



Motiva[®]
Key Papers

THE SURFACE TOPOGRAPHY OF SILICONE BREAST IMPLANTS MEDIATES THE FOREIGN BODY RESPONSE IN MICE, RABBITS AND HUMANS, DOLOFF ET AL, 2021

Published in

nature
biomedical engineering

SmoothSilk[®] Surface

This renowned study analyzes how different breast implant surfaces impact the body's immune response.



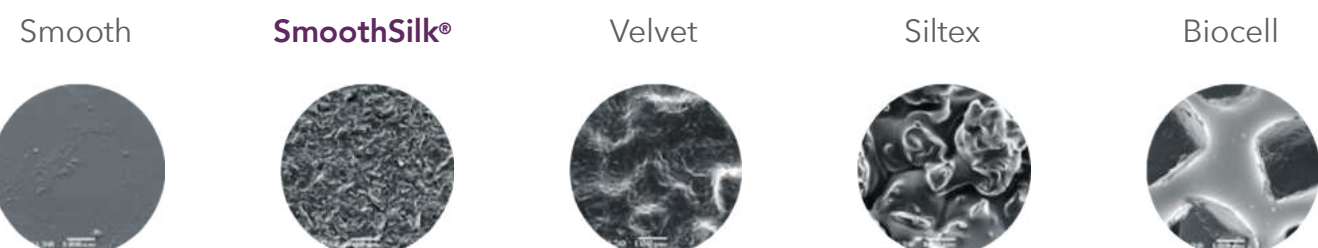
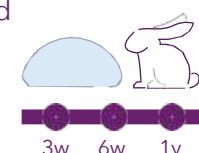
A HIGHLY ACCESSED, LANDMARK RESEARCH PAPER WITH AN IMPACT FACTOR OF, 29.234

Key Outcomes

- The surface architecture of the breast implants is an influential factor in altering the way in which the body's immune system responds.
- Among the surfaces tested the Motiva[®] SmoothSilk[®] surface provoked the least amount of inflammation and foreign body response, resulting in a low fibrotic capsule, thus reducing the risk of device-related complications such as capsular contracture.
- Motiva Implants[®] significantly demonstrated the lowest capsule thickness across all devices tested in the study.
- Motiva SmoothSilk[®] implants have enhanced biocompatibility, demonstrating a higher presence of anti-inflammatory cytokines, the lowest level of macrophages and an increased level of regulatory T-cells among the four other surfaces tested.

