Cohesive Breast Implants: Characteristics and Crosslinking Properties

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Gel-filled silicone implants have been in the marketplace for more than 30 years, having been introduced in the 1960s. They have gone through many iterations during this time, from round devices with Teflon patches on them, to form-stable devices undergoing premarket evaluation today. Plastic surgeons are frequently asked by patients and even insurance and regulatory agencies how the devices in clinical practice today are different from those used in the past. Surgeons are also subjected to new-device marketing campaigns containing a combination of scientific and qualitative language that can be confusing. Understanding some of the history of the devices' development, as well as some of the technical differences among them, will help place the shaped devices into perspective.

GENERATIONS OF GEL IMPLANTS

The evolution of silicone-based breast implants was described by Peters et al[1] in their seminal article of 1997, in which they identified three different "generations" of these devices. Other reports have reaffirmed this generational development.[2-4] Still other investigators cite the addition of texturing and anatomic shapes as evidence of additional generational development of these devices instead of refinements to existing devices. Regardless, most would agree that these gel-filled devices have evolved and that the current generation of cohesive gel implants offers distinct advantages over earlier versions.

First-generation implants featured thick shells and a firm gel and were produced until approximately 1979. Second-generation devices were significantly different from their predecessors, with thin shells and a thin, less viscous gel inside. In some instances, loss of shell integrity resulted in the gel freely flowing out of the implant into the capsule, with the shell collapsing into it. This produced a characteristic "linguine" sign in MRI examinations.[5] The shell wall was permeable to the short-chain structure of the gel, and when it diffused through the shell it was called gel bleed, detectable as a filmy layer on the exterior of the implant.

The current generation of breast implants is characterized by firmer gel and thicker, multilayer shells with barrier coats, resulting in extremely low gel bleed. These devices represent a dramatic departure from second-generation implants. The crosslinking of the gel is so complete that if the implant is cut in half, none of the gel flows out.

FIG. 1 Mentor Smooth Round Memory Gel implant cut in half.

Because of the characteristic "stickiness" of the gel, these implants are referred to as *cohesive,* meaning that the contents hold together and do not disperse when the shell is broken (Fig. 1). However, despite the increased firmness, these implants do not generally fracture. Although there were overlaps among different manufacturers when they abandoned generation two and moved to generation three, the latter have been in use for almost 20 years. There have been improvements and refinements in manufacturing techniques, but no significant design difference in generation three devices. The current generation of implants features low-bleed gel technology, which may explain why the implants do not seem to have high levels of capsular contracture as seen in early generations.

CHARACTERISTICS AND CROSSLINKING PROPERTIES

Although there are subtly different levels of cohesion among the current-generation implants that are available through FDA-sponsored trials, depending on the desired clinical characteristics and use, the basic characteristics remain the same. Generally, greater crosslinking of the gel results in a firmer, more form-stable device. When this is coupled with an asymmetric shell, unique shapes can be created for different clinical situations. Each manufacturer has taken its own approach to current-generation devices.

For example, Mentor uses an international scale to differentiate cohesive products. *Cohesive I*™ refers to the current round gel products being used in the Adjunct and Round Memory Gel studies currently under review by the FDA. *Cohesive II*™ is a slightly more firm gel used internationally in round gel implants. *Cohesive III*™ is the most firm option, and it is used in the Contour Profile Gel (CPG) product. The Mentor CPG device, the Inamed Style 410 introduced in 1993, and the less crosslinked Style 410 Soft Touch are the most crosslinked and are form-stable asymmetrical devices. These implants have textured shells to help maintain rotational stability.

Because of their ability to create and sustain a shape, these devices are referred to as *anatomic.* Although the data are still being analyzed, there are trade-offs for using the more firm anatomic gel products: They are more palpable, they require more precise surgical technique, and they run the risk of rotation. Different techniques, such as a longer incision, must be used for their implantation. These anatomic gels may repre-

sent a good option for patients with specific needs, such as those who need an implant to define breast shape (reconstruction or thin-tissue augmentation patients), but for patients with existing breast tissue, a round silicone implant is also an excellent choice. The surgeon must evaluate the benefits against the risks of the shaped devices and make the best choice for the patient.

However, there do appear to be disadvantages to too much crosslinking. Under extreme localized stress, firmer gels can fail along fracture planes *(gel fracture)*. There have been published reports of gel fractures in the most heavily crosslinked devices.[6] Gel fracture causes the shape of a device to become distorted, sometimes to the point that the implanted breast becomes misshapen. This type of device failure does not involve a ruptured shell, but a reoperation may be necessary to achieve a properly shaped breast mound. Clinicians have reported very few instances of this type of failure (rarely postimplantation, most commonly during insertion), and manufacturers are continuing to closely monitor returned devices for this type of device complaint.[6] A longer incision helps avoid gel fracture and overcome the wall friction associated with these textured devices.

