Form-Stable Silicone Gel Breast Implants

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KEYWORDS

• Breast augmentation • Breast implants
• Saline breast implants • Round gel breast implants
• Form-stable breast implants • Process engineering
• Toyota Production System • Lean manufacturing

The starting point for this article is the question of what is the optimal shape for a breast implant. Should the ideal device be round and "fill the breast envelope" or have a form that would "shape" the breast by serving as an internal framework for existing breast tissues? There are two schools of thought regarding breast esthetics, both of which are divergent, and neither approach provides the complete answer that will work for all patients seeking breast augmentation. I purposely oriented this article toward processes, system engineering, and operational excellence versus it being a treatise on my personal technique.

THE EVOLUTION OF SHAPED DEVICES

The concept of a shaped breast implant had been considered in the 1970s. Early teardrop-shaped, smooth surface, Dow-Corning devices had Dacron fixation patches on the back wall and were filled with first-generation non–form-stable gel. There was little analysis of the esthetic quality of outcomes from these devices or a process for their use. Early device failures in this design dissuaded plastic surgeons from shaped devices. Retrospective analysis of the outcomes performed years later showed that fixation patches contributed to device failure and that the first-generation gel was not form stable. Emphasis for many years was placed on round devices that would fill the breast envelope versus shaping the breast. No one had thought about formulating silicone gel to keep its shape inside the breast. The focus was wrongly on liquid gel formulations that would ultimately be problematic in terms of extracapsular gel migration.

Alternatives to round devices that would produce a natural-appearing outcome after breast augmentation were a topic of interest in breast esthetics. Experimentation first led Dr. John Tebbetts to develop a shaped saline device, the INAMED 468, and later the form-stable INAMED (now Allergan) 410 series as its successor. In theory, this device was intended to improve breast esthetics by virtue of its tapered upper edge and dimensions of height, width, and projection. The journey to producing this device was not without some missteps. Notably, the major error was thinking that a shaped saline breast implant would maintain shape changes within the breast. It was illogical to think that a shaped device filled with a liquid would retain its shape once implanted. This ability had already been proven wrong with the first-generation shaped devices (Dow).

Detractors quickly demonstrated that shaped saline-filled devices assumed a round shape within the breast. To complicate matters further, marketing communications by INAMED, the maker of the Style 468 device, were distasteful and portrayed women as sex objects. The credibility of breast shaping by devices was assailed once again, and plastic surgeons went back to thinking about the world in terms of round saline or gel devices (Adjunct Study Protocol).

The development of devices continued, with newer silicone gel formulations that could be

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vulcanized into a form-stable shape. This advance in biomaterials technology when combined with an exterior texture (Biocell, INAMED) on the implant shell reduced device rotation once implanted and appeared to be the answer. The release of the INAMED 410 occurred with the device being sold offshore starting in 1994. Form-stable gel devices had been successful in foreign markets where there was no restriction on their use. Notable breast surgery luminaries, such as Per Heden, MD, became interested in learning about how to optimally use these devices for cosmetic breast augmentation and reconstruction after mastectomy. Heden, Heitzman, and others performed the early work with the form-stable implants in a series of patients and documented their outcomes. Early reports of the outcomes were notable in terms of complications, buckling, infection, and capsular contracture. When viewed retrospectively, this situation occurred because the new device (form-stable shaped implant) was being placed using the process that surgeons had at the time for inserting a round device into the breast.

PERSONAL EXPERIENCE WITH FORM-STABLE DEVICES

Following the initial phase of the INAMED Core gel study in 1999, I was offered the opportunity to participate in the INAMED 410 study that started in 2001. I recall enthusiastically starting the study in 2001 yet without a defined process to use these devices. It was hardly different than being a test pilot who was told, ''here's the airplane, go fly it and tell us about your experience.'' Mention was made of using ''bio-dimensional planning'' and of not making the mistake of pocket over dissection. My initial cases went well in terms of excellent esthetic outcomes without adverse events otherwise. Patients were happy with the natural-appearing esthetics and ample breast size increase to a full C or D cup. After an initial few cases, I decided there was a need to formulate a new thought process to use form-stable implants.

CHANGES IN BREAST ESTHETICS AND LONG-TERM OUTCOMES

The subject of breast size and shape after augmentation is of great interest. Currently, there appears to be less emphasis on achieving a round breast outcome for many women who want breast augmentation, without the obvious stigma of upper pole roundness. Interestingly, some geographic areas in the United States seemingly have a preference for large volume round implants (eg, South Beach of Miami, Florida, and Orange County, California). Bigger more obvious breasts with upper pole fullness have been marketed to women as a ''sexy'' breast outcome.

The strategy of using high profile, round-shaped devices to achieve maximum volume enhancement may not be a good one if the net effect is tissue thinning, implant malposition (drop out), and upper pole traction rippling. Even in situations of staying within the measured base diameter of the breast, large volume augmentations have the potential to produce noncorrectable soft tissue deformities, including implant malposition (drop out).

Alternatively, form-stable devices produce excellent size increases for patients, with normal-appearing outcomes for most patients that fill a C or D cup size bra. It is now possible to customize breast augmentation based on individual measurements and tissue characteristics. The challenge is to help patients make good decisions on the front end of the process of breast augmentation that will produce great long-term outcomes with the least risk of problems attributable to mistakes in planning, such as an implant that is too wide or too large. Form-stable devices can produce spectacular natural outcomes that are coupled with high patient satisfaction. Alternatively, adverse events and less than perfect outcomes can occur if these devices are used with a round implant thought process.

TRANSITION FROM ROUND TO FORM-STABLE DEVICES

It has been 7.5 years since the start of the INAMED (now Allergan) 410 study and more than 5.5 years since the start of the MENTOR form-stable CPG study. From the perspective of having completed augmentation procedures in 250 patients, I offer the following commentary about how these implants have performed in my patients and what knowledge can be transferred that will make adoption of these devices easier. The best way to read the rest of this article is to let go of your current methodology regarding round breast implant surgery, because how you currently perform round implant breast augmentation may prevent you from achieving optimal use of form-stable breast implants.

All plastic surgeons who use round implants have a particular way in which they evaluate patients requesting breast implants for either cosmetic or reconstructive benefit. All have their own technique in surgery. All have a way of managing adverse events that occur in the short and long

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