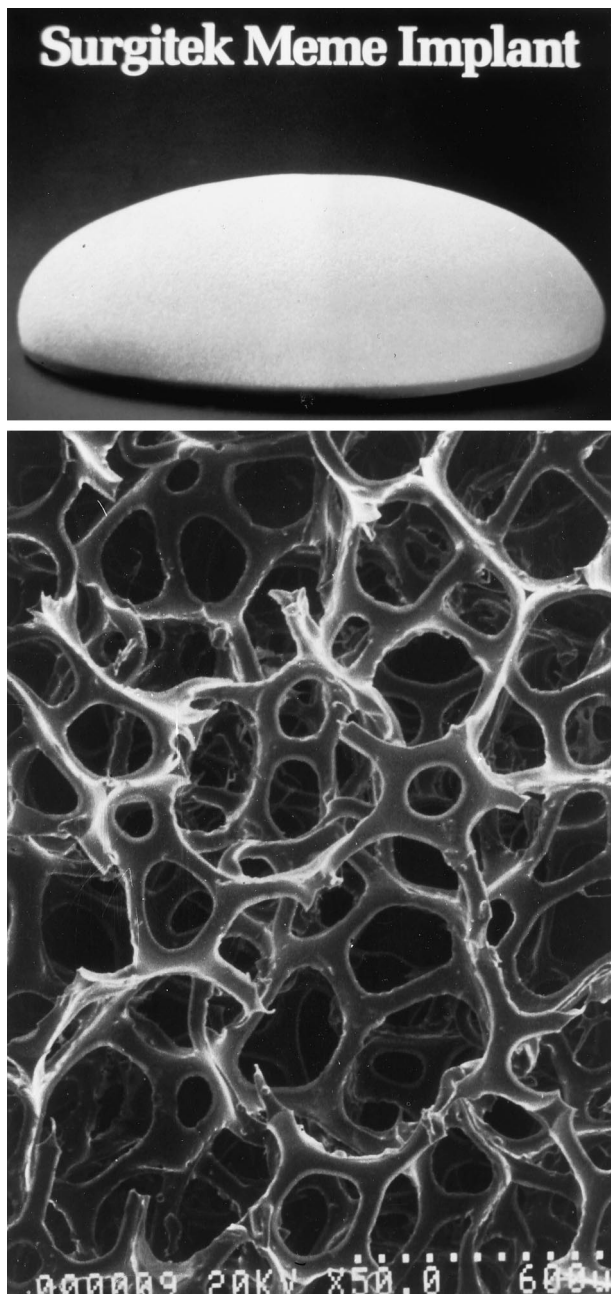


FIG. 1. (*Above*) Polyurethane-covered silicone gel-filled breast implant. (*Below*) The appearance of the polyurethane as seen by electron microscopy.

about the fate and toxicity of the polyurethane, the evidence is substantial that these implants were impressively resistant to capsular contracture, particularly for the first decade or so after their implantation.[9–11,16,40] The increasing popularity of polyurethane-covered implants through the 1980s coupled with their favorable record of infrequent capsular contracture naturally led to a search for other options in textured surfaces that would avoid the long-term doubts about polyurethane. In particular, there was the need of avoiding the possible breakdown products of polyurethane and avoiding the separation or delamination of the textured surface from the implant. This was true because the generally favorable reports regarding the use of polyurethane were tempered by some reports of late capsular contracture after the textured surface had delaminated from the implant, thus, effectively converting it to a smooth-surface device.

During the same time period of the 1970s and 1980s, other steps had also proven somewhat effective in dealing with the frequency of capsular contracture, particularly the use of low-bleed elastomer shells and saline-fill solutions, both of which effectively reduced the amount of silicone gel to which the tissues were exposed.[3,4,13,21,22,24,28,36]

Thus, textured-surface, silicone implants were developed in the late 1980s as an obvious alternative to the attached textured surface of polyurethane. Because of earlier work to improve the performance and decrease the silicone permeability of the elastomer shells, the textured-surface, silicone elastomer shells were developed at a time when all silicone breast implants were becoming available as stronger and less permeable versions of earlier materials. Four different types of textured surfaces were available more or less simultaneously: polyurethane, Biocell, MSI, and Siltex.