Animal Models

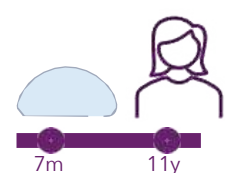
Human sized



Miniaturized



Human Cases

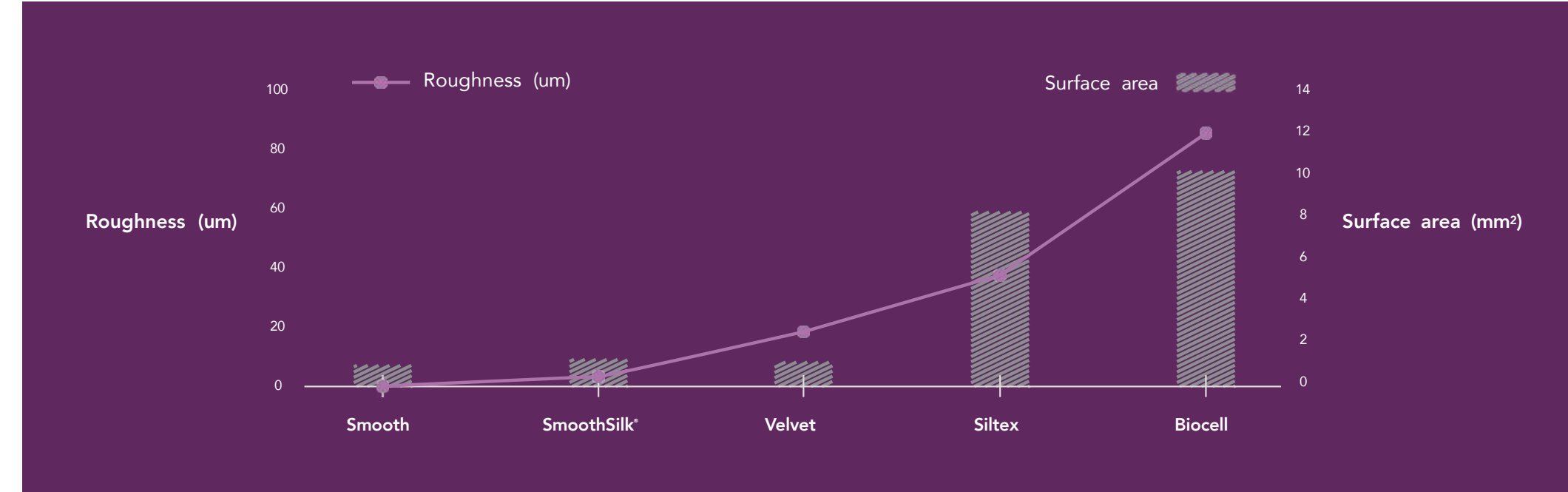


SmoothSilk® Surface

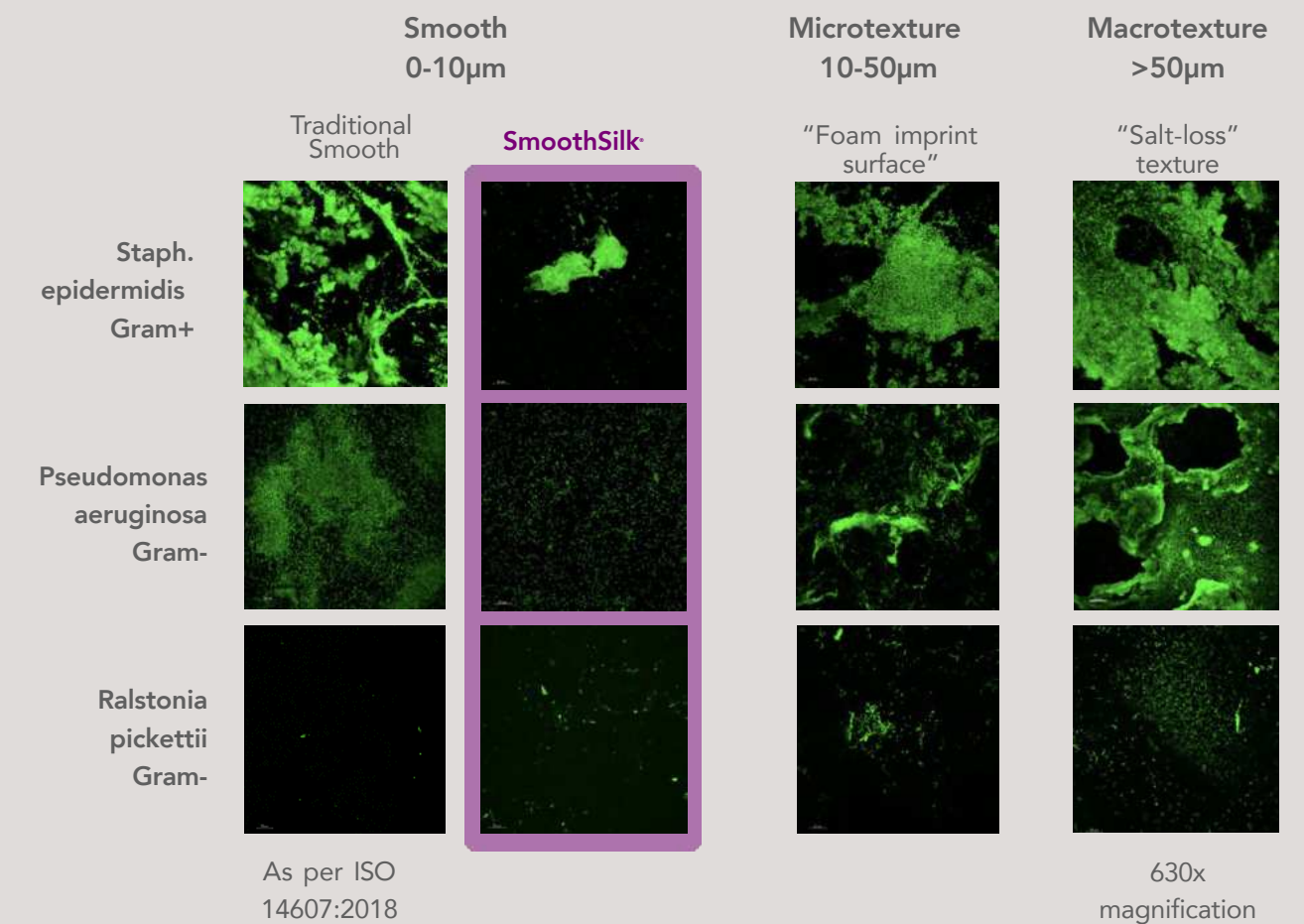
This study compares bacterial attachment and biofilm formation with Smooth, SmoothSilk®, Microtextured and Macrot textured breast implants.

Key Outcomes

- Bacterial biofilms have been associated with breast implant complications such as capsular contracture, double-capsule formation, and BIA-ALCL.
- Microtextured and Macrot textured surfaces harboured significant levels of bacteria, therefore increasing the risk of developing device-related complications as listed above.
- **SmoothSilk® demonstrated less bacterial growth in comparison to Traditional Smooth, Microtextured, and Macrot textured surfaced implants.**
- **The breast implant surface plays an influential role in the body's immune response with the SmoothSilk® 4-micron surface demonstrating a positive effect in comparison to the other surfaces studied.**



SmoothSilk®: Bacterial Attachment



SmoothSilk® Surface

This study analyzes the relationship between the surface area, surface roughness and bacterial growth of 11 breast implants varying in surface type for the purpose of identifying a new surface classification.

