

1 **AESTHETIC BREAST SURGERY**

2

3 **ORIGINAL ARTICLE**

4

5 **The 3-Year Results of a 100-Patient Prospective Study of Safety and Effectiveness of Mia**
6 **Femtech**

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9

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11

ACCEPTED MANUSCRIPT

1 **ABSTRACT**

2 **Background:** Conventional breast augmentation using different approaches and implant pockets
3 faces challenges such as societal stigma, long recovery time, invasion of the breast, and
4 complication rates. Prior minimally invasive approaches have failed to provide long-term safety,
5 effectiveness, and patient satisfaction.

6 This study introduces a minimally invasive breast harmonization procedure, performed with an
7 inflatable balloon and a bi-convex-shaped silicone-filled implant, addressing these limitations
8 with a safe and innovative solution.

9 **Objectives:** This prospective controlled study evaluates the safety and effectiveness of this
10 procedure, reducing surgical complications while providing a new treatment option for breast
11 enhancement.

12 **Methods:** A three-year, IRB-approved study enrolled 100 subjects undergoing this procedure,
13 utilizing an axillary incision with prepectoral implant placement. Safety was assessed by
14 monitoring the cumulative incidence of post-operative complications in scheduled visits and with
15 MRI evaluations in a randomized sub-cohort (33 participants). Patient satisfaction was measured
16 pre- and post-procedure using Breast-Q questionnaires and scar evaluation with POSAS.

17 **Results:** Effectiveness endpoint at 3 years reported a 75.3% bra increase of one to three cup
18 sizes. The overall Kaplan-Meier complication rate at 3 years was 3.2%, with low re-operation
19 rates and 93% follow-up compliance. There were no patient reports of nipple or breast sensitivity
20 loss, nor surgeon reported incision-related complications, implant rupture, capsular contracture
21 (Baker Grade III/IV), infection, seroma, rippling, hematoma, or BIA-ALCL.

22 **Conclusions:** This study demonstrates very low complication rates, faster recovery, and
23 enhanced patient satisfaction with this procedure, compared to conventional breast augmentation.
24 Its minimally invasive tissue-preservation approach introduces new surgical concepts, advancing
25 surgical techniques and technologies beyond conventional methods.

26
27 Conventional breast augmentation (BA) is one of the most sought-after surgical aesthetic
28 procedures practiced worldwide, with nearly 1.9 million women choosing this procedure in 2023
29 to improve their physical appearance and self-confidence.¹ However, the objectification and
30 stigmatization of breast implants, fear of surgery, downtime and recuperation, along with related
31 complications and reoperation rates, have led a large portion of women to avoid breast

1 augmentation surgery. Others have pursued the use of non-surgical alternatives such as breast
2 fillers to augment the breast shape and size.^{2,3} Although breast fillers were initially thought to
3 provide a quick, non-invasive solution, the onset of complications, including systemic infection,
4 granulomas, filler migration, disruption of essential mammography screenings, and the lack of
5 clinical safety evidence, prompted regulatory action and the prohibition of breast fillers in
6 several countries.⁴⁻⁷

7 Minimally invasive surgery (MIS) has revolutionized most medical specialties⁸
8 by overcoming challenges associated with conventional surgical methods. The development of
9 specialized instruments, coupled with enhanced imaging modalities, provide significant benefits.
10 These include greater precision in accessing complex anatomical structures, reduced reliance on
11 general anesthesia, shorter operative times, and improved patient outcomes. Smaller incisions
12 minimize trauma to surrounding tissues, and reduce postoperative pain,⁹⁻¹² leading to faster
13 recovery. These patient-centric advantages contribute to an improved quality of life during the
14 postoperative period.^{13,14} Smaller incisions and reduced scarring improve outcomes, addressing
15 both the functional and aesthetic concerns of patients.^{9,10}

16 In 2010, implant technology brought a new breast implant design to market that has
17 demonstrated long-term low device-related complications, such as capsular contracture and
18 rupture, and lower overall reoperation rates compared to other implants.¹⁵ Satisfaction data
19 highlights its distinctive rheological properties.¹⁵⁻¹⁷ In addition, previous series using more
20 superficial and less invasive techniques associated with this new generation of implants have
21 demonstrated satisfactory results and a low rate of complications.¹⁸⁻²¹

22 Despite these advancements, the continued use of conventional surgical techniques persists,
23 alongside consumer concerns. Meanwhile, the breast aesthetics consumer has evolved
24 significantly. Surgical procedures have declined, with a growing preference for minimally
25 invasive treatments—consumer acceptance of non-invasive options has risen 81% since 2017.²²
26 Today's aesthetic consumers are more informed and wellness-focused. Among women, 40% use
27 wellness apps and invest more in exercise and sports.²³ A study of 4,962 women (ages 20–60)
28 found that 6 in 19 are dissatisfied with their breasts, with 68% relying on compensatory methods
29 (padded, pushup bras, etc.). Concerns about traditional BA include fear of general anesthesia
30 (16%), painful recovery (16%), and post-operative logistics (18%).²⁴

1 At the same time, limitations due to the presence of scars on the breast have been listed as an
2 obstacle to the search for BA, and thus techniques that do not create breast scars, such as axillary
3 procedures, have proven beneficial in addressing the concerns in this group of patients.^{18,19,25-28.}

4 This increasingly active, health-conscious consumer embraces technology, aligning with the
5 broader Femtech sector—a rapidly growing field using innovation to address women's health
6 needs. The technology for the procedure outlined in this study was developed through a
7 collaboration between Establishment Labs (Alajuela, Costa Rica) and the senior author (C.R.) of
8 this manuscript. It was designed to meet both the demand for advanced, non-invasive treatments
9 and the evolving expectations of active, health-conscious patients.

10 The aim of this study was to evaluate the safety and effectiveness of a novel MIS, as a new
11 solution for women seeking breast enhancement. Here we report the 3-year outcomes in 100
12 consecutive patients and discuss the MIS technique and its intended design to provide safe,
13 reproducible, long-term outcomes while preserving the native breast tissue. New aesthetic
14 concepts such as “nesting” and “tenting” effects are introduced. The study also measured patient
15 and surgeon experience and as well as their satisfaction with the aesthetic results, using validated
16 measurement tools.

