Impact of Surgical Approach, Together with Placement and Breast Implant Texturing, on Capsular Contracture: An Analysis of 10-Year Prospective Multicenter Data

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Introduction: The etiology of capsular contracture in association with breast implants is a multifactorial process. In addition to the increasingly well-recognized role of subclinical infection and biofilms, a number of single-site studies in recent years have focused on the potential impact of incision selection on capsular contracture outcomes and have drawn different conclusions on which surgical approach is associated with the lowest contracture incidence. In order to further inform the surgical options selection process, newly available information from a large prospective, multicenter clinical dataset has been analyzed.

Methods: Data from the MemoryGel™ Core Study, a prospective, non-randomized, open-label clinical trial [*www.ClinicalTrials.gov* NCT00753922] were analyzed at the implant level by the Kaplan-Meier (KM) method to evaluate the combined impact of the following variables on the estimated cumulative incidence through 10 years of Baker III/IV capsular contracture in primary augmentation: incision (inframammary, periareolar, transaxillary), placement (subglandular, submuscular/subpectoral) and texturing (smooth, textured [Siltex™]). This implant level analysis was based upon a total of 1,112 device placements within these categories.

Results: The cumulative incidence of capsular contracture over 10 years post-implantation, by combined categories of incision and placement, are provided in Figure 1 for smooth devices and in Figure 2 for textured devices. The most pronounced impact of the surgical options evaluated involved the selection of textured versus smooth implants for devices placed subglandularly, regardless of the incision, with a several-fold, statistically significantly lower estimated incidence of contracture observed with textured devices.

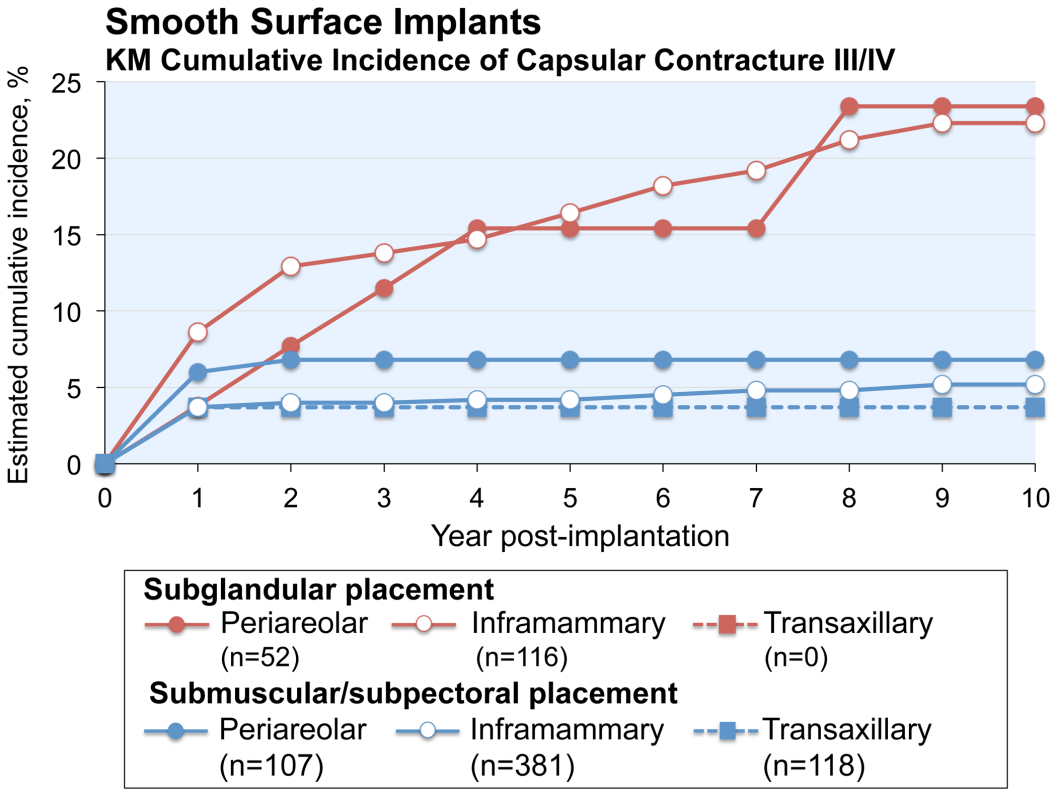

Figure 1. Kaplan-Meier estimated cumulative incidence of capsular contracture III/IV among primary augmentation patients with smooth surface implants.

