Present Technology and Future Directions

Dennis C. Hammond, MD

The question of whether shaped breast implants offer any practical advantage in aesthetic and reconstructive breast surgery has proved difficult to answer. There are many reasons for this difficulty, and understanding these reasons is almost as important as understanding the devices themselves. Because breast implants come in various sizes, shapes, textures, and compositions, the many design variables involved make it difficult to draw reasonable conclusions about the performance of a given device. In addition, the approach an individual surgeon takes when using breast implants can have a profound effect on how each device ultimately performs. Just a few of the many variables involved here include patient selection, patient and surgeon expectations, preoperative appearance of the breast, and pocket location for the implant. Taken together, these issues allow almost any conclusion to be reached regarding which type of breast implant will perform best, with the most important variable often being the preconceived notions of the surgeon.

The previous articles in this monograph have documented the efficacy of shaped breast implants for providing outstanding results in both aesthetic and reconstructive breast surgery. The goal of this article is to briefly examine the history of anatomic implant designs, describe the progression of the anatomic shape concept, and discuss the future directions that implant designs might take.

ANATOMIC IMPLANT DESIGN

After the original smooth-walled silicone gel breast implant was developed in 1963 by Cronin and Gerow,[1] design modifications began to be introduced that aimed to improve the results provided by these devices. As a result, the first anatomically shaped implant appeared in the late 1960s as a smooth-walled silicone gel product that had a Dacron patch attached to the back of the device. Later versions of this device had five Dacron patches. The purpose of the patches was to initiate tissue ingrowth to help keep the device properly oriented. The shape of the device was aggressive—the upper pole had a relatively sharp angle, and most of the volume was located in the lower half (Fig. 1). The design of this device was conceptually brilliant. This was the first time the shape of an implant was designed to create a specific breast contour, rather than let the implant fold and wrinkle passively as dictated by the overlying breast. Even though this was new technology, the designers demonstrated surprisingly accurate imagination. Unfortunately, this device was associated with a very high rate of capsular contracture, and it