Minor differences in the characteristics of current-generation implants can make significant differences in clinical behavior. For example, there are only two substantive differences between the Mentor Round Memory Gel™ and CPG™ cohesive breast implant devices: The firmness of the silicone gel filler and the contour shape. The difference in shape is controlled by the shape of the shell that surrounds the silicone gel filler, which in turn is determined by the mandrel on which the shell is formed during manufacture. The difference in firmness between the Round Memory Gel and the CPG is the result of a slightly higher crosslink density in the gel filler of the CPG product. This produces a firmer, more shape-retaining gel.

Crosslinking and Implant Firmness

A chemical crosslink is formed when two reactive sites on a crosslinker molecule attach, through chemical reaction, to two separate polymer chains containing sites that can react with the crosslinking molecule. A link is thus formed through chemical reactions between the bridging molecule (crosslinker) and two polymer chains (Fig. 2). The greater the number of crosslinks (crosslink density) the more firm a gel is. In other words, a structural property relationship is established between the chemical and physical characteristics of the material.

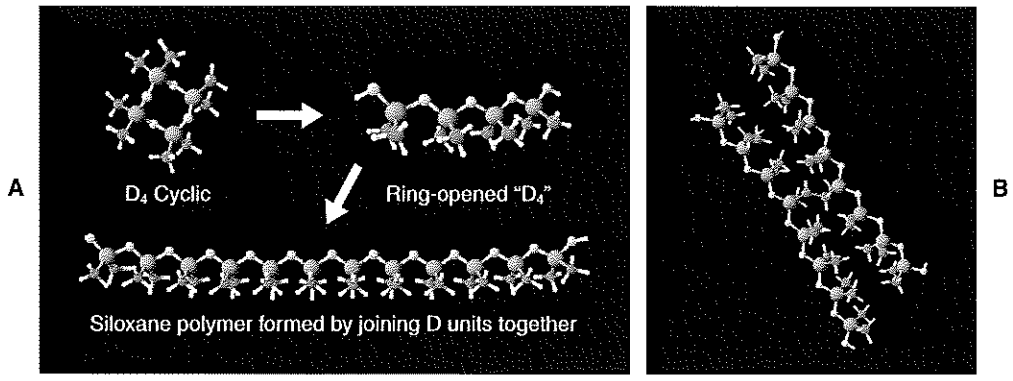

FIG. 2 **A,** Before crosslinking. **B,** After crosslinking.

The two reactive moieties that combine to form the crosslinks are silicon hydride (SiH) on the shorter crosslink molecules and vinyl groups that are pendant to (attached to) the polymer chains. The silicon hydride groups are internal to the shorter bridging molecules (the crosslinker). The pendant vinyl groups are spaced along the longer polymer chains. The firmness of the silicone gel filler depends directly on the number of crosslinks between the polymer chains, and, therefore, on the amount of crosslinker included in the formulation before the reaction between the silicone hydride (crosslinker molecule) and the polymer chains with the vinyl pendant groups. This means simply that, for a given set of polymers in a gel formulation, the *sole* determinant of gel firmness is the amount of crosslinker included in the formulation.

The implications of these technical details can be illustrated by research from one of the manufacturers. Mentor has demonstrated that crosslink density is the only discernible difference between Round Memory Gel and CPG devices by measuring physical and chemical properties of those devices. The data confirm that the physical properties (ultimate tensile properties, impact resistance, and cyclic fatigue results) of the shells of the two product families are statistically the same (Jerry Barbor, Mentor Corporation, personal communication, 2006). This is expected because the chemical components and processes for making the shells are essentially the same. Stated simply, the chemical bonds and the relative numbers of those bonds per unit volume of shell that are formed during the manufacture of the shells are identical for both families of products. The only differences in the shells of the two families are that the CPG devices have a contoured shape, and the texturing layer is slightly more porous and has a somewhat less amorphous silica reinforcing material than the shells of the Round Memory Gel family.

Similarly, the only difference between the gel filler of the CPG and Round devices is that the CPG gel formulation contains a slightly higher level of crosslinker relative to the vinyl polymer than does the Round. This means that the kinds of chemical bonds in the gel that are formed during the manufacture of the devices are the same for both product families. There is simply slightly more of the crosslink bonds in the gel filler of the CPG devices. Table 1 shows that the crosslink characteristics are similar for both Mentor and Inamed products.

Comparative chemical characterization of the silicone gel from Mentor Round and CPG devices has been undertaken, and Inamed's competitive offerings have also been well characterized. Chemical analysis reveals that the total extractable content of Mentor's gel fillers for both the Round Memory Gel and CPG devices is essentially identical. In addition, the content of individual low-molecular-weight (LMW) cyclic siloxane compounds is also comparable.