17

18 **METHODS**

19 **Study Design**

20 A total of 100 women undergoing bilateral Mia Femtech™ procedures (Establishment Labs,
21 Alajuela, Costa Rica) between December 2020 and April 2021 were studied prospectively from
22 pre-operative through 3 years of follow-up to assess the safety and effectiveness of the
23 procedure. A simple randomized magnetic resonance imaging (MRI) sub-study was conducted
24 on 33 patients at least 18 months post-implantation to assess for asymptomatic rupture and
25 visually confirm the plane of placement of the implant. A single patient from the sub-study was
26 randomly selected for a supplementary MRI analysis of the geometrical properties of the
27 implant.

28 The study was conducted by a board-certified plastic surgeon in San Jose, Costa Rica. All
29 patients underwent the informed consent process. The study follows the principles of the
30 Declaration of Helsinki and the United States FDA class 3 pivotal study design. The study

1 received review and approval from the institutional ethics committee (Comité Ético Científico de
2 la Fundación Inciensa, CEC-FUNIN-006-2020) on December 3, 2020.

3 **Study Participants and Data Collection**

4 Participants included female patients over 18 years old. Compared to conventional breast
5 augmentation studies, this study included additional inclusion criteria: patients seeking a small to
6 moderate volume enhancement, with a BMI between 18.5 - 24.9, breast width <14 cm,
7 intermammary distance <3 cm and no history of breast or axillary surgery. Minor anatomical
8 variations included cases of pectus excavatum, volumetric asymmetries, projection asymmetries,
9 discrepancies in the first breast segment (from the clavicle to the superior border of the breast),
10 and breast divergence. Additional exclusion criteria were patients with ptotic or tuberous breasts,
11 major chest wall asymmetries, or axillary deformities. Data were collected preoperatively to
12 establish baseline data and metrics, intraoperatively to evaluate procedural efficiency,
13 immediately postoperatively for recovery data, and at subsequent follow-up visits (24 hours, 1
14 week, 3 to 6 weeks, 3 months, 6 months, and years 1-3). Patient satisfaction was measured using
15 Pre- and Post-operative BREAST-Q validated scales (Augmentation Module, Version 2.0, 2017).
16 Surgeon Satisfaction was assessed by a validated 5-point Likert Scale, which measured how
17 satisfied/dissatisfied they were with the procedure and the overall experience. Evaluation of the
18 incisional scar was conducted using the validated Patient and Observer Scar Assessment Scale
19 (POSAS), incorporating both the patient's and clinician's assessments.²⁸

20 **MRI Sub-Cohort**

21 MRI data was collected from 33 participants selected using Minitab 19 Statistical Software. Each
22 participant underwent imaging utilizing a 1.5 Tesla machine, 18 to 21 months post-procedure.
23 The imaging sequences protocol included axial and sagittal T2-weighted fast spin echo (FSE)
24 and axial STIR with water and silicon suppression.

25 **Breast Implant Devices and Surgical Technologies**

26 All procedures were performed using the Mia System (**Figure 1**), which includes six approved
27 proprietary instruments produced by Motiva (Establishment Labs, Alajuela, Costa Rica): a
28 marking tool, a channel separator, two inflatable balloons (with the incorporated manual pump
29 and introducer), an implant injector, and the Motiva SmoothSilk Ergonomix2 Diamond
30 SmoothSilk silicone-gel-filled breast implants. There is an additional cost beyond the expense of
31 acquiring the implants alone, due to the single-use devices required for this technique.

1 **Surgical Approach**

2 ***Preoperative Assessment***

3 All patients received comprehensive preoperative evaluations to collect baseline data, determine
4 the patient's desired aesthetic outcome. Physical examinations of pre-existing breast tissue and
5 footprint were performed, including breast width and intermammary distance. Pre-existing tissue
6 coverage was assessed using high-resolution ultrasound (HRUS) with a dedicated linear probe at
7 10 MHz (LOGIQ V2, GE Healthcare Technologies, Inc., IL) and 3D imaging (Divina®,
8 Establishment Labs, Alajuela, Costa Rica) that measures pre-existing breast volume and
9 projection. Implant selection was determined by patient preferences and aligned with the
10 patient's anatomical landmarks.

11 ***Mia Procedure: Anesthesia Protocol***

12 All patients received premedication (750-1000 mg of Acetaminophen and 1 mg intravenous
13 Cephalosporine). Baseline monitoring was applied, and most of the procedures (90 patients)
14 were performed under conscious sedation, which consisted of intravenous infusion of an
15 amnestic, opioid analgesic, non-steroidal anti-inflammatory, antiemetic, induction agent, and/or
16 an optional gastroprotective agent as deemed appropriate by the surgeon. The first ten patients
17 were performed under general anesthesia, as the first anesthetic phase evaluation. A Tumescant
18 Local Anesthesia (TLA) solution was utilized (1 L of 0.9% normal saline, 1 g lidocaine, 2 mg
19 epinephrine, and 10 ml sodium bicarbonate).

20 The most used infiltration protocol was performed with the aid of HRUS and an infusion pump
21 connected to a cannula. The cannula was inserted into the upper corner of the axillary marking
22 and advanced into the pre-pectoral position, spanning the entire breast circumference up to the
23 final marking point. Following infiltration, a gentle massage supported uniform distribution,
24 followed by a wait time of 15 minutes to allow stable analgesia and vasoconstriction.^{29,30}

25 ***Mia Procedure***

26 All procedures were performed by the corresponding author of this article, a board-certified
27 plastic surgeon. Commercial distribution of this product will be limited to only board-certified
28 plastic surgeons. Preoperative breast markings were conducted with the patient standing and
29 their arms raised. Using the marking tool, three points were indicated to identify the incision site,
30 the pocket boundaries, and the final dissection location (**Figure 2**). The incision site was marked
31 in the axilla, measuring 2.0 to 4.0 cm in length and down to the fat compartment. A second

1 junction mark indicated the pocket diameter corresponding to the chosen implant's base. A final
2 third mark was drawn from the second junction mark through the center of the marking tool
3 towards the lower pole of the breast to denote the final dissection location, ensuring it remained
4 within 2 cm past the chosen pocket marking, which corresponds to the separator's tip length.
5 During all procedures, the patient was positioned in a supine position and their arms extended at
6 a 110° angle to facilitate access to the surgical site, deep access to the axilla, minimize skin
7 tension, and reduce the risk of incision tears. The technical basis of the axillary incision and
8 superficial dissection up to the lateral border of the pectoralis major muscle (PMM), with total
9 preservation of the anatomical structures of the axilla, was based on the axillary BA technique
10 previously described.^{18,19,26,27}

11 Following the initial incision, a channel separator was introduced into the center of
12 the incision and was headed toward the junction mark, before redirecting toward the Nipple-
13 Areola Complex (NAC) and advancing approximately 15-17 cm over the PMM and beneath the
14 breast tissue to the final dissection mark. To keep the incision as discreet as possible within the
15 axilla, the channel between the incision and the definitive pocket was angled close to the lateral
16 edge of the PMM. The transition between the axillary tunnel and the prepectoral tunnel, up to the
17 implant pocket, presents an angle of approximately 100°- 120°, **Video 1**.

