

Aesthetic Breast Surgery

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

Manuel Chacon-Quiros, MD; Marcos Sforza, MD, SBCP;
Pablo Solis-Chaves, MD; Giovanni Herrera-Mora, MD;
Giovanni Botti, MD, AICPE;
Alexandre Mendonça Munhoz, MD, PhD, SBCP;
Kristoff Verdonck, MD; Yoshinori Nagumo, MD;
Rosalyn Cole D'Incelli, CCRP; Jorge Villalobos-Alpizar, MD;
Christine Clausen-Oreamuno, MD; and Charles Randquist, MD

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Abstract

Background: Conventional breast augmentation using different approaches and implant pockets faces challenges such as societal stigma, long recovery time, invasion of the breast, and complication rates. Previous minimally invasive approaches have failed to provide long-term safety, effectiveness, and patient satisfaction. The authors of this study introduce a minimally invasive breast harmonization procedure, performed with an inflatable balloon and a biconvex-shaped silicone-filled implant, addressing these limitations with a safe and innovative solution.

Objectives: In this prospective controlled study, the authors evaluate the safety and effectiveness of this procedure, reducing surgical complications while providing a new treatment option for breast enhancement.

Methods: A 3-year, IRB-approved study enrolled 100 participants undergoing this procedure, utilizing an axillary incision with prepectoral implant placement. Safety was assessed by monitoring the cumulative incidence of postoperative complications in scheduled visits and with MRI evaluations in a randomized subcohort (33 participants). Patient satisfaction was measured pre- and postprocedure using Breast-Q questionnaires and scar evaluation with the Patient and Observer Scar Assessment Scale.

Results: Effectiveness endpoint at 3 years reported a 75.3% bra increase of 1 to 3 cup sizes. The overall Kaplan–Meier complication rate at 3 years was 3.2%, with low reoperation rates and 93% follow-up compliance. There were no patient reports of nipple or breast sensitivity loss, nor surgeon-reported incision-related complications, implant rupture, capsular contracture (Baker Grade III/IV), infection, seroma, rippling, hematoma, or breast implant-associated anaplastic large cell lymphoma.

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

Level of Evidence: 4 (Therapeutic)

Conventional breast augmentation (BA) is one of the most sought-after surgical aesthetic procedures practiced worldwide, with nearly

1.9 million women choosing this procedure in 2023 to improve their physical appearance and self-confidence.¹ However, the

Drs Chacon-Quiros, Solis-Chaves, and Herrera-Mora are plastic surgeons in private practice, Morenos, Costa Rica. Dr Sforza is a plastic surgeon, The Dolan Park Hospital, Birmingham, UK. Dr Botti is a plastic surgeon in private practice, Salò, Italy. Dr Munhoz is a plastic surgeon, Division of Plastic Surgery, Hospital Sírio-Libanês, São Paulo, Brazil. Dr Verdonck is a plastic surgeon in private practice, Diest, Belgium. Dr Nagumo is a plastic surgeon in private practice, Tokyo, Japan. Ms D'Incelli is the senior vice president of Clinical, Medical, and Regulatory Affairs and Dr Villalobos-Alpizar, and Dr Clausen-Oreamuno are physicians, Motiva Clinical and

Medical Affairs teams, Establishment Labs Holdings Inc., Alajuela, Costa Rica. Dr Randquist is a plastic surgeon in private practice, Saltsjöbaden, Sweden.

Corresponding Author:

Dr Manuel Chacon-Quiros, Avenida 3, San José, Morenos, Costa Rica.
E-mail: drmanuelchaconquiros@gmail.com; Instagram: [@manuelchaconmd](https://www.instagram.com/manuelchaconmd)

objectification and stigmatization of breast implants, fear of surgery, downtime, and recuperation, along with related complications and reoperation rates, have led a large portion of women to avoid BA surgery. Others have pursued the use of nonsurgical alternatives such as breast fillers to augment the breast shape and size.^{2,3} Although breast fillers were initially thought to provide a quick, noninvasive solution, the onset of complications, including systemic infection, granulomas, filler migration, disruption of essential mammography screenings, and the lack of clinical safety evidence, prompted regulatory action and the prohibition of breast fillers in several countries.⁴⁻⁷

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

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

Despite these advancements, the continued use of conventional surgical techniques persists, alongside consumer concerns. Meanwhile, the breast aesthetics consumer has evolved significantly. Surgical procedures have declined, with a growing preference for minimally invasive treatments—consumer acceptance of noninvasive options has risen 81% since 2017.²²

