

# Form-Stable Cohesive Gel Implants: Advantages and Technical Essentials

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The advent of form-stable cohesive gel implants represents a significant *device-related* advance in the history of breast implants. Perhaps even more significant, however, are advances in the *non-device-related* process of breast augmentation itself, which have re-defined the outcome and patient experience for this procedure.<sup>1</sup> These refinements in breast augmentation technique have been particularly salient for ensuring optimal use of form-stable breast implants.

Form-stable cohesive gel implants are a small subset of implants currently available in the United States, and they are available only through FDA premarket approval (PMA) clinical trials. There has been some confusion regarding what a cohesive gel implant actually is. Although all implant fillers are cohesive in the physical sense (whether saline or gel) the term *cohesive gel implant* has traditionally implied a form-stable device (e.g., Inamed 410, Mentor Contour Profile Gel [CPG]). Interestingly, even these devices are not truly form stable and exhibit different degrees of stability or cohesiveness in the various subgroups. These differences are cogent, because the benefits of form-stable implants that have been realized are a function of the form stability of the filler.

There is also no uniform opinion regarding the number of silicone implant generations that there have been. This is not the focus of this article, however, and in the end it is not truly important what generation an implant is. What is important are the device characteristics that ultimately impact soft tissue dynamics and patient outcomes.

Form-stable cohesive gel implants have been used internationally for longer than 10 years and have gained in popularity for aesthetic and reconstructive breast surgery. These implants may be available in the United States as soon as 2007 and will provide patients and surgeons with enhanced results if used properly. However, for most plastic surgeons in the United States there will need to be a transition from the technique used for smooth round saline implants to a more comprehensive approach.

## ADVANTAGES AND DISADVANTAGES

When considering the advantages and disadvantages of current-generation cohesive gel devices it is important to keep in mind that they are directly related to the specific characteristics of each device as well as the physical condition of the patient. Therefore generalizations are not possible, because what is true for one specific device and patient

### Advantages of Current-Generation Cohesive Gel Devices

- Long shell life
- Low risk of capsular contracture
- Less rippling than previous-generation devices
- Less soft-tissue stretch than previous-generation devices
- Cosmesis: Shape, maintenance of upper pole fill
- Safety
  - Minimizes negative effect of prosthesis on tissue
  - Less parenchymal atrophy than previous-generation devices
  - Less chance for traction rippling than previous-generation devices
  - Little gel migration if shell ruptures

may not be true for a different device. For example, rippling depends directly on the form stability of a device, which is determined by its degree of gel cohesiveness, the fill volume/mandrel volume ratio, gel-shell interaction, and the patient's skin quality. Hence, an implant that contains a firmer, more cohesive (more crosslinked) gel consistently produces very little rippling clinically (independent of patient soft tissue variables). An equally cogent point is that an implant that is more form stable and firm in one's hand will not necessarily be more firm or less natural in vivo. These types of misconceptions have no scientific basis.

Current data demonstrates increased longevity of the current-generation devices. The form stability of the filler results in less stress on the shell and in less folding, buckling, and wear over time. One study of 148 patients in Sweden who had 296 Style 410 implants placed during a 5- to 12-year period (mean follow-up 7 years) indicated that there were no clinical ruptures. However, MRI analysis revealed two ruptures (which were not confirmed or unconfirmed by surgical exploration) for a rupture rate of 0.6%, compared with 11.1% for earlier-generation, round gel devices.<sup>2</sup> Investigators from this same study describe these as lifetime devices.

Capsular contracture rates with the current form-stable devices have been low, likely because of two factors:

- The form-stable characteristics of the devices make them less compliant, which provides less mechanical advantage to a contracting capsule.
- These devices are typically associated with more refined surgical techniques that induce less tissue trauma and bleeding, which also impact capsule formation.<sup>3</sup>

Soft tissue stretch is not a fully controllable problem, but increased filler stability results in reduced stress on lower-pole soft tissue and likely less undesirable stretch over time.