18 Next, the inflatable balloon was introduced through the previously created channel to create the
19 placement position, then inflated to expand and create the pocket, thus pushing the breast tissues
20 radially. Hemostasis was maintained by the localized pressure of the balloon in conjunction with
21 the vasoconstriction of the blood vessels induced by epinephrine. After balloon expansion and
22 subsequent deflation, the balloon was removed from the pocket. The implant was inserted into
23 the pocket using the injector device, allowing a minimally invasive and no-touch technique
24 intended to reduce the risk of bacterial contamination and minimize trauma to the adjacent
25 tissues.^{28,31-36} Implant positioning was confirmed by HRUS before final closure. The

26 subcutaneous layer was closed in a standard fashion using a 3-0 absorbable monofilament suture
27 and topical skin glue for the epidermis layer. **Videos 2 and 3** present a Mia procedure performed
28 by the corresponding author of the study, and an endoscopic view following the pocket creation,
29 where the implant is positioned in a space between the posterior lamella and the breast gland,
30 within multilayered ligaments and fat, **Figure 3**.

1 All patients were discharged on the same day and instructed to wear a surgical bra for one
2 month, a supporting band for 2-15 days postoperatively, and to avoid strenuous activities during
3 the initial two weeks. Follow-up visits occurred on day 1 (24 hours), week 1 (within 3-7 days),
4 between 3 and 6 weeks, 3 months, 6 months, and years 1, 2, and 3.

5 **Data Analysis**

6 Study data were collected using an electronic data capture (EDC) system.

7 Qualitative/quantitative data were evaluated utilizing a data processor and statistical software.

8 Survival analysis was used to analyze cumulative adverse events during surgery and at follow-
9 up. The analysis of safety for the devices was performed via Kaplan-Meier cumulative incidence
10 methods. Each complication/event-related Kaplan-Meier risk was presented with 95%
11 confidence limits.

12

13 **RESULTS**

14 The demographics of participants undergoing this procedure, including the sub-cohort
15 participants, are listed in **Table 1**. The mean age was 28.6 years (range: 18-44 years). The mean
16 baseline BMI was 21.4 kg/m² (16-27 kg/m²), increasing to 22.9 kg/m² at 3 years. Regarding
17 physical activity levels, 77% of patients are classified as active. The mean baseline breast
18 volume was 219 cc (100-343 cc), which increased to 399 cc (216-697 cc) at 3 years.

19 The implant/surgery characteristics are presented in **Table 2**. The Mini projection implants were
20 used in 96% of the patients (96 total), and the Demi in 4% (4 patients). Implants with a volume
21 of 140 cc and 165 cc were used in most cases, 38 and 35 patients, respectively, accounting
22 together for 73% of the devices used. The pre-operative mean breast volume and projection were
23 218.8 cc and 4.2 cm, after the procedure, the values were augmented to 388.7 cc and 5.8 cm,
24 respectively (**Table 3**). The incision length was less than 3 cm in 85.5% of the cases.

25 The length of time required for each step of the procedure is depicted in **Figure 4**. The
26 intraoperative data showed a mean (range) Infiltration time of 6 minutes (1-24 minutes), mean
27 Procedure time (pocket dissection and implant placement) of 11 minutes (5-25 minutes), and
28 mean overall time (infiltration/procedure) of 27 minutes (13-61 minutes). The mean immediate
29 recuperation time was 42 minutes (24-68 minutes).

30 The mean overall time decreased from approximately 38 minutes in December/2020 (N=30
31 patients) to 22 minutes in April/2021 (N=40 patients) (**Figure 4**).

1 All patients returned for their follow-up visits through 6 months. Of the 100 patients, 98%
2 complete their follow-up visit at 1 year, 90% at 2 years, and 93% at 3 years (**Table 2**). Post-
3 operative data in **Figure 5** reported that 76% of patients returned to daily activities (e.g.,
4 showering and clothing) within 2.8 days (mean, range 1 – 6), and 61% returned to exercise by
5 20.1 days (mean, range 7 – 30).

6 At the three-year timepoint, 75.3% of patients measured a 1 to 3 cup increase in bra size,
7 comprised of 24.7% of patients with a one cup, 19.1% two-cup, and 31.5% had more than a two-
8 cup increase. The portion of patients reporting no full cup change was 19.1%, with 5.6%
9 reporting a decrease of one cup size (**Figure 6** and **Supplementary Figures 1 and 2**). With all
10 patients resulting in an increased circumference measured at areola.

11 The Kaplan-Meier (KM) risk rates are presented in **Table 4**. The overall KM complication rate
12 was 3.2%, and the overall reoperation rate was 1%. One patient reported pain at the three-year
13 follow-up. An MRI revealed no clinical or pathological findings, and no further action was
14 necessary as the pain resolved. There was one patient (1%) who reported a left breast
15 asymmetry, which was due to a superior implant malposition. A minor secondary procedure
16 confirmed the upward migration of the implant into the channel toward the axillary incision. The
17 intervention was performed via the inframammary fold to recreate the pocket with the inflatable
18 balloon and reposition the implant without necessitating an implant exchange. There were no
19 other cases of malposition. Palpability was reported in one patient (1.1%) at the 2-year follow-
20 up. There were no patient reports of nipple or breast sensitivity issues, nor were there any
21 implant rupture, capsular contracture, rippling, infection, seroma, hematoma, or breast implant-
22 associated anaplastic large cell lymphoma (BIA-ALCL) documented.

23 The MRI cohort of 33 patients (**Table 4**) verified all implants were intact with no clinical or
24 diagnostic signs of implant rupture (intracapsular or extracapsular), gel leaks, or fractures at the
25 19-month (average) imaging time. This MRI cohort confirmed that all implants were positioned
26 in the intended pre-pectoral plane (**Figure 7**).