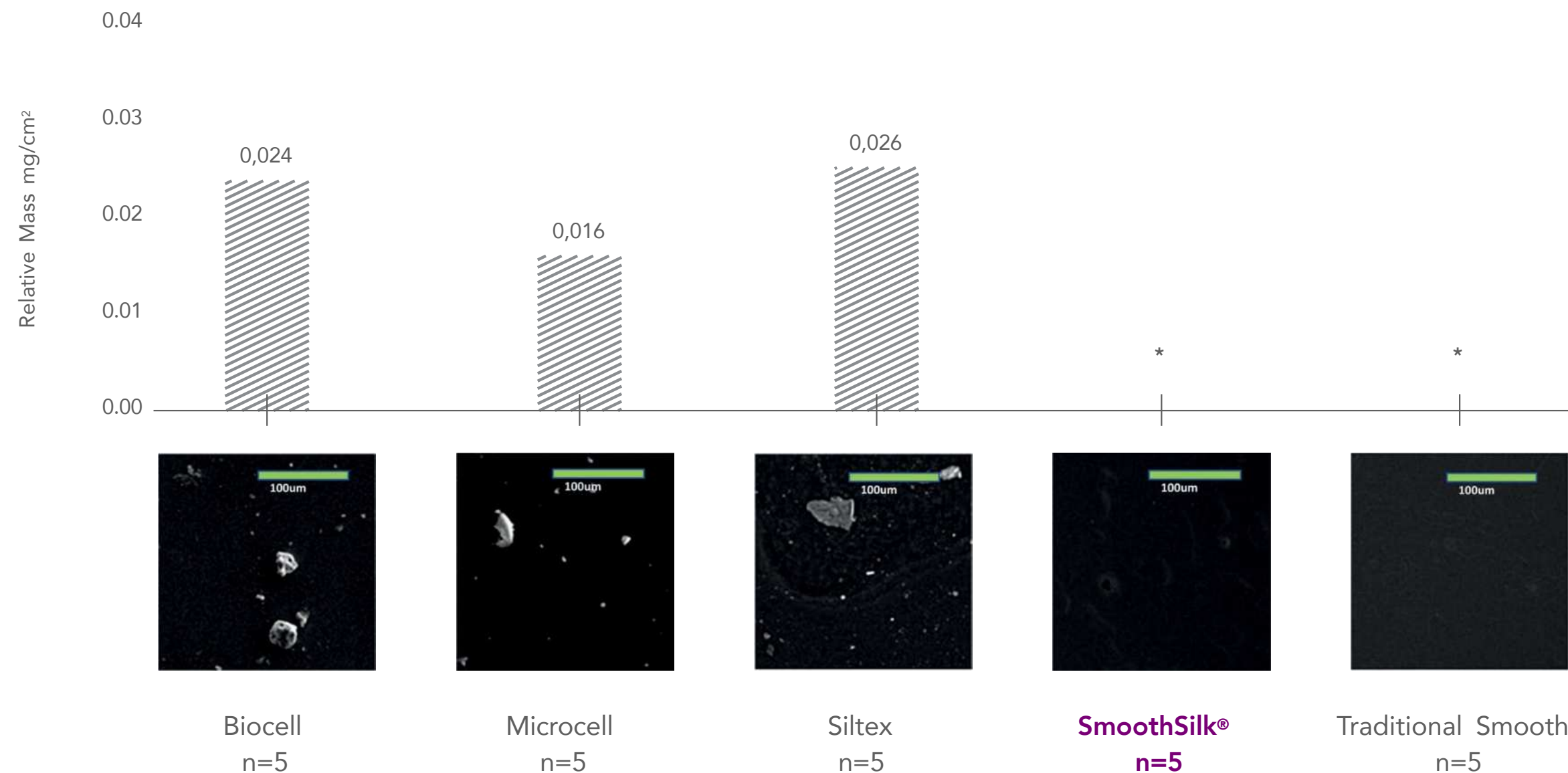
Key Outcomes

- After 24 hours of testing each breast implant surface, implants with a surface area classed as 'High' or 'Intermediate' had significantly higher levels of bacteria growth.
- **Motiva® SmoothSilk® presented with a Type 1/ 'Minimal' surface type and demonstrated the least amount of bacterial growth.**



SmoothSilk® Surface

This study investigates the size, quantity and material type of implant debris released from the outer shell of 5 different breast implants varying in surface roughness.



*Below detection limit of 0.0001mg/cm²

Mass (milligrams) of total particulate debris collected per implant surface.

Extracted from Hallab, ASJ, 2021

Key Outcomes

- Particles released from the breast implant (implant debris), may influence complications such as chronic inflammation and BIA-ALCL.
- Siltex, Microcell and Biocell released greater levels of debris in comparison to SmoothSilk®.

Debris composition:

- SmoothSilk®: <math><1\%</math> Silicone
- Traditional Smooth: <math><4\%</math> Silicone
- Siltex: >60% Silicone
- Biocell: >70% Silicone

- The particulate debris released from Motiva® SmoothSilk® implants were not only below the detection limits for particle analysis but were virtually absent on SEM* examination.

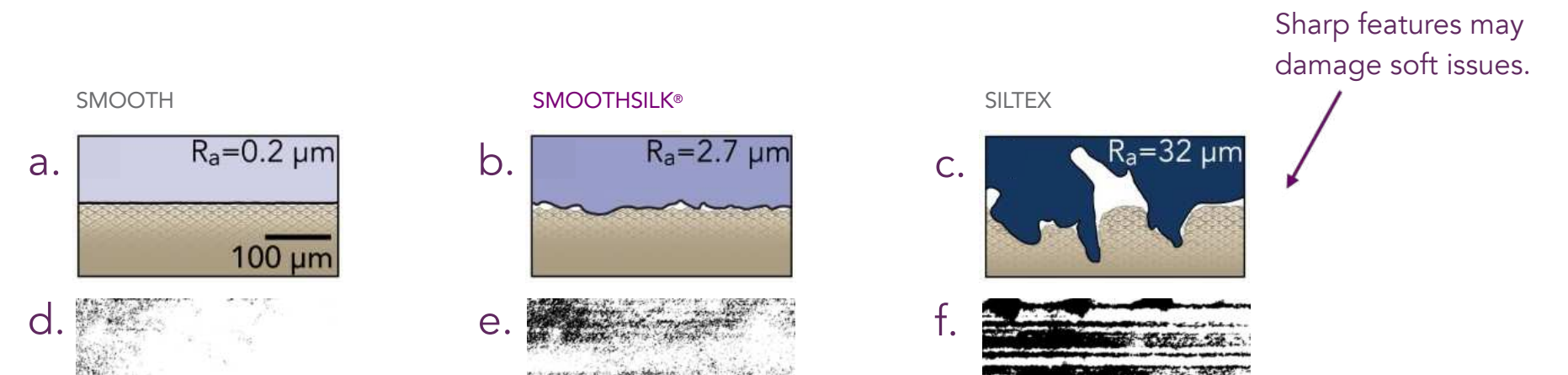
SmoothSilk® Surface

This study investigates the potential damage caused to the surrounding breast tissues by breast implants varying in surface roughness:

- Allergan Smooth: 0.2µm
- Motiva® SmoothSilk®: 2.7µm
- Mentor Siltex: 32µm

Key Outcomes

- Breast implants with a higher surface roughness demonstrated increased damage to the surrounding soft tissues, and remove more essential collagen from healthy cells.
- Increasing average roughness was shown to induce frictional shear stress. Results demonstrated the Microtextured surface induces significant cell death.
- **With the SmoothSilk® surface, the breast epithelial cells remained alive and retained their normal cellular structure.**



Images (a-c): Illustrations represent how three different breast implant surfaces interact with the adjacent breast tissue cells (beige).

Images (d-f): Illustrations reveal the amount of collagen removed (black) by each implant surface. Breast implants with a high surface roughness removed healthy collagen faster (Siltex).

SmoothSilk® Surface

This study investigates the anterior, posterior and radius aspect of different breast implant devices to determine the surface consistency of the outer shell.

