Five-Year Safety Data From the Breast Implant Follow-up Study: Comparison of Silicone Implants With National Norms and Saline Implants in More Than 48,000 Subjects Following Breast Augmentation

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Purpose: A large, multicenter, 10-year study is being conducted as part of an FDA requirement for post-approval data on safety concerns, particularly systemic diseases, thought to be associated with silicone-filled implants.

Materials and Methods: This study compared long-term safety in women following primary breast augmentation or revision-augmentation using Natrelle silicone implants versus national norms and saline implants. Targeted long-term outcomes include connective tissue diseases (CTDs), neurologic diseases, cancer, and suicide. For adverse events (AEs) occurring at national norm rates of 2.85/100,000 person-years to 1.2/10,000 person-years, the silicone cohort was compared with national norms. Adjusted relative risk (RR) of AEs was calculated for silicone versus saline cohorts.

Results: 42,873 subjects underwent primary augmentation (29,148, silicone; 13,725, saline) and 6837 subjects underwent revision-augmentation (5901, silicone; 936, saline) and were included. After ≥5 years of follow-up (>128,000 person-years, augmentation cohort; >24,300 person-years, revision-augmentation cohort), target AE rates were not significantly greater for the silicone cohort versus national norms, including cervical/vulvar cancer (augmentation: 17.1 [90% CI: 11.6–24.4] events per 100,000 person-years; revision-augmentation: 4.1 [0.2–19.5]; national norm: 10.3), brain cancer (4.7 [2.0–9.2]; 4.1 [0.2–19.5]; 5.4), multiple sclerosis (7.4 [4.0–12.5]; 11.3 [3.1–29.1];

24.6), Sjögren syndrome (7.5 [4.1–12.7]; 11.5 [3.1–29.7]; 6.9), and lupus/lupus-like syndrome (6.7 [3.5–11.7]; 7.7 [1.4–24.1]; 54.4). No dermatomyositis/polymyositis, polyarteritis nodosa, relapsing polychondritis, or Wegener's granulomatosis events were confirmed; 1 confirmed case each of morphea and scleroderma occurred. Silicone implants did not put subjects at significantly greater risk for any target AEs versus saline implants. The adjusted RRs (90% CIs) for silicone versus saline implants were brain cancer: 1.45 (0.20–10.24) augmentation, 0.00 (0–0) revision-augmentation; breast cancer: 0.71 (0.48–1.04), 3.35 (0.54–20.67); cervical/vulvar cancer: 1.42 (0.63–3.21), 0.28 (0.05–1.69); lupus/lupus-like syndrome: 0.90 (0.31–2.60), 0.09 (0.01–0.75); mixed CTD: 1.26 (0.20-7.78), NA; rheumatoid arthritis: 0.90 (0.35–2.32), NA; multiple sclerosis: 0.50 (0.20–1.27), NA; and reported suicide attempts: 0.78 (0.62–0.99), 1.27 (0.54–2.99). Risk of death was similar with silicone versus saline implants (RR [90% CI]: 0.91 [0.66–1.26] augmentation; 0.88 [0.41–1.89] revision-augmentation). Fewer than 0.1% of subjects in each cohort committed suicide. No implant-related deaths occurred.
Conclusions: Results through ≥5 years of follow-up confirm the safety of Natrelle silicone implants, providing an unprecedented look at a large number of subjects. No increased risk of systemic diseases for silicone implants versus population norms or saline implants was observed.