27 The results of the BREAST-Q patient questionnaire are presented in **Supplementary Figures 3**
28 **and 4**. Pre-procedure, 41% of patients reported “satisfaction with their breasts,” and at the 3-year
29 timepoint, 78% reported breast satisfaction. Patient satisfaction with the outcome of the
30 procedure was reported as 84% consistently through the 3 years. Surgeon satisfaction, assessed
31 by a 5-point Likert scale, reported that 90% of surgeons were “very satisfied” with the procedure

1 overall, 8% were “somewhat satisfied”, and 2% were “neither satisfied nor dissatisfied”. The
2 results of the surgeon's experience with the procedure are shown in **Supplementary Figure 5**.
3 The results of the POSAS scale measuring the quality of the right and left axillary scar (1 – best,
4 10 – worst) indicated a score of 1.0 from the surgeon's grading with the patient grade, a score of
5 1.9, are shown in **Supplementary Figure 6**.

7 **DISCUSSION**

8 Minimally Invasive Surgery has revolutionized most surgical specialties by enhancing precision
9 and reducing complications.^{9,23} Orthopedic and spine surgeries have illustrated the benefits of
10 minimally invasive techniques, resulting in smaller incisions, reduced postoperative pain,
11 quicker recovery times, and better cosmetic outcomes.^{9-14,32,33} Despite the advantageous adoption
12 in other specialties, MIS in plastic surgery remains under accessed, highlighting the opportunity
13 for implementation of these techniques.

14 The procedure evaluated in this study was developed to provide plastic surgeons and their
15 patients with a standardized, minimally invasive solution. It incorporates new efficiencies and
16 technologies, enabling a technique that significantly departs from conventional BA.

17 The minimally invasive and non-touch techniques utilized in this surgical approach are touted for
18 shortening the procedure under local anesthesia and recuperation durations, as well as other
19 clinical benefits such as the production of smaller scars, reducing surgical tissue trauma.³¹⁻³⁷

20 From an intraoperative perspective, the procedure demonstrated a significant reduction in overall
21 surgery and recovery times, in comparison to conventional surgery using subglandular, or
22 subfascial techniques, which are reported to last between 40 to 114 minutes, and 41 to 90
23 minutes, respectively.^{38,39} By comparison, the intraoperative process for this technique was
24 completed in an average of 27 minutes, including a mean induction period of 6 minutes for
25 infiltration, a waiting time of 15 minutes for the onset of the local anesthesia, with an actual
26 surgery duration of only 11 minutes.

27 The recovery duration averaged 41.7 minutes over the four-month enrollment period, with a
28 decrease to 24 minutes in the last phase of patient enrollment, demonstrating a short learning
29 curve for the medical team to gain the necessary experience to achieve both improved technique
30 and operative efficiency. All patients were discharged on the same day of surgery, and most
31 patients returned to their normal daily activities within 2.8 days and full exercise regimes by 20

1 days. This reduction in downtime can have a significant positive impact on the patient's
2 experience of breast augmentation surgery.

3 By reducing the surgery duration and recovery downtime, this procedure can be integrated into
4 the busy lives of the modern, active patient. This type of aesthetic enhancement is in a similar
5 category as other non-surgical cosmetic interventions and is the equivalent to time spent on
6 personal care, under 60 minutes^{40,41} signifying a potential to expand the consumer base to a
7 category of women.

8 Clinically, this reduction in intraoperative time may also improve patient outcomes as the length
9 of surgery can increase the probability of complications occurring, the recovery duration, and the
10 length of hospitalization.⁴¹ Another safety advancement is the elimination of general anesthesia,
11 promoting immediate ambulation, the removal of risks associated with general anesthetic
12 agents,⁴²⁻⁴⁴ and removing one of the most frequently cited patient barriers of surgery; the fear of
13 not waking up from the general anaesthetic.^{45,46}

14 Whether for aesthetic or reconstructive purposes, conventional BA surgery techniques disrupt the
15 internal supporting structures of the breast, which are predominantly supported by the skin and
16 the fascial system.^{47,48} These anatomical structures contribute to the overall shape and contour of
17 the breast and, when disrupted, can lead to complications such as malposition, which is reported
18 in traditional breast augmentation to be as high as 12%,⁴⁹ as a means for the procedure.⁵⁰

19 With this technique, these crucial native structures are not cut or compromised but rather
20 preserved. This is achieved with a three-pronged approach of hydro-dissection: the breast tissues
21 are moistened and separated with a tumescent solution, the nesting effect created by the
22 inflatable balloon, and the tenting effect, which allows for the use of less silicone volume.
23 Hydro-dissection is recognized for its effectiveness in separating dense collagenous tissues,
24 allowing for easier dissection and improved penetration with surgical instruments, as well as
25 reducing surgical bleeding, trauma, and overall surgical duration.⁵¹⁻⁵⁶

26 During this study, we encountered two instances of unintentional multi-plane implant placement,
27 which were identified during the procedure and led to the refinement of the breast infiltration
28 technique and the integration of HRUS. These combined efforts proved effective in facilitating
29 accurate prepectoral pocket creation, especially during early experience. The pocket location
30 with the inflatable balloon creates the breast tissue preservation space, behind the corpus
31 mammae and in front of the posterior lamella, within the boundaries of the circummammary

1 ligament (**Figure 3**). This 3-dimensional space is a nuanced departure from previous
2 subglandular or subfascial 2-dimensional planes, which further proves the utility of balloon
3 expansion for controlled pocket creation.

4 Traditional sharp cutting dissection or electrocautery to create the pocket, the inflatable balloon
5 utilized in this study atraumatically pushes the breast tissues radially, creating a “nest” around
6 the implant. This nesting concept refers to the result of elongating the breast tissues during a
7 controlled expansion of the inflatable balloon. The displaced tissue preserves uncut and thickens
8 the fibroglandular support surrounding the inflated balloon, forming a parenchymal enclosure or
9 nest around the implant. This method allows for positioning higher on the chest wall and
10 stabilization of the implant in the pocket by maintaining the essential breast ligaments and
11 supportive structures (**Figure 7**).

12 It is well documented in surgical literature that electrocautery (high thermal energy) might result
13 in several complications, including the devitalization of breast tissue, pain from the disruption of
14 sensory nerves in the costal periosteum, muscle contraction causing bleeding, inadequate
15 hemostasis, and thermal tissue damage in skin flaps.⁵⁷

16 As the third preservation prong, this surgical approach potentially reduces or remove the need to
17 use larger-volume implants in many women. However, this may be considered a limitation for
18 individuals seeking more voluminous enhancement. Breast implant weight increases mechanical
19 stress on supportive tissues,⁵⁸⁻⁶⁰ making preservation – especially of the circummammary
20 ligament – essential for optimal support. This study reported no cases of inferior implant
21 malposition. Furthermore, larger implants can exert significant pressure on the breast skin and
22 lower pole, potentially leading to soft tissue thinning and compromised long-term results.^{21,58-60}
23 Munhoz et al. observed a 96% satisfaction rate with SmoothSilk implants, averaging 191.47 cc,
24 achieving a natural breast shape with no reported implant exchanges.²¹

25 This is due to a “tenting effect”, which can only be achieved by the unique geometric
26 characteristics of the aforementioned implant, as it features a symmetrical double-sided apex
27 originating from its equator, enabling it to retain its uniform projection regardless of the position
28 against the chest wall or the mammary gland. At 180°, this implant geometry increases projection
29 by 22% compared to the same volume round implants, used in conventional BA, thereby
30 allowing for less silicone volume, i.e., a smaller implant size to achieve the desired projection.