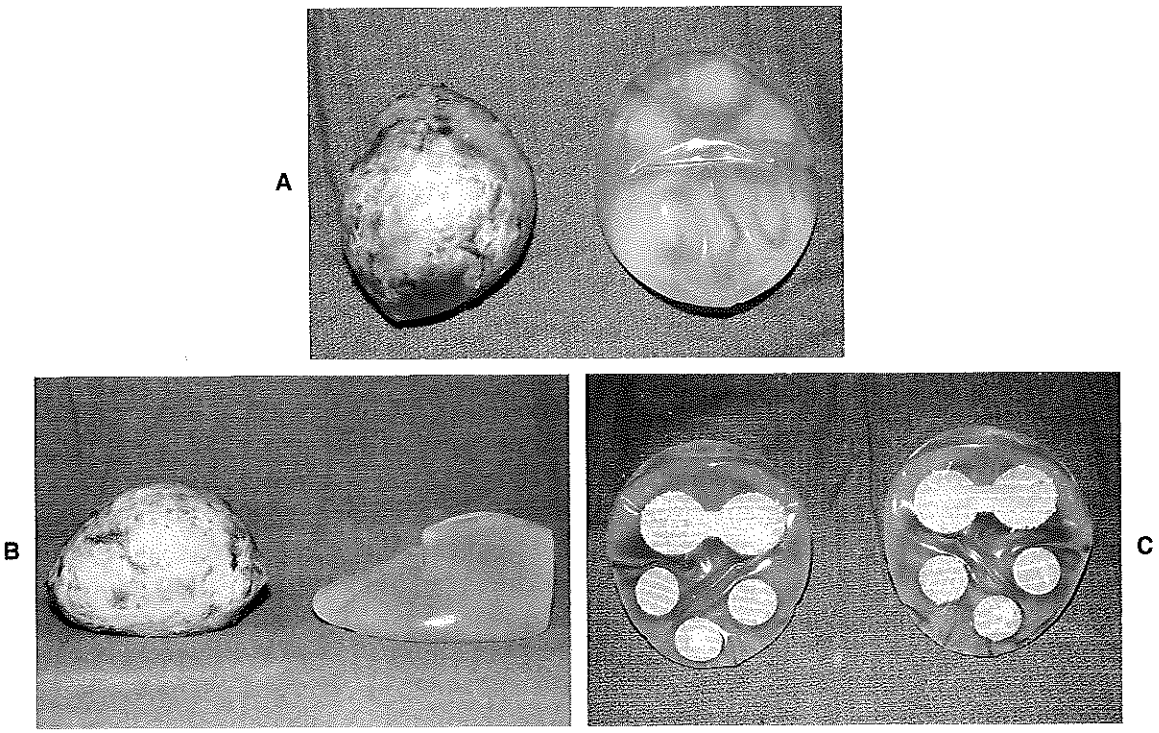

FIG. 1 **A** and **B,** Anteroposterior and lateral view of an early-design, shaped anatomic silicone gel implant before *(left)* and after *(right)* removal of a contracted capsule. **C,** With the implants turned over, the Dacron patches can be seen.

soon fell into disfavor. At the time it was felt that the Dacron patches somehow were responsible for the excessively high rate of capsular contracture. A saline alternative was eventually developed that had the same aggressive shape profile as the Dacron patched device; however, the shell was smooth, and there was no predictable way to ensure that the implant would not rotate and spoil the effect of the anatomic shape (Fig. 2).

The next significant step in anatomic implant design was the development of polyurethane-coated devices.[2] Two of these devices enjoyed significant popularity, the only difference between them being shape—the Meme implant (round) (Fig. 3, *A*) and the Replicon implant (shaped) (Fig. 3, *B*), both manufactured by Surgitek. The Replicon proved to be important in the history of breast implant development, because it was the first device manufactured with a textured surface. The polyurethane foam coating on these devices underwent a gradual biochemical degradation that created a low-grade inflammatory response in the capsule that formed around the device.[2] The result was a significant decrease in the rate of capsular contracture with these devices. In my own experience, the results obtained with these devices were some of the softest I have encountered. But what is more important, when using the Replicon device the interaction

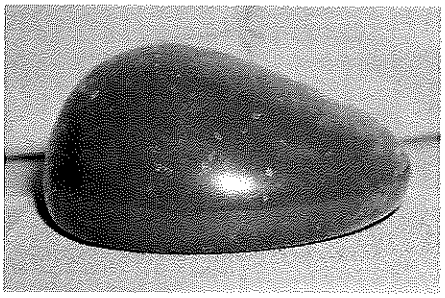

FIG. 2 An early-design, shaped saline implant. These devices were prone to malposition and rotation because the smooth surface provided no mechanism to hold them in the proper orientation.

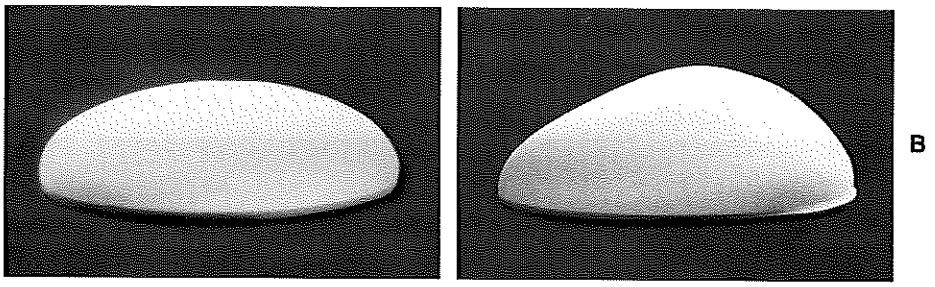

FIG. 3 **A,** Side view of the polyurethane foam–coated round Surgitek Meme silicone gel implant. **B,** Side view of the polyurethane foam–coated shaped Surgitek Replicon silicone gel implant.

between the capsule and the polyurethane foam coating prevented the implant from rotating. Thus the polyurethane foam coating served a dual purpose: preventing capsular contracture and fixing the implant in position.

