

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

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Abstract

Background: Silicone breast implants have been in use for breast augmentation for more than 50 years, but technological innovation has been lacking in implant design until recently.

Objectives: This study was designed to evaluate the complication and reoperation rates following breast augmentation utilizing the Motiva silicone breast implants.

Methods: This retrospective study evaluated the safety of Motiva implants in 5813 consecutive cases of breast augmentation. Implants with two different textured surfaces were evaluated: SilkSurface (nanotextured) and VelvetSurface (micro-textured).

Results: Implants were placed between April 2013 and April 2016. A total of 44 complications were reported, with an overall complication rate of 0.76%, and the rate of reoperation was 0.76% over an interval of 3 years. There were no late complications and no cases of primary capsular contracture. No differences in complication rates were observed because of the implant date. However, among patients who received implants 300 to 499 cc in volume, complication rates were significantly lower with SilkSurface compared with VelvetSurface implants. Advanced statistical analysis supported the validity of the low complication rate reported in this study.

Conclusions: Overall, these findings suggest that Motiva silicone breast implants are associated with very low rates of complication and reoperation, and that the nano-textured SilkSurface implant is associated with fewer complications than micro-textured implants.

Level of Evidence: 3

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The development of the first silicone breast implants in 1962 marked a pivotal advancement in plastic surgery. However, since Tom Cronin and Frank Gerow developed the first silicone breast implants with Dow Corning in that year, a debatable technological progress has been lacking in the ensuing 50 years. This shortcoming becomes even more apparent when it is contrasted with the advancements in other fields of medicine.

Silicone is a biomaterial that has been very widely utilized in medicine since before World War II. However, with the preponderance of research and novel developments in medicine, the original Dow Corning thick silicone elastomer outer shell device, filled with a silicone gel, does not differ significantly from the prosthesis available today.

Silicone gel-filled breast implants have been commercially available for decades, but were utilized outside the auspices of the FDA for 14 years, until 1976, when they were classified as a class III medical device. In 1992, the FDA declared a “voluntary” moratorium on the sale of silicone breast implants in the United States. Over a decade later, Allergan and Mentor obtained clearance to commercialize round silicone breast implants once again, followed by Sientra with round and shaped implants, and then Allergan and Mentor with their shaped devices. By 2006, these three manufacturers were free to operate in the U.S. market again. However, these devices have remained largely unmodified from their original technologies and carry the same risks for complications today as they did a decade ago.

In the same year of the FDA reintroduction of silicone breast implants (2006), a group of lead engineers from the silicone industry, along with experts from the field, embarked on developing new and improved silicone breast implants. These advanced concepts would incorporate a series of new features designed to update the technology and improve the safety and efficacy of silicone implants.

The objective of this paper is to evaluate the safety of Motiva Implants (Alajuela, Costa Rica) for breast augmentation, a group of surgeons at a single plastic surgery center analyzed the safety outcomes of nearly 6000 consecutive breast augmentation cases. Two surfaces of Motiva Implants were evaluated: SilkSurface and VelvetSurface. This article presents a preliminary report of 3 years of experience with over 11,000 units of Motiva Implants.

METHODS

This retrospective study evaluated the experience with Motiva Implant silicone breast implants for breast augmentation in consecutive patients over a 3-year interval. All procedures were performed in a single center (Dolan Park Hospital, Bromsgrove, England) by a group of 16 plastic surgeons. All patients provided written informed consent,

and this study was designed utilizing the principles of the Declaration of Helsinki. The primary outcomes of this study were the rates of complications and reoperation following breast augmentation utilizing Motiva Implants.

Study Participants

From April 2013 to April 2016, a total of 5813 consecutive female patients had breast surgery with Motiva Implants and were included in this analysis. The implant sizes utilized ranged from 125 cc to 1050 cc. There were no exclusion criteria. Study patients underwent one of four breast augmentation procedures: primary augmentation, primary augmentation with mastopexy, secondary augmentation (ie, implant replacement), or secondary augmentation with mastopexy.

This analysis included only data for the original devices implanted at baseline; if a previous implant was changed due to complications, the authors excluded the data of the replacement device.

