Patient Acceptance of Adequately Filled Breast Implants Using the Tilt Test

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Adequate fill of any breast implant, regardless of shell characteristics, shape, or filler material, is important to prevent implant shell wrinkling, folding, or collapse that could potentially decrease the life of the implant. Implant shell life is a major factor that affects reoperation rates. The greater the necessity of reoperations, regardless of implant type, the greater the rate of local complications, necessitating additional surgery with additional risks and costs to patients. Palpable shell folding, visible wrinkling or rippling, palpable shifts of filler material, sloshing, and compromised aesthetic results can result from an underfilled implant. Any of these complications can necessitate reoperations with increased risks and costs to patients.

This is a study of 609 consecutive patients from January of 1993 to December of 1998 who were given detailed preoperative informed consent and a choice of implant shape and type and who chose the increased firmness associated with an implant that is adequately filled to pass the tilt test. This study addresses two questions: (1) Will patients accept the increased firmness of an implant that is filled to pass the tilt test? and (2) Is adequate fill by the tilt test useful clinically to help reduce the incidence of postoperative rippling, wrinkling, and spontaneous deflation in saline implants? Patients were followed by postoperative examinations and questionnaires. No patient requested implant replacement to a softer implant postoperatively, and no reoperations were performed for visible rippling or wrinkling. The spontaneous deflation rate over this 6-year period was 9 of 1218 implants, or 0.739 percent. If patients will accept more firmness with an adequately filled implant, regardless of the filler material, surgeons might worry less about recommending an adequately filled implant to patients, and manufacturers might feel more comfortable producing adequately filled implants and redefining fill volumes for underfilled implants. More adequately filled implants could potentially reduce risks of reoperations by reducing premature shell failure and shell wrinkling complications. (*Plast. Reconstr. Surg.* 106: 139, 2000.)

All breast implants, regardless of shell characteristics, shape, or filler material, should be adequately filled to prevent implant shell wrinkling, folding, or collapse, which could decrease the life of the implant or cause complications that require reoperation.[1–5] Implant shell life is a major factor that affects reoperation rates. The greater the need for reoperations, regardless of implant type, the greater the rate of local complications. More complications necessitate additional surgery, with its additional risks and costs. A loss of shell integrity is not the only complication that can result from an underfilled implant. Palpable shell folding, visible wrinkling or rippling, palpable shifts of filler material, sloshing, and compromised aesthetic results can all result from an underfilled implant, whether the implant is prefilled by the manufacturer or filled intraoperatively by the surgeon. Any of these complications can necessitate a reoperation, with increased risks and costs to patients.

If the upper shell of an underfilled implant collapses, ripples, or folds when the implant is tilted upright during a tilt test to simulate the position of the implant in the patient,[1] additional stresses on the shell may occur in localized areas of the shell. If an implant is filled adequately to prevent upper shell collapse or folding, localized stresses on a collapsed or folded shell could be reduced. The greater the fill volume over the mandrel displacement volume of an implant shell, regardless of implant shape or filler material, the firmer the implant will feel.

This study addresses two questions. (1) Will patients accept the increased firmness of an implant that is filled to pass the tilt test?[1] (2) Is adequate fill by the tilt test useful clinically to help reduce the incidence of postoperative rip-

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pling and wrinkling in saline implants? If patients will accept more firmness with an adequately filled implant, surgeons might worry less about recommending an adequately filled implant to patients, and manufacturers might feel more comfortable producing adequately filled implants and redefining fill volumes for underfilled implants. More adequately filled implants, regardless of the filler material or whether the implant is prefilled by the manufacturer, could reduce the risks of reoperation by reducing premature shell failure and shell wrinkling complications.

Patients and Methods

Patients

From September of 1993 through December of 1998, 609 patients underwent bilateral augmentation mammaplasty through inframammary, axillary, and periareolar incisions. Before any consultation with the surgeon, all patients were seen by patient educators and were given a choice of incision location, implant type, and pocket location; patients were informed of the tradeoffs of each choice, depending on individual tissue characteristics and wishes. Patients ranged in age from 18 to 58 years and had an average age of 26 years.