Today's aesthetic consumers are more informed and wellness focused. Among women, 40% use wellness apps and invest more in exercise and sports.²³ A study of 4962 women (ages 20-60) found that 6 in 19 are dissatisfied with their breasts, with 68% relying on compensatory methods (padded, pushup bras, etc). Concerns about traditional BA include fear of general anesthesia (16%), painful recovery (16%), and postoperative logistics (18%).²⁴

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

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

The aim of the authors of this study was to evaluate the safety and effectiveness of a novel MIS, as a new solution for women seeking breast enhancement. Here, we report the 3-year outcomes in 100

consecutive patients and discuss the MIS technique and its intended design to provide safe, reproducible, long-term outcomes while preserving the native breast tissue. New aesthetic concepts such as “nesting” and “tenting” effects are introduced. The authors also measured patient and surgeon experience as well as their satisfaction with the aesthetic results, using validated measurement tools.

METHODS

Study Design

A total of 100 women undergoing bilateral Mia Femtech procedures (Establishment Labs) between December 2020 and April 2021 were studied prospectively from preoperative through 3 years of follow-up to assess the safety and effectiveness of the procedure. A simple randomized MRI substudy was conducted on 33 patients at least 18 months postimplantation to assess for asymptomatic rupture and visually confirm the plane of placement of the implant. A single patient from the substudy was randomly selected for a supplementary MRI analysis of the geometrical properties of the implant.

The study was conducted by a board-certified plastic surgeon in San Jose, Costa Rica. All patients underwent the informed consent process. The study follows the principles of the Declaration of Helsinki and the United States FDA Class 3 pivotal study design. The study received review and approval from the institutional ethics committee (Comité Ético Científico de la Fundación Inciensa, CEC-FUNIN-006-2020) on December 3, 2020.

Study Participants and Data Collection

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

MRI Subcohort

MRI data were collected from 33 participants selected using Minitab 19 Statistical Software (Minitab LLC, State College, PA). Each participant underwent imaging utilizing a 1.5 Tesla machine, 18 to 21 months postprocedure. The imaging sequences protocol included axial and sagittal T₂-weighted fast spin echo and axial short tau inversion recovery (STIR) with water and silicon suppression.

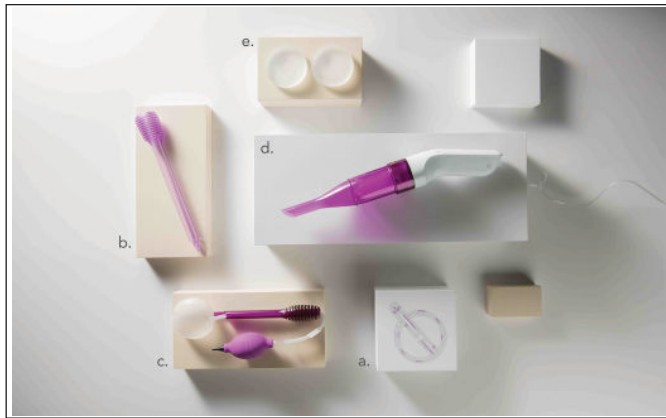


Figure 1. Mia Femtech minimally invasive system, which contains 5 Motiva proprietary tools, including a marking tool (a), channel separator (b), inflatable balloon (with the incorporated manual pump and introducer (c), implant injector (d), and Ergonomix2 Diamond implants (e). Image reproduced with permission from Establishment Labs.

Breast Implant Devices and Surgical Technologies

All procedures were performed using the Mia System (Figure 1), which includes 6 approved proprietary instruments produced by Motiva (Establishment Labs): a marking tool, a channel separator, 2 inflatable balloons (with the incorporated manual pump and introducer), an implant injector, and the Motiva SmoothSilk Ergonomix2 Diamond SmoothSilk silicone-gel-filled breast implants. There is an additional cost beyond the expense of acquiring the implants alone, because of the single-use devices required for this technique.

