Breast implant design has now come full circle with the recent development of the MENTOR® MemoryGel® Xtra Breast Implant. To understand the significance of this device it is helpful to review breast implant design over the years. The very first implant designs from the mid to late 1960’s incorporated a smooth walled, anatomically shaped device that featured textured patches made of Dacron adhered onto the back of the implant. (Figure 1 A, B)

The tissue incorporation created by these patches was a very important design feature as it was realized early on that an anatomically shaped implant must maintain its orientation to effectively shape the breast, and any element of postoperative rotation would variably compromise the aesthetics of the result. These patches stimulated a very aggressive ingrowth of soft tissue and thus, very solidly held the devices in the proper orientation.

Unfortunately, likely because of faulty silicone materials, these devices were associated with a very high rate of complications with capsular contracture being a particularly severe problem, and soon fell into disfavor. Moving forward, it was demonstrated that “round” implants, meaning implants that were symmetrically designed with regards to the base width and the height of the device, provided very satisfying results in breast surgery. Different design modifications including different fill materials, shell constructions, and dimensions dominated the attention of the plastic surgery community for many years. The topic of implant fill material merits specific mention as the physics of the different fill materials require different strategies for fill volume. When an...
implant shell is filled with a less cohesive silicone gel, the tendency for the gel to variably flow allows the implant to be underfilled relative to its maximal fill volume. This creates an implant that has a very soft feel as the implant variably collapses under the effect of external pressure or gravity, and assumes a shape partially dictated by the forces applied to it (Figure 2 A,B). The deleterious effect of this partial shell collapse is folding and wrinkling of the implant shell which places stress points that ultimately, over time, can lead to shell failure (Figure 3 A,B).

To counteract this tendency for the shell to wrinkle, and although off-label, overfilling implant shells with saline became a popular strategy as the collapse of the device when placed upright could be minimized. While effective in many patients, this strategy tended to create a firmer feeling breast with rounded distortion in the upper pole.

To maximize shape and limit the saline “water balloon” feel effect, anatomically shaped, highly cohesive gel filled implants were then developed. By incorporating a firmer, more cohesive gel in an anatomically molded shell, an array of desired shapes could be created using a gel that resisted collapse of the upper pole of the device (Figure 4 A,B).
Theoretically, it was expected that these devices would limit folding and wrinkling in the implant shell resulting in greater longevity and improved aesthetic results. This is exactly what has been noted in several publications to date.\textsuperscript{1,2} Despite these advantages, acceptance of the shaped implant concept has been less than universal. Namely, complications related to implant rotation and a firm feel to the breast have been noted. The result of this progression of engineering and design advances has been that the “perfect” breast implant has yet to be fully realized and continuing efforts to improve the performance of these devices is warranted.

It is with this history in mind that the most recent development of the MENTOR\textsuperscript{®} MemoryGel\textsuperscript{®} Xtra Breast Implant becomes important. During the original approval granted by the FDA to the MemoryGel\textsuperscript{®} line of breast implants, a range of fill volume was allowed for each individual device. Up until now, the fill volume used for these devices was chosen to be on the lower end of what was allowable. As such, these devices are somewhat underfilled, resulting in a soft, malleable implant that conforms to the pressures of the overlying soft tissue. In essence, it is the soft tissue that shapes the implant. While this implant design has provided excellent clinical results for years\textsuperscript{4}, the utility for a less malleable and more projecting\textsuperscript{5} implant was realized by many. This need has been met by offering a line of implants using the same MemoryGel\textsuperscript{®} Implant construction, but now one that is filled more toward the high end of the allowable fill volume stipulated by the FDA (Figure 5 A,B).

With the alteration of precision filling each specific SKU in design, come some very interesting advantages. Because the implant is more closely situated towards a maximal fill volume relationship, less pressure on the device is required to meet resistance to deformation. In other words, the implant maintains back to front projection in the presence of a force applied to the apex of the device such as happens when the implant is placed under the breast. In fact, MemoryGel\textsuperscript{®} Xtra Breast Implants provide comparable firmness to Natrelle Inspira Breast Implants based on bench top testing.\textsuperscript{6*} However, due to the shell construction and the use of a less cohesive gel, when the implant is compressed from side to side, it maintains a very soft feel. In a blinded comparison, 9 out of 10 consumers chose MemoryGel\textsuperscript{®} Breast Xtra implants as feeling more like natural (or real) breasts than Inspira Responsive and Inspira Cohesive breast implants.\textsuperscript{7**}

While these parameters can be measured, there are some theoretical advantages that may be observed as well. Due to the maximal fill volume relationship of the shell and the gel, wrinkling is likely to be less of a problem. This may provide an advantage in patients with a thin soft tissue envelope where visible wrinkling in the implant could become problematic, thus compromising the quality of the aesthetic result. As well, if wrinkling were less common, the implant rupture rate might be reduced as one would expect that the shell over time would experience less stress. Long term study will be required to document the validity of these potential advantages.