Preoperative Consultation

All patients received detailed, written patient information sheets before their initial patient educator consultation. All patients had a 30- to 45-minute consultation with a patient educator before the surgical consultation to review all information contained in the written information sheets and to answer preliminary patient questions. Portions of the patient educator and surgeon consultations were specifically scripted with the following information to ensure that all patients were similarly informed about implant fill issues and tradeoffs:

1. Saline implants are the only option currently available to women in the United States for primary breast augmentation.
2. Saline implants are available in two basic shapes, round and anatomic (patients were shown examples of both types of implants filled to the manufacturers' recommendations). Other variations of these shapes are available from different manufacturers. Textured surface and smooth surface implants are available. You may choose any implant you desire from any manufacturer.
3. Because of the "watery" characteristics of saline, the amount of saline placed in the implant could affect whether the implant shell ripples, collapses, or folds when the implant is upright in your body.
4. Implant shell rippling can be visible in different portions of the breast after augmentation if the overlying tissues are thin, depending on the surgical techniques and pocket location chosen. Even with submuscular placement, rippling can be visible at the outer portions of the breast.
5. Implant shell collapse and/or folding of the shell may produce stresses on the shell that might contribute to earlier shell failure, which would necessitate replacing the implant.
6. Visible rippling after augmentation can detract from the quality of your result and, in certain circumstances, require additional surgery.
7. To prevent shell folding, more saline filler can be added to the implant. The tradeoff of adding more filler is increased firmness of the implant.
8. The degree of increased firmness depends on the amount of filler added and individual patient tissue characteristics. The tighter the tissues or the larger the implant, the firmer the result.
9. The fill volumes for the McGhan style 468 anatomic implant have been defined using a tilt test to try to prevent upper shell collapse, shell folding, or shell wrinkling due to underfill. The tradeoff that you must consider before choosing an implant is that any implant that is filled adequately to prevent shell collapse, folding, or wrinkling will be firmer than an implant that is underfilled.
10. Avoiding visible wrinkling or rippling after the placement of saline implants depends on the selection of an appropriate pocket location for the implant. The thinner the tissues, the greater the need for adequate tissue cover over the implant, possibly requiring a pocket location partially under muscle. The larger the implant we select and the thinner your overlying tissues, the greater the

risk of visible irregularities, regardless of the amount the implant is filled.

11. If you choose an adequately filled implant to prevent shell collapse, your implant will be filled to pass the tilt test to determine adequacy of fill. If you choose a McGhan style 468 anatomic implant, the manufacturer's recommended fill volume is already defined to pass the tilt test. After surgery, we will ask your impressions of whether you feel your breast is excessively firm, and we will replace your implants at no cost to you if you desire softer or less filled implants.

Pocket Location and Surgical Techniques

Implant pocket location was based on clinically quantifiable criteria. Patients who had a pinch thickness of skin and subcutaneous tissue of 2 cm or more, as measured by calipers in an area superior to the breast parenchyma, were offered a choice of submammary or subpectoral pocket location. They were informed about the mammographic considerations, tradeoffs, and risks associated with each pocket location. Patients with a less than 2 cm pinch thickness superior to the parenchyma were not offered submammary placement, and all patients with this pinch thickness had implants placed subpectorally. A total of 215 patients had submammary placement and 394 patients had subpectoral placement. When subpectoral placement was performed, pectoralis origins were divided across the inframammary fold to increase fold level accuracy and predictability. The division of pectoralis origins medially along the sternum to further narrow the intermammary distance was avoided to prevent visible irregularities due to implant borders or readherence of muscle cut edges to subcutaneous tissues.

The Implants

All patients in this series requested anatomically shaped implants when given a choice of round or anatomic implants. All patients underwent augmentation mammaplasty with McGhan style 468 textured silicone shell, anatomically shaped, saline-filled mammary implants. All implants were filled within the manufacturer's recommended range. During the design of the 468 implant, every size implant used in the study was filled at 5-cc increments within the manufacturer's recommended fill range and, at each 5-cc increment, all sizes passed the tilt test[1] without visible shell collapse or folding in the upper pole of the implant. Once fill volumes were defined for each implant size using the tilt test, the tilt test was not performed on every implant at every operation. Implant fills ranged from 195 to 450 cc, with a median fill of 285 cc and an average fill of 270 cc.