Implants and Surgical Approach

Motiva Implants are gel-filled silicone devices available with two types of surfaces. The implants utilized in this study were either SilkSurface or VelvetSurface. Motiva Implants are available in a range of shapes, sizes, base diameters, and projections. Unlike most textured silicone breast implants, the surfaces of these Motiva Implants are manufactured under proprietary techniques utilizing negative imprinting with 3-dimensional (3D) technology. Motiva Implants SilkSurface is a hierarchical micro/nano surface that is engineered to optimize biocompatibility by structuring a uniform topography utilizing 3D imprinting on the polydimethylsiloxane (PDMS) material to build the outer shell of the breast implants. The manufacturing process for the SilkSurface is particle-free and utilizes no projection of foreign materials to create the surface topographies, allowing a uniform and controlled shell thickness. SilkSurface has been physically characterized utilizing the latest technologies such as scanning electron microscopy (SEM), 3D image topography, profilometry, and white light interferometer, and it has proven a consistent surface roughness of 4000 nanometers in average (Ra), a median height of profile of $13 \pm 2 \mu\text{m}$, a kurtosis value of 3.1 ± 0.4 , a skewness value of 0.4 ± 0.2 , and an average of 49,000 contact points per cm^2 , which shows a consistent distribution of the peaks providing increased contact points and as a result a contact angle of $131^\circ \pm 4^\circ$ (Figure 1). This contact angle shows how the topography increases hydrophobicity when compared with a smooth PDMS surface contact angle of less than $110^\circ \pm 4^\circ$.¹ The chemical composition of the SilkSurface has been X-ray photoelectron

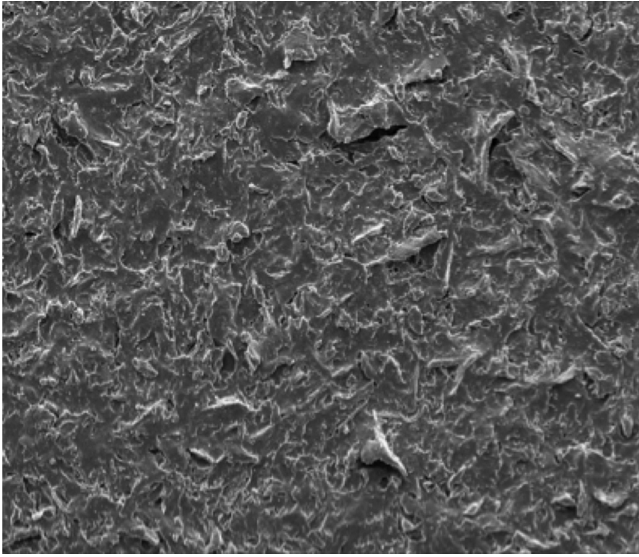


Figure 1. SilkSurface scanning electron microscopy (SEM) image at 300 µm scale.

spectroscopy (XPS) analyzed to assure an atomical level at which the production process of the PDMS does not affect the chemical properties. All of the surface properties from SilkSurface were designed to reduce the abrasion when the implant is in contact with the tissue by reducing fibroblast adhesion activity and complying with the design of micro/nano features that is better suited to an implant inside the body.^{2,3}

Motiva Implants VelvetSurface is a micro surface engineered to optimize biocompatibility by structuring a uniform micro-topography utilizing 3D imprinting on the PDMS material to build the outer shell of the breast implants. The manufacturing process for the VelvetSurface is also particle-free and utilizes no foreign materials projected or stamped, allowing a uniform and controlled shell thickness. VelvetSurface has been physically characterized similar to the SilkSurface and has proven a consistent surface roughness of $17 \pm 3 \mu\text{m}$, a median profile height of $57 \pm 15 \mu\text{m}$, a kurtosis value of 2.6 ± 0.3 , and a skewness value of 0.1 ± 0.2 , which shows a consistent distribution of the peaks providing increased contact points and, as a result, a contact angle of $119^\circ \pm 3^\circ$. This contact angle shows how the topography increases hydrophobicity (hydrophobic surfaces have contact angles $>90^\circ$ and are known to show higher biocompatibility) when compared with a smooth PDMS surface contact angle of less than $110^\circ \pm 4^\circ$. The VelvetSurface implant has 1800 to 2200 contact points per cm^2 , with a mean depth of 40 to 100 microns and a profile roughness parameter (Ra) of 7001 (Figure 2).

All surgeries were performed under general anesthesia. The incision site (inframammary, periareolar, T mastopexy) and the site of implant placement (submuscular,

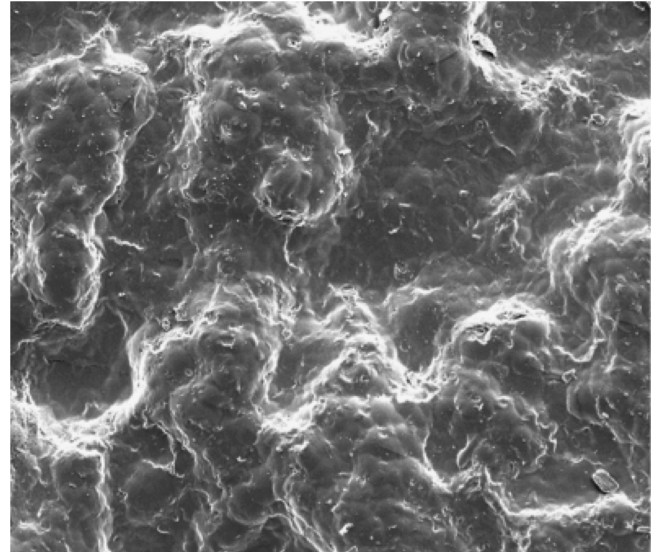


Figure 2. VelvetSurface scanning electron microscopy (SEM) image at 300 µm scale.