\* Head-to-head compression benchtop testing between MemoryGel\textsuperscript{®} Xtra (n=4) and Natrelle Inspira (n=3).
\** Head-to-head blinded in-person tabletop product comparison (MemoryGel Xtra vs. Inspira Responsive vs. Inspira Cohesive) with 452 respondents.
CLINICAL CONSIDERATIONS

In my clinical experience, the advantages afforded by the MemoryGel® Xtra Breast Implant design can be most effectively realized in patients who present with thin skin envelopes, those who require a narrower base diameter for a given volume, and in those patients seeking additional projection.

CLINICAL CASES

CASE 1: Revision Augmentation

This 36-year-old woman presented with a history of undergoing a previous capsulectomy with placement of a 300 cc high profile smooth round implant as primary treatment for capsular contracture. She remained soft and demonstrated an aesthetic result, however, after several years presented requesting an increase in breast size (Fig 6 A,B).

Due to her thin soft tissue framework and her narrow breast base diameter, a MemoryGel® Xtra implant was chosen as the implant of choice for her revision. Pre-operative evaluation focused on using a 450 cc implant for her revision. Despite this significant increase in implant volume, a modest increase in base diameter from 11.1 to 11.9 cm was required to accommodate this new implant (Fig 6C). Her postoperative result demonstrated an aesthetic breast shape with the desired amount of upper pole fullness (Fig 6 D,E,F).

Figure 6 A, B: Preoperative appearance of a 36-year-old woman after capsulectomy and placement of a 300 cc high profile smooth round MemoryGel® Implant. The patient desires an increase in implant size.

Figure 6 C: Preoperative marks demonstrating a planned implant size increase from 300 cc to a 450 cc high profile MemoryGel® Xtra Implant with a minimal 8 mm increase in implant base diameter from 11.1 cm to 11.9 cm.

Figure 6 D, E, F: Postoperative 6 week result demonstrating an aesthetic breast shape with no excess upper pole fullness despite the increase in implant volume.
CASE 2: Primary Reconstruction

This 36-year-old woman presented with a strong family history of breast cancer along with positive at risk gene testing. She opted to proceed with bilateral nipple sparing mastectomy and immediate tissue expander and ADM breast reconstruction (Fig 7 A,B). After complete filling of her 13 cm expanders to 520 cc, she presented for second stage reconstruction. She desired a full augmented appearance to her breasts, therefore, a high profile smooth round MemoryGel® Xtra Implant with a 595 cc fill volume and a 13.1 cm base diameter was utilized as her implant of choice to complete her reconstruction (Fig 7 C). Her result demonstrates an aesthetic breast contour and the desired full rounded appearance to the breast (Fig 7 D,E).

SUMMARY

By precision filling MemoryGel® Xtra Breast Implants, a device that provides greater projection retention than the traditional MemoryGel® line, while maintaining a soft, pliable feel is created without dramatically changing the overall design and engineering of the device. This implant can be particularly useful in patients with thin soft tissue envelopes, patients who present with a narrow breast base diameter, and in those patients seeking extra projection. Theoretical advantages of decreased implant wrinkling and an improvement in the overall rupture rate may be realized, although long term study is necessary to document these potential advantages.
REFERENCES
5. Product Dimensions for MemoryGel and MemoryGel Xtra Breast Implants

IMPORTANT SAFETY INFORMATION:
MENTOR® MemoryGel® Breast Implants are indicated for breast augmentation in women at least 22 years old or for breast reconstruction. Breast implant surgery should not be performed in women with active infection anywhere in their body with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions or are pregnant or nursing.

Breast implants are not lifetime devices and breast implantation is not necessarily a one-time surgery. The most common complications with the MemoryGel® Breast Implants include reoperation, capsular contracture, asymmetry, and breast pain. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel-filled breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture.

Patients should receive a copy of Important Information for Augmentation Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants or Important Information for Reconstruction Patients about MENTOR® MemoryGel® Silicone Gel-Filled Breast Implants. Your patient needs to read and understand the information regarding the risks and benefits of breast implants, with an opportunity to consult with you prior to deciding on surgery.

For detailed indications, contraindications, warning and precautions associated with the use of MemoryGel® Breast Implants. Please refer to the Instructions for Use (IFU) provided with each product, or online at www.mentorwwllc.com.