One limitation of the Replicon device was that the shape was not as aggressive as earlier designs. As a result, a strategy employed at that time was to stack a smaller Meme implant on top of the lower pole of a larger Replicon device to increase overall projection and create a more shaped construct.[2] This was a very forward-thinking concept and was made possible by the textured polyurethane surface that tended to hold the two devices in position. Unfortunately, uncertainties arose about the polyurethane surface and the breakdown products of the foam-lattice network, and claims were made that these breakdown products were carcinogenic. Subsequent scientific work disputed these claims, but the manufacturer of these devices withdrew from the implant market. Recently several European and South American companies have had some success reintroducing devices coated with polyurethane foam. Whether these devices can ultimately regain access to the U.S. market remains to be seen. However, the benefits demonstrated by the shape concepts used in these early devices were largely responsible for the advances that followed.

FIG. 4 Oblique view of a stacked tissue expander *(left)*, which was essentially two expanders with separate valves. The expander on top was designed to preferentially expand the lower pole of the breast. The differential expander *(right)* was designed to accomplish the same task because the thinner and more pliant silicone envelope in the lower half of the device allowed the lower pole to balloon out as it expanded.

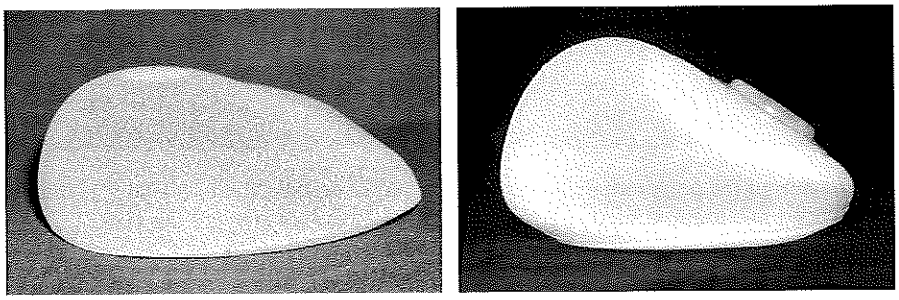

FIG. 5 Lateral view of two different versions of anatomically shaped textured tissue expanders with integrated valves for inflation.

The next significant advance in shaped design came with the development of shaped tissue expanders. This development was fueled by the concept that, after mastectomy, the skin envelope could be differentially expanded to prepare for placement of an implant. To this end, devices designed by Manders, Fisher, and Maxwell in the late 1980s all provided evidence that the shape of an expander could effectively influence the shape of the breast during expansion (Figs. 4 and 5). The shapes of tissue expanders used most commonly today are still influenced by the early designs (Fig. 6).

Another design feature introduced with these expanders was silicone texturing on the surface. Several types of textured surfaces were developed, all attempting to reduce the rate of capsular contracture as noted with polyurethane foam.[3] The effect of surface texturing on the breast capsule proved to be mainly structural, because a capsule integrates itself into the surface of an implant as dictated by the aggressiveness of the texture. However, the inflammatory response noted with polyurethane has not been seen with silicone texturing. Therefore the results of clinical studies have been mixed regarding the