Surgical Approach

Preoperative Assessment

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

Mia Procedure: Anesthesia Protocol

All patients received premedication (750-1000 mg of acetaminophen and 1 mg intravenous cephalosporine). Baseline monitoring was applied, and most of the procedures (90 patients) were performed under conscious sedation, which consisted of intravenous infusion of an amnestic, opioid analgesic, nonsteroidal anti-inflammatory, antiemetic, induction agent, and/or an optional gastroprotective agent as deemed appropriate by the surgeon. The first 10 patients were performed under general anesthesia, as the first anesthetic phase evaluation. A tumescent local anesthesia solution was utilized (1 L of 0.9% normal saline, 1 g lidocaine, 2 mg epinephrine, and 10 mL sodium bicarbonate).

The most utilized infiltration protocol was performed with the aid of HRUS and an infusion pump connected to a cannula. The

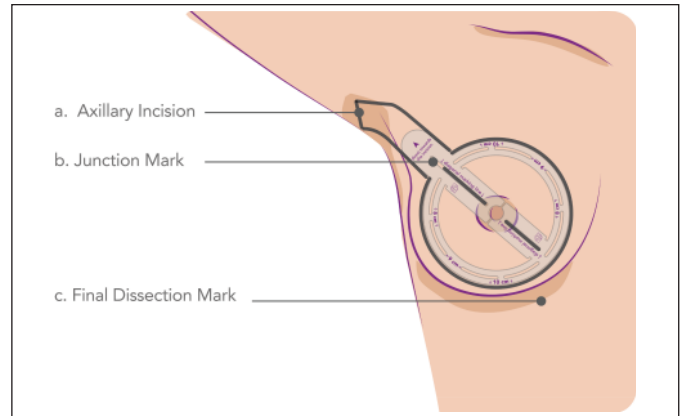


Figure 2. Preoperative patient markings identifying the incision site (a), the pocket boundaries (b, superolateral), and the final dissection location (c). Image reproduced with permission from Establishment Labs.

cannula was inserted into the upper corner of the axillary marking and advanced into the prepectoral position, spanning the entire breast circumference up to the final marking point. Following infiltration, a gentle massage supported uniform distribution, followed by a wait time of 15 min to allow stable analgesia and vasoconstriction.^{29,30}

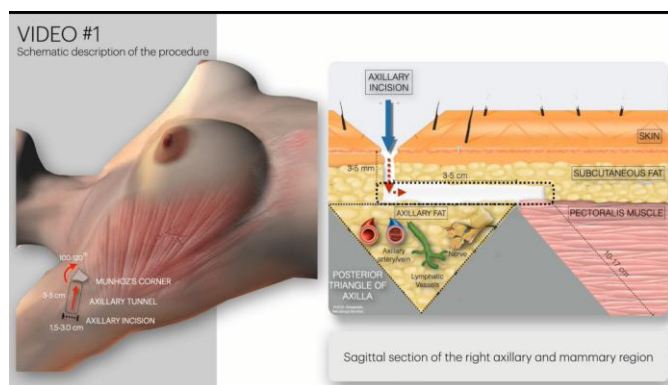
Mia Procedure

All procedures were performed by the corresponding author of this article, a board-certified plastic surgeon. Commercial distribution of this product will be limited to only board-certified plastic surgeons. Preoperative breast markings were conducted with the patient standing and their arms raised. Using the marking tool, 3 points were indicated to identify the incision site, the pocket boundaries, and the final dissection location (Figure 2). The incision site was marked in the axilla, measuring 2.0 to 4.0 cm in length and down to the fat compartment. A second junction mark indicated the pocket diameter corresponding to the chosen implant's base. A final third mark was drawn from the second junction mark through the center of the marking tool toward the lower pole of the breast to denote the final dissection location, ensuring it remained within 2 cm past the chosen pocket marking, which corresponds to the separator's tip length.

During all procedures, the patient was positioned in a supine position and their arms extended at a 110° angle to facilitate access to the surgical site, deep access to the axilla, minimize skin tension, and reduce the risk of incision tears. The technical basis of the axillary incision and superficial dissection up to the lateral border of the pectoralis major muscle (PMM), with total preservation of the anatomical structures of the axilla, was based on the axillary BA technique previously described.^{18,19,26,27}

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

Next, the inflatable balloon was introduced through the previously created channel to create the placement position, and then inflated



Video 1. Watch now at <http://academic.oup.com/asj/article-lookup/doi/10.1093/asj/sjaf196>