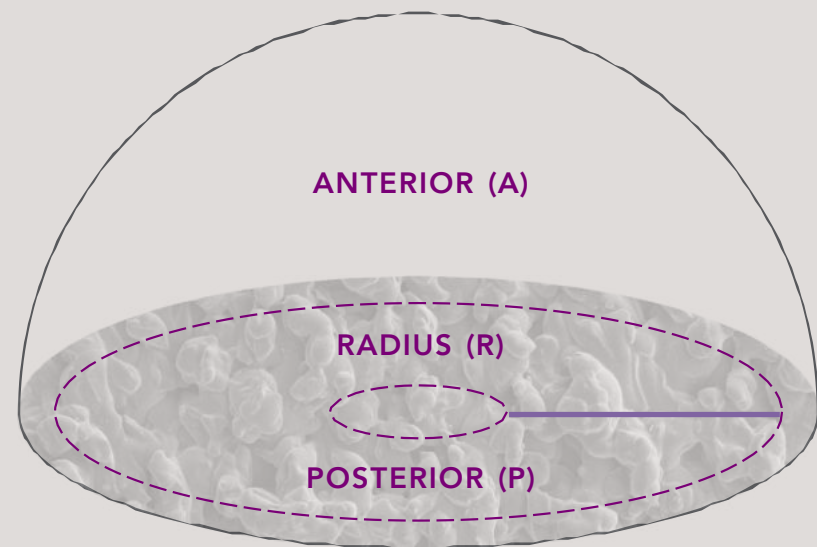
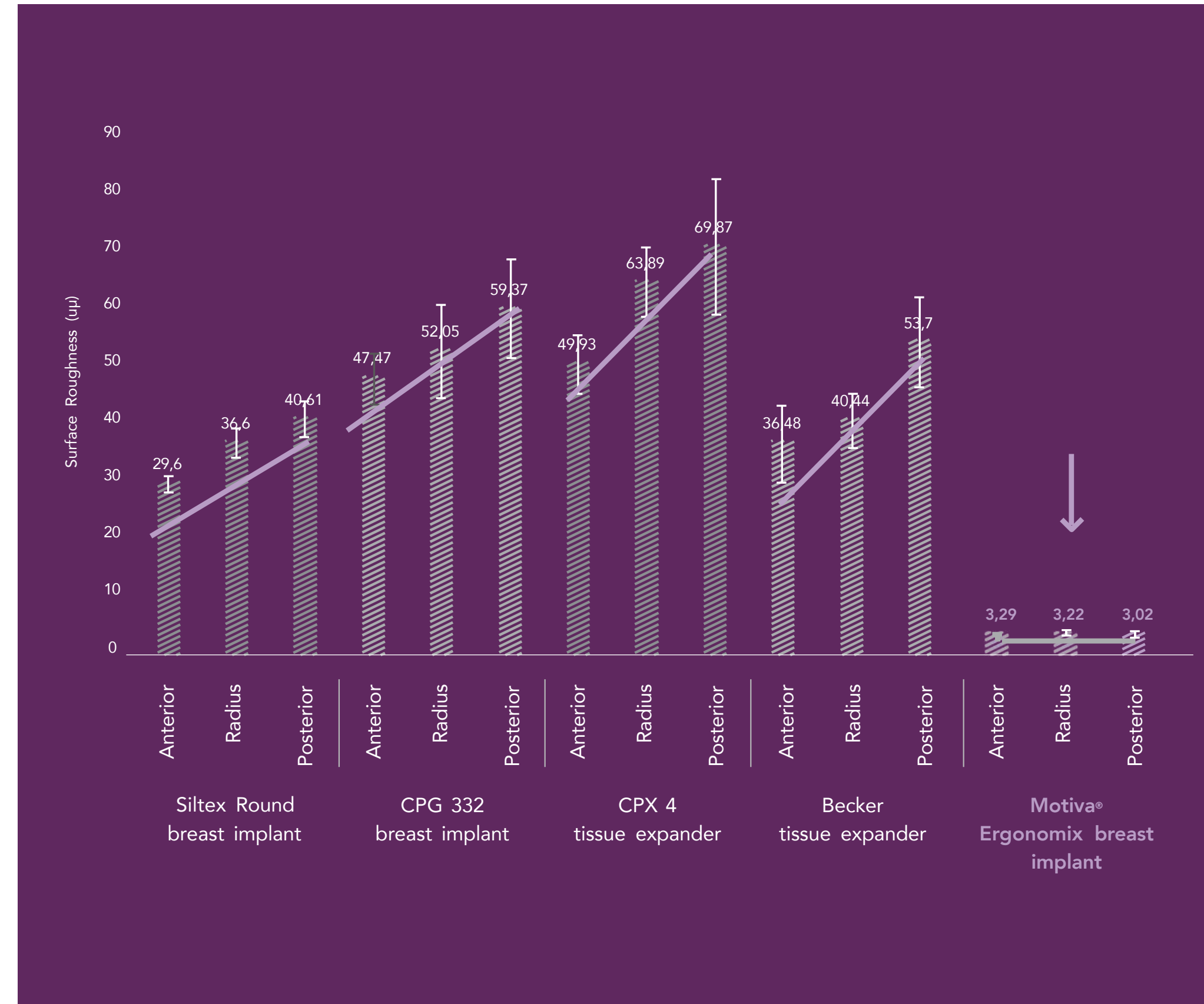


Image demonstrates anterior, posterior and radius aspect of the device.

- Samples taken from the anterior, posterior and radius aspect of the SmoothSilk® Surface demonstrated consistency in surface roughness.
- Inconsistencies in surface roughness were apparent in all devices containing a Microtextured surface. Samples taken from the anterior, posterior and radius aspect of the SmoothSilk® Surface demonstrated a consistent surface roughness.



Clinical Outcomes - Aesthetics

A retrospective study focusing on complications post primary and revisionary breast augmentation or augmentation-mastopexy in 356 patients implanted with SmoothSilk Ergonomix®. Further, satisfaction with aesthetic results were assessed by the 3 performing surgeons, and operated patients.

298

Breast Augmentation

(Primary and Secondary)

58

Augmentation-Mastopexy

(Primary and Secondary)

Mean follow up: 3 years

Capsular Contracture 0.28%

Baker grade III: 1 Case

Hematoma 0.84%

Bottoming out 0.28%

Rupture, double capsule, infection 0%

98% of the patients were "extremely satisfied or very satisfied" with aesthetic results

Transitioning to SmoothSilk Ergonomix®, Key Surgical Considerations

- Utilize a tight pocket, precisely matching this to the diameter of the implant.
- Fixate the IMF to stabilize the breast implant.
- Position the implant slightly higher than intended as a drop of 5mm is expected within the first 6 months.
- When the distance between the native IMF and the lower edge of the areola is less than 4cm and/or a volume of greater than 300cc is used, the native IMF should be readjusted by lowering its position additionally utilizing a suture between the Scarpa's fascia and deep fascia to prevent inferior dislocation of the implants.

Clinical Outcomes - Aesthetics

A six-year study following the introduction of Motiva® breast implants into two centers heavily dominated by textured breast implants.

This study provides technical recommendations on how to efficiently incorporate Motiva® SmoothSilk® implants into surgical practice to optimize post-breast augmentation outcomes, minimize complications and minimize the learning curve when transitioning to these devices.

Key Surgical Considerations

- **Tight pocket:** Create a tight pocket with a hand-in-glove approach to prevent implant displacement.
- **IMF fixation:** Stabilize the inferior pole of the breast by securing the tissues to the chest wall to control the implant within the pocket.
- **IMF positioning:** In cases where a new IMF is required, the degree to which it can be lowered could be reduced due to the implants' tendency to expand the lower pole.
- **Additional considerations:** Patients with weaker breast tissues, pseudoptotic breasts or stretch marks may require additional stabilization techniques.



