Evolutionary Development of Cohesive Gel Implants: A New Era in Implant Technology

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Cohesive gel implants represent a positive advance in the evolution of breast implant technology. Although cohesive silicone gel is not new technology, having been used in implants since the mid-1980s, the use of the word *cohesive* to describe this gel is relatively recent and refers to the solid consistency of the gel compared with the more liquid fill that was used in some silicone gel implants in the early 1970s. In this context *cohesive* means that the silicone fill is not liquid or semiliquid; it is a solid unit that maintains its softness, holds together uniformly, and retains a natural feel that greatly resembles that of natural breast tissue. The development of cohesive gel implants can best be understood by reviewing the evolution of silicone breast implants.

BACKGROUND

In 1963 the silicone gel implant was introduced by Cronin and Gerow.[1] This first-generation device had a very thick shell with thick seams around the edge; it contained a firm, dense gel. In response to surgeons' requests for thinner, more natural-feeling implants, a second generation of implants was developed and introduced in the 1970s. These second-generation devices had very thin shells with a thin, almost liquid silicone gel filling. The fragile shells proved to be susceptible to rupture with potential for gel leakage. The third generation of implants, introduced in the mid-1980s, sought to address problems associated with the first two generations of implants. These implants were similar to devices manufactured today by the major implant manufacturers. Today's devices have thicker silicone shells with a barrier layer to inhibit gel bleed through the shell; the gel contained within this shell is cohesive and acts as a unit, holding together firmly. Cohesive gel implants have lower rates of rupture and contracture than earlier models, with significantly reduced potential for gel diffusion or bleeding through the shell.

The concept of cohesive gel implants can be traced to the Replicon (Surgitek), an anatomically shaped, polyurethane-coated, silicone-filled implant that was popular in the 1980s. Early results using this implant were very good, but there were long-term problems with polyurethane degradation. Once the polyurethane was gone, the remaining

thin, pliable shell could not maintain the implant shape, causing weakening and visible folds that eventually resulted in rupture and silicone leak. In addition to the effects of gravity, constrictive forces acted on the implant to deform its initial anatomic shape.

Tebbetts[2] is credited with introducing the concept that both the shell and its contents contribute to implant shape. This idea has influenced subsequent research, leading to the development of what we now call *cohesive gel implants*. By adding a crosslinker to the silicone in different amounts, manufacturers discovered that they could vary the softness of the material. From this, a soft implant filler was created that maintains its shape after molding. This gel is different from what we have seen with standard implants, where the silicone sinks to the bottom of the implant when it is held up and, when implanted, the implant shape is controlled by the tissue surrounding it. The concept of preventing this from happening was a great step forward in breast implant surgery. Unfortunately, because of the 1992 moratorium on silicone gel implants in the United States, further U.S. development ceased, and progress for bringing this development into clinical use has taken place in Europe and the rest of the world.

During the past decade cohesive silicone gel implants have been used extensively in Europe. As a result of this activity, large series can now be reported that document the efficacy of these devices, which have become the gold standard for breast implants used outside the United States.

CHARACTERISTICS OF THE COHESIVE GEL IMPLANT

The consistency of cohesive gel implants contributes to their appeal and long-term effectiveness. These implants have a firmer texture than the standard gel implants formerly available in the United States. If one is cut in half, or if a preshaped area is removed with scissors, there is no gel extrusion, even if the implant is squeezed. Thus even with rupture the shape is maintained and there is no evidence of gel migration. This phenomenon results from more crosslinking during the manufacture of the gel. Another advantage is that these implants may last longer than other implants.

It must be understood that these are *not* regular gel implants. They offer significant advantages over previous generations. They are long-lasting and maintain their shape after implantation, which may be round or anatomic. The shape is stable over time. No matter what position the patient assumes, the shape remains constant. Conventional implants fail in the fold areas; these implants do not form folds, and even if the shell fails, there is no significant gel migration. In a standard implant, the shape tends to be controlled by the capsule; in cohesive gel implants, the implant controls the shape—thus most are anatomically shaped. The gel consistency ranges from soft (I) to medium (II) to firm (III). It is the firm type that is used most frequently. The breast may be somewhat firmer with a firm implant, but the shape is well maintained, and these implants have found great favor among patients and their partners. Obviously, with softer, less cohesive gels, the implant shape is less stable. An additional modification is that anatomic teardrop implants are textured, which increases friction and prevents the implant from rotating—an essential element in the design of this implant.

Although implant rupture is rare (one Swedish study of several thousand implants reported only a single rupture[1]), it is important to know what happens if one of these devices should rupture. If a rupture occurs, migration of gel is unlikely because of the

consistency of the gel, which has been characterized as having a "gummy bear" consistency. Thus if migration occurred, it would be in microscopic amounts. It also seems likely that microscopic migration can occur through the shell, but this does not appear to cause problems.