Video 3. Watch now at <http://academic.oup.com/asj/article-lookup/doi/10.1093/asj/sjaf196>

to expand and create the pocket, thus pushing the breast tissues radially. Hemostasis was maintained by the localized pressure of the balloon in conjunction with the vasoconstriction of the blood vessels induced by epinephrine. After balloon expansion and subsequent deflation, the balloon was removed from the pocket. The implant was inserted into the pocket using the injector device, allowing a minimally invasive and no-touch technique intended to reduce the risk of bacterial contamination and minimize trauma to the adjacent tissues.^{28,31-36} Implant positioning was confirmed by HRUS before final closure. The subcutaneous layer was closed in a standard fashion using a 3-0 absorbable monofilament suture and topical skin glue for the epidermis layer. **Videos 2** and **3** present a Mia procedure performed by the senior author of the study, and an endoscopic view following the pocket creation, where the implant is positioned in a space between the posterior lamella and the breast gland, within multilayered ligaments and fat (**Figure 3**).

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

Data Analysis

Study data were collected using an electronic data capture system. Qualitative/quantitative data were evaluated utilizing a data processor and statistical software. Survival analysis was utilized to analyze cumulative adverse events during surgery and at follow-up. The



Video 2. Watch now at <http://academic.oup.com/asj/article-lookup/doi/10.1093/asj/sjaf196>

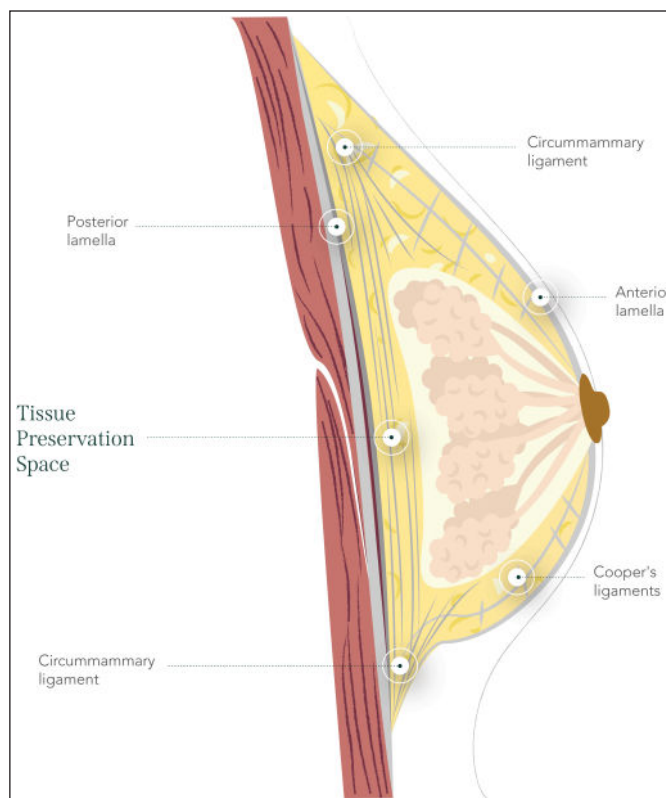


Figure 3. Breast tissue preservation space located between the corpus mammae and the posterior lamella. Image reproduced with permission from Establishment Labs.

analysis of safety for the devices was performed through Kaplan-Meier (KM) cumulative incidence methods. Each complication/event-related KM risk was presented with 95% CIs.

RESULTS

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

Table 1. Participant Demographics

Characteristics: overall	Participants (N = 100)
Mean age (range), years	28.6 (18-44)
Mean BMI, mean (range), kg/m ²	Baseline: 21 (16-27)
Professional employment, %	57
College/university graduate, %	62
Physical activity, % ^a	
Level 0	23
Level 1	10
Level 2	36
Level 3	26
Level 4	5

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

Table 3. Preoperative and Postoperative Breast and Implant Measurements

Variable	Mean (range)
Preoperative breast volume, cc	218.8 (103-343)
Preoperative 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)
Postoperative breast volume, cc	388.7 (201-776)
Postoperative breast projection, cm	5.8 (4.2-7.3)

The implant/surgery characteristics are presented in Table 2. The Mini projection implants were utilized in 96% of the patients (96 total), and the Demi in 4% (4 patients). Implants with a volume of 140 and 165 cc were utilized in most cases, 38 and 35 patients, respectively, accounting together for 73% of the devices utilized. The preoperative mean breast volume and projection were 218.8 cc and 4.2 cm, after the procedure, the values were augmented to 388.7 cc and 5.8 cm, respectively (Table 3). The incision length was <3 cm in 85.5% of the cases.