subglandular, dual plane) were selected by the treating surgeon based on patient characteristics and preferences. Implant size, projection, and base diameter were selected by individual patients, in consultation with the treating surgeon. The most commonly utilized approach was inframammary access, with subpectoral placement of the implant utilizing a dual-plane technique. No insertion device such as a plastic bag or funnel was utilized, and no pocket irrigation with antibiotics or other solutions was utilized. All patients were discharged with oral antibiotics for 7 days. Postoperative management included antibiotic and analgesic therapy for 7 days, and wearing compressive bandages on the upper pole for 1 week, followed by sports bras for 6 weeks, with no ventral decubitus or exercise for 3-4 weeks. No massage was recommended after surgery.

A free, 3-year postoperative care system was utilized to ensure patient follow-up and reporting of adverse events. Our aftercare scheme covers up to 3 years and includes any free revisions. The patients need to return within the first year to renew for the next 2 years; otherwise, the aftercare is voided. As previously stated, patients who fail to attend the mandatory appointments are persistently contacted and informed about the risks of losing the aftercare. All of the patients returned for the mandatory first-year follow-up, thus the 100% returning rate was achieved.

Statistical Analysis

The primary method of analysis for the complication and reoperation data was survival analysis utilizing the Kaplan-Meier product limit. To corroborate findings, the authors estimated the confidence interval (CI) for each complication for all types of procedures. In our analysis,

we utilized the Wilson score interval, which is more suitable for small probabilities than the normal approximation interval. However, we also provided the latter for comparison, because it is the standard technique utilized in most studies. If our assumption is correct, a CI indicates with a specified level of certainty that the true risk rate in the population will likely be in the estimated range. Whereas the standard CI or Wald interval approximates the distribution of error around the observed risk rate, the Wilson score interval yields an interval that is consistent with the observed risk rate at the specified confidence level. Therefore, no observed complication in a sample results in a standard CI that contains only 0, but the Wilson interval provides a no-zero upper bound of the risk rate that could have resulted in no complications due to randomness. This additional analysis is particularly important, because the study only reflects a preliminary 3-year experience.

RESULTS

Between April 2013 and April 2016, a total of 5813 consecutive female patients had breast augmentation with Motiva Implants. The study population included 4103 breast augmentations, 838 mastopexy augmentations, 698 implant replacements, and 174 mastopexy implant replacements. The group's age ranged from 18 to 72 years old, with an average of 28.2 years old \pm 10.98 (standard deviation).

Inframammary access was utilized in 97% of the primary augmentation procedures (3980 of 4103). Axillary access was not utilized in any cases. The dual-plane technique with subpectoral placement was performed in 79% of all cases (4592 of 5813). No subfascial placement was performed. The study comprises all patients operated in a 3-year interval. The minimum interval was 12 months, and the longest interval was 3 years and 6 months, with a mean of 23.03 months. Because of the postoperative care agreement, all patients had a follow-up appointment within 1 year with the same original surgeon when they were examined and diagnosed or not with complications. This is a retrospective study, so at the time of the examinations, surgeons were merely treating their patients to achieve the optimal outcome and they had no intention of collecting data for analysis.

A total of 2506 patients (43.1%) received SilkSurface implants and 3307 patients (56.9%) received VelvetSurface implants. Approximately two thirds of the participants (67.6%) selected implant volumes between 300 and 499 cc. Information about smoking habits was not collected, but smoking was not an exclusion criterion.

The numbers of patients by volume category and implant surface are shown in Table 1.

Table 1. Participants Receiving SilkSurface and VelvetSurface Motiva Silicone Implants, by Implant Volume Category

Volume (cc)	SilkSurface, N (%)	VelvetSurface, N (%)	Total, N (%)
0-299	310 (5.3)	612 (10.5)	922 (15.9)
300-499	1749 (30.1)	2182 (37.5)	3931 (67.6)
500-700	447 (7.7)	513 (8.8)	960 (16.5)
Total	2506 (43.1)	3307 (56.9)	5813 (100)

Complications

To examine complication rates arising from the different types of breast surgery performed with the Motiva Implants, we estimated the CIs and carried out a cumulative hazard function analysis. The statistical analysis of the overall risk rates describes the potential benefits of SilkSurface and VelvetSurface implants, whereas the hazard function provides a more detailed account of the incidence of complications.