31 The tenting effect recruits preserved breast tissue into the posterior region of the breast, which is

1 typically occupied by silicone gel when a device with standard projection, base, and shape is
2 used in conventional breast augmentation. The sample MRI substudy patient showed a
3 significant increase in breast projection due to the recruitment of breast tissue with the implant
4 and technique utilized for this procedure, **Figure 7**. Recruiting breast tissue facilitates projection
5 and reduces the amount of silicone needed, thereby lessening mechanical stress and
6 complications associated with larger implant volumes, such as tissue thinning and parenchymal
7 atrophy⁵⁸

8 The study reported zero patient reports of loss of nipple or breast sensation, also an improvement
9 from traditional methods. The preservation was not limited to the supportive breast tissues alone
10 but also the sensory innervation of the breast, due to implant weight causing nerve compression,
11 and to conventional pocket dissection and implant insertion, as these approaches can disrupt the
12 fourth and fifth anterior intercostal nerves, compromising the viability and sensation of the
13 breast.⁶¹

14 There were no implant-related complications reported throughout the 3-year study, including no
15 cases of capsular contracture or implant rupture. A comparable low incidence of these device-
16 related complications with Motiva implants has also been observed in literature¹⁵⁻²¹ and recently
17 evidenced in the FDA clinical trial results, in which the capsular contracture and rupture rates
18 were 0.5% and 0.6%, respectively, through five years.¹⁵ Implant rupture is of particular relevance
19 given the degree of deformation required to insert these devices via minimally invasive routes.
20 However, as demonstrated in the MRI sub-study, there were no cases of implant rupture or gel
21 fracture, corroborating the rupture results associated with this implant brand observed in other
22 studies.¹⁵⁻²¹

23 The high-strength silicone dispersion with an increased viscoelasticity of the elastomer shell
24^{17,18,20} enables the implant to be injected through a minimal incision and to endure greater
25 deformation without compromising shell integrity, essential for this procedure.

26 The effectiveness outcomes in the study are aligned with the patient's and surgeon's experience
27 of this procedure. A portion of subjects reported either no change or a decrease in their 3-year
28 cup size compared with their baseline. This paradoxical finding correlated with an overall
29 increase in BMI and the associated expansion of the inframammary circumference of the thorax.
30 According to the European Standard for measuring cup size, used in this study, all these patients
31 had an increase in the areolar circumference of the thorax after the procedure and this

1 measurement remained relatively stable during the follow-up time. Thus, the reduction in cup
2 size results from the differential reduction between the inframammary circumference and the
3 areolar circumference measure. The results of the BREAST-Q showed high patient satisfaction
4 (84%) with the outcome and an 87% increase in breast satisfaction at the three-year follow-up.
5 Similarly, the POSAS scar results found that the patient's perception of the scar resembled that of
6 their own skin. This is important as another barrier cited by women who avoid breast implants is
7 due to perceived objectification and stigmatization.⁶² In our study, while device and surgical
8 technology are integral to improving patient outcomes, the learning curve associated with
9 surgical practice change can be a deterrent for the surgeon and preclude the adoption of new
10 techniques.^{63,64} However, 90% of surgeons were "very satisfied" with their overall experience
11 and none "dissatisfied", thus conducive to the adoption of new surgical devices and practices.
12 This prospective 3-year follow-up study has limitations that should be considered when
13 interpreting the findings. First, the small sample size and single-center design restrict statistical
14 power, potentially limiting generalizability. Second, demographic representation may affect the
15 generalizability of the findings, as the relatively small implant size employed in this procedure
16 could limit the subset of patients who may benefit from it. Variability in assessment methods—
17 whether self-reported or clinician-evaluated—introduces potential bias, influencing the
18 consistency of data collection. Taken together, these considerations could be addressed in future
19 research involving larger, multicenter cohorts and direct comparisons with conventional
20 techniques, to strengthen reliability and improve external validity.

21

22 CONCLUSIONS

23 The study reported minimal device-related complications and minimal technique-related
24 complications, leading to positive clinical outcomes and low reoperation rates. This MIS
25 technology enables breast tissue preservation, promoting low-inflammatory breast stability
26 without using the pectoralis muscle, enhanced recruitment and redistribution of breast tissue into
27 the final volumetric result, and shorter operating times without general anesthesia. Additionally,
28 it allows for quicker discharge times and a shorter, straightforward recovery that aligns with the
29 lifestyle of an active modern woman.

1 Mia Femtech and the novel concepts explored in this study represent a paradigm shift in BA
2 surgery, as moving away from conventional techniques toward a new practice of breast tissue
3 preservation.

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1 **Figure Legends**

2

3 **Figure 1:** Mia Femtech Minimally Invasive System: Image with the five Motiva proprietary
4 tools, including a. Marking Tool, b. Channel Separator, c. Inflatable Balloon (with the
5 incorporated manual pump and introducer), d. Implant Injector, and e. Ergonomix2 Diamond
6 implants. From Establishment Labs; with permission.

7

8 **Figure 2:** Preoperative patient markings identifying the incision site, the pocket boundaries, and
9 the final dissection location. From Establishment Labs; with permission.

10

11 **Figure 3:** Breast Tissue Preservation Space located between the corpus mammae and the
12 posterior lamella. From Establishment Labs; with permission.

13

14 **Figure 4:** Graph showing the intraoperative timing of the overall Mia procedure and the timing
15 for the individual steps, and the progressive time decrease (in minutes). Infiltration:
16 Administration of tumescent local anesthesia in the prepectoral space. Mia Procedure: Pocket
17 creation and implant placement. Overall Time: Infiltration and procedure combined. Immediate
18 Recuperation: Time spent in the recovery room.

19

20 **Figure 5:** Graph of post-procedure timing: Return to activities.