Dow Corning developed and manufactured the MSI surface, which is an extremely regular surface of projecting, minute silicone rubber papillae created with laser technology (Fig. 2). Mentor Corporation developed the Siltex surface, which is a patterned surface created as a negative contact imprint off of a texturing foam (Fig. 3). The McGhan Medical Corporation developed the Biocell surface, which is an aggressive open-pore textured surface created with a lost-salt technique and that seems, at least in many ways, similar to polyurethane (Fig. 4).
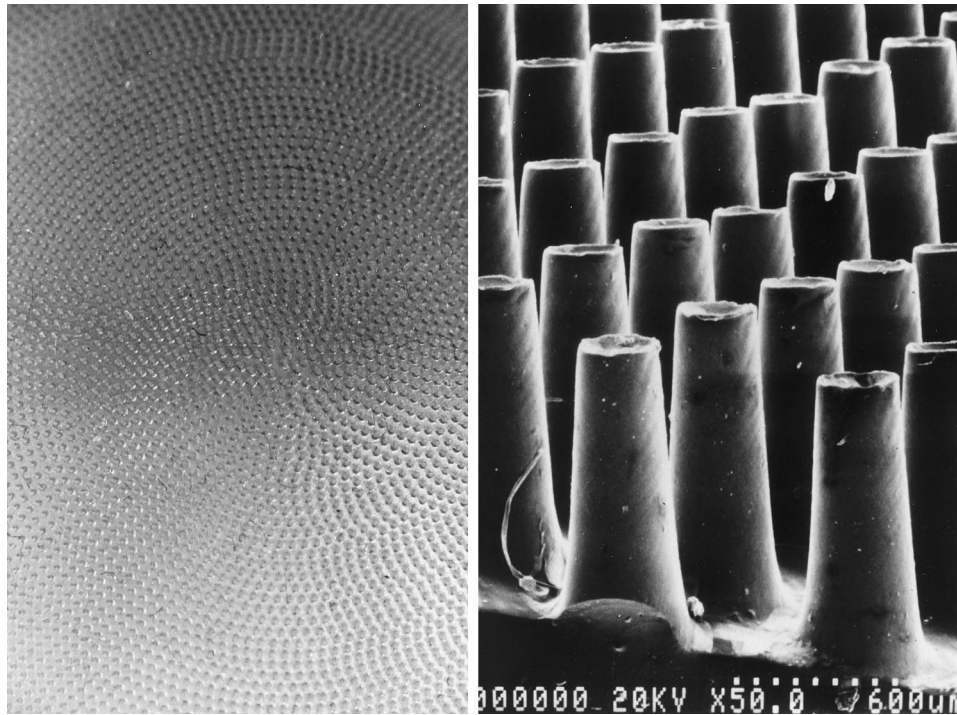
FIG. 2. (*Left*) The MSI textured surface. (*Right*) A close-up view of its surface as seen by electron microscopy.

The various textured surfaces became available at approximately the same time and could be found on silicone gel–filled implants, saline-filled implants, and tissue expanders. Because much of this innovation occurred just before and during the FDA hearings on silicone implants, there has been only a modest amount of information available regarding how, and how well, these textured surfaces work. However, certain things did become clear. First, each of the available textured surfaces was manufactured differently, looked different, and behaved differently in the clinical environment. Second, textured surfaces behaved differently, depending on whether they were used on silicone gel implants, saline implants, or expanders. The evidence is convincing that neither the MSI nor the Siltex textured expanders or implants induced the type of tissue ingrowth as seen with polyurethane. The Biocell expanders, on the other hand, usually incited tissue ingrowth, whereas the Biocell implants did so only occasionally.[41] Whereas the MSI and Siltex surfaces were resistant to tissue ingrowth, the Biocell surface promoted ingrowth, particularly when native tissues were placed in intimate contact with the Biocell surface such as was seen with tissue expansion or a tight pocket around an implant.

With the voluntary withdrawal of the poly-

urethane-covered implant from the U.S. market in 1991 by Bristol Myers, the demand for other textured-surface breast implants was immediate. As a result of the FDA hearings of 1991 and 1992 and the contemporaneously extremely hostile litigation environment, Dow Corning ceased its breast implant business and the MSI surface was simultaneously withdrawn, despite early, quite favorable anecdotal experience with it.

In the United States, by early 1992, two types of textured surfaces were available on tissue expanders and saline-filled implants: the Biocell surface and the Siltex surface. Mentor at that time was the only manufacturer approved to market textured-surface, silicone gel–filled implants in an FDA-approved "adjunct study." More recently, McGhan has won approval by the FDA for its own adjunct study, which includes its Biocell textured-surface, silicone gel–filled implants. For practical purposes, we have had nearly 10 years of clinical experience with two types of textured-surface breast implants. Many surgeons have had their own individual experiences with these various devices, and we now have a handful of reasonable studies on which to make some judgment.