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

The mean overall time decreased from ~38 min in December/2020 ($n = 30$ patients) to 22 min in April/2021 ($n = 40$ patients; Figure 4).

All patients returned for their follow-up visits through 6 months. Of the 100 patients, 98% complete their follow-up visit at 1 year, 90% at 2 years, and 93% at 3 years (Table 2). Postoperative data in Figure 5

Table 2. Device and Surgery Characteristics

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

reported that 76% of patients returned to daily activities (eg, showering and clothing) within 2.8 days (mean, range 1-6 days), and 61% returned to exercise by 20.1 days (mean, range 7-30 days).

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

The KM risk rates are presented in Table 4. The overall KM complication rate was 3.2%, and the overall reoperation rate was 1%. One patient reported pain at the 3-year follow-up. An MRI revealed no clinical or pathological findings, and no further action was necessary as the pain resolved. There was 1 patient (1%) who reported a left breast asymmetry, which was because of a superior implant malposition. A minor secondary procedure confirmed the upward migration of the implant into the channel toward the axillary incision. The intervention was performed through the inframammary fold to recreate the pocket with the inflatable balloon and reposition the implant without necessitating an implant exchange. There were no other cases of malposition. Palpability was reported in 1 patient (1.1%) at the 2-year follow-up.

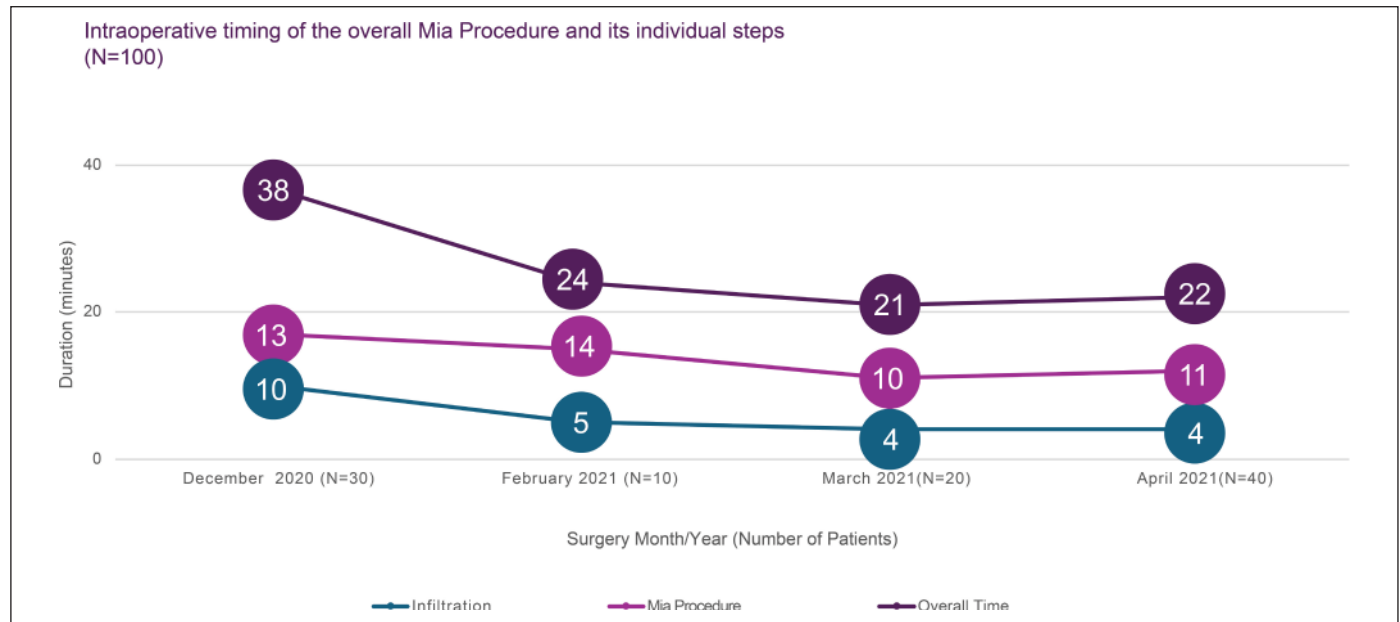


Figure 4. Graph showing the intraoperative timing of the overall Mia procedure and the timing for the individual steps, and the progressive time decrease (in minutes). Infiltration: administration of tumescent local anesthesia in the prepectoral space. Mia procedure: pocket creation and implant placement. Overall time: infiltration and procedure combined. Immediate recuperation: time spent in the recovery room.

