A New Concept Breast Implant - Two-Year Follow-up Results in 472 Patients

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Abstract

Background: There is a need for a saline-filled implant that gives a natural result, since many women are more comfortable having saline in their breast implants than silicone gel. To address the well-known problems of current single-lumen saline implants, a new implant design was developed. It is a double-lumen with a baffle structure in the outer lumen that controls fluid movement to prevent bouncing, supports the upper pole to prevent collapse and the edges to minimize wrinkling.

Methods: An FDA clinical trial began February 2009, with 502 women enrolled by February 2010: 399 for primary augmentation and 103 for replacement of existing saline or silicone gel implants. Investigators were 45 ABPS certified plastic surgeons at 35 sites. A total of 472 patients completed 2-year follow-up visits, a rate of 94%.

Results: For the 472 patients with 2-year follow-up, patient satisfaction with the outcome was 94.3% for primary and 92.3% for replacement augmentations; surgeon satisfaction was 96.5% for primary and 93.4% for replacement augmentations. Adverse events were tabulated by Kaplan-Meier risk rates of first occurrence: Baker class 3 or 4 capsule contracture - 3.8% for primary, 8.2% for replacement augmentations; moderate to severe wrinkling - 3.8% for primary, 12.0% for replacement augmentations; deflation - 4.8% for primary, 3.3% for replacement augmentations. One deflation was from a surgical needle puncture and one was indeterminate because the implant was damaged after removal. All other deflations were due to early manufacturing defects that were identified and corrected.

Conclusions: Two-year data from 472 women indicates this new concept implant has a high rate of patient and surgeon satisfaction, with a low rate of wrinkling and capsule contracture. It may offer women an alternative to current single-lumen saline and silicone gel implants (Figures 1 & 2).

Figure 1 & 2. Comparison of implant shapes.