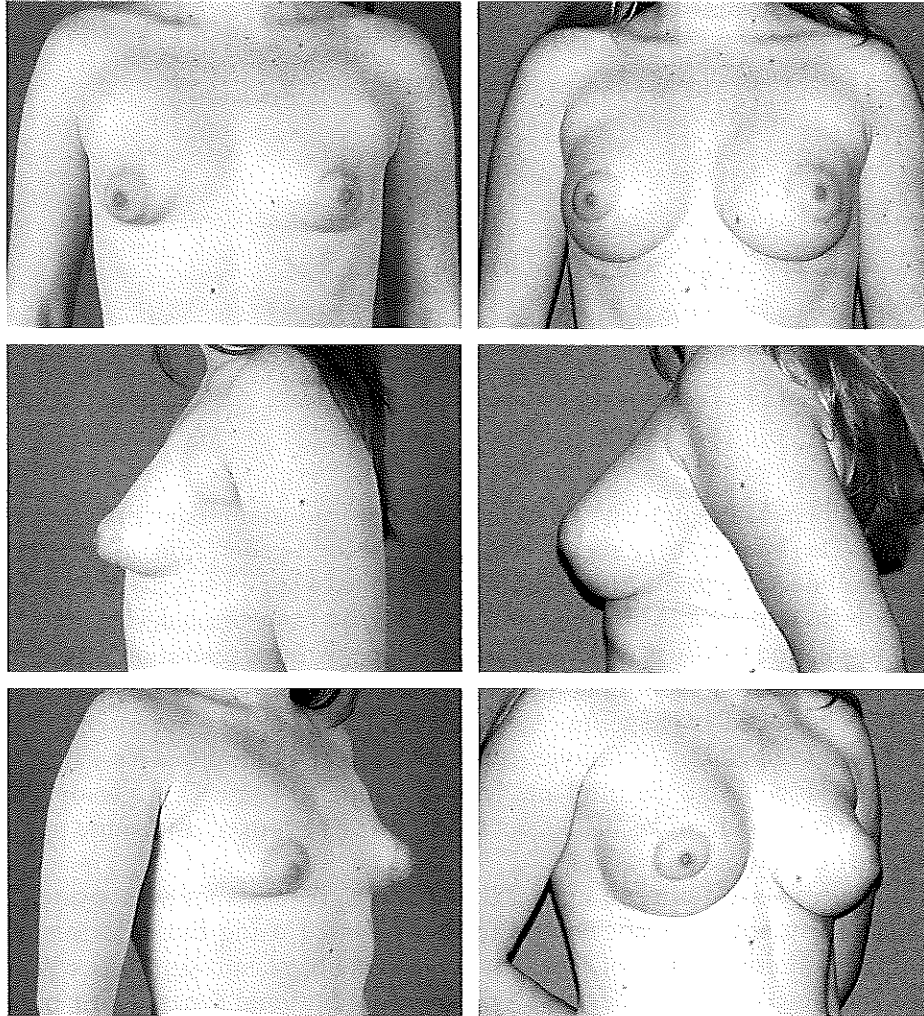


FIG. 1

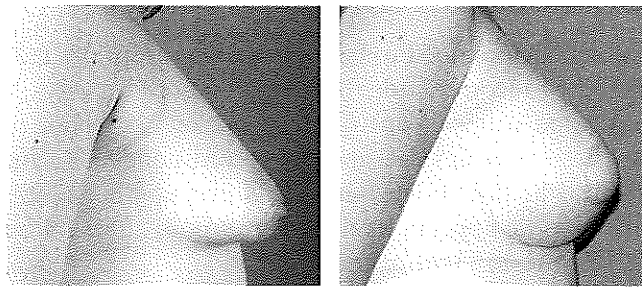


FIG. 2

FIG. 3

The ability of these new devices to favorably shape the breast is clinically evident as seen in this patient, who has excellent expansion and correction of a constricted lower pole. The breast has a different response to form-stable devices compared with earlier generations of gel and saline devices. The control of fill distribution within the breast is unparalleled, which allows for maintenance of upper pole fill over time that was not previously possible with other implants.