21

22 **Figure 6:** Pre-procedure (A, frontal; C, lateral left, and E, lateral right) and 3-year post-Mia
23 procedure images (B, frontal, D, lateral left, and F, lateral right), with SmoothSilk Ergonomix2
24 Diamond Mini 140 cc implant. Baseline photos present a 28-year-old patient with an initial cup
25 AA and breast volume of 203 and 198 cc in the right and left breast, respectively. Three-year
26 photos present a final cup size B, and the total breast volume increased to 365 (R) and 331 (L)
27 cc. The results post-Mia procedure demonstrates procedure stability.

28

29 **Figure 7:** MR images of a 41-year-old female patient show (A) a T2 axial MRI of Motiva
30 SmoothSilk Ergonomix2 Diamond Implants (Mini projection, 140 cc) and (B) T1 sagittal MRI of

1 Motiva SmoothSilk Ergonomix2 Diamond Implants (Mini projection, 140 cc), confirming
2 implant position and preserved surrounding breast tissues.

3

4

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1 **Table 1. Participant Demographics**

Characteristics: overall	Participants (N=100)
Mean Age (range), y	28.6 (18 - 44)
Mean BMI, mean (range), kg/m ²	Baseline: 21 (16 - 27)
Professional Employment, (%)	57
College/ University Graduate, (%)	62
Physical activity, (%)*	
Level 0	23
Level 1	10
Level 2	36
Level 3	26
Level 4	5

2
 3 *Physical activity was assessed based on weekly hours using the following scale: 0 = no physical
 4 activity (sedentary), 1 = 1–4 hours per week, 2 = ≥5 but <7 hours per week, 3 = ≥8 but <10 hours
 5 per week, and 4 = ≥10 hours per week or classified as a high-performance athlete.

6
 7

1 **Table 2. Device and Surgery Characteristics**

Device Characteristic	Cumulative Total, n (%)
Projection Mini Demi	192 (96%) 8 (4%)
Volume (cc) ≤100 101-125 126-140 141-165 166-170 171-190	14 (7%) 22 (11%) 76 (38%) 70 (35%) 4 (2%) 14 (7%)
Incision Length: <3 cm 3-4 cm Not recorded	171 (85.5%) 11 (5.5%) 18 (9%)
Implant Placement: Prepectoral Plane Submuscular Plane	100 (100%) 0 (0%)
Patient Follow-Up: 24 h - 6 months Year 1 Year 2 Year 3	100 (100%) 98 (98%) 90 (90%) 93 (93%)

2
3

1 **Table 3. Pre- and post-operative breast and implant measurements**

Variable	Mean, (range)
Pre-operative breast volume, cc	218.8 (103-343)
Pre-operative breast projection, cm	4.2 (2.8 – 5.7)
Implant volume, cc	148.2 (100-190)
Implant projection, cm	3.2 (2.8 – 3.8)
Post-operative breast volume, cc	388.7 (201-776)
Post-operative breast projection, cm	5.8 (4.2 – 7.3)

2
3

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1 **Table 4. Kaplan-Meier Risk Complications through 3 years.**

Complication	3-year (n=100, 95% Confidence Interval)
Capsular contracture (Baker Grade III/IV)	0%
Rupture, Suspected or confirmed*	0%
Infection	0%
Seroma	0%
Hematoma	0%
Superior Malposition**	1.0% (0.0,3.0%)
Inferior Malposition	0%
Lateral Malposition	0%
Medial Malposition	0%
Rippling	0%
Loss in Nipple Sensation	0%
Loss in Breast Sensation	0%
Any Complication	3.2% (0.0,6.8%)
Any Reoperation	1.0% (0.0,3.0%)

2

3 *Includes overall rupture rate and MRI cohort combined.

4 **1 Superior Malposition: (L) implant with reposition procedure.

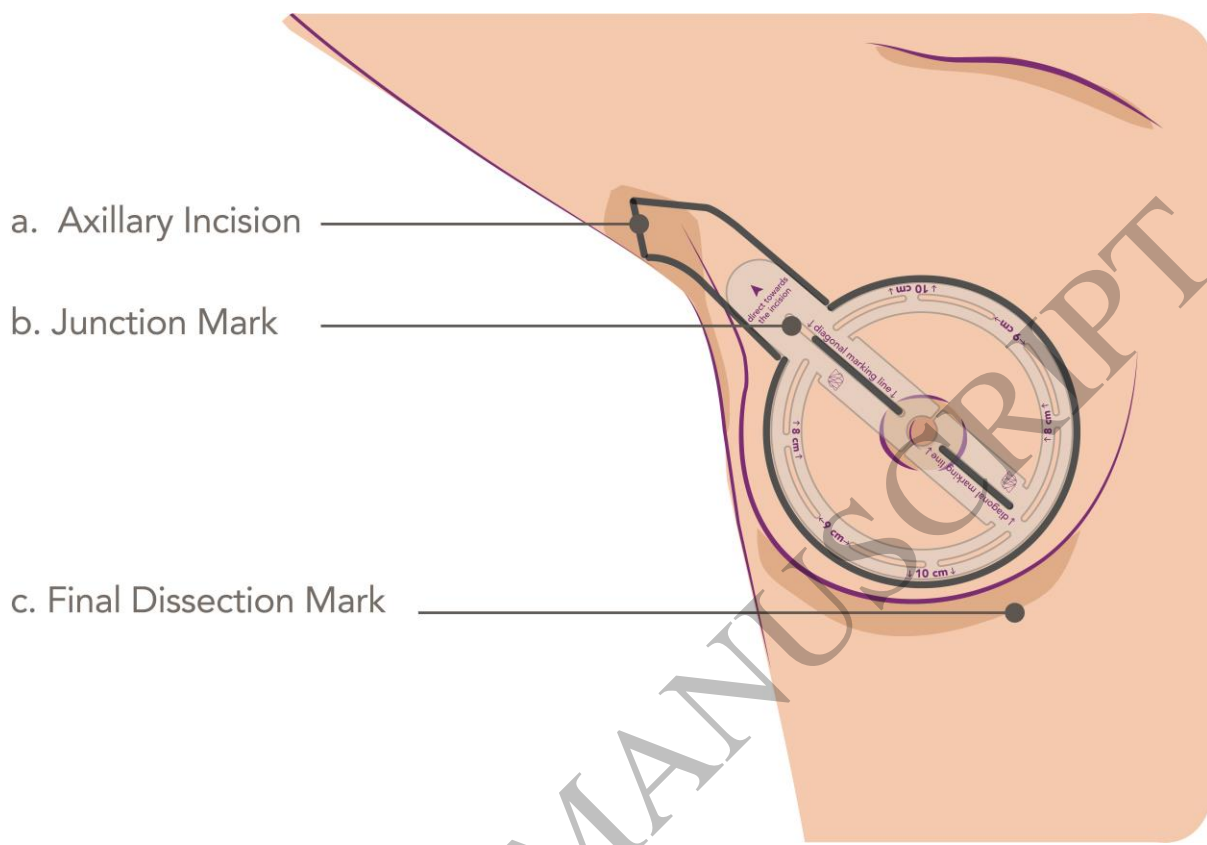
5

6



Figure 1
159x100 mm (x DPI)