The stage was initially set in 1981 with reports first by Capozzi and Pennisi, and eventually by many others, that polyurethane-covered,
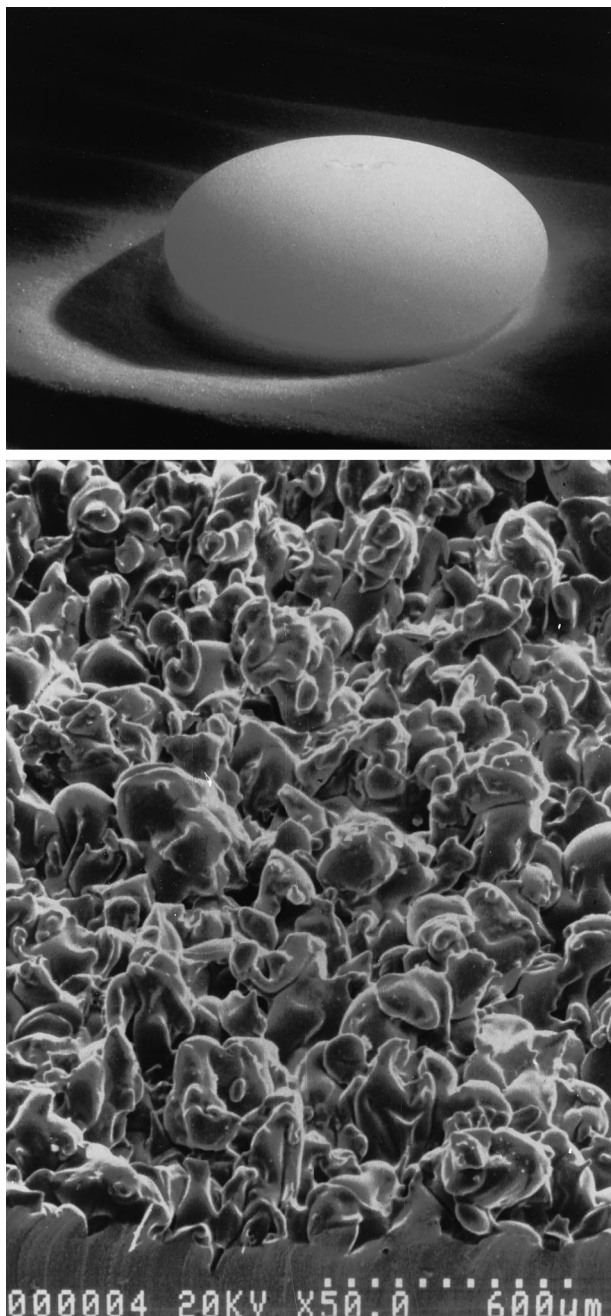
FIG. 3. (*Above*) The Siltex textured-surface, saline-filled breast implant. (*Below*) A close-up of its surface as seen by electron microscopy.

silicone gel–filled implants produced a dramatic lowering of the capsular contracture rate compared with the smooth silicone gel–filled implants available at that time.[1,5–7,9–11] During the same time period, several studies demonstrated that saline-filled implants had a significantly lower rate of capsular contracture than silicone gel–filled devices.[3,4,13,21] Asplund, in a 1984 report on submuscular breast reconstruction, described a 54 percent capsular contrac-

ture rate around those early-design smooth, silicone gel–filled implants and a 20 percent rate around smooth, saline-filled implants. Some of these patients were radiated, which helps explain the high frequency of capsular contracture in both groups. On a follow-up of this same study published 6 years later in 1990, the incidence of capsular contracture at 6 years remained stable and was 50 percent in the silicone gel group and 16 percent in the saline-filled group. The report by Lavine in 1993 reviewed 1091 women who had undergone mostly subpectoral breast augmentation by using smooth, saline-filled implants over a 10-year period with an overall capsular contracture rate of 6.1 percent. Thus, even without the benefit of textured surfacing in these studies, saline-filled implants placed subpectorally had fairly well proven to have a lower incidence of capsular contracture than the early versions of smooth-surface, silicone gel–filled implants. The problems with saline-filled devices, on the other hand, have had more to do with deflation, visibility, and palpability.

Much of the impetus for developing a textured surface, thus, was focused primarily on the silicone gel–filled implant, for which there was more of a history of a problem with capsular contracture. Publications by Hakelius and Ohlsén in 1992 and Pollock in 1993 gave early support to a lower capsular contracture rate with textured-surface, gel implants.[19,20] Hakelius and Ohlsén performed a 1-year, randomly assigned, double-blinded study of subglandular breast augmentations in 25 women by using a more modern design McGhan smooth, silicone gel implant on one side and a McGhan, Biocell, textured silicone gel implant on the other side. The textured silicone gel device performed dramatically better, and 12 of the 25 women ultimately asked to replace the smooth implant on one side. Forty-four percent of the smooth, silicone gel–filled implants had capsular contracture, whereas none of the textured implants did.

