Investigational breast implant affords 'natural' look and feel in patients with minimal breast tissue

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New Orleans — The investigational Style 410 Cohesive Gel Breast Implant (Inamed) offers patients a "natural and proportional" look, but using this new device requires surgeons to look at breast augmentation in a new way. These observations were among the key benefits and challenges cited by one of the lead investigators, Bradley Bengtson, M.D. He reported on the findings at the American Society for Aesthetic Plastic Surgery (ASAPS) annual meeting here. Dr. Bengtson is in private practice at Plastic Surgery Associates in Grand Rapids, Mich., and he is associate program director at the Plastic Surgery Training Program, Grand Rapids. "Surgeons should look at implanting the 410 style implant as a brand new procedure similar to when they did their first SMAS facelift versus a skin-only facelift. The dissection is different, the anatomy is different and the results are different," according to Dr. Bengtson, who reported his phase 3 clinical results on 224 of the new implants — the largest current series with the Style 410 in the United States.

According to Dan Cohen, vice president, Inamed Corp., the Style 410 was not part of the premarket approval application (PMA) for Inamed's responsive silicone breast implant, which failed to win recommendation from a U.S. Food and Drug Administration (FDA) advisory panel in April (see related story, cover). The PMA application for the Style 410 implant was submitted to the FDA in December and is still under consideration, Mr. Cohen says.

Different requirements The Style 410, which is marketed internationally as the Bio-dimensional Cohesive-Gel Matrix, requires a hand-in-glove pocket dissection, with the incision best placed through an inframammary incision.

"The implant is textured, form-stable, holding its shape in all positions, and being shaped, it has to be placed perfectly vertically in the pocket," Dr. Bengtson says. "If you stick with the techniques that you're used to using with smooth, round saline or silicone implants you may find yourself in trouble. The implant has to fit the pocket perfectly so that it doesn't shift or rotate."

The procedure must be performed completely bloodless. "If there's no bleeding then not only can recovery be fast-tracked, but there's a decreased risk of hematoma or seroma that could allow the implant to shift or rotate," he explains.
Outcomes With an average 28 month follow-up (six to 40 months), no patient in the Style 410 series has required re-operation for implant-related complications. There have been no infections, no hematomas, no malpositions or rotations and no major Baker III-IV operative capsulectomies. Complications included four unilateral mild Baker II capsular contractions, two small superior pole seroma/hematomas that resolved and two 1.0 cm lateral skin dehiscence, which were closed. The only re-operations in the series were three patients, among the first 24, who elected to have a size change, and three patients who required repeat mastopexy for recurrent ptosis.

"I tell my patients that my goal for their breast augmentation is to put in the largest breast implant possible that's proportional to their breast and to their body to minimize the number of re-operations, for the implant to last as long as possible with the best cosmetic outcome with minimal complications," Dr. Bengtson says. "This implant really satisfies these goals better than any other. It's the best cosmetic result from the standpoint that it has the least edge palpability, it has no palpable wrinkling or rippling and it is soft, and with its low capsular contraction rate also softens with time. Style 410 breasts are so soft that they appear and feel natural in the vast majority of cases," he adds.

Patient selection Effective outcomes with the Style 410 require careful patient selection and education. "This implant is not the right choice for patients desiring over-augmentation. It should be used for patients who are looking for restoration of volume that's been lost, or augmentation that is proportional to their body," Dr. Bengtson says. "The implant – particularly the base width of the implant – should match the base width of the breast. In my practice, in the Midwest, it's a very easy 'sell,' because that's what most patients are looking for. For the most part, they are soccer moms who've had a couple of children and want restoration of the volume that they've lost." In Miami, Dallas or Hollywood, where "natural" and "proportional" may not be the goals, Dr. Bengtson points out, the Style 410 may not be the best choice.

"If your patient is a C and wants to be a D, it matters much less which type of implant you use, but if your patient has no breast tissue and is thin, the breast implant becomes the breast, so it is very important what the specific implant's characteristics are," Dr. Bengtson says. "If the patient is thin with no coverage, then any little imperfection, wrinkle, ripple or palpability can really show through. In these patients with very minimal breast tissue or no breast tissue, which is very common in my practice, you cannot beat the advantages and results of the Style 410 Cohesive Gel implant," he adds.