

Risk Factor Analysis for Capsular Contracture, Malposition, and Late Seroma in Subjects Receiving Natrelle Style 410 Form-Stable Silicone Breast Implants

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ABSTRACT

Purpose: This study analyzed potential risk factors for capsular contracture, malposition, and late seroma in subjects receiving Natrelle 410 textured silicone breast implants.

Materials and Methods: Pooled data from 2 similarly designed, ongoing, prospective, multicenter clinical trials of subjects receiving Natrelle 410 breast implants were analyzed. Univariate and multivariate Cox proportional hazards regression analysis was performed to evaluate the association of subject, implant, surgical, and facility factors with the development of capsular contracture, malposition, and late seroma in subjects who underwent primary breast augmentation, revision-augmentation, primary breast reconstruction, and revision-reconstruction.

Results: In total, 17,656 subjects received Natrelle 410 breast implants for augmentation (n=5059), reconstruction (n=7502), revision-augmentation (n=2632), and revision-reconstruction (n=2463); median follow-up was 4.1 years, 2.1 years, 2.6 years, and 2.3 years, respectively. Significant risk factors for capsular contracture in the primary augmentation cohort included subglandular device placement (strongest multivariate risk factor; adjusted risk ratio [aRR]: 2.89; $P<.0001$), older device age, and periareolar incision site (both $P<.0001$). In the primary reconstruction cohort, significant risk factors were higher body mass index (BMI) (aRR: 1.03; $P=.0026$) and absence of betadine pocket irrigation (aRR: 2.00; $P=.0006$). The only significant risk factor in the revision-augmentation cohort was older subject age (aRR: 1.47; $P<.0001$). No

significant risk factors were identified in the revision-reconstruction cohort. Significant risk factors for malposition included longer incision size in the primary augmentation cohort (aRR: 1.44; $P=.0003$) and capsulectomy performed at time of implantation in the primary reconstruction cohort (aRR: 1.55; $P=.0028$). In both revision cohorts, the risk was 2 to 3 times greater for implant surgeries performed in physicians' offices versus hospitals or stand-alone surgical facilities (both $P<.0001$). Risk of malposition was not associated with any subject- or device-related factors. The incidence of late seroma (31 cases out of 31,992 implants) was insufficient to perform a risk factor analysis. Twenty-nine cases occurred with submuscular placement, one with subglandular placement, and one was unknown; no trends were observed for subject age, BMI, incision site, or device size, style, or age.

Conclusion: These analyses reaffirm the low rates of complications in subjects receiving Natrelle 410 breast implants in primary and secondary surgical settings. Knowledge of the risk factors associated with capsular contracture and implant malposition offers additional guidance to surgeons for reducing complication rates and optimizing outcomes.