In the publication by Harlan-Pollock in 1993 reviewing 197 subglandular breast augmentations (98 Mentor, smooth, double-lumen silicone gel and 99 Mentor, Siltex surface, silicone gel), the smooth implants had a 21 percent incidence of capsular contracture, whereas the textured-surface implants had a 4 percent incidence. Coleman's two reviews of his experience, the first at 1 year and the other after 3 years, confirmed that after subglandular breast
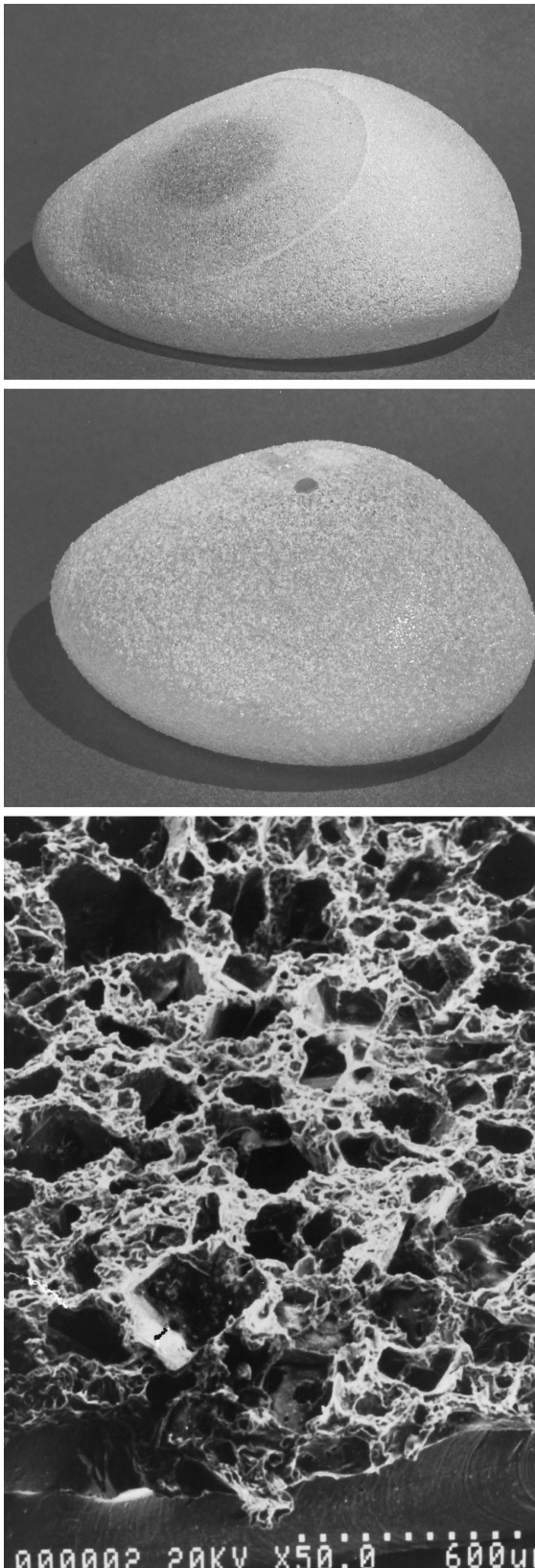
FIG. 4. (*Above*) The Biocell textured-surface, tissue expander. (*Center*) The Biocell textured-surface, saline-filled breast implant. (*Below*) A close-up of the implant's textured surface as seen by electron microscopy.

augmentation, the Mentor Siltex textured surface was dramatically effective in reducing capsular contracture to 11 percent of patients compared with 59 percent for smooth Mentor gel-filled implants.

Multicenter data presented on behalf of both Mentor and McGhan Corporations would seem to be in general agreement with the above studies. The Mentor multicenter "adjunct" study, composed of more than 1500 investigators and more than 15,000 Siltex textured-surface, silicone gel–filled implants in a variety of clinical situations, has produced a capsular contracture incidence per breast of roughly 5 percent. The McGhan prospective clinical study of silicone gel–filled implants yielded a similar 5.5 percent textured-surface, implant capsular contracture incidence per implant at 4 years. During the same time period, smooth-surface, McGhan gel implants used in breast augmentation had a 10.6 percent incidence per implant of capsular contracture.[42] In both the McGhan and Mentor studies, the data for subglandular and submuscular implants have so far been lumped together, so that no conclusion can be drawn yet from those studies on subpectoral positioning. The above data for McGhan was reported per implant, and in the case of breast augmentation, with mostly unilateral capsular contracture, the per-patient incidence of contracture was 15.8 percent for smooth gel implants and 9.2 percent for textured gel implants.