If rupture occurs it is difficult to diagnose, and evaluation by mammography or MRI may be necessary. From the studies and data available, it appears that the silicone stays inside the capsule. Furthermore, scientific evidence has clearly established that silicone is not related to any health problems. Thus a ruptured implant is not a cause for concern, apart from the aesthetic issues that need to be addressed.

PUBLISHED REPORTS

Numerous reports in the world literature emphasize the potential value of cohesive gel implants. In 2001 Niechajev[3] reported excellent results with these devices. He noted that the margin for error with these implants is small and reported on a new implant design that he had developed using an anterior marking suture and a posterior fixing plate. Fruhstorfer et al[4] placed contour profile gel (CPG) breast implants in 35 patients, 10 of which were cosmetic and 25 of which were reconstructive. Patient satisfaction with breast shape was excellent; 85% of breasts were soft, and there were no significant aesthetic complications. Heden et al,[5] who have the world's most extensive experience with anatomic cohesive gel implants, stated that these implants can produce very predictable results with a high degree of patient satisfaction. Chantal et al[6] presented a case in which a cohesive gel implant was anchored to the chest wall with 3-0 braided polyester sutures. Reoperation at 1 week and MRI after 6 months showed no evidence of silicone leakage. This was a significant contribution. Graf et al[7] in 2003 reported on 263 patients with cohesive gel implants placed in the subfascial plane. They noted that there was no evidence of palpable edges. With subpectoralis implantation, there was no distortion of pectoralis movement even with larger implants of 310 cc. Capsule formation (Baker II) was seen in six patients (2.3%). There was unilateral displacement in eight patients, of which three required surgery. Mira,[8] in a comprehensive 2003 survey comparing cohesive gel implants with standard implants, noted the advantages of the cohesive devices and commented how surprising it was that, despite more than a half century of experience with breast implants, it has taken so long to recognize that they are more than a substitute for volume—they also play a key role in providing breast contour and shape.

These studies reflect worldwide experience with cohesive gel implants. Unfortunately, since the FDA moratorium on silicone gel implants in 1992, the United States has not been able to actively participate in the revolution that is taking place in implant technology. We have been largely limited to saline-filled implants, and as a result have fallen behind our international colleagues. At the moment there are three ongoing studies in the United States: first-time augmentation, revision of breast augmentation, and breast reconstruction following mastectomy. It is hoped that the large prospective studies underway in the United States will lead to FDA approval of these implants in the near future, thereby giving U.S. surgeons the ability to offer patients the cohesive silicone gel implants that represent the state of the art today and are the gold standard of implant technology.

CONCLUSION

Cohesive gel implants offer potential for improving long-term results of breast surgery. Some of the benefits of these implants include the following:

- They are available in three consistencies, graded I, II, and III. As the consistency becomes thicker, the profile increases from low to moderate to increased moderate to high.
- They maintain shape regardless of the patient's position.
- They do not form folds, and thus there is decreased likelihood of failure.
- If a shell fails, there is little likelihood of gel migration.
- An implant controls the shape of the breast and therefore the shape will not change even with significant trauma. This stability increases with the thicker gel types.

REFERENCES

1. Cronin TD, Gerow FJ. Augmentation mammaplasty: A new "natural feel" prosthesis. In Broadbent TR, ed. Transactions of the Third International Congress of Plastic Surgery. Amsterdam: Excerpta Medica, 1964.
2. Tebbetts JB. Dimensional Augmentation Mammaplasty Using the BioDimensional System. Santa Barbara, CA: McGhan Medical, 1994.
3. Niechajev I. Mammary augmentation by cohesive silicone gel implants with anatomic shape: Technical considerations. Aesth Plast Surg 25:397-403, 2001.
4. Fruhstorfer BM, Hodgson EL, Malata CM. Early experience with an anatomical soft cohesive silicone gel prosthesis in cosmetic and reconstructive breast surgery. Ann Plast Surg 53:526-542, 2004.
5. Heden P, Jernbeck J, Hober M. Breast augmentation with anatomical cohesive gel implants: The world's largest current experience. Clin Plast Surg 28:531-552, 2001.
6. Chantal M, Melis P, Marco R. Suturing of a textured breast implant filled with cohesive gel to prevent dislocation. Scand J Plast Reconstr Surg Hand Surg 37:236-238, 2003.
7. Graf RM, Bernardes A, Rippel R, et al. Subfascial breast implant: A new procedure. Plast Reconstr Surg 111:904-908, 2003.
8. Mira J. Anatomic asymmetric prostheses: Shaping the breast. Aesthetic Plast Surg 27:94-99, 2003.