The Tilt Test

The tilt test[1] is a simple test that any surgeon can perform on any implant, regardless of implant shape, shell characteristics, filler material, or fill volume, to assess the amount of fill necessary to prevent upper shell collapse and shell folding when the implant is placed upright (simulating its position in a standing patient). After filling the implant to the desired volume, place the implant in the palm of the hand (Fig. 1, *above, left*). With the other hand, evenly support (but do not add pressure to) the lower pole of the implant (Fig. 1, *above, right*) in a manner similar to the support provided by even the most lax soft-tissue envelope after it has fully relaxed after augmentation. Tilt the implant vertically (Fig. 1, *below, left*). If the upper pole of the implant collapses, folds, or wrinkles, the implant is underfilled with respect to preventing shell collapse and folding. An adequately filled implant (Fig. 1, *below, right*) does not experience upper shell collapse or folding when the implant is upright. To ensure adequate fill to prevent upper pole collapse, it is essential to put minimal pressure on the lower pole of the implant with the supporting hand.

Patient Follow-Up

Patient follow-up ranged from 3 months to 5 years, with an average follow-up of 22 months. Routine postoperative follow-up visits were scheduled at 2 days, 3 weeks, 3 months, 1 year, 2 years, and every 2 years thereafter. During follow-up visits at 3 months and later, patients were asked the following questions.

1. Are your breasts too firm? A little bit? A lot?
2. Would you exchange your implants for softer ones to achieve more softness if the softer implants had even a remote risk of shell folding or premature shell failure?

Questionnaire

Questionnaires were sent to 200 randomly selected patients from the series at least 6