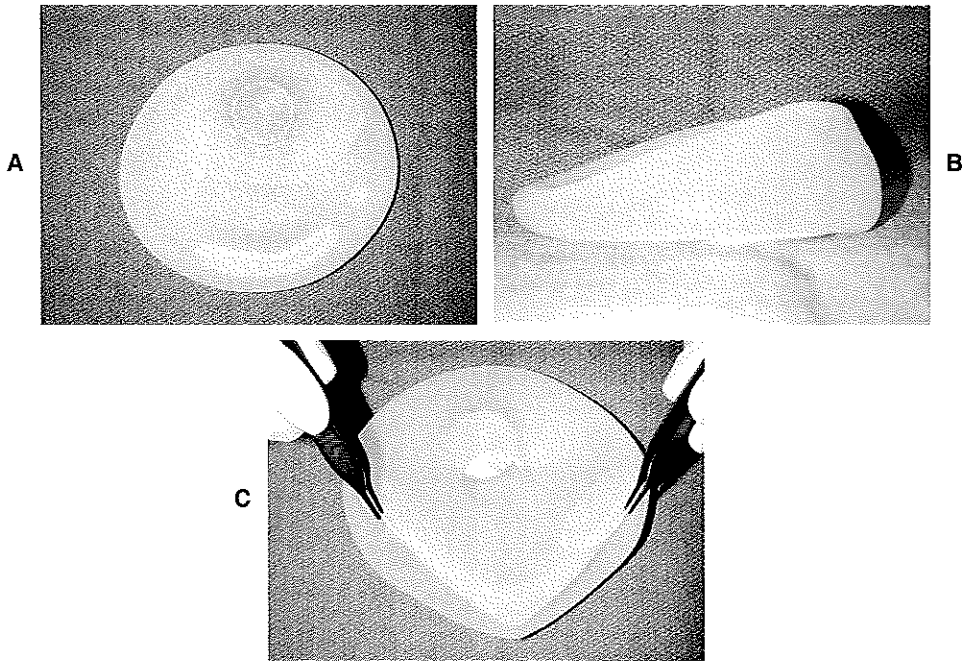

FIG. 6 **A** and **B**, Anteroposterior and lateral view of a more recent design showing an aggressive shape with a textured surface. **C**, Two reinforced tabs at the base of the device allow the expander to be sutured in position to prevent postoperative rotation.

effect of silicone surface texturing in relation to the development of capsular contracture. Whether these textured surfaces actually decrease the rate of capsular contracture can be argued, but one unique feature of the most aggressive textures is tissue ingrowth. As collagen fibers form around the implant, the open pore network of the textured surface creates a three-dimensional structure that is variably penetrated by the capsule, creating a semirigid, Velcrolike bond. This "bond" between the capsule and the textured surface occurs more consistently and more completely with tissue expanders than with implants because the pressure in the tissue expander pushes the textured surface into the capsule, helping to ensure maximal contact and enhancing the chances for capsule ingrowth into the interstices of the textured surface. Although the effect of tissue ingrowth on reducing the rate of capsular contracture remains uncertain, one very beneficial result of this interaction between the implant surface and the capsule is that the implant is locked into position when ingrowth occurs. Even if no ingrowth develops, a textured surface still provides an element of friction that helps the implant resist rotation.

Further advancement in breast implant design slowed significantly because of controversy related to the safety of silicone gel. Although subsequent scientific work documented benign interaction of silicone with the body, the use of implants filled with silicone gel was restricted to only a few investigators. Practically speaking, the only devices available for use in breast surgery in the United States through all of the 1990s were filled with saline. Despite this limitation, the utility of shaped implants continued to be investigated as it applied to saline implants. Several different implants were developed,

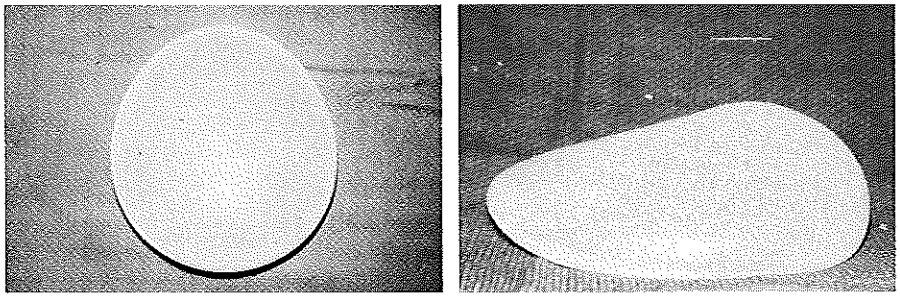

FIG. 7 Anteroposterior and lateral view of a shaped saline implant, tall height design.

