

Prospective Analysis of Primary Breast Augmentation on Body Image: Results from a Nationwide Study

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Purpose: A large, multicenter US study was conducted in 2006 as part of an FDA-mandated post-approval study of Natrelle[®] silicone-filled breast implants. Our purpose is to describe long-term patient-reported outcomes with primary breast augmentation, specifically to address changes in body image over time and by implant type: silicone gel versus saline-filled devices.

Methods: Primary breast augmentation patients enrolled in the prospective, multicenter study received 2 previously validated BREAST-Q scales measuring body image (satisfaction with breasts and psychosocial well-being). The surveys were administered preoperatively and at postoperative years 1 and 4. Scores were transformed to a 100-point scale, where a higher score indicated a better outcome. Student *t* tests and effect size calculations were used to evaluate differences in preoperative and postoperative mean scores.

Results: Of the baseline study population (N=17,899), 77.1% completed the preoperative questionnaire (12,061 silicone; 1,734 saline implants); the postoperative survey was completed by 71.1% of the sample at year 1 and by 46.2% at year 4 (data collection is still ongoing at year 4). Significant improvements are found in body image as measured by the 2 scales; satisfaction with breasts increased by a mean of 57.0 points (31.8 preoperatively to 88.2 at year 1, $P<.00001$), and psychosocial well-being increased by a mean of 30.2 points (59.6 preoperatively to 89.6 at year 1; $P<.0001$). Large effect sizes are noted for both satisfaction with breasts (2.0 at year 1; 1.8 at year 4) and psychosocial well-being (1.2 at year 1; 1.0 at year 4). The improvement in body image is largely stable over time (Figure). In comparing silicone implants with saline implants, mean scores of satisfaction with breasts and of psychosocial well-being are significantly higher at year 1 and at year 4.

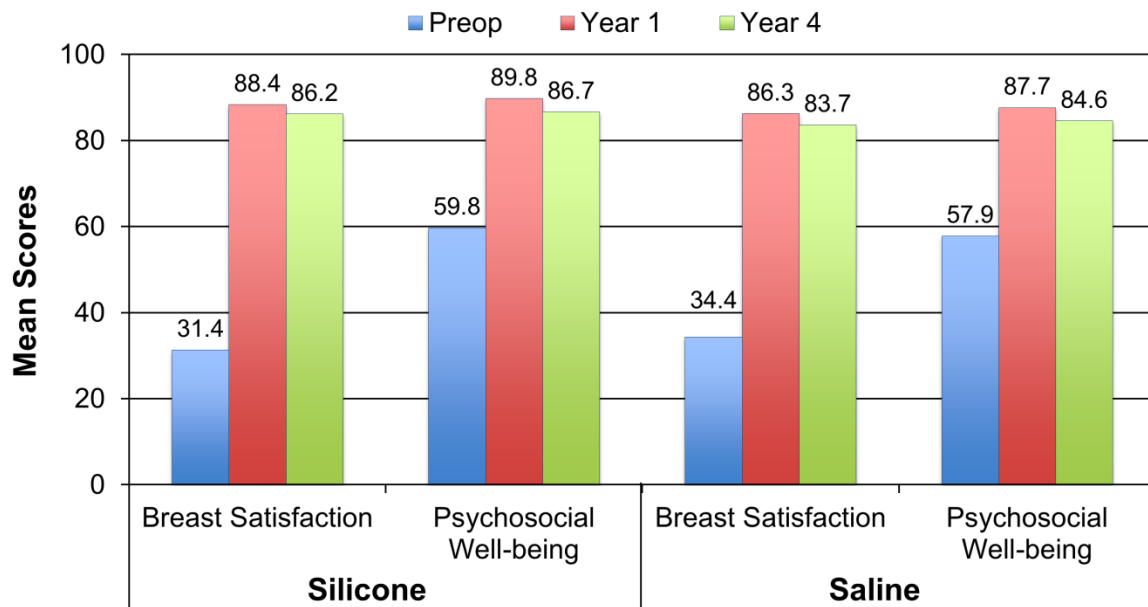


Figure. Subject satisfaction with breasts and psychosocial well-being with elective breast augmentation comparing subjects with silicone versus saline-filled devices preoperatively and at years 1 and 4 postoperatively.

Conclusions: Significant improvements in body image are found among women receiving breast augmentation with Natrelle silicone or saline-filled breast implants, and the results appear stable over time. Outcomes were better in those with silicone versus saline-filled devices; however, this may be of more statistical than clinical significance. These data support the effectiveness of these medical devices in improving women's quality of life.