The data we have reviewed strongly support certain conclusions. Polyurethane-covered implants were effective at reducing capsular contracture compared with a wide variety of early versions of smooth, silicone gel–filled devices available in the 1970s and early 1980s. Saline-filled, smooth implants were also somewhat effective at reducing the incidence of capsular contracture compared with smooth, gel-filled devices, particularly when placed subpectorally. And, both the McGhan Biocell textured surface and the Mentor Siltex textured surface are generally effective in reducing the incidence of capsular contracture. Interestingly, to date, there have been no published reports directly comparing the efficacy of the mildly aggressive Siltex textured surface with the more aggressively textured McGhan Biocell surface. Several studies have looked at the benefits of submuscular or subpectoral positioning over subglandular placement, with the evidence supporting a reduction in capsular con-

tracture with implants under some muscle particularly with saline-filled implants.[2,8] Information on the combined benefits of submuscular positioning and surface texturing awaits further studies and their publication.

The initial work on textured surfaces and saline-filled devices was in expanders. Maxwell's landmark study on breast reconstruction with Biocell textured surface, integrated-valve, anatomic tissue expanders dramatically demonstrated the effectiveness of these devices not only in avoiding capsular contracture but in achieving a satisfactory breast shape.[43] However, there was contradictory information in both animal models and clinical experience, with some authors finding no advantage in reducing capsular contracture by using textured surfacing in inflatable devices. Nevertheless, at least in breast reconstruction, textured-surface, integrated valve, inflatable tissue expanders have been accepted by many as preferable to smooth devices.[42,44]

Against this background of information first on textured surfaces and then on saline-filled devices, we have additional information specifically on textured-surface, saline-filled implants. However, before looking at these data, it is critical to remember that even smooth-surface, saline-filled implants placed subpectorally have a favorable record in terms of capsular contracture.[21,22,28] Also, there are two benefits of subpectoral positioning with saline-filled implant: decreased capsular contracture and decreased implant visibility and palpability. In 1994, Burkhardt and Demas reported their experience with Mentor's Siltex textured, saline-filled implant used randomly on one side of subglandular breast augmentation.[23] The Siltex side had a 2 percent incidence of capsular contracture compared with 40 percent on the opposite side with a smooth implant. Of interest in this study is the preference of some of the patients for their firmer smooth inflatable implant over the opposite side's softer textured implant, because the smooth device was less palpable or visible. In 1995, Burkhardt and Eades reported on a similar study comparing McGhan's Biocell textured-surface, saline-filled implant to its smooth counterpart again in subglandular breast augmentation.[29] Thirteen percent of textured devices exhibited Baker class III or IV capsular contracture compared with 23 percent of smooth devices. Unlike the Mentor textured-surface implants, neither the patients or the

surgeons could distinguish clinically between the smooth and textured implants.

Tarpila et al. from Sweden performed a similar study in subglandular augmentation in 21 women by using McGhan Biocell and smooth, saline-filled implants randomly on opposite sides.[35] The implants were overfilled 10 cc, and antibiotics or antibacterials were not used locally or systemically. At 1 year, 29 percent of textured and 38 percent of smooth implants exhibited Baker III capsular contractures, a difference that did not reach statistical significance.

Of special interest is the McGhan multicenter study combining subglandular and subpectoral breast augmentation. At 4 years, the capsular contracture incidence per patient for smooth saline-filled implants was 7.4 percent, and 8 percent for textured-surface, saline-filled implants; no significant difference. The incidence of capsular contracture per breast would have been roughly half of that, i.e., 3.7 percent and 4 percent, respectively.

Both Truppmann and Mladick have separately reported an incidence of capsular contracture near 1 percent in subpectoral augmentation with smooth saline-filled implants.[22,28,42] On the basis of these studies and earlier studies on breast reconstruction with saline-filled implants, it seems clear, particularly for saline-filled devices, that subpectoral positioning is very protective against capsular contracture. With an incidence of near 1 percent as reported by Mladick[22] and others around smooth, saline-filled implants for breast augmentation placed subpectorally, it is not clear that surface texturing has much additional to offer in avoiding capsular contracture when submuscular placement is being considered. Thus, although the benefit of submuscular positioning of saline-filled implants in avoiding capsular contracture seems unequivocal, the information on surface texturing for saline devices is more complicated.