The measured LMW cyclic siloxane concentrations in Inamed's corresponding devices *should be* essentially the same, based on data presented to the FDA in April of 2004. The conclusion that can be drawn from the foregoing is that the chemical constituents of the Mentor and Inamed products are similar. One can therefore speculate with a fair degree of certainty that the significant difference between the less cohesive devices and the more cohesive devices in the Inamed product lines is the crosslink density, as is the case with Mentor's devices.

We know that the greater firmness of the Mentor CPG devices compared with the Round devices is created by a simple increase of the crosslinker in the gel formulation, and this difference does not manifest significantly in the chemical characteristics of the filler. However, the difference in cohesiveness can be evaluated from physical measure-

TABLE 1 Crossover Modulus of Mentor and Inamed Silicone Gel Breast Implant Fillers (dynes/cm^2)

Mentor		Inamed	
Memory Gel (Round)	CPG (Contour)	Style 110 (Round)	Style 410 (Contour)
1242	2468	873	2999

ments of the modulus using rheology. The crossover modulus is directly proportional to the cohesiveness or stiffness of the filler. Typical crossover modulus data from samples of devices from each family are presented in Table 1.

The difference in crosslink density between the Mentor product families is considered slight. Based on nominal formulations, the theoretical portion of total vinyl moieties involved in the crosslinking of Round devices is approximately 11.3%, compared with approximately 14.5% for CPG devices. It is interesting to note that the less cohesive Inamed Style 110 has a lower crossover modulus (is less firm) than the corresponding Mentor Round product. The Inamed Style 410 has a higher crossover modulus (is more firm) than the corresponding Mentor CPG product. Nevertheless it should be apparent that the crossover modulus for these products represents a continuum of cohesiveness from the same generation of implants.

CONCLUSION

Most of the world today has embraced cohesive gel devices as the gold standard for breast implant surgery, whereas the U.S. experience has been limited to FDA clinical trials. However, FDA approval of these devices is on the horizon, and U.S. surgeons will soon gain access to them. The issue to address then will be whether the differences in shape and firmness really present a significant advantage to plastic surgeons and their patients. We should be able to answer this question more completely once the preapproval studies are complete, and the data are reported. More importantly, we will ultimately have a great deal of clinical data showing how these implant design changes are incorporated, not into the practices of expert researchers, but into the practices of the average plastic surgeon who chooses to use them.

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Editorial Commentary

Dr. Cunningham has produced a very succinct review of the present situation regarding cohesive gel implants. He points out the advantages of these implants but also adds a word of caution that they must be carefully assessed over time, and an objective evaluation needs to be made to be absolutely certain that these implants are superior to saline-filled implants. It is beneficial to have a certain degree of caution before jumping into deep waters and emerging with some significant problem. This is a very useful article, because it is a prelude to those that describe the experiences of many authors who use this type of implant. In the clinical situation there are certainly pitfalls that largely can be avoided by using proper techniques. It is useful to pay attention to the information in this article.

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Of all the evolutions of breast implants, the second generation is probably the most troublesome one. However, both the first-generation and the troublesome second-generation devices are quickly becoming extinct as patients with these implants show up for replacement surgery.

The latest generation of implants is notable for having a sandwiched barrier layer of polydimethylsiloxane (PDMS), with phenyl groups along the chain, that does a reasonable job of stopping gel bleed. Today's silicone gels contain a nonreactive PDMS fluid that is more than 10,000 mW and trapped in the three-dimensional crosslink network. Gel bleed today is miniscule compared with the old gels and is not composed of short-chain segments. Dr. Cunningham also points out the problem of gel fracture, which is discussed in other articles in this issue.

Many doctors may not be aware of how these implants are produced—manufacturers still rely heavily on handwork to make them. Over the last few years, Mentor has developed the first completely mechanized equipment that can manufacture implant shells with remarkable consistency. By mechanization, these companies can create better, more consistent products of higher quality and more stringent tolerances. This is definitely a win-win arrangement for all concerned.

Materials testing methods are typically used to assess batches of products to ensure that they meet specifications. It is probably not necessary for surgeons to know the technical details of the rheology tests that are done, however Dr. Cunningham points out that the crossover modulus may be used to put a number to the degree of firmness. The absolute value of the number is not important of course, but the rank order of the devices is interesting and correlates well with my clinical experience. Yes, the 410 devices are stiffer than the CPG devices, and the soft touch devices are less stiff than the CPG devices. The information of the degree of stiffness is of value in this regard, and perhaps manufacturers should publish these standardized ASTM numbers on their specification sheets.

Finally, I agree that these devices represent the gold standard of breast augmentation. It remains to be seen whether the devices will be used appropriately when they become generally available in the United States. It is my hope that the U.S. plastic surgery societies and the FDA will agree on an implementation path that includes clinical instruction for surgeons, ensuring that patients get the best devices possible using a best practices model.

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