### Disadvantages of Current-Generation Cohesive Gel Devices

- Require refined, meticulous process and technique
- Cost
- Require long incision that may limit certain approaches
- Firm
- Increased risk for rotation compared with round device
- Not appropriate for oversized requests
- Difficult secondary surgery

The safety benefits may turn out to be the most important aspect of these devices for patients. The known local effects of ruptured second-generation silicone implants have been well documented.<sup>4</sup> An exceedingly low rate of shell integrity loss in current-generation devices, coupled with the fact that the shell from these devices can be completely removed, and the filler will maintain its shape without migration, make many of the FDA's concerns about gel implant rupture irrelevant with the form-stable devices.

Disadvantages of cohesive gel implants include a requirement for more precise preoperative and intraoperative techniques (see box). This transition to a less familiar technique may make cohesive gel implants less appealing to some U.S. plastic surgeons. The costs of these devices are higher, incisions must be longer, and some approaches may be more difficult or not possible.

For the typical plastic surgeon in the United States, requests for a "Baywatch breast" by uneducated patients will not be effectively addressed using these devices, because oversized augmentations are not ideal. In the end, U.S. plastic surgeons will need to weigh the pros and cons of the devices; however, the additional benefits for patients will likely be the driving force for increased use of form-stable cohesive implants.

### TECHNICAL CONSIDERATIONS

Form-stable cohesive gel devices need to be used with appropriate technique, but this is the case for any implant—recommended technique should always be followed. If the surgeon does not have good surgical control of the pocket (e.g., poor tissue, specific revision circumstances) these new devices are not recommended. Claims that these implants are too firm and do not move naturally have not been universally observed. However, the implant capsule appears likely to have more effect on both of these issues than does the degree of cohesion within the implant.

### ESSENTIALS FOR SUCCESS

Success with current cohesive gel devices requires redefining how most U.S. plastic surgeons approach both aesthetic and reconstructive breast surgery. Although the current cohesive gel devices allow improved results, the real advances in breast augmentation are not about the implant. The techniques that have been used with success using these new devices will help minimize problems and optimize outcomes with any implant.

Breast augmentation is a process that includes the following important components<sup>1</sup>:

- Patient education and informed consent
- Tissue-based clinical planning
- Meticulous surgical technique
- Defined postoperative management

These four components should be performed consistently for every breast augmentation patient. When performed together they work synergistically to optimize outcomes. The goal is to maximize the quality outcome for the patient and minimize reoperation rates.

The data to support this process come from independently published series, peer-reviewed series, and series presented at national meetings, all indicating reoperation rates of 3% or less (compared with the standard 15%-24% from PMA studies over the past 15 years).<sup>5-10</sup>

Patient education is the most essential component of all, and patients should be given ample time using written material and patient educator sessions to define what their expectations are on paper. This is followed by a surgeon's consultation to reconcile the patients wishes with the reality of what is possible with their particular tissue configuration, allowing the patient to make final choices based on the comprehensive knowledge provided.

Tissue-based clinical planning is one large hurdle for plastic surgeons in the United States. A general reform from arbitrary and subjective implant selection and planning to logical, objective decisions based on tissue analysis will be required for successful implementation of the current cohesive gel devices. The high five planning process is a refinement of previous planning systems and allows surgeons to focus on the five critical decisions that determine outcomes in breast augmentation.<sup>5</sup> This system uses five measurements, the most important of which is the surgical base width of the breast, which is determined by taking the breast width minus the soft tissue thickness (Fig. 4). This