The published data we have reviewed from several different studies suggest then that subglandular breast augmentation with smooth, saline-filled implants may yield a capsular contracture incidence per implant of between 23 and 40 percent. Surface texturing has the potential to reduce that incidence to somewhere between 2 and 29 percent. However, the Siltex textured saline-filled implant may have the disadvantage of being more palpable and visible than its smooth counterpart, to some extent

possibly negating its advantage of less capsular contracture in the subglandular position. The McGhan Biocell textured surface also seems effective at reducing the incidence of subglandular capsular contracture, but the McGhan Biocell saline-filled implant also may be more visible and palpable, than a smooth implant. Although there is no evidence that the Mentor Siltex textured, saline-filled implants experience tissue ingrowth, the McGhan Biocell saline implant will achieve ingrowth in some patients. The tighter the pocket and the more pressure exerted by the implant against surrounding native tissues, the more likely ingrowth will occur. However, it is not clear that tissue ingrowth around implants is necessarily desirable, although many if not most surgeons prefer tissue ingrowth around expanders.

Of course, there is more to breast surgery than just capsular contracture. What about shape, appearance, feel, and mammography? My personal experience with saline-filled implants began in the late 1980s when I substituted smooth saline implants occasionally for smooth double-lumen silicone gel–filled im-

plants in subpectoral breast augmentation. In most patients, they did fine in terms of capsular contracture (Fig. 5). Although we initially used them with a dilute intraluminal solution of Solu-medrol, we stopped that practice because of the evidence and our own experience that submuscular saline-filled implants do not need the help of steroids. Our experience with subglandular, saline-filled implants has not been quite as favorable. Both in primary and secondary cases of subglandular breast augmentation, some smooth and some textured saline-filled implants have been more palpable and more visible than subpectoral implants. And, it is our impression that there have been more capsular contractures, although we have not studied these patients carefully enough yet to quantitate the difference. And when the implants are placed subpectorally, there is the important added advantage of improved mammography.

Based on the published studies and our own clinical experience, we make these recommendations. For reasons of softness, shape, feel, appearance, and mammography, saline-filled implants do best when placed beneath all or
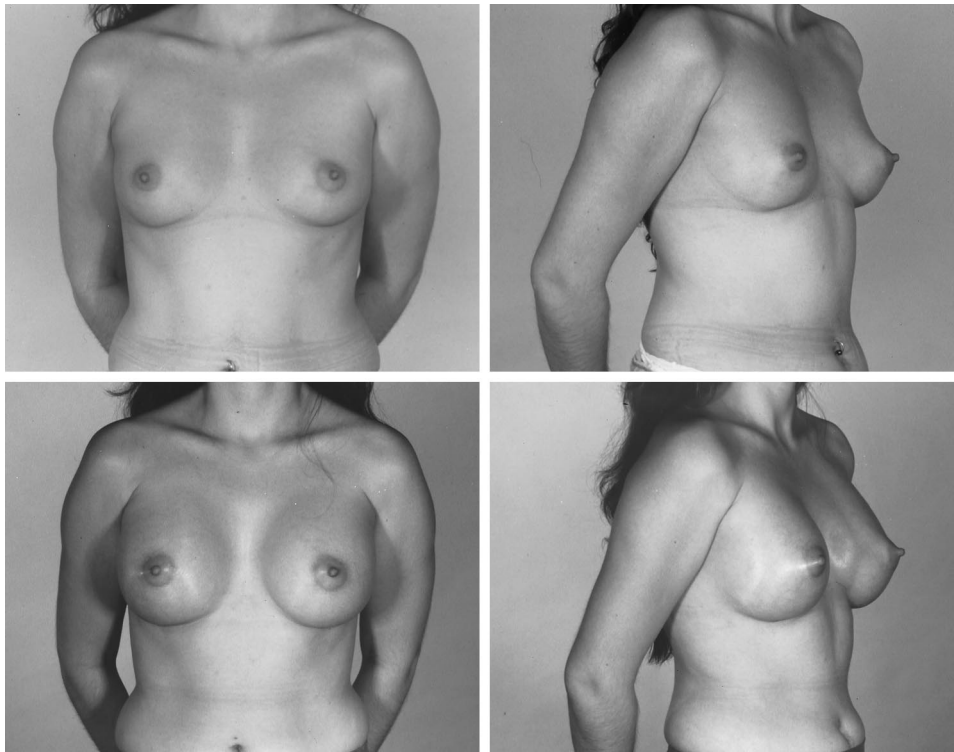


Fig. 5. A patient before (*above*) and after (*below*) subpectoral augmentation mammaplasty using 360-cc round, smooth-surface, saline-filled breast implants. A patient with healthy and sufficient soft-tissue coverage such as this would also be an appropriate candidate for a subglandular breast implant for which surface texturing would provide added protection against capsular contracture without undue risk of undesirable palpability or visibility. The subpectoral approach is still preferable in terms of mammography.