The reported complications and associated risk rates are listed in Table 2. A total of 44 complications were identified (0.76%). The most prevalent complication was infection following breast augmentation ($n = 7$), whereas early seroma with implant replacement had the highest risk rate (1.51%). There was one case of implant rupture that was analyzed, and a metal injury of the device was verified. Therefore, there was no reported implant rupture for device failure. There were no reported occurrences of late seroma, persistent swelling, breast pain, rippling, capsular contracture (Baker Grade III/IV) in primary cases, or redness/rash. All patients were reviewed 24 hours and 1 week after their surgery. A low rate of hematomas was found, which could be attributed to the experience of the surgeons, because no special technique was applied to the surgery. No significant difference in the hematoma rate was found among the two types of the surfaces.

The total reoperation rate was 0.76%. The resulting 95% Wilson CI was 0.56% to 1.01%. Thus, assuming a 5% significance level, the highest rate that our result is consistent with is 1.01%. In addition, the power of our test to detect risk rates of 1.02% or 1.10% are 62% and 80%, respectively. Therefore, we can infer that it is highly unlikely that the "true" complication rate of our method is larger than 1.10%, thus we observed such a low risk rate only by chance.

Because we have not observed any late seroma, persistent swelling, breast pain, rippling, capsular contracture, and redness, we can have confidence that the overall risk rate of these complications across implant types and procedures is between 0.0% and 0.07%. However, for specific procedure and implant types, it is possible that we could observe higher risk rates in different samples (Table 2).

Table 2. Complication Rates Following Primary Breast Augmentation or Mastopexy Augmentation, or Secondary (ie, Implant Replacement) Breast Augmentation or Mastopexy Augmentation Using Motiva Implants

Implant surface	Primary augmentation, % (95% CI), [critical rate]		Implant replacement, % (95% CI), [critical rate]		Primary mastopexy augmentation, % (95% CI), [critical rate]		Mastopexy implant replacement, % (95% CI), [critical rate]	
	Silk	Velvet	Silk	Velvet	Silk	Velvet	Silk	Velvet
N	1765	2338	301	397	361	477	75	99
Early seroma	0	0.13 (0-0.27) [0.38]	0.33 (0-0.98) [1.86]	1.51 (0.31-2.71) [3.26]	0	0.42 (0-1.0) [1.52]	0	1.01 (0-2.98) [5.5]
Infection	0	0.30 (0.08-0.52) [0.62]	0	0.25 (0-0.74) [1.41]	0.28 (0-0.82) [1.56]	0.21 (0-0.62) [1.18]	0	0
Hematoma	0	0.04 (0-0.13) [0.24]	0	0.50 (0-1.20) [1.81]	0	0.42 (0-1.0) [1.25]	0	0
Wound dehiscence	0.11 (0-0.27) [0.40]	0.04 (0-0.13) [0.24]	0.66 (0-1.58) [2.39]	0	0.55 (0-1.32) [1.99]	1.26 (0.26-2.26) [2.72]	0	0
Rupture	0	0	0	0	0	0.21 (0-0.62) [1.18]	0	0
Implant malposition	0	0	0	0.25 (0-0.74) [1.41]	0	0	0	0

SilkSurface vs. VelvetSurface

The overall complication rate with SilkSurface implants was 0.36% (95% CI, 0.19% to 0.68%). By comparison, the complication rate with VelvetSurface implants was 1.06% (95% CI, 0.76% to 1.47%). Because the CIs for the two implant surfaces do not overlap, we can conclude that SilkSurface implants have a significantly lower total risk rate than VelvetSurface implants.

We also compared the risk rates for complications that occurred with both SilkSurface and VelvetSurface implants (Table 2). In this analysis, the CIs of the risk rates for specific complications do overlap. Therefore, we cannot exclude the possibility that in another sample, the complication rates with the two implant types could be the same or that the other implant could have a lower rate than in this sample. Nevertheless, we observed that VelvetSurface implants had higher complication rates for each type of breast surgery, contributing to their higher overall risk rate.

Hazard Functions and Risk Rates for Complications

To examine the incidence of the complications over time, we analyzed the Kaplan-Meier hazard rates for different implant types, implant sizes, and dates of insertion. The cumulative hazard function shows the expected number of complications (rate times total number of patients) up to a given postsurgical week. The increments of the cumulative hazard function provide information about the underlying hazard function; if the slope is increasing, it means that the complication rate is rising, and complications are more likely to occur during time periods with steeper slopes. When the line is flat, no complications occur.

Kaplan-Meier analysis was conducted on the entire sample (Figure 3). The analysis reveals that the hazard function is steepest in the first 10 weeks after implant placement, which indicates that most of the complications occurred in this period. By 25 weeks after implant placement, a further increase in complications is minimal, suggesting that there were very few complications after this time point. Following the 45th week, the hazard rate is flat (ie, no further complications occurred). The cumulative hazard rate at this point is 0.76%, indicating that more than 99.2% of patients did not have any complication up to 1 year, which was the last follow-up visit in this analysis. Although it is possible that more complications occurred after this period, it is very unlikely that the overall hazard rate increased significantly, given the shape of the cumulative hazard function.