A total of **2106** Motiva Implants®
N = 516 Round PLUS
N = 1,590 Ergonomix®

1053

Patients, followed up
at 4-years

0.4% Capsular Contracture	0.2% Rupture
2.9% Malposition*	0% BIA-ALCL
4.9% Total overall complications	



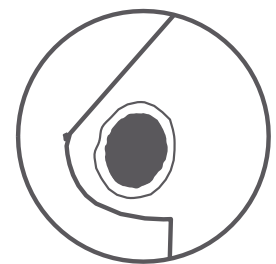
*Overall malposition rates were 2.9% over the 6-year study period. The rate of malposition decreased to 0.5%, with zero cases of bottoming out following modifications to the surgeon's surgical technique three years into the transition period.

IMF Reference: Inframammary fold

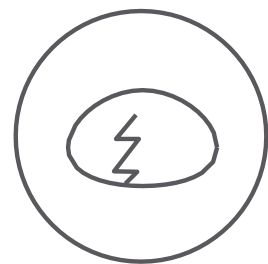
Clinical Outcomes

- Aesthetics

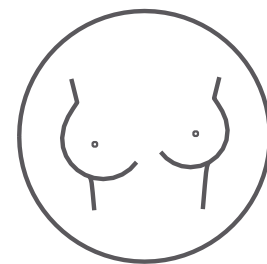
This paper systematically reviews 13 published studies mentioning Motiva® SmoothSilk® breast implants, specifically focusing on post-operative surgical, and device related complications in breast augmentation.



0.54%
Capsular
Contracture



0.02%
Rupture



0.04%
Implant
displacement

4784
Patients

followed up at 1-4 years

2126 Primary augmentation
376 Secondary augmentation

13 studies

(from 2018 to 2022)

•10 retrospective
•3 prospective



Clinical Outcomes

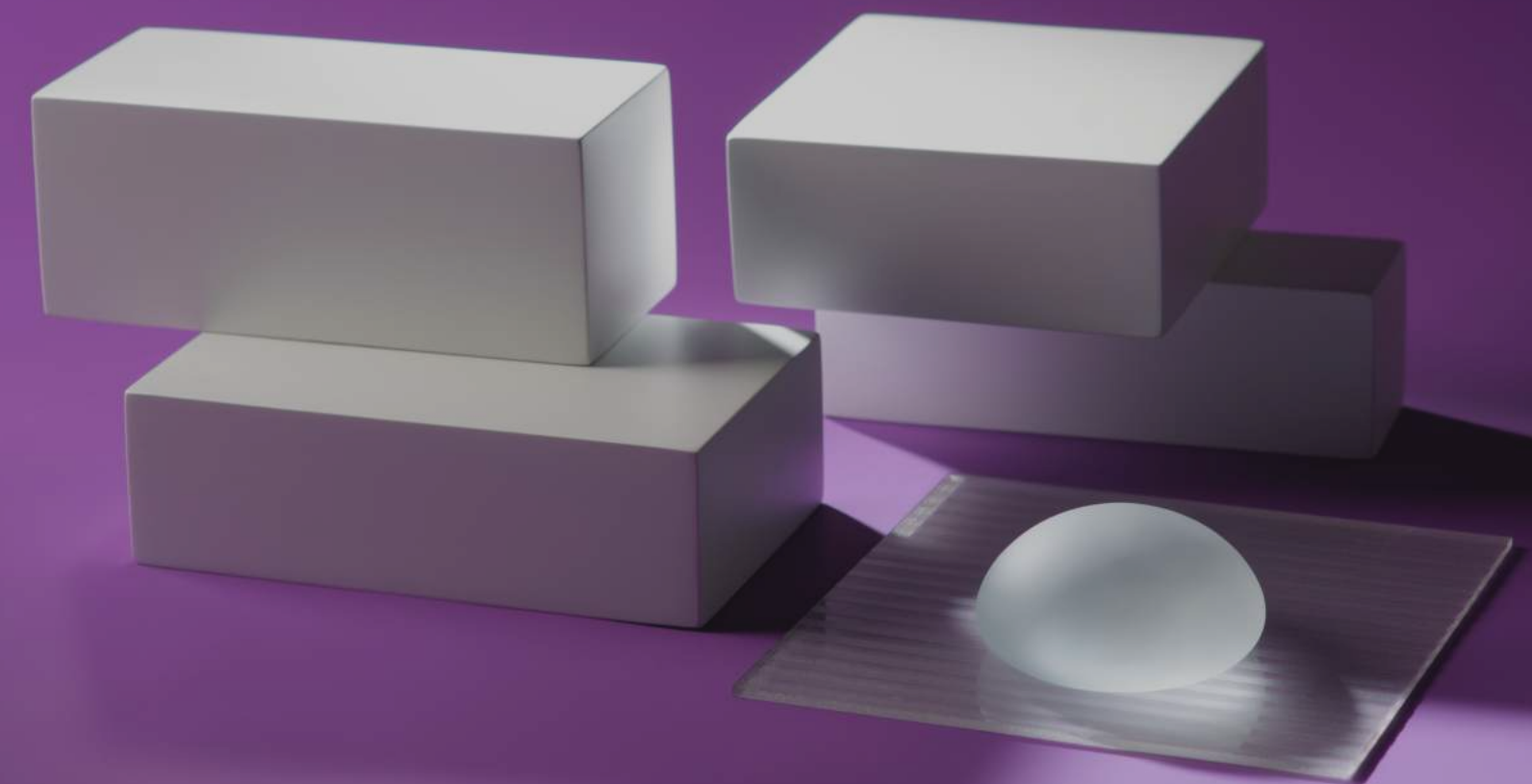
- Aesthetics

A retrospective, single center, multi surgeon study between 2014 and 2023. This study aimed to investigate the effectiveness of total capsulectomy combined with implant replacement using Motiva Ergonomix® to resolve capsular contracture and minimize recurrence rates.

- 51 patients with Grade III/IV capsular contracture
- Explanted implants were macro-textured 79%, micro-textured 19% and 2% polyurethane. (NO MOTIVA® OR SMOOTH IMPLANTS WERE EXPLANTED)
- 15 of the other manufactured explanted implants exhibited silicone bleeding, and 10 showed rupture
- All implants replaced with Motiva SmoothSilk Ergonomix® (50/51 submuscular plane* and mean volume of 235cc).
- Follow up period of 1-9 years

Key Outcomes

- 1 case (1.96%) of capsular contracture during the follow up
- Moving an implant from a subglandular to a submuscular pocket helps to reduce the relapse of capsular contracture
- The combination of total capsulectomy and implantation of Motiva SmoothSilk Ergonomix® implants significantly reduces the recurrence rate of capsular contracture.