some portion of the pectoralis major muscle. In very thin and small-breasted women without ptosis, even more or total muscle cover is an option. This finding is particularly true for saline-filled implants, even more so than for gel-filled implants because of possible palpability, visibility, and rippling problems from saline. On the other hand, subglandular placement is a more reasonable option in patients with some breast tissue and subcutaneous fat, and a healthy, reasonably thick, elastic youthful skin envelope. The healthier the soft-tissue cover, the better subglandular saline-filled implants perform and feel. Published reviews support the proposition that textured-surface implants offer some special advantage in these patients for reducing capsular contracture when the implant is placed subglandularly (Table I). The ptotic patient with stretched out and thin skin is problematic. Although subpectoral positioning risks creating a double-bubble with the breast hanging below the implant, subglandular positioning with a textured saline-filled implant placed just beneath thinned-out breast skin runs the risk of visible rippling and an implant that is too easily palpated. The same may be true for the patient who has had previous breast implants, for whom those implants may have thinned or stretched out the soft tissues (Table II). In these difficult situations, repair of the soft tissues by using mastopexy or flap techniques may be necessary to use a saline-filled implant.

However, surface texturing may also play a role when trying to control breast shape (Fig. 6). The various designs of anatomic, saline-filled implants come with textured surfaces. Although not proven, it is believed by some that these textured surfaces along with careful surgical dissection and appropriate postoperative care may help to reduce implant rotation and mobility so as to create and best control breast shape. Although for reasons of capsular contracture, mammography, and implant palpability, this is better done subpectorally; it can also be done in the subglandular space in patients with adequate soft tissue. Because of the very low risk of capsular contracture around subpectoral, smooth-surface, round saline-filled implants, there would seem to be little advantage in the use of round, textured-surface, saline-filled implants in the subpectoral position, except for reasons of personal preference or perhaps in a patient who has a poor record with capsular contracture associated with an earlier smooth round device.

Technically, breast augmentation with smooth, round saline-filled implants resembles historical techniques with silicone gel implants, for which implant mobility and large pocket dissection were desirable. With this large-pocket approach by using saline-filled implants, particularly larger ones, there may be a tendency for increased soft-tissue stretching and thinning as a possible result of the repetitive water-hammer effect of the salt water. Although also possible with silicone gel–filled implants, particularly textured ones, this effect was not commonly seen with them. Such soft-tissue stretching would likely increase the risk of rippling, palpability, and ptosis.

The textured-surface, saline-filled implants are designed to retain softness without the need for the mobility seen with smooth ones. In breast augmentation with the McGhan Biocell textured-surface implant, where tissue ingrowth or some adherence is a real possibility, precise pocket dissection and conservative implant volumes (volumes of 380 cc or less) can yield breasts with minimal implant mobility, palpability, rippling or ptosis, yet with reasonable softness and an attractive, more natural shape. However, the drawback of this approach is a certain lack of mobility, a solution that some surgeons and patients do not accept. The Mentor Siltex surface, although effective at re-

TABLE I

Capsular Contracture around Silicone Gel-Filled Implants

| Study | Manufacturer | Textured Surface | Cap. Contr. around Subgland. Smooth Gel (%) | Cap. Contr. around Subgland. Textured Gel (%) | Cap. Contr. around Smooth Gel (site not specific) (%) | Cap. Contr. around Textured Gel (site not specific) (%) |
|---|---|---|---|---|---|---|
| Hakelius | McGhan | Biocell | 44 | 0 | | |
| Pollock | Mentor | Siltex | 21 | 4 | | |
| Coleman | Mentor | Siltex | 59 | 11 | | |
| Mentor Adj. Clin. | Mentor | Siltex | | | n/a | 5 |
| McGhan Core Clin. | McGhan | Biocell | | | 10.6 | 5.5 |

Cap. Contr., capsular contracture; Subgland., subglandular; n/a, not applicable; Adj. Clin., adjunct clinical trial; Core Clin., core clinical trial.