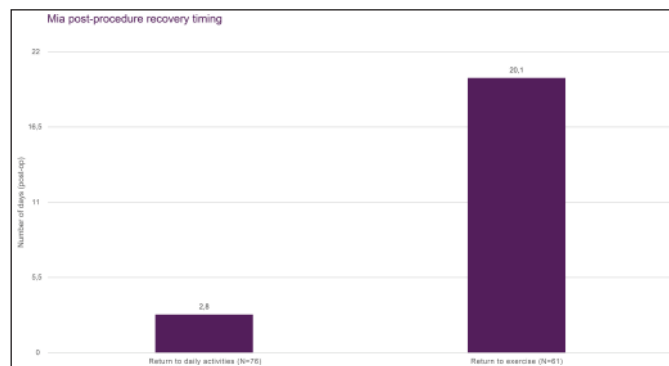


Figure 5. Graph of postprocedure timing: return to activities.

There were no patient reports of nipple or breast sensitivity issues, nor were there any implant rupture, capsular contracture, rippling, infection, seroma, hematoma, or breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) documented.

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

The results of the BREAST-Q patient questionnaire are presented in Supplemental Figures 3 and 4. Preprocedure, 41% of patients reported “satisfaction with their breasts,” and at the 3-year time point, 78% reported breast satisfaction. Patient satisfaction with the outcome of the procedure was reported as 84% consistently through the 3 years. Surgeon satisfaction, assessed by a 5-point Likert scale, reported that 90% of surgeons were “very satisfied” with the procedure overall, 8% were “somewhat satisfied,” and 2% were “neither satisfied nor dissatisfied.” The results of the surgeon’s experience with the procedure are shown in Supplemental Figure 5.

The results of the POSAS scale measuring the quality of the right and left axillary scar (1—best, 10—worst) indicated a score of 1.0

from the surgeon’s grading with the patient grade, a score of 1.9 is shown in Supplemental Figure 6.

DISCUSSION

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

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

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

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

The recovery duration averaged 41.7 min over the 4-month enrollment period, with a decrease to 24 min in the last phase of patient enrollment, demonstrating a short learning curve for the medical team to gain the necessary experience to achieve both improved technique and operative efficiency. All patients were discharged on