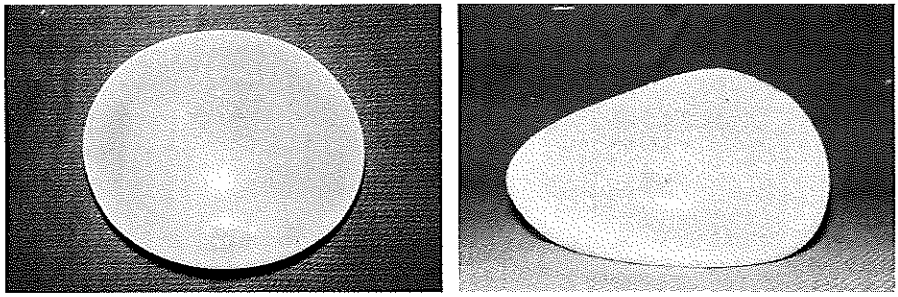

FIG. 8 Anteroposterior and lateral view of a shaped saline implant, short height design.

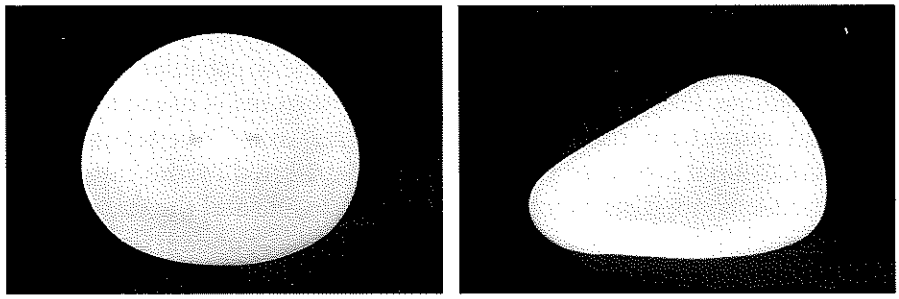

FIG. 9 Anteroposterior and lateral view of a more aggressively shaped saline implant, short height design.

and an attempt was made to correlate shape and implant height. Ultimately several different devices were developed with differing heights and projections (Figs. 7 through 9). The major drawback of these devices relates to the characteristics of the saline fill. To avoid the shell wrinkling associated with underfilling any saline implant, particularly when placed upright, considerable attention to the degree of implant fill is required, and there is a real tendency to slightly overfill these devices to avoid this problem. This filling tendency is a detriment to the device's shape, because the aggressiveness of the shape diminishes with increased volume. Specifically, the upper pole of a shaped saline im-

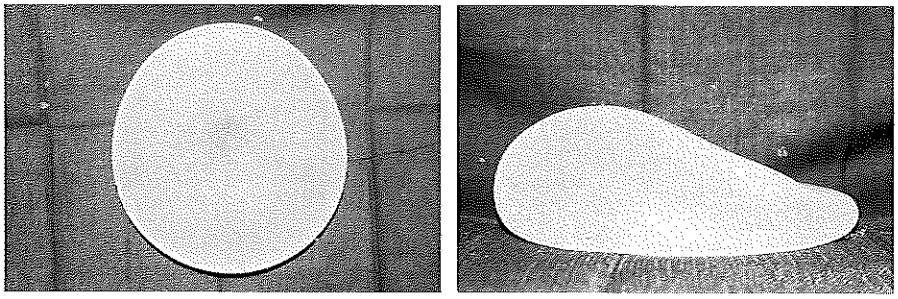

FIG. 10 Anteroposterior and lateral view of a minimally cohesive anatomically shaped silicone gel implant with an aggressive shape.