TABLE II
Capsular Contracture around Saline-Filled Implants

| Study | Manufacturer | Textured Surface | Cap. Contr. around Smooth Subglandular (%) | Cap. Contr. around Textured Subglandular (%) | Cap. Contr. around Smooth (site not specific) (%) | Cap. Contr. around Textured Gel (site not specific) (%) |
|---|---|---|---|---|---|---|
| Burkhardt (1994) | Mentor | Siltex | 40 | 2 | | |
| Burkhardt (1995) | McGhan | Biocell | 23 | 13 | | |
| Tarpilla | McGhan | Biocell | 38 | 29 | | |
| McGhan Core Clinical Study | McGhan | Biocell | | | 3.7 | 4 |

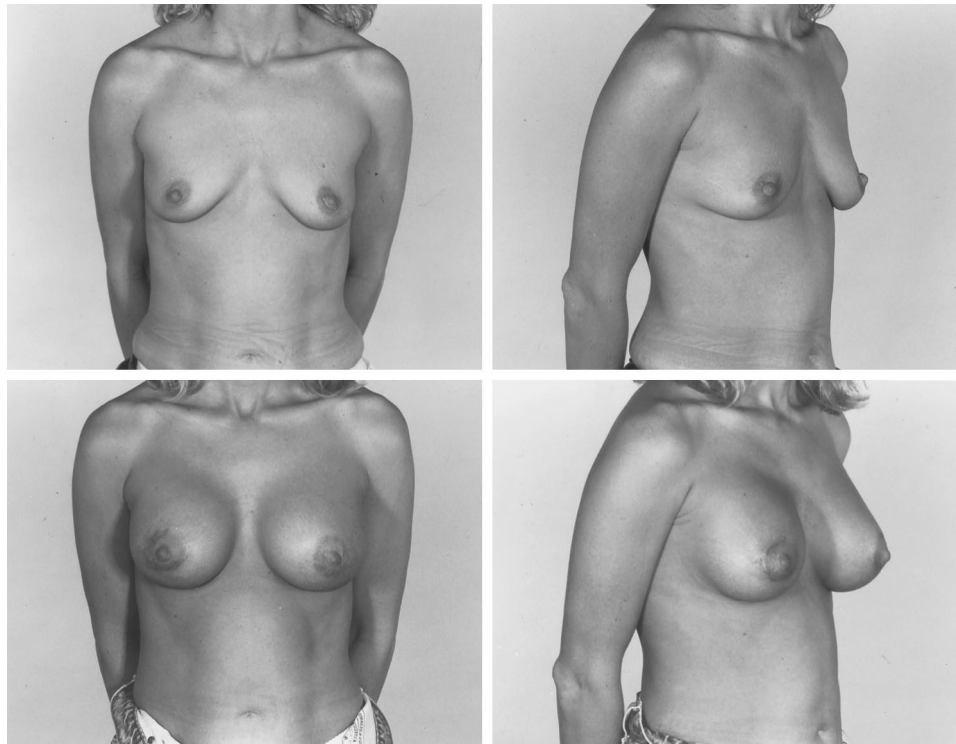Cap. Contr., capsular contracture.



Fig. 6. A patient (*above*) before and (*below*) after subpectoral augmentation mammaplasty using 300-cc anatomic, textured-surface, saline-filled breast implants. A patient with this much soft tissue might also be a reasonable candidate for a subglandular, textured, anatomic implant with precise pocket dissection.

ducing capsular contracture, does so without tissue ingrowth or adherence. Clinically, the technique and results with the Mentor Siltex surface more closely resemble those with un-encapsulated smooth implants for which mobility rather than adherence is the rule. When the Biocell surface is used in secondary cases or after large pocket dissections, tissue ingrowth and adherence are also less likely, and in those circumstances too, mobility rather adherence is the rule. For that reason, anatomically shaped textured implants are best used only when there is some control over the pocket size, shape, and fit to the implant; otherwise, the implant will lose its proper orientation.

In conclusion, whereas capsular contracture has been the historical bug-bear associated with the efficacy of silicone gel–filled breast implants, palpability, visibility, and rippling as well as capsular contracture have been the problems with saline-filled ones. Surface texturing has, thus, played a more important role in silicone gel–filled implants than in saline-filled ones. Textured, saline-filled breast implants make the most sense in two scenarios: first, with anatomic designs where the goal is to better control and create a certain breast shape; and second, in patients with adequate soft tissue for whom subglandular positioning is desired for whatever reason. For routine subpectoral breast augmentation, there are not, at the present time any clear documented advan-

tages or for that matter disadvantages to round textured, saline-filled implants. Subpectoral positioning of saline-filled implants alone seems very effective at reducing the incidence of capsular contracture without the added risk of increased palpability and implant visibility, which may occur in subglandular positioning of textured saline-filled implants particularly in patients with inadequate soft-tissue cover.

*Scott L. Spear, M.D.*
*Division of Plastic Surgery*
*Georgetown University Medical Center*
*3800 Reservoir Road, N.W.*
*Washington, D.C. 20007*
*spears@gunet.georgetown.edu*

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