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a. Axillary Incision

b. Junction Mark

c. Final Dissection Mark

Figure 2
159x110 mm (x DPI)

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ACCEPTED MANUSCRIPT

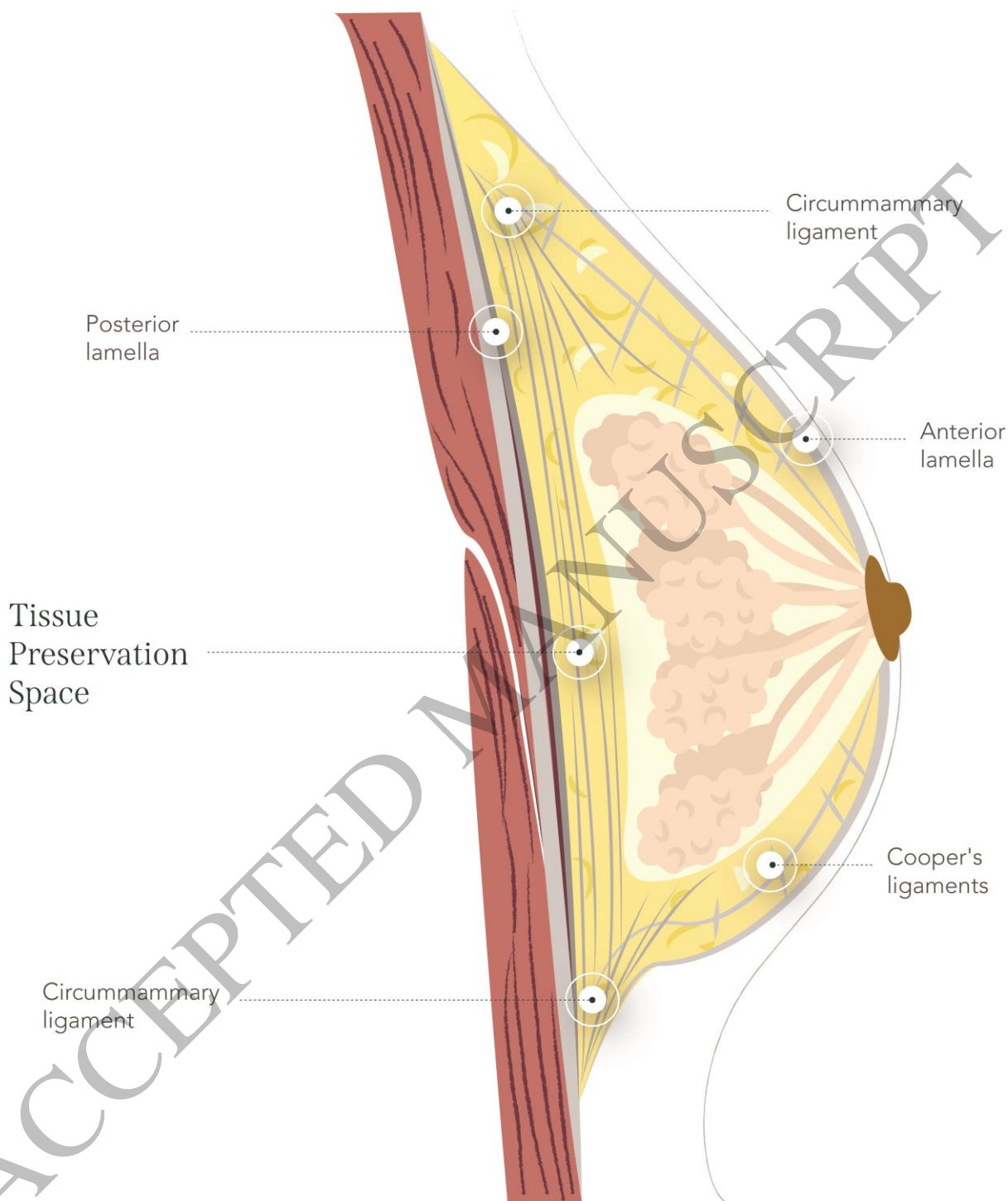


Figure 3
159x190 mm (x DPI)

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Intraoperative timing of the overall Mia Procedure and its individual steps
(N=100)

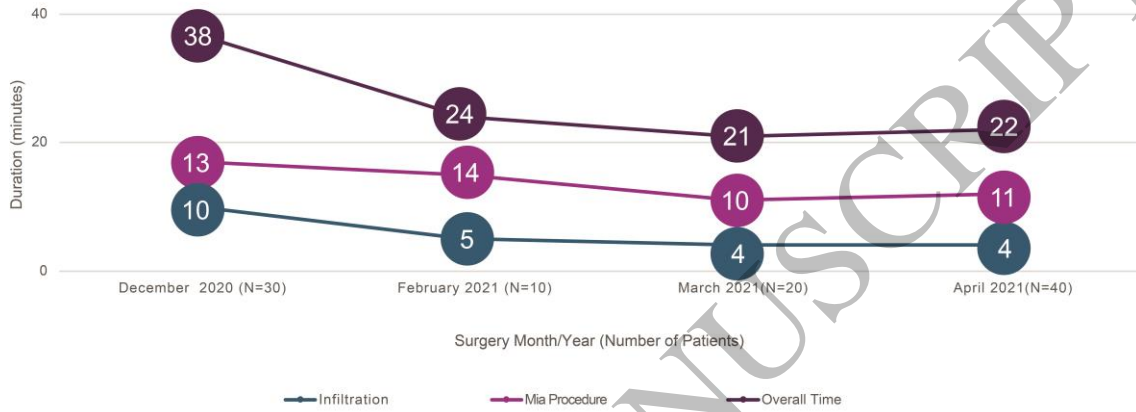


Figure 4
159x92 mm (x DPI)