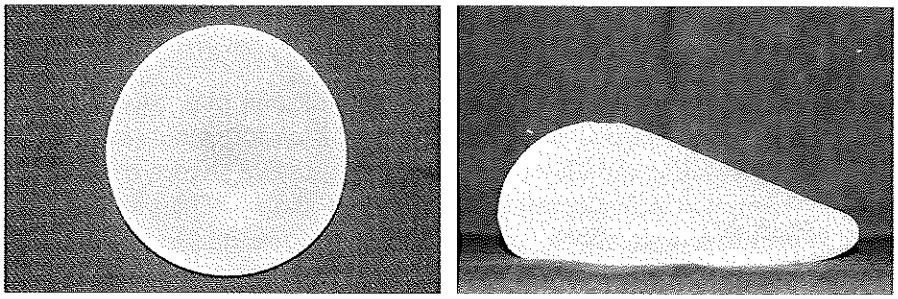

FIG. 11 Anteroposterior and lateral view of a strongly cohesive anatomically shaped silicone gel implant with an aggressive shape.

plant tends to develop an increasingly convex contour as the volume increases so that, if one is overfilled too much, it differs little from a round implant. For this reason, many surgeons have questioned not only the utility of these devices, but also the validity of using anatomic shapes.

As restrictions have eased on silicone gel devices, lessons learned over the past 30 years have been applied to a new generation of devices. These shaped silicone gel implants fall generally into two categories based on the cohesiveness of the gel used to fill them. Several relatively noncohesive, aggressively shaped, textured silicone gel implants were introduced for use in aesthetic and reconstructive breast surgery (Fig. 10). Later a much more cohesive line of textured gel-filled devices was introduced, again with an aggressive shape (Fig. 11). The more-cohesive devices were designed to offer several different heights and projections. The previous articles in this monograph have documented the results obtained using these devices. Of all the shaped devices developed over the past 30 years, these shaped silicone gel implants have provided, in my experience, the best and most consistent aesthetic results I have seen in both aesthetic and reconstructive breast surgery. Specifically, they offer precise control of the upper pole of the breast.

The less-cohesive shaped gel implants are softer than the more-cohesive gel implants and, given that they are less crosslinked, tend to wrinkle, because the gel cannot fully support the outer shell of the device, particularly when the implant is placed upright. This wrinkling can be visible in patients with a thin, soft tissue envelope. Studies of

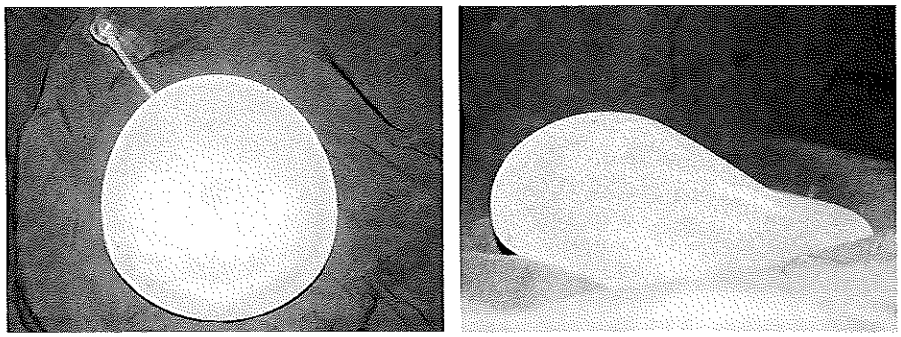

FIG. 12 Anteroposterior and lateral view of an anatomically shaped implant with a combination of a gel outer lumen and a saline inner lumen. The fill valve and tubing can be seen.