Analysis by Date of Insertion

The analysis revealed no apparent differences between groups regarding the date of implant insertion (ie, 2013-2014 vs 2015-2016). Therefore, the authors decided to expand the analysis comparing these groups. Utilizing Kaplan-Meier analysis, the complication rates were 0.81% and 0.70% for insertions performed in 2013-2014 and 2015-2016, respectively. The difference between these two rates was not significant, and the incidence of complications in the two groups was similar (Figure 4). Therefore, at the 5% significance level, we cannot reject the null hypothesis that the two groups have the same risk rate. Finally, test statistics did not identify a significant difference in complication rates between groups ($P = 0.64$ in all tests). Therefore, we statistically conclude that the risk rates and hazard curves are the same for Group A (insertion in 2013-2014) and Group B (insertion in 2015-2016), which enable us to compare different cohorts of the sample.

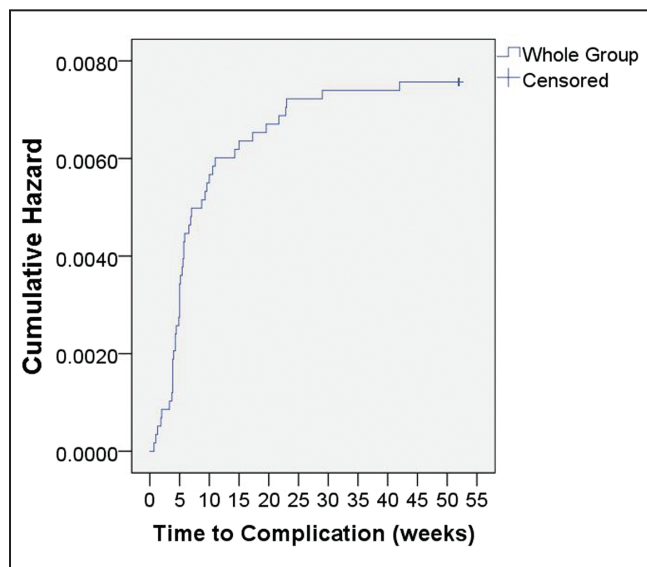


Figure 3. Kaplan-Meier cumulative hazard rate of the entire patient sample (N = 5813). The hazard function increases most in the first 10 weeks following implant placement, indicating that most complications occurred during this period. After 25 weeks, a further increase in the complication rate is minimal, indicating that very few complications occurred after this time.

Analysis by Implant Surface Type

In addition, we evaluated the difference in hazard rates between SilkSurface and VelvetSurface implants for different implant volumes. Significant differences in complication rates between SilkSurface and VelvetSurface implants were identified only in participants who received implant volumes 300 to 499 cc (Table 3). This result was significant even when following adjustment for significance level with Bonferroni correction to account for multiple tests (comparison of overall hazard rates between SilkSurface and VelvetSurface implants, between different insertion dates, and between three different implant volumes). In contrast, the increments in cumulative hazard rates for the SilkSurface and VelvetSurface implants are very similar for the smaller and larger implant volumes (Figures 5 and 6), whereas those in the cumulative hazard functions are markedly different for SilkSurface and VelvetSurface implants with mid-sized volumes of 300 to 499 cc (Figure 7).

The obtained results are compatible with the surgeons' expectations in relation to minimal rates of complications throughout the years (Figures 8 and 9).

DISCUSSION

Fifty-four years after the development of the first breast implant, surgeons are still faced with high complication

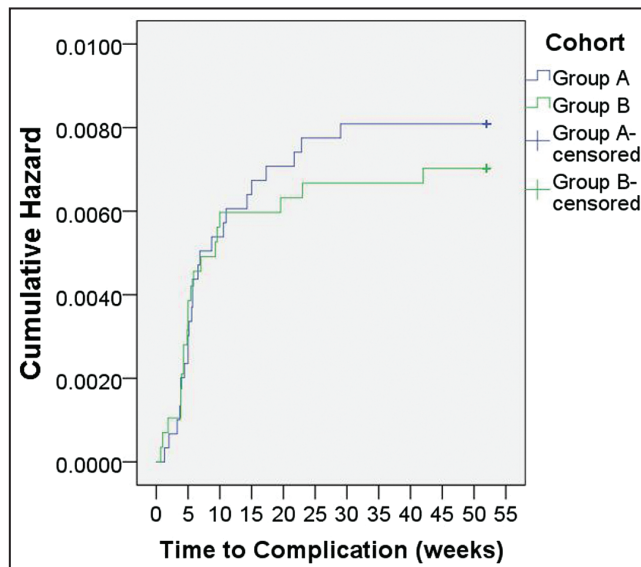


Figure 4. Kaplan-Meier hazard complication rates for patients with implant placement performed in 2013-2014 (Group A) and 2015-2016 (Group B).

and revision rates when utilizing most commercially available silicone breast implants. Indeed, the 3-year core studies from the FDA-approved manufacturers revealed high reoperation rates, even for primary augmentations. For example, Sientra's overall reoperation risk rate in 3 years was 12.6%,⁴ Mentor's was 15.4%,⁵ and Allergan's was 23.5%.^{6,7} These high reoperation rates signify a clear unmet need for technological innovation to improve the safety and durability of silicone breast implants.