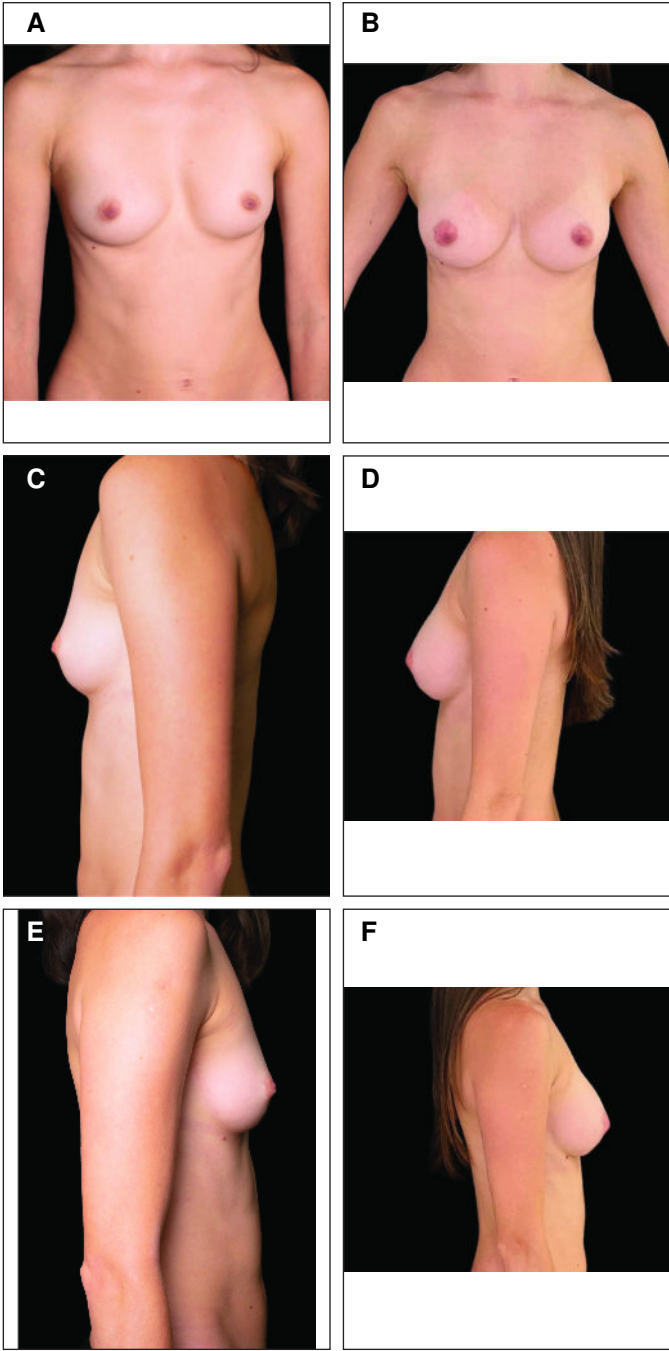


Figure 6. Preprocedure (A, frontal; C, lateral left, and E, lateral right) and 3-year post-Mia procedure images (B, frontal, D, lateral left, and F, lateral right), with SmoothSilk Ergonomix2 Diamond Mini 140 cc implant. Baseline photos present a 28-year-old patient with an initial cup AA and breast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

the same day of surgery, and most patients returned to their normal daily activities within 2.8 days and full exercise regimes by 20 days. This reduction in downtime can have a significant positive impact on the patient's experience of BA surgery.

By reducing the surgery duration and recovery downtime, this procedure can be integrated into the busy lives of the modern, active patient. This type of aesthetic enhancement is in a similar category as other nonsurgical cosmetic interventions and is the equivalent to

Table 4. Kaplan–Meier Risk Complications Through 3 Years

Complication	3-year (n = 100, 95% CI)
Capsular contracture (Baker Grade III/IV)	0%
Rupture, suspected, or confirmed ^a	0%
Infection	0%
Seroma	0%
Hematoma	0%
Superior malposition ^b	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%)

^aIncludes overall rupture rate and MRI cohort combined. ^bOne superior malposition: (L) implant with reposition procedure.

time spent on personal care, under 60 min signifying a potential to expand the consumer base to a category of women.^{40,41}

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

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

With this technique, these crucial native structures are not cut or compromised but rather preserved. This is achieved with a 3-pronged approach of hydro-dissection: the breast tissues are moistened and separated with a tumescent solution, the nesting effect created by the inflatable balloon, and the tenting effect, which allows for the use of less silicone volume.

Hydro-dissection is recognized for its effectiveness in separating dense collagenous tissues, allowing for easier dissection and improved penetration with surgical instruments, as well as reducing surgical bleeding, trauma, and overall surgical duration.⁵¹⁻⁵⁵

During this study, we encountered 2 instances of unintentional multi-plane implant placement, which were identified during the procedure and led to the refinement of the breast infiltration technique and the integration of HRUS. These combined efforts proved effective in facilitating accurate prepectoral pocket creation, especially during early experience. The pocket location with the inflatable



Figure 7. MRIs of a 41-year-old female patient show (A) a T₂ axial MRI of Motiva SmoothSilk Ergonomix2 Diamond Implants (Mini projection, 140 cc) and (B) T₁ sagittal MRI of Motiva SmoothSilk Ergonomix2 Diamond Implants (Mini projection, 140 cc), confirming implant position and preserved surrounding breast tissues.

balloon creates the breast tissue-preservation space, behind the corpus mammae and in front of the posterior lamella, within the boundaries of the circummammary ligament (Figure 3). This 3-dimensional space is a nuanced departure from previous subglandular or subfascial 2-dimensional planes, which further proves the utility of balloon expansion for controlled pocket creation.

