

Shaped Versus Round Silicone Breast Implants: Are There Real Differences in Patient Outcomes?

John Canady, MD; Michael Schwiers, MS; Roger N. Wixtrom, PhD

Disclosure/Financial Support: Dr. Canady is an employee of and shareholder in Mentor Worldwide LLC. Michael Schwiers is an employee of Ethicon Endo-Surgery, Inc. Dr. Wixtrom is a consultant to Mentor Worldwide LLC.

INTRODUCTION: The recent introduction of shaped silicone breast implants in the United States has been accompanied by a certain degree of skepticism over whether there are real demonstrable differences in patient outcomes in comparison to round implants. In order to further inform such discussions, and to directly address the potential impact of surgeon-to-surgeon variability in technique, a comparative analysis was performed of the long-term incidence of infection, capsular contracture, reoperation and device removal among surgeons who participated in the pivotal clinical trials of both round and shaped silicone breast implants.

METHODS: Data from surgeons who simultaneously enrolled primary augmentation patients in both the MemoryGel® and MemoryShape™ Core Studies (prospective, non-randomized, open-label, multicenter clinical trials www.ClinicalTrials.gov NCT00753922 & NCT00812097) were analyzed by the Kaplan-Meier (KM) method with respect to the estimated cumulative incidence through 10 years. Z-scores were calculated to test for significance.

RESULTS: Three surgeons enrolled ten or more patients in both pivotal trials, including a total of 122 patients (range = 33-52) with MemoryGel® round devices and 74 patients (range = 11-48) with MemoryShape™ shaped devices. The 10-year cumulative incidence of contracture at the three surgeon's sites were 12.4%, 5.5% and 24% for the MemoryGel® round implants and 2.2%, 0% and 0% for the MemoryShape™ shaped implants, with the observed differences between round and shaped devices at each site of borderline significance ($p=0.053$), no significance ($p=0.14$) and significant ($p=0.001$), respectively. When the results for the three surgeons were pooled, the estimated cumulative incidence of contracture through 10 years was significantly different ($p=0.0005$) between the round implants (13.7%) and the shaped implants (1.4%). With the exception of a significantly lower ($p=0.007$) estimated cumulative incidence of reoperation for shaped versus round devices for one of the surgeons, no other significant differences between round and shaped devices with respect to the KM estimated cumulative incidence of infection, any reoperation, or device removal were observed for the individual surgeons or for the pooled results.

CONCLUSION: The findings through 10-years among primary augmentation patients of surgeons who participated in both the MemoryGel® round and MemoryShape™ shaped Core Studies are consistent with the corresponding overall findings of these studies that demonstrated a significantly lower contracture incidence for shaped (3.8%) versus round (12.1%) silicone breast implants ($p<0.0001$).