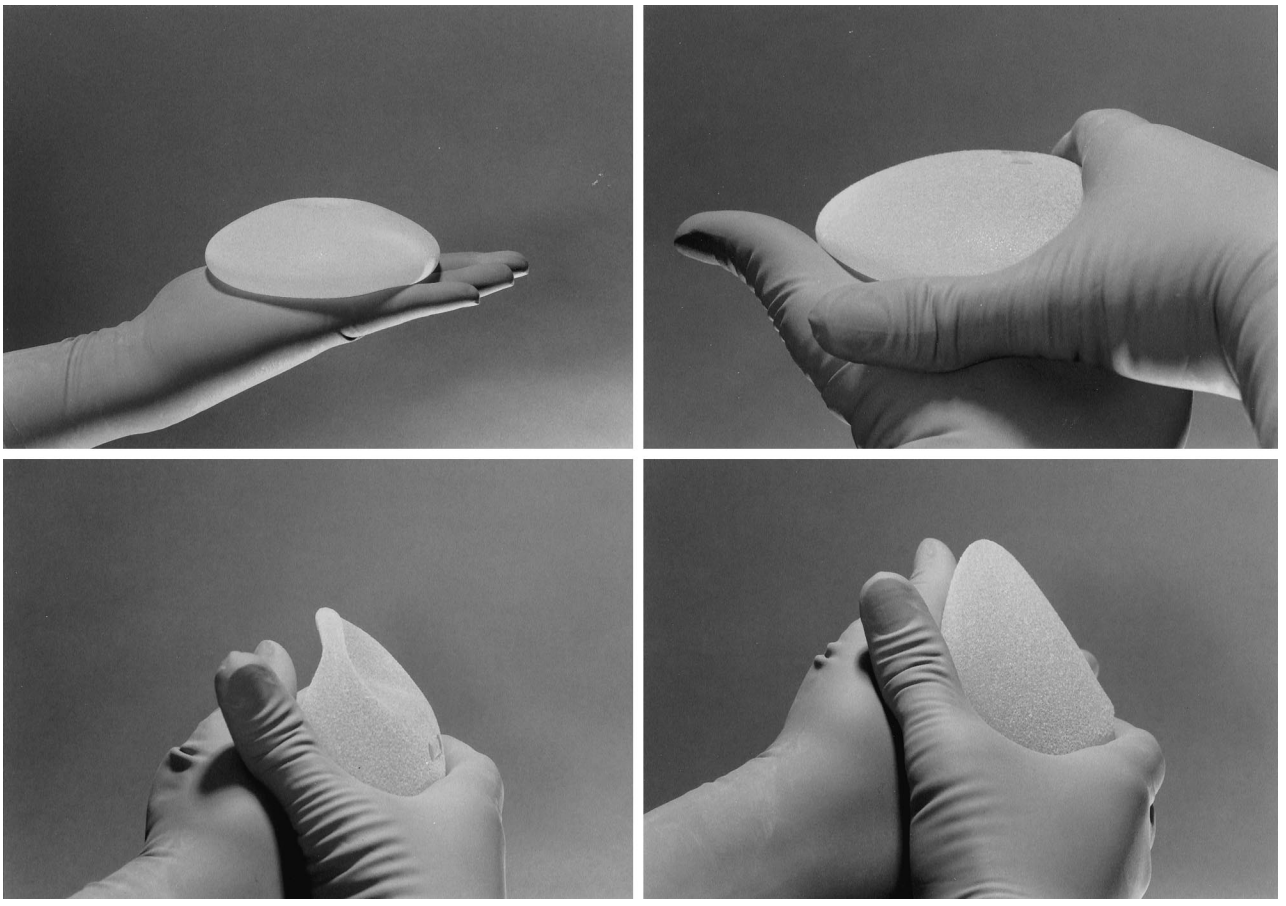

FIG. 1. (*Above, left*) After filling the implant to the desired volume, place the implant in the palm of the hand. (*Above, right*) With the other hand, evenly support (but do not add pressure to) the lower pole of the implant in a manner similar to the support provided by even the most lax soft-tissue envelope after it has fully relaxed after augmentation. (*Below, left*) Tilt the implant vertically. If the upper pole of the implant collapses, folds, or wrinkles, the implant is underfilled with respect to preventing shell collapse and folding. (*Below, right*) An adequately filled implant does not experience upper shell collapse or folding when it is placed upright. To ensure adequate fill to prevent upper pole collapse, it is essential to put minimal pressure on the lower pole of the implant with the supporting hand.

months after augmentation. The questionnaires included the following questions.

1. Now that your tissues have relaxed, do you feel that your breasts are excessively firm? Yes/No
2. If having a softer implant might even remotely increase either the risk of the implant wearing out sooner or the occurrence of another complication that could result in your needing another operation sooner, would you want a softer implant? Yes/No

RESULTS

Preoperatively, when given a choice of round or anatomic implants and the information about implant fill issues described previously, 609 of 667 patients chose an anatomically shaped, textured, saline-filled implant with adequate fill to pass the tilt test. All 609 patients were informed preoperatively of and accepted the tradeoff of slight increased firmness compared with an underfilled implant.

Follow-Up

Patients were seen in follow-up evaluations at 0 to 3 months (586 of 609 patients; 96.2 percent), 6 to 12 months (467 of 609 patients; 76.7 percent), 13 to 36 months (326 of 609 patients; 53.5 percent), and 37 to 60 months (248 of 609 patients; 40.7 percent).

Capsular Contracture

Six patients in the series developed 8 clinically significant capsular contractures that were manifest by moderate to severe breast firmness, shape distortion and/or implant displacement, and discomfort (6 of 609 patients, 0.985 per-

cent; 8 of 1218 breasts, 0.657 percent). Two of these six patients developed bilateral, clinically significant capsular contractures. Two unilateral contractures occurred in patients with submammary placement, and all remaining contractures occurred in patients with subpectoral placement. Four of the six patients developed the contractures in the first 6 months, and both patients with bilateral contractures had this complication occur in the first 6 months. The other two patients developed contractures during pregnancy and nursing at 26 and 43 months after the operation, respectively. All underwent reoperations. All had a complete capsulectomy and implant replacement with a new implant of the same type. Two of the six patients developed recurrent contractures.

Postoperative Follow-Up Questions

During the follow-up visits, patients had the following responses to the questions described above. When asked if their breasts were too firm at 3 weeks, 47 percent of patients said yes; 11 percent said they were a little too firm, and 36 percent said they were much too firm (a lot). When asked this question at 6 months, 18 percent of patients thought their breasts were too firm; 13 percent had breasts that were only a little too firm, and 5 percent had breasts that were much too firm. After 6 months, 8 percent of patients thought their breasts were too firm; 6 percent had breasts that were a little too firm, and 2 percent had breasts that were much too firm.

At each follow-up visit, patients were also asked if they would like to exchange the implants for softer ones if the softer ones had even a remote risk of shell folding or premature shell failure. No patient in the entire series at any follow-up interval requested reoperation for exchange to a softer implant.

Questionnaire Answers

Of the 200 questionnaires sent to patients at least 6 months postoperatively, 82 (41 percent) were returned within 3 weeks. Answers to the questionnaire were as follows. When asked the question, "Now that your tissues have relaxed, do you feel that your breasts are excessively firm," 16 patients (20 percent) said yes and 66 patients (80 percent) said no. When asked the question, "If having a softer implant might even remotely increase either the risk of the implant wearing out sooner or the occurrence of another complication that might result in your needing another operation sooner, would you want a softer implant," 6 patients (7 percent) said yes and 76 (93 percent) said no.