*1 patient was changed to a subglandular plane due to presence of double bubble and capsular contracture

Clinical Outcomes - Aesthetics

This study evaluates the safety, efficacy, and aesthetic outcomes of the SmoothSilk Ergonomix2® implants in breast augmentation and compares these results to the world's first ergonomic implant; SmoothSilk Ergonomix®.

82
Patients

51: Ergonomix®

31: Ergonomix2®

'Natural and harmonious'



SmoothSilk Ergonomix2® implants results in a **'natural feel'** with **increased softness** and pliability in comparison to SmoothSilk Ergonomix®.

Key Outcomes

Analysis demonstrates that SmoothSilk Ergonomix2® implants:

1. Closely mimics the biomechanical behaviour of the natural breast tissue with:
 - Enhanced softness*
 - Improved breast contour symmetry**
 - Natural feel and movement**
2. Minimizes occurrence of rippling.

'Surgical learning curve'

- Create a precise, tight pocket
- Utilize supportive techniques e.g. fascial sling
- Fixate the IMF for implant stability
- Place the SmoothSilk Ergonomix2® implant directly in the desired final position due to the subsequent lower pole expansion.

'After successfully transitioning through the surgical learning curve with Ergonomix2® a notable reduction in surgical time was demonstrated, decreasing this from 60 minutes to 25 minutes.'

*Compared to macrot textured anatomical, SmoothSilk® Round and Ergonomix®.

** Compared to Ergonomix®.

Szychta, P. Advancements in Aesthetic Breast Augmentation: Evaluating the Safety, Efficacy, and Naturalistic Outcomes of Ergonomix2® Implants. Aesth Plast Surg (2024).

<https://doi.org/10.1007/s00266-024-03994-3>

Clinical Outcomes - Aesthetics

A prospective, single-arm, multicenter, 10-year pivotal study on the safety and effectiveness of Motiva SmoothSilk® Round and SmoothSilk Ergonomix® implants submitted to the FDA with patients undergoing primary and revision augmentation surgery with an MRI sub-study at 1, 2 and 3 years to screen for implant rupture.

Level of Evidence **2**

3 Year Motiva® IDE study

560

Patients

451

Primary Augmentation Cohort

109

Revision Augmentation Cohort

218

MRI Sub-study

Follow up period: 3 years

Key Complications Kaplan-Meier Risk Analysis:

Primary Augmentation	Motiva 3-Year (N=451) 95% CI ¹
Capsular Contracture (Grade III/IV)	0.5%
Rupture, suspected or Confirmed (MRI Cohort)	0.6%
Breast Pain	0.7%
Infection	0.9%
Implant removal with or without replacement	1.6%
Any Complication*	8.4%
Any Reoperation**	6.1%

*Any device or non-device-related event, including reoperation.

**Any surgery on the breast or chest area, device or non-device related, including size change.

Key Outcomes

- High patient annual follow-up compliance at 3 years:
 - Primary Augmentation 92.4%
 - Revision Augmentation 88.7%
- High satisfaction rates amongst patients and surgeons
 - Patients: Primary augmentation 97.1% and Revision augmentation 87.5%
 - Surgeons: Primary augmentation 99% and Revision augmentation 95.5%
- Low palpability/visibility:
 - Primary augmentation 0.2%
 - Revision augmentation 0%
- Low wrinkling/rippling:
 - Primary augmentation 0.5%
 - Revision augmentation 0%
- No reported breast cancers, BIA-ALCL, or BIA-SCC.
- Kaplan Meier risk rate of Connective Tissue Disease and Rheumatologic illnesses 0%
- **The 3-Year FDA submitted data from the Primary & Revisional Augmentation cohorts demonstrates the safety and efficacy of Motiva SmoothSilk Round[®] and Ergonomix[®] Implants.**

Clinical Outcomes - Reconstruction

A retrospective study focusing on the clinical outcomes from 156 patients undergoing primary, or revisionary breast reconstruction procedures using SmoothSilk Ergonomix® implants.

156 patients
(269 breasts)

Mean follow-up
period: **14 months**

257 breasts
Direct to implant
reconstruction

12 breasts
Tissue expander-
to-implant

Breast Q revealed high levels of patient satisfaction with SmoothSilk Ergonomix® implants

Results

Capsular Contracture: Total 12 breasts (4.46%)

- Non-Irradiated breasts: 4 breasts (1.49%)
- Adjuvant radiotherapy: 6 breasts (2.24%)
- Preoperative radiotherapy: 2 breasts (0.73%)

Hematoma: Total 4 breasts 1.49%

Seroma: Total 6 breasts 2.23%

The author states the **capsular contracture** results presented in this study are a lower rate compared to other published studies described in the literature in relation to breast reconstruction:

Brand A: 20%

Brand B: 11.7%

Brand C: 13.2%

Reoperation rates were lower than other post-marketing studies of common implant manufacturers.^{2,3,4}

1. Kaplan HM, Rysin R, Zer M, Shachar Y. A single surgeon's experience with Motiva Ergonomix Round SilkSurface silicone implants in breast reconstruction over a 5-year period. J Plast Reconstr Aesthet Surg. 2023. doi: 10.1016/j.bjps.2023.01.047

2. Doren EL, Pierpont YN, Shivers SC, Berger LH. Comparison of Allergan, Mentor, and Sientra Contoured Cohesive Gel Breast Implants: A Single Surgeon's 10-Year Experience. Plast Reconstr Surg. 2015;136(5):957-966. doi:10.1097/PRS.0000000000001675

3. Spear SL, Murphy DK; Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: Core Study results at 10 years. Plast Reconstr Surg. 2014 Jun;133(6):1354-1361. doi: 10.1097/PRS.0000000000000021.

4. Stevens WG, Calobrace MB, Alizadeh K, Zeidler KR, Harrington JL, d'Incelli RC. Ten-year Core Study Data for Sientra's Food and Drug Administration-Approved Round and Shaped Breast Implants with Cohesive Silicone Gel. Plast Reconstr Surg. 2018 Apr;141(4S Sientra Shaped and Round Cohesive Gel Implants):7S-19S. doi:10.1097/PRS.0000000000004350.

