Long-Term Clinical Performance of MemoryShape™ Silicone Breast Implants in Breast Augmentation: Prospective Data Through 9 Years

David A. Caplin, MD; Janet M. Vargo, PhD; John Canady, MD; Dennis Hammond, MD

Purpose: The recent FDA approval of shaped, form-stable breast implants adds an important alternative to round gel implants for patients undergoing aesthetic breast surgery. The purpose of this analysis was to report key safety and efficacy outcomes associated with the Mentor MemoryShape™ (formerly Contour Profile Gel™, CPG™) through 9 years of use in women undergoing breast augmentation and revision surgery.

Methods: The MemoryShape™/CPG™ (NCT identifier NCT00812097) Core study is a non-randomized, open-label clinical trial designed to assess the long-term safety and efficacy of this device in women undergoing breast augmentation or reconstruction surgery. The cumulative incidence of complications and reoperations was estimated using the Kaplan-Meier (KM) method. Rupture rates were analyzed for patients with MRI scans at 1, 2, 4, 6, and 8 years postoperatively. Global patient satisfaction was assessed by asking the patient if she would decide to have breast implant surgery again.

Results: Overall, 56% of primary augmentation (N=572) and 61% of revision-augmentation patients (N=124) provided follow-up data at 9 years post-implantation. The cumulative 9-year estimated incidence rates for key complications by patient are summarized in Table 1. The incidence of capsular contracture III/IV remained below 5% in women who underwent primary augmentation through 9 years (Figure 1). Implant rotation rates were 1.1 (95% CI: 0.5, 2.4) in primary augmentation and 1.7 (95% CI: 0.4, 6.6) in revision-augmentation cohorts, respectively. The most common reasons for the 139 reoperations performed through 9 years in primary augmentation patients included breast mass/cyst (n=29), patient request for size change (n=16), and calcification (n=11), with breast mass and calcification generally associated with biopsies to assess potential breast cancer. Patient request for size change was the most common reason for reoperation among revision-augmentation patients (accounting for 7 of 45 reoperations). At the 9-year follow-up, 292 of 301 (97.0%) primary augmentation and 59 of 63 (93.7%) revision-augmentation patients indicated satisfaction.

Table 1. Kaplan-Meier Estimated Cumulative Incidence Rates of Key Complications Through 9 Years in Primary and Revision Augmentation

Kaplan-Meier Estimated Cumulative Incidence Rates Through 9 Years

Key Complications	Primary Augmentation (N=572)	Revision Augmentation (N=124)
Capsular Contracture III/IV	3.4 (2.1, 5.5)	15.6 (9.8, 24.4)
Infection	0.9 (0.4, 2.1)	1.9 (0.5, 7.4)
Implant removal with or without replacement	8.6 (6.4, 11.4)	23.1 (16.1, 32.5)
Any reoperation	21.2 (17.9, 25.0)	33.0 (25.0, 42.8)
Rupture* (MRI cohort)[†]	3.1 (1.3, 7.4)	9.9 (3.3, 27.7)
Cosmetic Complications[‡]		
Ptosis[¶]	5.1 (3.5, 7.4)	11.0 (6.2, 19.0)
Size change (patient request)	3.6 (2.4, 5.6)	11.7 (6.7, 20.1)
Wrinkling	2.8 (1.7, 4.7)	7.2 (3.6, 14.0)
Hypertrophic scarring	0.9 (0.4, 2.2)	0.9 (0.1, 6.1)
Asymmetry	0.7 (0.3, 1.9)	3.5 (1.3, 9.2)
Size change (physician assessment)	0.2 (0.0, 1.2)	2.7 (0.9, 8.2)

*By-patient rate, based on follow-up through patient's last MRI exam. The follow-up rate at 9 years was 51% for primary augmentation and 61% for revision-augmentation patients.
[†]N=252 for primary augmentation cohort. N=56 for revision-augmentation cohort.
[‡]Mild occurrences excluded with the exception of size change.
[¶]Single case reported in each cohort was severe.

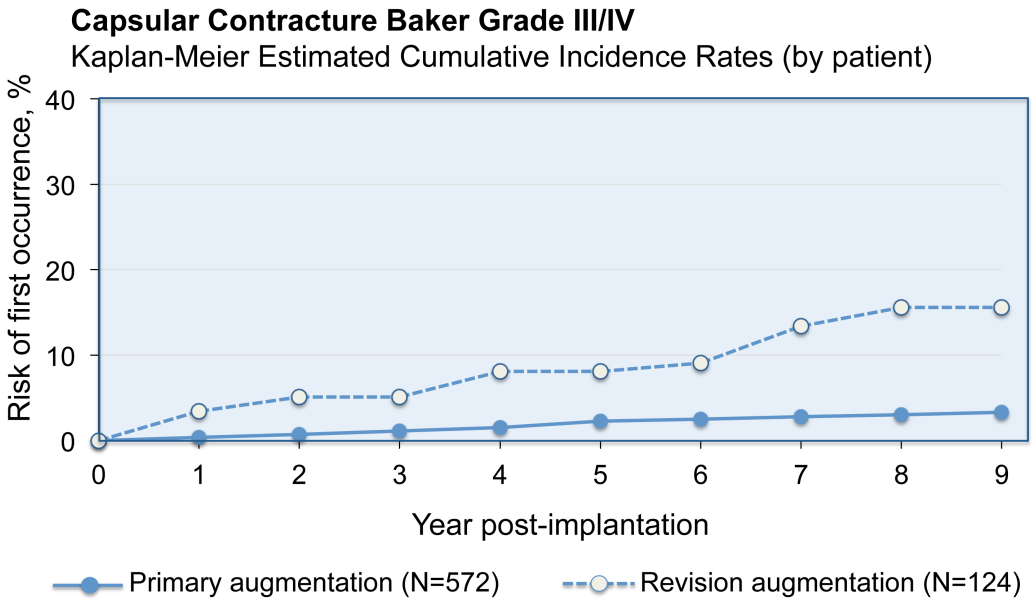

Figure 1. Kaplan-Meier estimated cumulative incidence rates of capsular contracture Baker Grade III/IV in primary and revision augmentation.

Conclusion: Prospective data through 9 years affirm excellent long-term clinical performance and high levels of patient satisfaction with shaped implants in women undergoing breast augmentation. In addition to lower rates of capsular contracture and rupture than their round counterparts, shaped gel implants are an important option for breast augmentation, particularly for patients with limited or no ptosis, constricted breasts, and those who prefer a natural slope to the upper pole of the breast.

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Dr. Caplin is a consultant and speaker for Mentor Worldwide LLC. Dr. Vargo is an employee of Mentor Worldwide LLC. Dr. Canady is an employee of and shareholder in Mentor Worldwide LLC. Dr. Hammond has received compensation for research from Mentor Worldwide LLC and Allergan; is a consultant for Musculoskeletal Transplant Foundation, Lifecell, and Surgical Specialties Corporation; and has a royalty agreement with Specialty Surgical Products, Inc.