The Motiva Implants are a novel breast implant technology. The authors believe that the properties of the surfaces of the implants were more relevant to the outcomes; however, they acknowledge that data about the gel should also be incorporated in future studies.

The results of this 3-year experience demonstrate excellent safety outcomes with the Motiva Implants in breast surgery. There were no serious adverse events and no cases of implant rupture for device failure, capsular contracture (Baker III/IV) in primary cases, double capsules, or late seromas. The authors presented consistent real-world data and they strongly believe that their free, 3-year aftercare system is a strong method for patient retention and follow up, because the financial commitment with the model compels the patients to return for follow-up consultations if any issues occur. Anecdotally, the same group of surgeons utilizing the same aftercare system for the last 7 years reported substantially different results utilizing other types of silicone breast implants (ie, non-Motiva Implants). The

Table 3. Statistical Comparisons of Hazard Rates for Complications by Implant Surface (SilkSurface VelvetSurface) and Category of Implant Volume

Implant volume (cc)	Complications, N (%)	Test	Chi-square	P value
0-299	SilkSurface: 310 (5.3) VelvetSurface: 612 (10.5)	Log rank (Mantel-Cox)	0.913	0.339
		Breslow (Generalized Wilcoxon)	0.919	0.338
		Tarone-Ware	0.916	0.338
300-499	SilkSurface: 1749 (30.1) VelvetSurface: 2182 (37.5)	Log rank (Mantel-Cox)	12.170	<0.001
		Breslow (Generalized Wilcoxon)	12.164	<0.001
		Tarone-Ware	12.167	<0.001
500-700	SilkSurface: 447 (7.7) VelvetSurface: 513 (8.8)	Log rank (Mantel-Cox)	0.185	0.667
		Breslow (Generalized Wilcoxon)	0.185	0.667
		Tarone-Ware	0.185	0.667

The only statistically significant difference between the Velvet and Silk surface implants was in the volume category 300 to 499 cc.

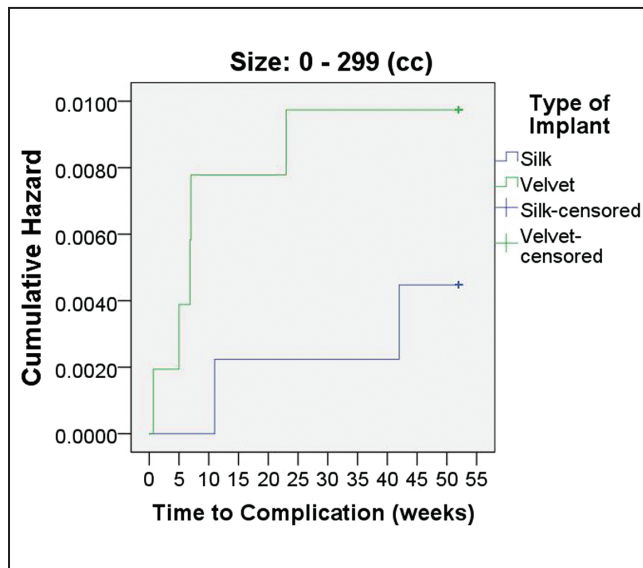


Figure 5. Kaplan-Meier hazard rates for patients implanted with small-sized (0-299 cc) SilkSurface and VelvetSurface Motiva Implants.

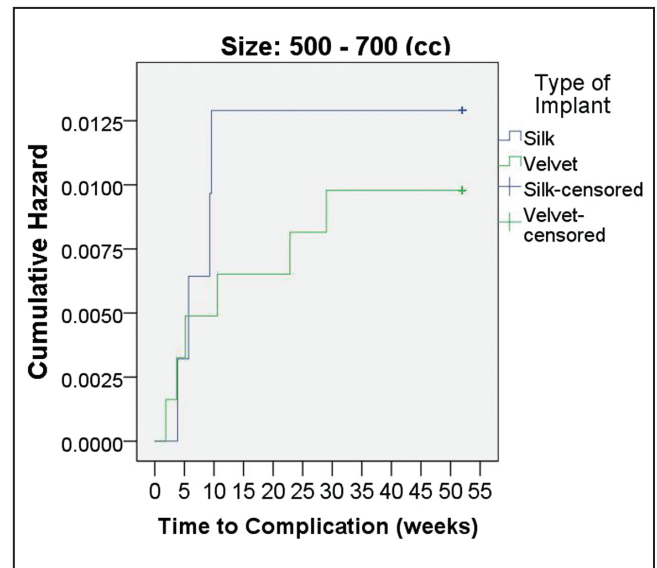


Figure 6. Kaplan-Meier risk rates for patients implanted with large-sized (500-700 cc) SilkSurface and VelvetSurface Motiva Implants.