Clinical Outcomes - Reconstruction

With many surgeons in the clinical setting switching from textured breast implants to smooth, this study aims to describe the early experience with Motiva® Ergonomix® implants for patients undergoing breast reconstruction.

211 (321 breasts)

Mean follow-up period: 2.5 years

64.5%

**Immediate
Breast Reconstruction**

35.5%

**Delayed
Breast Reconstruction**

Complication	Complication Rate
Capsular contracture	0.9%*
Hematoma	1.8%
Infection	1.8%
Seroma	0.6%
Skin Necrosis	2.8%
Implant flipping	0.3%
Animation deformity	1.2%

*Capsular contracture Baker Grade III/IV presented in only 3 breasts after receiving radiotherapy.

Key Outcomes

- Radiotherapy and smoking were identified as major contributing factors towards the overall complication rate
- Early follow-up demonstrated high levels of patient satisfaction with the implants and appearance of the breasts, alongside high scores in terms of the patients physical well-being.

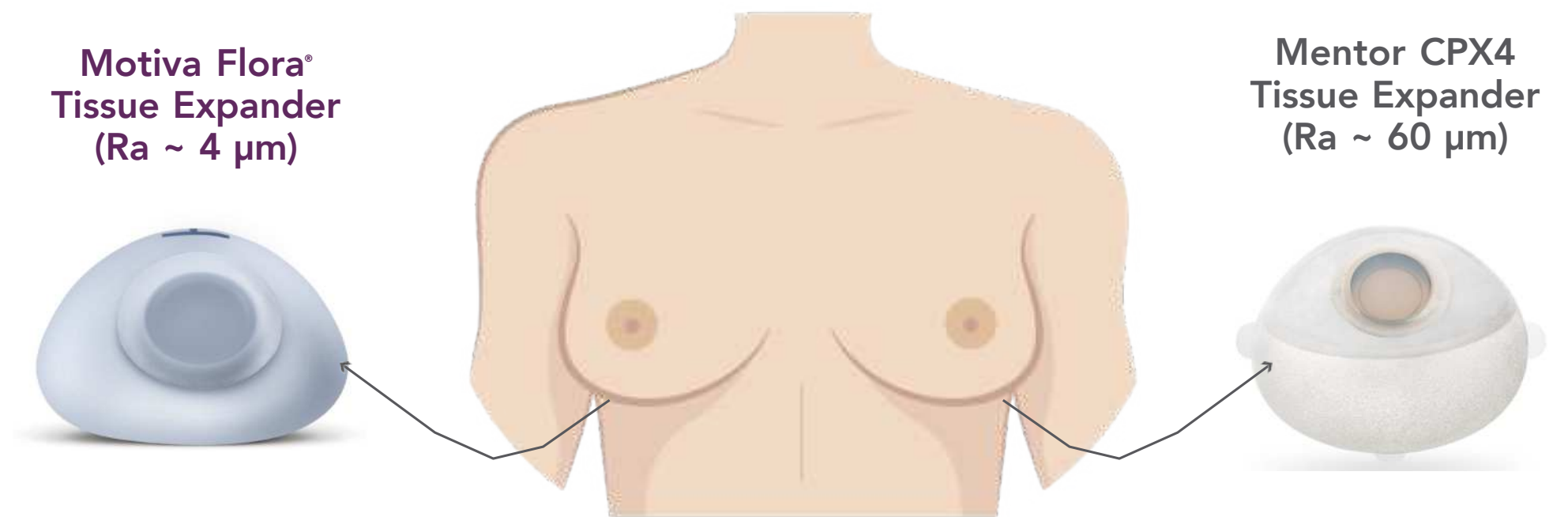
Clinical Outcomes - Reconstruction

A randomized double-blinded (surgeons and patients), controlled clinical study involving 7 women who underwent a prophylactic skin-sparing mastectomy and immediate tissue expander based reconstruction. Two different types of tissue expanders were used; Motiva Flora® and Mentor CPX4 with the aim to assess postoperative clinical outcomes such as capsule thickness, seroma formation, comfortability and practicality.

Patients with the Motiva Flora® SmoothSilk® tissue expander reported:

- Less breast pain
- Less discomfort
- Less nipple sensitivity
- Significantly higher aesthetic results
- Significantly higher comfortability

7 Patients



Tissue expander placement was randomized to the left, or right breast after mastectomy.

Key Outcomes

- Overall, the capsule formed around the Flora® SmoothSilk® tissue expander was significantly thinner through ultrasound, and histological analysis.
- Radiological examination showed periprosthetic fluid was significantly increased around Mentor's CPX4 expander.
- Higher levels of patient and surgeon satisfaction with Motiva Flora® in comparison to CPX4.

Clinical Outcomes - Reconstruction

This prospective, single center, observational study explores the concept of multi-stage composite breast reconstruction with repeated sessions of autologous fat grafting to increase mastectomy flap thickness and provide better pre-pectoral implant coverage.

- 25 patients (50 breasts) underwent bilateral expander to implant breast reconstruction using autologous fat grafting and reverse expansion
- Mean follow up 17 months
- Motiva Flora® Tissue Expander used in all patients followed by Motiva SmoothSilk Ergonomix® in 19 patients & Polytech Anatomical in 6 patients.