these devices are ongoing to determine what considerations may become important in the future. However, the cohesive devices, because of the more stable support of the implant shell, resist wrinkling and allow much more aggressive shapes to be created. With these devices the implant provides most of the breast shape. When a device is properly chosen with respect to length, width, and projection, the results can be outstanding. The gel used in these implants is so cohesive that rupture is eliminated as a complication—the significance of this advantage cannot be overstated. However, it must be noted that these newer, more cohesive, shaped devices are associated with some of their own problems. Issues such as implant rotation despite using textured surfaces must be addressed. Interestingly, cases of gel fracture have also been noted wherein cohesive devices have been inserted through incisions that are too small. In these instances the outer shell of the implant remains intact, but the shape of the device is altered because of a disruption in the internal cohesive gel. When gel fracture is noted during insertion, it is advisable to replace the altered implant and enlarge the incision to allow a new device to be inserted without injuring it.

THE FUTURE

Although significant improvements in implant design have clearly been made, further design modifications are on the horizon. Improvements in shape, size, and projection will undoubtedly be forthcoming as experience grows with these devices. Manipulating the cohesive nature of the gel will likely provide softer devices and yet allow sufficient support to prevent wrinkling. Also, issues regarding patient selection and how to use these implants optimally will become better defined.

One new concept that has emerged in European studies involves a combination gel and saline device that incorporates texture and an anatomic shape with the ability to moderately adjust its volume. This device uses relatively cohesive gel and has an inner saline bladder fixed to the lower pole (Fig. 12). A remote fill tube is used to add saline as needed. Early results are encouraging, although it remains uncertain when such a device may become generally available in the United States.

CONCLUSION

Surgeons and manufacturers have been developing modifications to shape, texture, dimension, and fill of implants, manipulating each variable to produce the highest quality devices that achieve the best possible results for aesthetic and reconstructive breast surgery. As we emerge from the cloud created by the controversy of silicone gel safety, the quality of these devices will only improve—and the future is indeed bright.

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Editorial Commentary

This article is a useful reminder of what breast implant technology is available at the moment and what can be expected in the future when we look back on the road we have traveled and the implant modifications that have been introduced. We see that this road has sometimes been a rocky one. Changes in implant design have been frequent and often instituted for the wrong reasons—especially when resulting from ill-considered government intervention. Fortunately, as a result of the vast experience of surgeons outside of the United States, we can publish results on cohesive implants. In addition to this, we in the United States will be able to use these implants safely because of the experience of our European colleagues. This has placed us in a favorable position that is well-documented in Dr. Hammond's contribution.

Not only have surgeons benefited from these developments but our patients have as well. When cohesive gel implants become freely available we will be able to offer our patients a safe, satisfactory product that is unlikely to cause local problems and is long lasting. However, as pointed out in this article, this is not the end of the line—it is probably the beginning of a new line. Research and development will continue until eventually the truly ideal implant will emerge.

Ian T. Jackson, MD

Dr. Hammond outlines the history of breast implant devices to the present day and then looks beyond to outline possibilities for the future. This excellent summary gives the reader a sense of why things are as they are today. Dr. Hammond provides the reader with valuable background information that creates perspective for surgeons. In his opening paragraph, Dr. Hammond indicates his uncertainty regarding whether shaped cohesive III devices offer any practical advantage. This may be because U.S. surgeons have

been severely restricted in their device choices since 1992. Surgeons who have workaday experience with third generation cohesive gel devices routinely tout their advantages in various situations.