overall revision rate for this group from 2010 to 2013 utilizing a different, macro-texture, FDA-approved implant (N > 10,000) was 8.43 %, which is more than an order of magnitude higher than the rate reported in this analysis.

Statistical Analysis and Confirmation

Because of the very low revision rate identified in this analysis (<1%), we applied statistical analyses beyond the standard Kaplan-Meier risk analysis to confirm the clinical relevance of our results.

Survival analysis determines the expected time until an event occurs.⁸ These estimates are clinically useful, particularly when counseling patients regarding

the incidence and timing of potential complications. The hazard function at a given time specifies the rate at which patients experience a complication, given that they have not had any complication up to that time. It is usually more informative to see how the hazard rate changes over time, which we can see from the cumulative hazard. In our study, we verified that a plateau in hazard rates occurred in every group after 25 weeks, independent of the surgery or implant, indicating that there was no further increase in complications after this time.

Furthermore, we analyzed the complication rates over the entire follow-up period. This analysis allows for the comparison of risk rates between different groups. Because

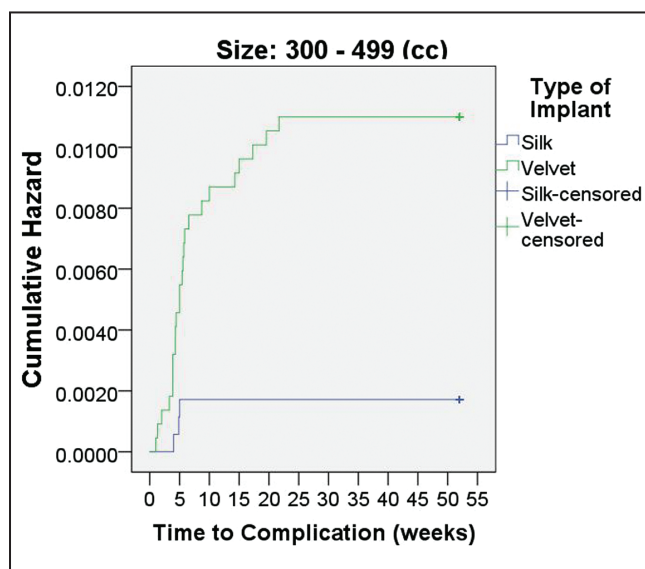


Figure 7. Kaplan-Meier hazard rates for patients implanted with mid-sized (300-499 cc) SilkSurface and VelvetSurface Motiva Implants.

the risk rate is a random variable, it changes from sample to sample.⁵ Therefore, we estimated the Wilson CI, which provides the upper bound of the risk rate that is consistent with our sample.⁹

The Role of New Surfaces in Breast Implant Safety

Capsular contracture and implant rupture are two of the most important potential adverse outcomes of breast augmentation, and contracture is the most common reason for revisional surgery.¹⁰ Many studies have reported relatively high rates of capsular contracture, particularly with smooth (non-textured) implants. For example, a 6-year outcomes study of Inamed silicone breast implants in 940 patients (half of whom were augmentation patients, most of whom received smooth implants) reported a capsular contracture rate of 15% to 20% and an implant rupture rate of 3.5%.¹¹ Long-term studies and meta-analyses comparing smooth and textured implants have reported a significantly higher risk rate for capsular contracture with smooth vs textured implants.¹²⁻¹⁵

Texturing of silicone breast implants was originally developed to optimize implant positioning and minimize capsular contracture. However, the aggressive texturization utilized in the manufacture of many implants has been associated with risk for seroma and double capsule formation.¹⁶ Furthermore, many textured implants are still associated with a reduced but significant rate of capsular contracture. For example, a 5-year follow-up study of 1010 textured silicone breast implants reported a 6.6%

rate of capsular contracture in the overall study population, and a Kaplan-Meier risk of contracture of 10.7% following primary augmentation.¹⁷ At 5 years, 8.5% of implants were removed following primary augmentation. A second study reported an 8% rate of capsular contracture at 9 years following implantation of form-stable textured silicone implants.¹⁸ These studies suggest somewhat improved risk for contracture with implants with textured surfaces, but many patients remained at risk for this adverse outcome.