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

It is well documented in surgical literature that electrocautery (high thermal energy) might result in several complications, including the devitalization of breast tissue, pain from the disruption of sensory nerves in the costal periosteum, muscle contraction causing bleeding, inadequate hemostasis, and thermal tissue damage in skin flaps.⁵⁶

As the third preservation prong, this surgical approach potentially reduces or removes the need to use larger-volume implants in many women. However, this may be considered a limitation for individuals seeking more voluminous enhancement. Breast implant weight increases mechanical stress on supportive tissues; making preservation—especially of the circummammary ligament—essential for optimal support.⁵⁷⁻⁵⁹ This study reported no cases of inferior implant malposition. Furthermore, larger implants can exert significant pressure on the breast skin and lower pole, potentially leading to soft tissue thinning and compromised long-term results.^{21,57-59} Munhoz et al observed a 96% satisfaction rate with SmoothSilk implants, averaging 191.47 cc, achieving a natural breast shape with no reported implant exchanges.²¹

This is because of a “tenting effect,” which can only be achieved by the unique geometric characteristics of the aforementioned implant, because it features a symmetrical double-sided apex originating from its equator, enabling it to retain its uniform projection regardless of the position against the chest wall or the mammary gland. At 180°, this implant geometry increases projection by 22% compared with the same volume round implants, utilized in conventional BA, thereby allowing for less silicone volume, that is, a smaller implant size to achieve the desired projection. The tenting effect recruits preserved breast tissue into the posterior region of the breast, which is typically occupied by silicone gel when a device with standard projection, base, and shape is utilized in conventional BA. The sample MRI

substudy patient showed a significant increase in breast projection because of the recruitment of breast tissue with the implant and technique utilized for this procedure (Figure 7). Recruiting breast tissue facilitates projection and reduces the amount of silicone needed, thereby lessening mechanical stress and complications associated with larger implant volumes, such as tissue thinning and parenchymal atrophy.⁵⁷

The authors of this study reported zero patient reports of loss of nipple or breast sensation, also an improvement from traditional methods. The preservation was limited not only to the supportive breast tissues but also to the sensory innervation of the breast. Implant weight causing nerve compression, conventional pocket dissection, and implant insertion can disrupt the fourth and fifth anterior intercostal nerves, compromising the viability and sensation of the breast.⁶⁰

There were no implant-related complications reported throughout the 3-year study, including no cases of capsular contracture or implant rupture. A comparable low incidence of these device-related complications with Motiva implants has also been observed in literature and recently evidenced in the FDA clinical trial results, in which the capsular contracture and rupture rates were 0.5% and 0.6%, respectively, through 5 years.¹⁵⁻²¹ Implant rupture is of particular relevance given the degree of deformation required to insert these devices through minimally invasive routes. However, as demonstrated in the MRI substudy, there were no cases of implant rupture or gel fracture, corroborating the rupture results associated with this implant brand observed in other studies.¹⁵⁻²¹

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

The effectiveness outcomes in the study are aligned with the patient's and surgeon's experience of this procedure. A portion of participants reported either no change or a decrease in their 3-year cup size compared with their baseline. This paradoxical finding correlated with an overall increase in BMI and the associated expansion of the inframammary circumference of the thorax. According to the European Standard for measuring cup size, utilized in this study, all these patients had an increase in the areolar circumference of the thorax after the procedure and this measurement remained relatively stable during the follow-up time. Thus, the reduction in cup size results from the differential reduction between the inframammary circumference and the areolar circumference measure. The results of the BREAST-Q showed high patient satisfaction (84%) with the outcome and an 87% increase in breast satisfaction at the 3-year follow-up. Similarly, the POSAS scar results found that the patient's perception of the scar resembled that of their own skin. This is important as

another barrier cited by women who avoid breast implants is because of perceived objectification and stigmatization.⁶¹ In our study, although device and surgical technology are integral to improving patient outcomes, the learning curve associated with surgical practice change can be a deterrent for the surgeon and preclude the adoption of new techniques.^{62,63} However, 90% of surgeons were “very satisfied” with their overall experience and none “dissatisfied,” thus conducive to the adoption of new surgical devices and practices.

This prospective 3-year follow-up study has limitations that should be considered when interpreting the findings. First, the small sample size and single-center design restrict statistical power, potentially limiting generalizability. Second, demographic representation may affect the generalizability of the findings, because the relatively small implant size employed in this procedure could limit the subset of patients who may benefit from it. Variability in assessment methods—whether self-reported or clinician evaluated—introduces potential bias, influencing the consistency of data collection. Taken together, these considerations could be addressed in future research involving larger, multicenter cohorts and direct comparisons with conventional techniques, to strengthen reliability and improve external validity.

CONCLUSIONS

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

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

Supplemental Material

This article contains [supplemental material](https://doi.org/10.1093/asj/sjaf196) located online at <https://doi.org/10.1093/asj/sjaf196>.

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