Complications

One patient developed a very low-grade, unilateral infection more than 6 weeks postoperatively; it was manifest only by fluid accumulation around the implant, which cultured a mycobacterium species after 4 weeks in culture. The infection was treated by removing the implant; it then resolved rapidly. One patient in the series developed a hematoma that required evacuation after severe physical exertion 1 week after augmentation.

Nine implants deflated (9 of 1218 breasts; 0.739 percent); four partially deflated, and five completely deflated. One deflation had a definite iatrogenic cause: it was due to a needle puncture during incision closure. This was recognized, and the implant was replaced at surgery. Two other deflations were probably iatrogenic; they occurred within 3 months of surgery. The other six deflations occurred more than 6 months postoperatively. All patients underwent implant replacement with similar implants. All deflation data were confirmed with the implant manufacturer's complaint and return data.

No other complications occurred. Specifically, no postoperative rippling or wrinkling deformities occurred that were clinically significant or that required reoperation. No patient who could palpate any portion of the implant shell or edges due to thin tissue requested reoperation.

DISCUSSION

The adequacy of implant fill is an important issue that can significantly affect outcomes in breast augmentation patients. Gutowski et al.,[3] in their multicenter outcomes study of 995 saline implants in 504 patients with a mean 6-year follow-up, found that underfilling an implant by more than 25 cc increased the risk of implant deflation (odds ratio, 3.3; $p = 0.0400$). Lantieri et al.,[2] in a series of 407 patients with 709 saline implants, found that the percent of fill (implant fill volume per minimum recommended fill volume $\times$ 100) was significantly associated with spontaneous rupture. In their series, a mean difference of 13.9 percent (89.2 percent versus 103.1 percent) was found between deflated and nondeflated implants ($p < 0.0001$), which prompted their conclusion that

"these data suggest that underfilling is a major cause of deflation."

Raj and Wojtanowski[4] documented a 7.25 percent spontaneous deflation rate in round, textured saline implants in a series of 345 consecutive augmentations over a 7-year period. When implants were filled within the manufacturer's recommended fill range in 305 patients, the deflation rate was 7.21 percent. No deflations occurred in 21 patients whose implants were filled above the manufacturer's recommendations. The authors found that the spontaneous deflation rate was inversely proportional to the fill volume.

Dowden and Reisman[5] stated the following:

> Knowing that patients who experience wrinkling are likely to be dissatisfied and to return for reoperation for overfill and knowing that wrinkling is associated with premature implant failure, in our opinion, the surgeon should fill the implants to the optimal volume, regardless of whether that lies within the erroneously estimated registered Food and Drug Administration ranges. Further, it is our conviction, supported now by data, that for many styles of saline implants, exceeding the manufacturer's rating to decrease wrinkling actually prolongs the life of the implant.

In all of these publications, the authors agree that underfill is potentially detrimental to patients, but no currently published study defines underfill or optimal fill. How does a surgeon make these critical determinations? What is adequate fill, and how can a surgeon make a practical, clinical determination of adequate fill?

In these three published series of patients,[2–4] the authors discuss underfill as related to the manufacturer's recommended fill volumes for the saline implants. None of the studies, however, provide specific guidelines for the amount of fill that an implant should contain or clinically practical methods of determining adequate fill. One key question is whether the manufacturer's recommended volume is optimal to prevent complications; these studies suggest that the answer is no.

To minimize complications and reoperations, manufacturers' recommended fill volumes should be based on criteria to minimize shell stresses and implant deflation. Several questions must be answered. (1) Are manufacturers' fill volumes for current implants adequate to maximize shell life? (2) On what criteria are recommended fill volumes based? (3) How do these criteria relate to implant shell stress and potential shell longevity? (4) Are manufacturers using defined, consistent, quantifiable methods to define optimal implant fill volumes? (5) Are these criteria consistently applied, regardless of the shape, filler material, size, or shell characteristics of the implant? (6) Are implant fill volumes being defined to maximize the shell life of the implant or do manufacturer or surgeon marketing considerations affect recommended implant fill volumes? (7) Is there a clinically practical test that every surgeon could use to subjectively evaluate the adequacy of fill with respect to implant shell collapse or folding that could be applied intraoperatively?