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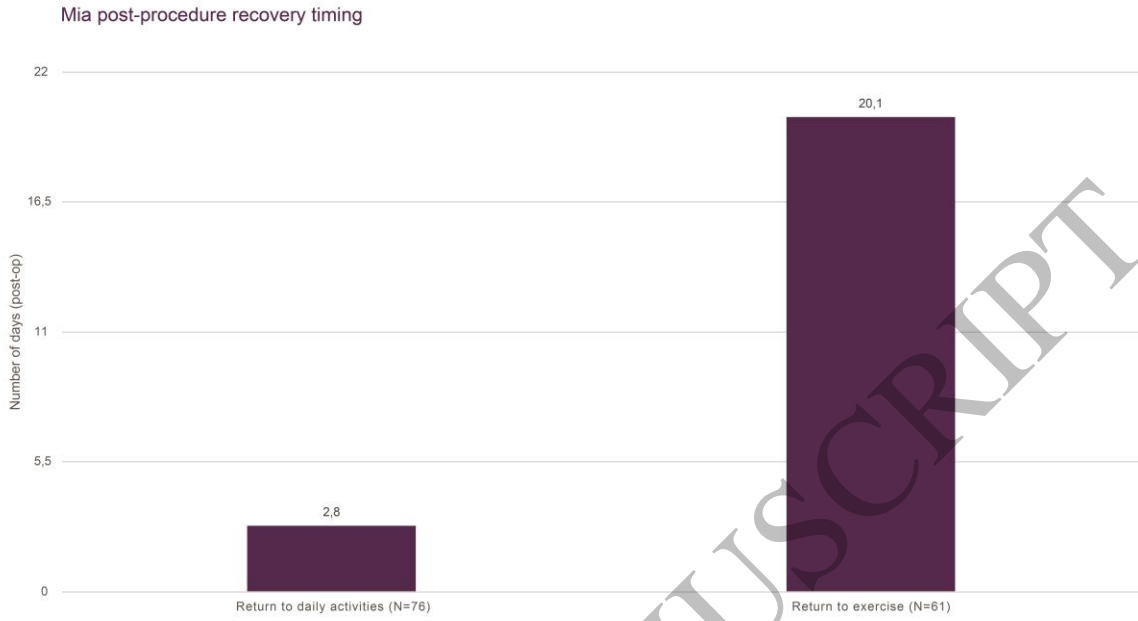


Figure 5
159x86 mm (x DPI)

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Figure 6A
159x173 mm (x DPI)

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Figure 6B
159x155 mm (x DPI)

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Figure 6C
159x214 mm (x DPI)

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Figure 6D
159x141 mm (x DPI)

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Figure 6E
159x235 mm (x DPI)

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Figure 6F
159x139 mm (x DPI)

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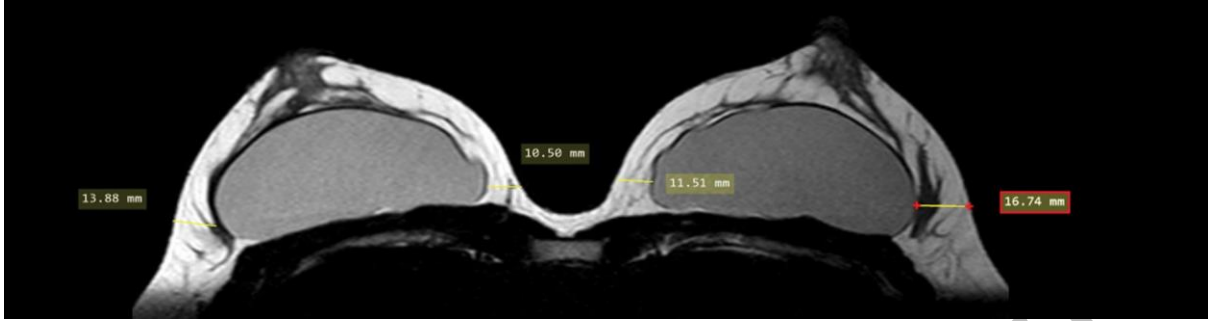


Figure 7A
159x42 mm (x DPI)

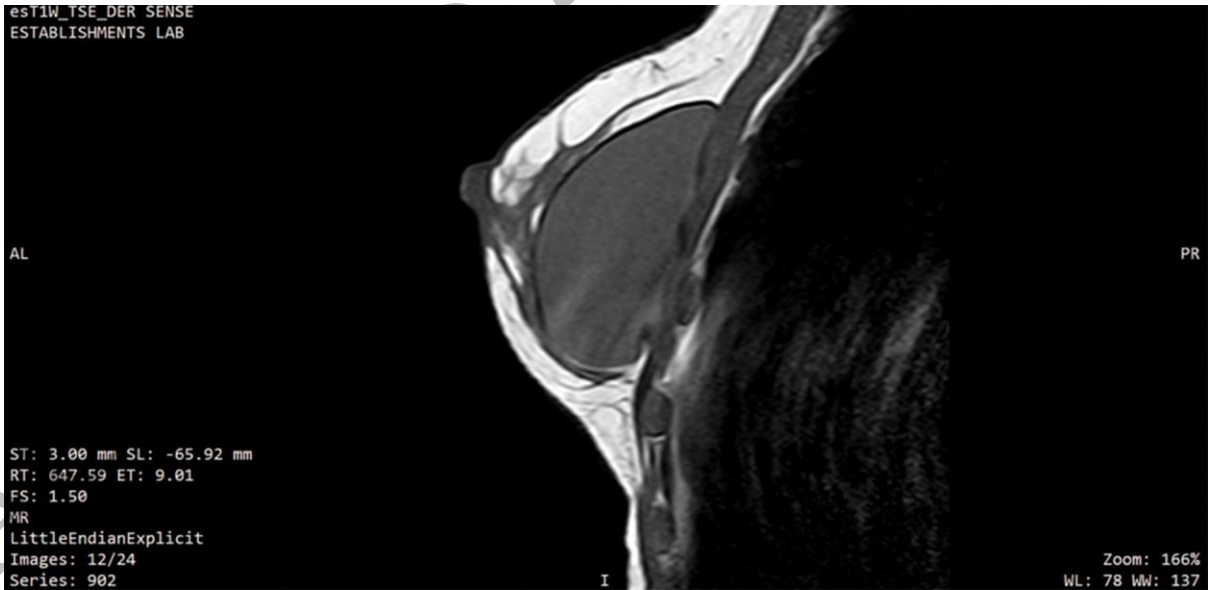


Figure 7B
159x77 mm (x DPI)