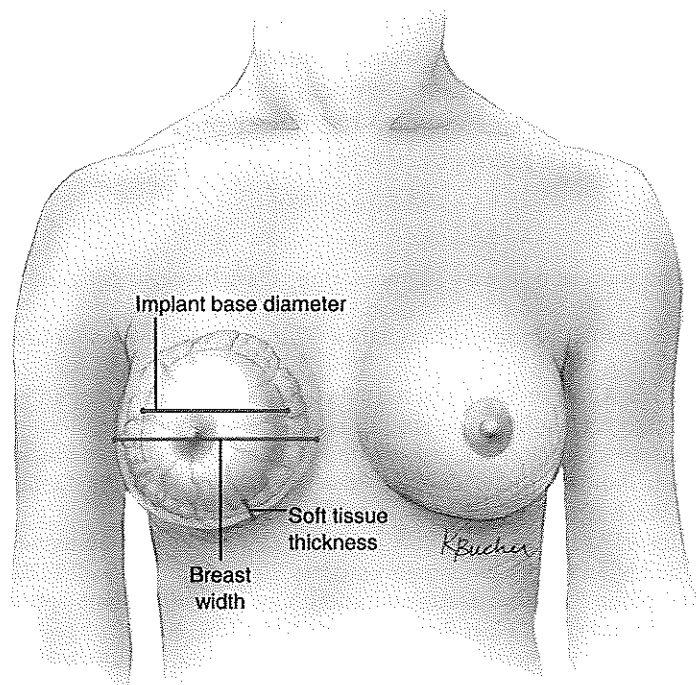


FIG. 4

planning process takes no longer than 5 minutes to perform, and it allows the surgeon to logically make all important decisions preoperatively regarding the following:

- Soft tissue coverage
- Implant volume
- Implant type
- IMF position
- Incision

The surgical technique is templated and systematic to minimize intraoperative decisions and maximize precise, atraumatic, bloodless dissection under direct vision. Creating a precise pocket to match the selected implant size is paramount.

Postoperative adjuncts (e.g., drains, pain pumps, narcotics, bras, straps, and restrictions) are minimized or eliminated, and specific postoperative instructions are given to allow the patient to return to normal activities within 24 hours and enhance the overall experience.

The four essential components of breast augmentation have proven efficacious with all implants, but they are required for successful implementation of the current generation of cohesive devices in the United States.

Using these devices for breast reconstruction facilitates the surgeon's ability to obtain symmetry because of the many different implant sizes available. Additionally, these implants exhibit less rippling under the thin soft tissues of reconstructed breasts. It is essential for surgeons to control the pocket during the initial phases of tissue expansion using precise, retroactive, expanded pocket-width planning to allow the subsequent use of these devices.

## CONCLUSION

Currently the rest of the world has embraced form-stable cohesive gel devices, whereas the U.S. experience has been limited to FDA clinical trials. However, full approval of these devices is on the horizon. When that time comes, U.S. surgeons will be required to adopt a different approach to breast implant surgery to optimize results and allow implementation of these devices without significant problems. The potential for superior outcomes will drive surgeons to recognize the power of these new devices and acquire the necessary training to use them effectively.

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### ***Editorial Commentary***

Dr. Adams provides us with some very useful basic information about cohesive gel implants. The material is clearly presented and should be digested and stored in preparation for the implants becoming available in the United States. Certain areas are highlighted to produce precise pockets created by accurate and, hopefully, bloodless dissection. Precision is extremely important when using cohesive gel implants, because it greatly minimizes the possibility of unsatisfactory results, including asymmetries and a need for further intervention. Rereading this chapter will help emphasize this point and will stimulate surgeons to concentrate on precision of technique.

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Dr. Adams makes a salient point, separating factors attributable to the implant from those properly belonging to the surgeon. Thus, even though we now believe that we have a better implant, we still need to look at other factors. The concept of "form stability" requires some elucidation. To take things to the extreme, a rock or a concrete block is form stable, because at standard temperatures and pressures it deforms or flows imperceptibly to the human eye. But clearly these form-stable devices would make very poor implant materials. When we say an implant is form stable, what we really mean to say is that it is less likely to pool at the bottom of the pocket than an old-fashioned, syrupy, less-cohesive device. A form-stable device must still be deformable with pressure or movement; otherwise it would not fulfill its other obligations for the attainment of a good result. The underlying principle here is that there are degrees of stability, and some applications require a device that is more stiff whereas other applications require softer devices. For example, less-deformable devices will be superior in situations where an abnormal skin envelope requires specific pressure to be applied on the inside of the pocket to expand the skin where it is needed. Softer devices will better match postpartum women who have softer parenchyma so that the parenchyma-device interface will be less palpable. However, this does not decrease the requirement for a proper tissue cover. Thin tissue overlying a soft device is a recipe for rippling and a poor outcome. Once a surgeon has gained enough experience with these devices, it will be abundantly clear that how it feels coming out of the box will be an excellent indicator of how it will feel in situ. Firmer implants are firmer, and softer implants are softer. Interestingly, the only clinical study on the subject was published merely as a letter to the editor.<sup>1</sup>