The manufacturers' recommended fill volumes of all currently available, round, saline- or silicone-filled implants are not consistently defined. The displacement volume of the mandrel used to manufacture the implant is usually a factor in determining recommended fill, but final recommended implant fill volume is often influenced by subjective criteria, such as increasing firmness as additional volume is added to an implant shell.

To prevent upper shell collapse with any implant when placed upright (its position in the patient when she is standing), regardless of the shape or filler material of the implant, adequate filler material must be inserted into the shell. Regardless of the type of filler material, the more filler volume added above a specific mandrel displacement volume, the firmer the implant will be to palpation. Implant firmness compromises the "naturalness" of the result, which is a concern of both surgeons and patients. If patients and surgeons request a maximally soft and natural implant, manufacturers will try to meet these market demands. Older, silicone gel–filled implants were designed to be underfilled for optimal naturalness, but they were more prone to shell folding and possible premature shell failure. If fill volume has any effect on implant shell longevity and if reoperation rates are a clinical concern, surgeons and manufacturers must seek a balance between naturalness and adequate fill volume to maximize shell longevity. The person to whom this balance is ultimately

most important is the patient, and the patient should be fully informed preoperatively of her choices and alternatives with respect to balancing naturalness with adequate fill to maximize the life of her implants.

Many factors can affect the life of an implant shell. No valid laboratory model exists that accurately mimics the widely variable tissue characteristics, motion effects, capsule influences, and surgeon influences that can affect the life of an implant. In the absence of such a model, scientifically proving the specific influences of adequate fill on a wide range of implant shells is difficult. Ten- to 20-year data in a clinical study that incorporates and controls for all of the factors listed above would be necessary to definitively answer fill questions.

In the absence of a short-term, fully scientific answer, long-term patient welfare concerns raise certain questions. Could shell folding even possibly stress an implant shell more than no shell folding or minimal shell folding? For a fixed-size implant shell, could increasing fill volume to pass a practical, clinical test such as the tilt test even remotely reduce the risks of folding or rippling? If the answer to either question is yes, the obvious follow-up questions are the following: Why not fill an implant shell more to reduce the risks of shell folding and premature fold fatigue failure? Why not take very simple steps that could potentially increase implant shell life and that might substantially reduce reoperation rates and local complication rates while clinical data are being accumulated? Plastic surgeons should do these things if the tradeoffs are acceptable to the patient. Surgeons and manufacturers should seek every conceivable improvement to increase implant shell life and decrease local complication and reoperation rates, with their attendant risks and costs.

The tilt test does not totally duplicate the clinical environment of an implant in a patient. It is certainly subject to many variables, such as the amount of pressure applied to the lower pole of the implant by the hand as it supports the upright implant. However, if minimal, even pressure is applied to the lower pole of the implant, the test simulates the worst-case scenario of minimal tissue back-pressure on the implant, which occurs in a thin breast with a loose envelope. A breast with these tissue characteristics is the most prone to visible underfill rippling or visible traction rippling. Most importantly, the test is simple and universal, can be performed on any type of implant at any time, and provides an objective appraisal of the adequacy of fill volume necessary to prevent upper pole collapse of the implant. Obviously, many other factors affect upper pole collapse in any patient. These factors include individual patient tissue characteristics, shell characteristics, capsule formation and contracture, and implant shape and size.

Nevertheless, absent a more clinically reliable test, the tilt test can provide valuable information. In my practice, it has been an invaluable clinical tool to avoid visible wrinkling and rippling for more than 10 years. The question is not whether the tilt test is perfect, the question is whether a better, more reliable, accurate, and simple clinical test is available. Until an accurate laboratory model that duplicates the clinical environment is available and until the long-term data from that model are available, what is better than the tilt test? Absent an objective clinical test, current rates of underfill rippling and premature shell failure due to underfill are unlikely to change.

Surgeons who have minimal experience with adequately filled implants may have concerns about excessive firmness when they pick up or palpate an adequately filled implant. Because current manufacturer's recommended fill volumes for most round implants in the United States are insufficient to prevent shell folding with the implant upright (similar to the position of the implant in the patient),[1] surgeons can fill to the limits of recommendations for current round implants and achieve a softer result in the breast compared with an implant with more fill that passes the tilt test. Recognizing the complications that can result from underfilling, many surgeons intuitively overfill inflatable implants[5] to try to reduce local complication risks, such as rippling, to prolong shell life but, in doing so, they technically void the manufacturer's warranty.

