51 Cohesive Breast Implants: A Significant Difference?

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51.1 Three Generations of Gel Implants

It may seem quite surprising to most of the plastic surgeons around the world that the Americans are the last to be able to use silicone gel implants without significant restrictions being placed on them. The FDA Advisory Panel recommended approval of the devices in the spring of 2005, and the Agency issued "Approvable" letters in the summer of the same year to the two domestic manufacturers of the devices. Despite this scientific foundation for these devices, they were not finally approved until November of 2006. The round devices have not been approved, and it is felt that the shaped devices, currently so popular in Europe, will not be evaluated for at least a year after final approval of the round devices.

In his standard setting article of 1997, Dr. W. Peters concisely characterized the three different "generations" of silicone based breast implants [1]. This description has been reaffirmed as the standard citations by others [2–4]. Each generation had specific characteristics that distinguish it as significantly different than the preceding iteration of the devices.

The first generation implants featured thick shells and a firm gel. They were produced until approximately 1979. Second generation devices were significantly different from their predecessors, with thin shells, and a thin less viscous gel inside. The gel was almost liquid in consistency. Loss of shell integrity resulted in the gel freely flowing out of the implant into the surrounding scar capsule, with the shell collapsing into it, producing the characteristic "linguini" sign on MRI [5]. The implants had no effective barrier layer, so the shell wall was permeable to the shorter chain fragments of the gel, and when it diffused through the shell was called gel bleed and was detectable as a film layer on the exterior of the implant.

Surgeons are currently implanting the third generation of breast implants. Generation three implants are characterized by firmer gel and thicker multi-layer shells with a barrier coat, resulting in extremely low gel bleed. These devices represent a dramatic departure from generation two implants. The devices never have an exterior film layer, and the cross linking of the gel is so complete that if the implant is cut in half, none of the gel flows out of it (Fig. 51.1).

To describe this characteristic "stickiness" of the gel in these implants, they are all referred to as "cohesive," meaning the contents hold together and will not disperse when the shell is broken. Despite the increased firmness, generally, these implants do not fracture.

Fig. 51.1. Sample of Mentor smooth round MemoryGel implant cut in half

There were differences from manufacturer to manufacturer regarding when they abandoned generation two and moved to generation three; the current devices have been in use for almost 20 years. There have been no significant design differences in these generation three devices, but there have been improvements and refinements in manufacturing techniques. Many feel that the negligible level of small chain fragments which escape from the devices explains why they do not seem to have high levels of capsular contracture as seen in early generations.

51.2 What Are Cohesive Gel Implants?

The manufacturers have regulated the levels of cohesion among the generation three implants to obtain the desired clinical characteristics and usage of the device, but the basic class characteristics remain the same across the generation. Generally, greater cross-linking of the gel results in a firmer, form stable device. When this is coupled with an asymmetrically shaped shell, unique shapes can be created for different clinical situations.

For each manufacturer, the description of the device varies. Mentor has a scale used internationally to differentiate the different cohesive products. Cohesive 1 refers to the current round gel products being used in the Adjunct and Core Gel studies, currently under review by the FDA. Cohesive 2 is a slightly more firm gel used internationally in round gel implants. Cohesive 3 is the most firm (form-stable) option and it is used in the CPG product. The Mentor CPG device, the Inamed style 410 introduced in 1993, and the less cross linked 410 "Soft Touch," represent the most cross linked end of the generation three spectrum, and are form stable asymmetrical devices. These devices have textured shells to help maintain their rotational stability.

These devices are referred to as "anatomical" gels because of this ability to create and sustain a shape. While the clinical data is still being analyzed, there are both advantages and liabilities with the more firm shape stable gel products: they are more palpable, they require more precise surgical technique when implanting, and run the risk of rotation. Different techniques, such as a longer incision, must be used for their implantation. This evolutionary difference in the anatomical gels may represent a good option for patients with specific needs, such as patients who need the implant to define the breast shape (reconstruction or thin tissue augmentation patients), but for patients with existing breast tissue, a round silicone implant is also a great choice. The surgeon must evaluate the benefits versus the risks of these shaped devices, and make the best choice for the patient

In addition, there appears to be some disadvantage to too much cross linking, as there have been published reports of implanted devices with gel fractures in the most cross linked device, the Inamed 410 [6]. Under extreme localized stress the firmer gels can fail along fracture planes (gel fracture). With gel fracture the shape of the device will become distorted, even to the point that the implanted breast will become 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.