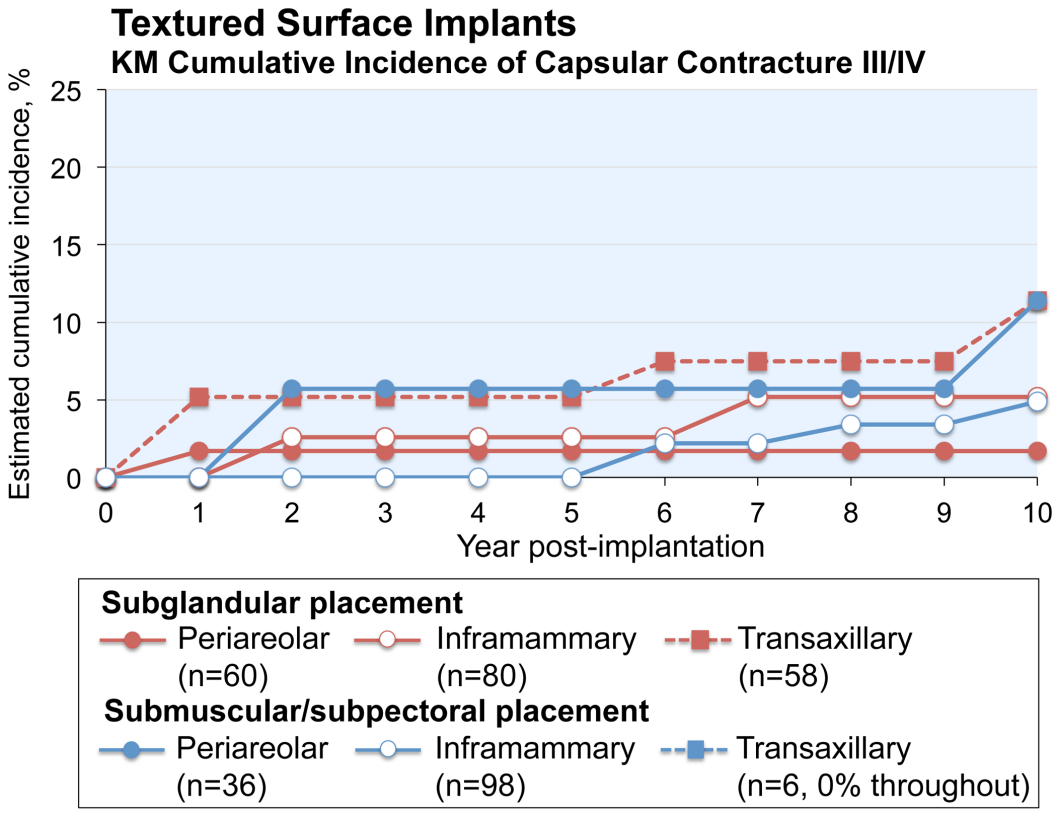

Figure 2. Kaplan-Meier estimated cumulative incidence of capsular contracture III/IV among primary augmentation patients with textured surface implants.

Conclusion: Analysis of 10-year, prospective, multicenter clinical data suggests similarly low long-term capsular contracture incidence rates are achievable with use of either smooth or textured devices, and any of the incision options, depending on the specific combination of surgical approach, placement and texturing selected. The data from this study also suggest that textured devices may produce a lower capsular contracture rate when used in the subglandular plane.

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