The Motiva SilkSurface and VelvetSurface silicone implants utilized in this study were created utilizing novel technologies. Rather than being aggressively textured with the projection of salt or sugar crystals onto the implant, like many other implants, the surfaces of the Motiva Implants are obtained utilizing negative imprinting with 3D technology. The resulting surfaces have very low roughness parameters and promote a more natural interaction between the implant and the surrounding tissues, potentially reducing inflammation in the postoperative period and chronic inflammation after recovery. This improved interaction with native tissues may limit the risk for capsular contracture and allow the implant to better adapt to the normal movement of the breast. When held, these implants feel smooth. However, the high number of contact points may act to prevent fibroblast aggregation and capsular contracture.

Interestingly, the current study clearly identified a difference in the complication rates between the SilkSurface and VelvetSurface implants, and a significantly higher rate of complications with the VelvetSurface implants in the 300 to 499 cc volume category. In 2013, Bayat et al¹⁹ reported a significant effect for surface texture on cell behavior, and they clearly demonstrated that cells adhere more strongly to textured implant surfaces. This finding suggests that cells exhibit greater adhesion in the presence of numerous surface characteristics, such as density of points of contact or topographies, surface roughness, and contact angles. The hierarchical micro/nano-topographical structure of the SilkSurface implant, together with its lower roughness and increased number of points of contact, may have helped with the significant reduction of complications. This possibility requires confirmation in future studies. However, Langer et al²⁰ already established that nano-scale roughness has profound effects on cells, especially when designing new materials (and surfaces) for biological interaction.

Moreover, in 2015, Bayat et al²¹ proposed that surfaces with topographies closer to cellular dimensions produce an attenuation of the acute foreign body reaction. In the current study, the absence of late seromas and primary capsular contracture over a 3-year period was probably



Figure 8. (A, C, E) Preoperative photographs of this 22-year-old woman. (B, D, F) Postoperative photographs taken at 12 months. She underwent bilateral breast augmentation surgery using VelvetSurface 315 cc implants, inserted on a dual-plane type 2.

demonstrated by the surfaces of the hierarchical micro/nano topographies. The correlation of this new exclusive topography of the SilkSurface implants and the reduction

in the foreign body reaction is a promising theory that must be validated by long-term clinical studies.



Figure 9. (A, C, E) Preoperative photographs of this 26-year-old woman. (B, D, F) Postoperative photographs taken at 12 months. She underwent bilateral breast augmentation surgery using SilkSurface 335 cc implants, inserted on a dual-plane type 2.

New Technology Promise and Limitations of the Study

Motiva Implants (SilkSurface and VelvetSurface) were engineered to optimize biocompatibility by structuring

uniform hierarchical micro/nano and micro-topographies utilizing a proprietary 3D nanotechnology imprinting on the PDMS material, in order to build the outer shell of the breast implants. These surfaces were designed to improve compatibility between implants and tissues, minimizing

inflammation and possibly, as this study shows, inflammation-related complications such as capsular contracture, double capsules, and late seromas. The manufacturing process for both surfaces is particle-free and utilizes no foreign particle projection to create the surface, allowing a uniform and controlled shell thickness. Motiva Implants SilkSurface and VelvetSurface have a high-performance membrane (TrueMonobloc), which integrates all components of the implant in the same tensile force, surpassing the strictest mechanical specifications of international quality standards.

The shell has a patented barrier layer indicator that ensures the presence of layer-barrier technology, which minimizes the diffusion of silicone gel to the tissues. These devices are 100% silicone gel-filled with controlled viscosity and elasticity, designed to prevent gel fracture, simulate the appearance and natural feel of the breasts, and reduce complications such as ripples and furrows. A particular characteristic of Motiva implants is the presence of an FDA-cleared radiofrequency microtransponder for unique device identification, which can be accessed externally after implantation for traceability purposes.

Prospective studies are the gold standard of research, and the retrospective design utilized in this study is its main limitation. We utilized advanced statistical analysis to explore the significance of our data in an attempt to confirm the clinical significance of the findings. Future studies should utilize a prospective, randomized design to prevent the introduction of bias.

CONCLUSIONS

The Motiva silicone breast implants utilized in this study demonstrated an excellent safety profile, with very low rates of early complications and no late complications. There were no cases of device-related implant rupture, no cases of primary capsular contracture (Baker III/IV), no double capsules or late seromas, and a very low rate of reoperation. The hierarchical micro/nano-topographical surface of the SilkSurface Motiva Implants appears to be associated with significantly lower complication rates.

Disclosures

Dr. Sforza serves as coordinator of the Medical Advisory Board, has a consulting agreement with Establishment Labs Holdings, Inc., is a US clinical trial investigator, has received an option grant in September 2016 for 36,953 Class A Ordinary Shares in Establishment Labs Holdings, Inc., and the author's institution on April 17, 2014 entered into a Supply Agreement with Establishment Labs Holdings, Inc.

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