To illustrate how minor differences in the characteristics of generation three devices can make a significant difference in clinical behavior, it is important to note there are only two substantive differences between Mentor Core and CPG cohesive breast implant devices: (1) the firmness of silicone gel filler and (2) the contour shape. The difference in shape of the devices is derived from the shape of the shell that surrounds the silicone gel filler. This shape is determined by the mandrel upon which the shell is formed during manufacture. The difference in firmness of the gel filler between Core and CPG is the result of a slightly higher crosslink density in the CPG product. This produces a firmer, more shape-retaining gel.

51.3 Technical Differences Among Cohesive Gel Devices

A chemical crosslink is formed when two reactive sites on a crosslinker molecule attach, through chemical reaction, to two separate polymer chains that contain sites that can react with the crosslinking molecule. Thus a link is formed through chemical reactions between the bridging molecule (crosslinker) and two polymer chains. The greater the number of crosslinks (crosslink density) the more firm a gel will become.

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 upon the number of crosslinks between the polymer chains, and, therefore, upon the amount of crosslinker included in the formulation before the reaction between the silicon 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.

Mentor has demonstrated the fact that crosslink density is the only discernible difference between Core and CPG devices by measuring physical and chemical properties of those devices [7]. 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. This is as expected since the chemical components and processes for making the shells for the two families are essentially the same.

Since the chemical intermediates and manufacturing processes for producing the shells for the Core (Round) and CPG devices are essentially the same, the chemical character of the two are identical, and homogeneous across the generation three devices. Stated simply, the chemical bonds and the relative numbers of those bonds per unit volume of shell that are formed in 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 (1) have a contoured shape and (2) the texturing is slightly more porous (a less rough surface) than the shells of the Core (Round) family.

Similarly, the only differences in the gel filler of the CPG and Core (Round) devices is that the CPG gel formulation contains a slightly higher level of crosslinker relative to the vinyl polymer than does the Core (Round). This means that the kinds of chemical bonds in the gel that are formed in the manufacture of the devices are the same in both product families. There is simply slightly more of the crosslink bonds in the gel filler of the CPG devices.

It is highly likely that Mentor and Inamed are similar in chemical constituents, and this is borne out in the physical data presented in the Core Gel studies in 2005 [8]. The only significant difference is the level of diphenyl compounds incorporated in the Inamed shell elastomer. One can speculate then with a fair degree of certainty that the singular significant difference in the less cohesive to the more cohesive devices in the Inamed product lines is the crosslink density, as is the case with Mentor devices.

It should be noted that any change in the design of an implant will often involve compromises. The increase in firmness of the gel filler in breast implants is no exception. Under extreme localized stress the firmer gels can fail along fracture planes (gel fracture). With gel fracture the shape of the device will become distorted, even to the point that the implanted breast will become 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. Mentor has experienced very few instances of this type of failure but is continuing to closely monitor returned devices for this type of device complaint.

The issue is not whether cohesive gel implants represent a new generation of devices, they probably do not, but whether the differences in shape and firmness really present a significant advantage to plastic surgeons and their patients. We will be able to answer this question with authority once the preapproval studies are completed and the data reported. More importantly, we will ultimately have 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.

References

1. Peters W, Smith D, Fornasier V, Lugowski S, Ibanez D (1997) An outcome analysis of 100 women after explantation of silicone gel breast implants. Ann Plast Surg 39:9
2. Collis N, Sharpe DT (2000) Silicone gel-filled breast implant integrity: A retrospective review of 478 consecutively explanted implants. Plast Reconstr Surg 105:1979
3. Hölmich LR, Friis S, Fryzek JP et al (2003) Incidence of silicone breast implant rupture. Arch Surg 138:801
4. Hölmich LR, Kjøller K, Fryzek JP et al (2003) Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. Plast Reconstr Surg 111:723
5. Gorczyca DP, Debruhl ND, Mund DF, Bassett LW (1994) Linguine sign at MR imaging: Does it represent the collapsed silicone implant shell? Radiology 191:576
6. Brown MH, Shenker R, Silver SA (2005) Cohesive silicone gel breast implants in aesthetic and reconstructive breast surgery. Plastic Reconstr Surg 116:768–779
7. Personal communication, June 2006, Dr Jerry Barber, Mentor Corp, Santa Barbara, CA
8. FDA Core Gel presentations, General and Plastic Surgery Devices Advisory Panel Silicone-Gel Filled Breast Implants: Inamed and Mentor, April 12, 13, 2005, Bethesda, MD