Clinical Paper Summaries

Title: Preliminary 3-Year Evaluation of Experience with SilkSurface and VelvetSurface Motiva Silicone Breast Implants: A Single-Centre Experience With 5813 Consecutive Breast Augmentation Cases

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Summary: This real-world study looked at how frequently complications and reoperations occurred after Motiva SilkSurface (nanotextured) and VelvetSurface (micro-textured) implants were used. Most of the patients studied were breast augmentation patients, but others were mastopexy augmentation, implant replacement or mastopexy implant replacement patients. Nearly all surgical incisions were in the inframammary area, and the majority of patients had implants under their chest muscle. During the study, 0.76% of all patients suffered complications and needed reoperations, but nobody suffered late complications or capsular contractures. One group who received 300 to 499 cc SilkSurface implants had fewer complications than those who received 300 to 499 cc VelvetSurface implants. Therefore, Motiva® breast implants are very safe as very few patients have complications and need reoperations, especially if using nano-textured SilkSurface implants.

Study aim: To evaluate the safety of Motiva® Implants for breast augmentation.

Study objective: To evaluate the complication and reoperation rates in breast augmentations with the Motiva SilkSurface and VelvetSurface silicone breast implants.

Study design: Retrospective, single-center study over 3-years.

- **Number of patients**: 5813
- **Patient eligibility criteria**: Female patients who had breast implant surgery procedures with Motiva® Implants for primary augmentation, primary augmentation and mastopexy (breast lifting surgery), secondary augmentation (i.e. implant replacement), or secondary augmentation and mastopexy. Implant sizes ranged from 125-1050 cc.
- **Patient exclusion criteria**: None
- **Duration**: 3 years
- **Endpoints**: NA
- **Outcomes**: Primary outcomes were the rates of complications and reoperation following breast augmentation with Motiva® Implants.
- **Methods**: All surgeries were performed in a single centre by a group of 16 plastic surgeons. Only data from original devices implanted at the start of the study was included; if the

device was changed due to complications, the data from the replacement device was excluded. The sites for surgical incision (inframammary, periareolar, T mastopexy) and implant placement (submuscular, subglandular, dual plane) were chosen by the surgeon based on his patient's characteristics and preferences. Implant size, height and base diameter were selected by the patient, with advice from her surgeon. No insertion aids (e.g. a plastic bag or funnel) were used and the implant area was not washed with antibiotics or other solutions. At discharge, patients took oral antibiotics and painkillers for 7 days, wore compression bandages on the upper breast for 1 week followed by sports bras for 6 weeks, and avoided massage, exercise as well as laying on their stomachs for 3-4 weeks. A free, 3-year after-surgery care program was provided to ensure that patients were monitored and all adverse events were detected and resolved without cost to the patient. Patients were seen by their surgeons within 1 year of surgery to detect any complications.

Study analysis/AEs: Complication and reoperation data were analysed, and the chance that a complication would occur in a pre-determined range for all implant procedures, was calculated.

Study results summary:

- 4103 breast augmentations, 838 mastopexy augmentations, 698 implant replacements and 174 mastopexy implant replacements were analyzed.
- The patients ranged in age from 18 to 72 years old, with an average of 28.2 years.
- Inframammary incision sites were used in nearly all (97%) primary augmentations.
- The dual-plane technique and implantation under the pectoral muscle was used in the majority (79%) of cases. The implant was never placed under the fascia (connective tissue).
- Under half (43.1%) of patients received SilkSurface™ implants. 56.9% of patients received VelvetSurface™ implants. Two-thirds of patients (67.6%) chose implant volumes between 300 and 499 cc.
- The total reoperation rate was very low (0.76%).
- 44 complications arose, with infection after augmentation occurring most frequently. Early seroma after implant replacement occurred in only 1.51% of cases. The implants never failed due to rupture, while late seroma, persistent swelling, breast pain, rippling, capsular contracture (Baker Grade III/IV) in primary cases, and redness/rash were never detected.
- Most complications began in the first 10 weeks after implantation, and after 25 weeks, no further *increase* in complications occurred. After the 45th week, there were no further complications. After 1 year, over 99.2% of patients had no complications.
- VelvetSurface™ implants had higher complication rates with each type of breast surgery, and therefore a higher risk and overall incidence of complications (1.06%) than SilkSurface™ implants (0.36%). Significant differences in complication rates between these implants were seen only in patients with 300-499 cc implants, especially the VelvetSurface™ implants.

Study conclusions/outcomes/follow-up:

- These consistent, real-world results prove the safety of Motiva® implants in breast surgery.

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- The complication rates differed between the SilkSurface™ and VelvetSurface™ implants, but more complications were seen with the 300-499 cc VelvetSurface™ implants.
- There were no serious adverse events and no cases of capsular contracture (Baker III/IV) in primary augmentations, double capsules, late seromas or implant rupture causing device failure.
- The overall surgical revision rate for the same surgeon using a different, macro-texture, FDA-approved implant was 8.43%, much higher than the rates with Motiva® implants.
- SilkSurface™ implant's topography, lower roughness and multiple contact points may reduce complications, but this must be confirmed in long-term clinical studies.

Weaknesses/limitations:

- Because of its retrospective design, the results of this study had to be confirmed statistically. Prospective study data is required to further verify the clinical significance of these findings.

Key selling outcomes/messages:

Motiva® SilkSurface™ and VelvetSurface™ Implants are more compatible with tissues and cause minimal inflammation or inflammation-related complications such as capsular contracture, double capsules, and late seromas.

How/where would one use to explain/promote Motiva product: NA

Customer/Competitor comebacks/responses/objections: NA

Comparisons with competitor: NA