The "generations" of breast implants are important insofar as they help doctors keep in mind what the probabilities are when they are seeing patients in the clinic. It makes no sense to keep breaking down the taxonomic categories into finer and finer slices that are of dubious value.

I respectfully disagree with Dr. Adams about whether devices that are firmer in the hand are firmer in situ. Rippling and firmness are definitely related. A rock-solid im-

plant made of, well, rock, would not ripple; neither would it feel good to the touch. Firmer implants are less likely to ripple or wrinkle, but at the expense of feeling firmer. That is fine in a younger patient with firm parenchyma, but it may become an issue in the fatty breast. In the end, it is not just the surgeon but the patient who needs to make a decision about which is most important for her. Most doctors are aware that an implant with some moderate encapsulation will not have rippling, even if the capsule is thin. Pressure against the device is important to help maintain the shape of the device, and therefore the softest breasts with the thinnest capsules have the greatest chance of revealing underlying implant irregularities (rippling). Firmer implants will feel firmer in situ and will wrinkle less, period.

Dr. Adams quotes a surgeon who states that “these are lifetime devices.” I do not think that Dr. Adams really believes this—in fact he and I agree that we should strongly resist the temptation to make statements that might mislead our patients into thinking that these devices last forever. All implants have a potential to fail, and all patients should be told that they are likely to require another operation in their lifetime. Telling patients that they have a lifetime device will only lead to disappointment in the long run.

Dr. Adams notes that these devices have a lower capsular contraction rate, and he attributes this to better surgical technique. Perhaps, but I don’t think I became a better surgeon because of the technique I use with these devices. I had a low capsule rate with saline devices, and it became lower with the gel devices. I can’t explain it, but this needs further investigation to see if it is a real phenomenon or merely wishful thinking on our part.

These cohesive gel devices are definitely built better than previous types, and if my wife, sister, or child needed a device, I would want them to choose one of these devices over any other type. However, it would be unrealistic to assume that these devices remove the possibility that material can escape from the gel matrix. Surgeons must be aware that nonreactive silicone oils are absorbed into the gel to make it soft, and, if the shell integrity is breached, these moieties could equilibrate with the serous bath surrounding the device, although the total amount is extremely low. The risks we are talking about are orders of magnitude smaller than with the more liquid varieties of silicone, but we need to know that the shell still plays a pivotal role in separating the gel from the patient.

In Dr. Adams’s discussion of the essentials for success, I think the most important criterion for success is refusal to operate on patients who are not good candidates. The worst cases I have seen should never have had augmentation in the first place. Until surgeons are willing to refuse cases, there will continue to be bad outcomes. With proper patient selection as outlined by Dr. Adams, and appropriate surgeon training, the incidence of poor or bad outcomes should be close to zero. There is no excuse for 15% reoperation rates. Reading between the lines of the FDA submissions, we can see that “patient request” is a common reason for reoperation. The common reasons for patient request are unsatisfactory size and unsatisfactory shape. Again, reading between the lines, it seems as though patients are sometimes dealing with poor shape outcomes because surgeons do not understand the dynamics of a Snoopy (or waterfall) breast or its opposite, the double bubble. These patients often have soft breasts, but not an aesthetic outcome, and therefore they rightly seek correction. These are rather predictable outcomes and can be avoided completely with appropriate training.

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