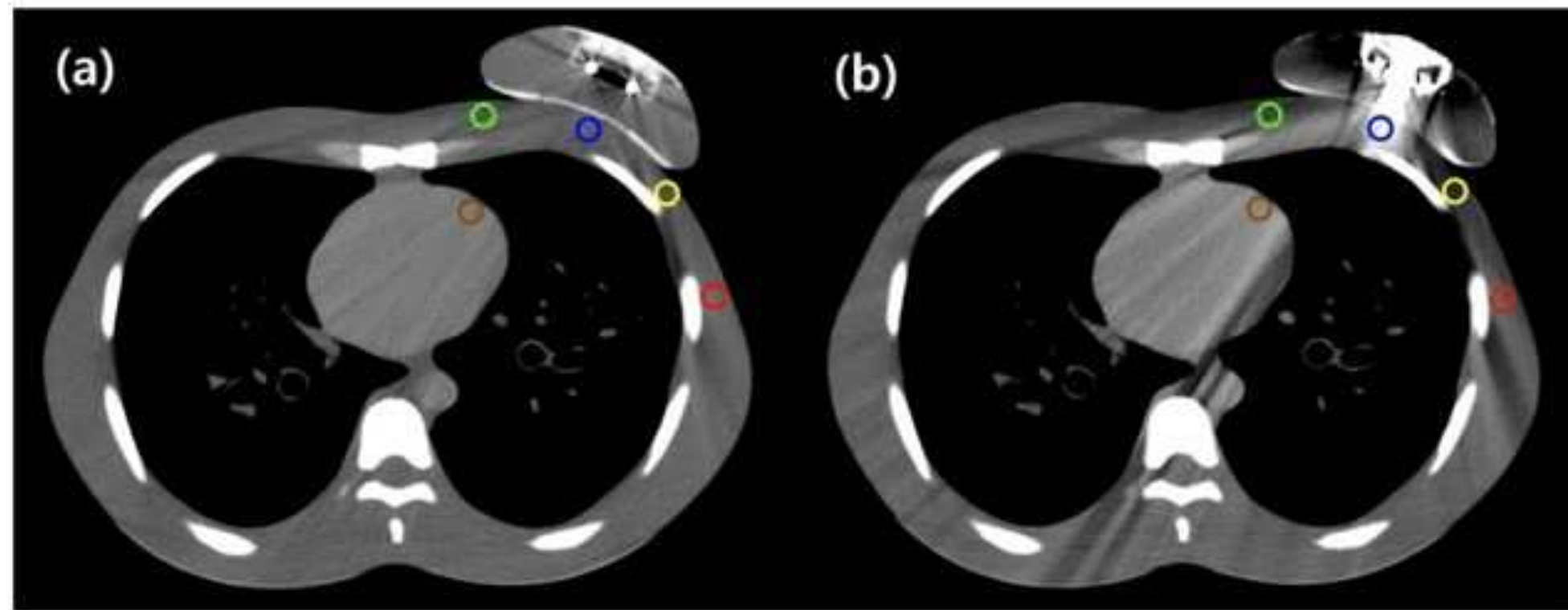
Complication	Complication Rate % (n=cases)
Capsular contracture (Grade III & IV)	0% (n=0)
Expander Rupture (Iatrogenic)	6% (n=3)
Hematoma	2% (n=1)
Rippling	4% (n=2)
Infection	4% (n=2)

*Complications not specified to which brand or implant

- In all 25 patients, a significant increase, almost double, in soft tissue thickness was achieved following repeated fat grafting for better implant coverage, allowing the positioning of the implant in the pre-pectoral plane
- Patients with a lower BMI tended to achieve a higher percentage increase in thickness with fewer sessions and lower volumes of autologous fat injected when compared to those with a higher BMI.

Clinical Outcomes - Reconstruction

This study compares a traditional tissue expander featuring a metallic port and the Motiva Flora® SmoothSilk® tissue expander containing RFID technology; specifically analyzing post-mastectomy radiotherapy planning for patients diagnosed with left-sided breast cancer.



CT image demonstrating the appearance of artifacts created by two types of tissue expanders;
a) Motiva Flora® RFID port, b) Traditional tissue expander with a metallic port

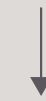
The RFID port featured in the Motiva Flora® SmoothSilk® tissue expander reduces the artifact that can be visualized on CT imaging due to the ports lower density materials.



The reduced artifact allows for a clear, and more visible image of the breast to be captured which in turn allows;



Increased accuracy when planning radiotherapy.



The outcome: Precise levels of radiotherapy are delivered to the patient thus reducing undesired clinical toxicity to vital organs such as the heart and lungs, unlike conventional tissue expanders featuring magnetic ports which can result in the patient receiving more radiotherapy than required.

Clinical Outcomes - Reconstruction

559 patients
867 tissue expanders

MRI-CTE (Motiva Flora®)
103 patients
161 tissue expanders
4.7 months mean follow-up

TTE (Mentor & Allergan)
456 patients
706 tissue expanders
4.9 months mean follow-up

This retrospective, single center study explores and compares the clinical outcomes and radiation protocol impacts of MRI-Conditional Tissue Expanders (MRI-CTE's) versus Traditional Tissue Expanders (TTE's) in postmastectomy breast reconstruction.

Complications* & Outcomes	MRI-CTE (Motiva) (%) N=161	TTE (Mentor & Allergan) (%) N=706
Hematoma	2 (1.2%)	8 (1.1%)
Seroma	3 (1.9%)	45 (6.4%)
Infection/Cellulitis	3 (1.9%)	44 (6.2%)
Malposition/Rotation	5 (3.1%)	26 (3.7%)
Mastectomy Skin Flap Necrosis	7 (4.3%)	50 (7.1%)
Mastectomy Skin Flap Necrosis Requiring Revision	2 (1.2%)	22 (3.1%)
TE Exposure	0 (0%)	4 (0.6%)
TE Removal with Immediate Replacement	1 (0.6%)	20 (2.8%)
TE Removal without Replacement	2 (1.2%)	12 (1.7%)
MRI Required During Expansion	3 (1.9%)	6 (0.8%)
TE Removal Due to MRI	0 (0%)	6 (0.8%)

*Complications were tracked from expander placement to either exchange to a permanent implant or expander loss/removal.

MRI-CONDITIONAL TISSUE EXPANDERS IN BREAST RECONSTRUCTION: CLINICAL OUTCOMES AND RADIATION THERAPY IMPLICATIONS, CLEMENS ET AL, 2025



Results

- In cases requiring MR imaging, 0/3 patients in the Flora® cohort required explantation to safely undergo scanning, whereas 6/6 patients in the TTE cohort required prior device removal.
- During radiation planning, the Flora® cohort required less artifact management, with a mean artifact diameter of 1cm compared to 4cm in the TTE group. This reduction enabled more accurate radiation delivery (up to 75%) minimizing underdosing of the target and overdosing of adjacent healthy tissue.
- The Motiva Flora® cohort group had a significantly lower rate of infection/cellulitis compared to the TTE cohort (1.9% vs. 6.2%) and showed a trend toward lower rates of seroma (1.9% vs. 6.4%).

Key Takeaways

- Motiva Flora® Tissue Expander may contribute to improved clinical outcomes with fewer surgical interventions and enhanced precision in radiation treatment planning.
- Motiva Flora® demonstrated enhanced surgical outcomes in addition to providing improved accuracy in radiation dose calculations.
- Reduced manual interventions for artifact adjustment decrease time and also the potential for human error, enhancing the overall precision of radiation treatment delivery.



Medical Education
by Establishment Labs