Dr. Hammond also reviews the history of texture applied to devices, noting that currently available textures were developed by trying to emulate the success of polyurethane foam in attenuating the scourge of capsular contracture. Various texture-creating processes have been tried, but two main types have survived. One takes an imprint of polyurethane foam by pressing a sheet of silicone against a sheet of foam, whereas the other uses a salt-loss technique to create a more aggressive, higher-friction surface.* Neither surface typically allows tissue ingrowth (so-called *Velcro adhesion*) during routine implant use. An exception to this occurs with Biocell devices (with salt-loss texture) under high pressures, as in tissue expansion. In my experience, this phenomenon is not typically seen with either surface in routine uncomplicated breast implant use.†

In addition, Dr. Hammond raises the very important issue of device malrotation. Shaped devices risk a type of complication that simply does not exist in round devices.‡ A shaped device that rotates in the pocket results in an odd shape, because the upper pole projection is too great. I have seen this unfortunate complication with both Siltex and Biocell implants. Trying to find reasons for malrotation in some cases and not others creates consternation and frustration. However, in my experience, common causes for malrotation (after the implant has been properly inserted) are inadequate or improper pocket dissection (surgeon factors); undue external pressure, such as patients sleeping with their arms under their breasts (patient factors); and the coefficient of friction of the surface of the device (device factors). Any of these causes may result in malrotation,§ and the surgeon should keep these in mind when counseling patients and using these implants.

*There are primarily two different approaches to manufacturing implant texture. The first involves pressing processed silicone sheets against a sheet of foam under pressure creating a "foam print," much like creating a footprint while walking. The original process was acquired by Mentor and forms the basis for the Siltex surface. On the other hand, the salt loss technique involves a different strategy. Silicone shells are dipped in liquid silicone dispersion and are then sprinkled with salt crystals, partially cured, redipped, and finally rubbed so that the salt crystals are partially exposed. After washing, the salt crystals dissolve, leaving behind their angular shapes permanently cast in the silicone shell. This more aggressive texturing is used by Inamed in their Biocell surface.

†A curious phenomenon is sometimes seen when a layer of tissue coats the Biocell surface, which itself becomes the new interface with the implant pocket. In my experience, this capsule within a capsule phenomenon is typically only seen with the Biocell surface, not the Siltex, but this type of inner capsule is not unusual in Biocell devices. There sometimes is some adherence at the upper pole, and the inner capsule is less well formed at the inferior pole.

‡Infrequently, round devices may flip back to front, and, depending on the degree of silicone crosslinking present, may be visible in some patients. This problem is not easily seen with low crosslinked devices, because they tend to assume the shape of the pocket they reside in and respond to gravity by flowing to the lowest points.

§Creating an adequate, precisely shaped pocket helps prevent rotational pressures that would cause a device to rotate. Shaped devices are heavier at the bottom, so that patients with malrotation sometimes have spontaneous correction after being upright.

Dr. Hammond also correctly points out that wrinkling of an implant is an important issue and that, as surgeons, we want to avoid evident wrinkling on the surface of the breast at rest. Whether an implant wrinkles depends on several factors, implant factors being only one subset of the universe of causes. I have seen wrinkling with all devices, regardless of manufacturing technique, and in all implant locations—even in patients that were appropriately selected.* Wrinkling of devices is related to the quality, quantity, and location of the skin, fat, and parenchyma, and the pressure applied to the surface of the implant by the tissues. An implant on the table is subject to atmospheric pressure, but an implant in situ is subject to other pressures (natural breast weight, muscle activity, and so on). Additionally, remember that the breast is dynamic: it moves, and the manner in which these devices respond to acceleration forces is also an important factor of wrinkling. Also keep in mind that devices with less crosslinking may be prone to more wrinkling, as are patients with thinner skin, less parenchyma, and less fat.

These authors have written a very concise review of a very complex issue. Hopefully the reader is stimulated to read more on this fascinating topic and perhaps contribute to our knowledge base to help give our patients even better results.

Claudio De Lorenzi, BA, MD

*If the definition of *wrinkling* is "regular undulations visible on the surface of the breast," then I have also seen wrinkling in breasts without implants (such as when patients are asked to bend over and let their breasts hang downwards—the weight of the parenchyma pulls the skin and sometimes causes tension wrinkling of the upper pole).