Manufacturers have been hesitant to define higher fill volumes, especially for round implants, possibly due to fears of a loss of business in the marketplace if surgeons think that an implant is too firm and due to the increased costs associated with obtaining Food and Drug Administration approval for modified fill volumes. Currently, no published data suggest that adding enough fill to enable any implant to pass the tilt test will place additional stresses on the implant shell that might affect shell life.

In fact, manufacturers routinely subject shells to extremes of stress during tests of shell elongation; these extremes far exceed the stresses that one might expect from moderate increases in fill volume for a specific shell displacement volume.

Every patient having breast augmentation should be informed of implant fill issues and the tradeoffs of different choices. If a patient does not wish to accept slightly increased firmness with an adequately filled implant, the patient should sign an informed consent document acknowledging that inadequate implant fill to achieve a softer breast might have future consequences. Further, the document should acknowledge her acceptance of the possible increased risks of premature shell failure, visible or palpable wrinkling or rippling, the increased risk of reoperation, the increased risks in general, and increased costs. If a patient prefers a slightly softer breast, regardless of potential future consequences, that is certainly her choice; however, she must be fully informed.

If a patient is willing to accept the slight increased firmness of an implant to achieve adequate fill and to reduce the risks of shell collapse, folding, wrinkling, rippling, and premature shell failure, the responsibility then lies with surgeons and implant manufacturers to ensure adequate implant fill. Something as simple as adequately filling an implant could substantially reduce the risks and costs of reoperations in a large number of patients long term.

Choosing an optimal implant pocket location on the basis of measurable soft-tissue thickness and avoiding excessively large implants that can excessively stretch a patient's tissues further reduce the risks of rippling due to traction rather than an underfilled implant. Assuring adequate fill volume to pass the tilt test is helpful in avoiding underfill rippling. Traction rippling is caused by any type of implant pulling on a capsule attached to thin overlying soft tissues, and this problem is certainly not unique to textured implants. Optimizing soft-tissue coverage and avoiding excessively large implants, especially in thin patients, are critically important to avoid traction rippling with any type of implant. Rigid adherence to these principles prevented clinically significant traction rippling in this series of patients.

It is not acceptable for surgeons to arbitrarily fill implants to whatever volume they choose for whatever reasons they choose without informing patients of fill issues, possible effects on outcomes, possible additional future risks and costs, and potential conflicts with manufacturers' warranties. Arbitrary fill volumes, without specific criteria, could subject many patients to increased risks and costs. Although many surgeons intuitively overfill round, inflatable implants to prevent the problems of underfilling,[1,5] filling past manufacturers' recommended fill volumes potentially deprives the patient of the benefits of the manufacturer's warranty. Manufacturers should address this important issue for the potential welfare of the patient, regardless of the costs. Absent valid scientific data to support the safety of underfill for the sake of softness, manufacturers should, at the least, redefine fill volumes to prevent shell wrinkling until the data are available, regardless of implant shape, type, or filler material.

If history is an indicator, manufacturers are unlikely to address fill issues unless forced to do so by their customers, surgeons and patients. Surgeons need a clinically useful method of estimating adequate implant fill, and manufacturers should recognize and address the potential benefits of maximizing product longevity and minimizing the risks of complications and reoperations for augmentation patients. This should be done sooner rather than later. History reminds us of the potential price of not doing so.

Conclusions

Based on clinical experience in 609 augmentation patients who chose adequately filled implants with the potential tradeoff of increased firmness: (1) Given preoperative informed consent and information about implant fill issues, 609 of 667 patients selected an adequately filled implant (manufacturer's recommended fill volumes defined by the tilt test) with increased firmness compared with a more underfilled, softer implant that they were told might possibly fail earlier than an adequately filled implant. (2) Of the 609 patients with adequately filled anatomic implants who were followed for up to 5.5 years, no patient requested an exchange to a softer implant. (3) Use of the tilt test to define manufacturer's recommended fill volumes to prevent shell collapse resulted in a series of 609 patients with saline implants who had no occurrence of visible un-

derfill wrinkling or rippling that required reoperation. The tilt test is a clinically useful and reliable indicator of adequate implant fill to prevent underfill rippling. (4) The deflation rate (spontaneous and/or iatrogenic) over this 6-year period for patients who were seen in follow-up was 9 of 1218 implants or 0.739 percent. This figure will undoubtedly increase with time and continued follow-up.

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