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Innovations in Nipple-areolar Complex Reconstruction: Evaluation of a New Prosthesis

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Background: The reconstruction of the nipple-areola complex (NAC) is a crucial step for completing breast restoration with patient satisfaction. Surgical reconstruction or tattooing of the NAC may not be preferable or feasible for some patients. There is no universal method for NAC that is ideal for every patient or clinical situation. Various approaches often do not maintain projection over time. Over time, several techniques have been perfected, including the C-V flap, to improve and support projection for patients with bilateral implant-based reconstructions.
Methods: We used, for the first time, prosthetic devices for NAC reconstruction and examined the safety of these devices associated with ease of implantation and patient satisfaction levels using a survey conducted during a 1-year follow-up. We enrolled 20 individuals who opted for these NAC prostheses following unilateral or bilateral breast reconstruction and following NAC excision.
Results: Ninety percent of the participants expressed satisfaction or high satisfaction with the appearance and balance of the new NAC. The prosthetics enhanced the overall body self-image and self-regard of all the study participants. Except for 4 patients, there were no reports of skin adverse reactions, infections, or erosion.
Conclusions: Encouraged by these auspicious outcomes that indicate a significant rate of safety and satisfaction, we believe that this straightforward, noninvasive, affordable medical device deserves consideration as a reconstructive option for all patients seeking breast reconstruction, promoting full body integrity. *(Plast Reconstr Surg Glob Open 2025; 13:e6410; doi: 10.1097/GOX.0000000000006410; Published online 10 January 2025.)*

INTRODUCTION

Breast cancer remains the most common cancer diagnosis among women.[1] Despite the favorable outcomes associated with more conservative treatment approaches, there are instances where mastectomy, accompanied by the removal of the nipple-areola complex (NAC), becomes an unavoidable necessity. The breast holds significant symbolism for women, embodying femininity, fertility, and maternity. The loss of 1 or both breasts deals a deep blow to a patient's self-image, self-worth, and confidence.[2,3] Consequently, breast reconstruction, including the restoration of the NAC following mastectomy, is deemed essential. Various techniques for breast reconstruction exist, each aiming to restore the desired shape and volume of the breast.[4] Studies have demonstrated that these procedures have a positive impact on women's overall quality of life.[5,6] Despite these advancements, the absence of the NAC leaves the reconstructed breast appearing incomplete, which can alter a woman's body perception and self-image. The NAC is an essential part of breast anatomy, and its reconstruction[7] provides patients with a sense of completeness and normalcy. The reconstruction of the NAC not only restores aesthetic appearance but also represents a crucial step toward physical and psychological integrity, significantly improving patients' quality of life.[8] Currently available alternatives for NAC reconstruction include surgical techniques such as autologous tissue transplantation, reconstruction with local or pedicle flaps, and reconstruction with medical tattoos.[9–14] Each of these options has specific advantages and limitations, and the choice of the

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most suitable technique depends on the patient's preferences, their breast morphology, and the plastic surgeon's opinion. Prostheses can be a beneficial choice in NAC reconstruction for several reasons. First, prostheses offer a minisurgical solution that avoids additional procedures or invasive interventions. This can be particularly advantageous for patients who wish to avoid further surgery or are not suitable for traditional surgical techniques. This newly developed NAC prosthetic solution has not yet been subjected to any study evaluating its safety and effectiveness. As such, our prospective study seeks to assess its safety, tolerance, and potential adverse reactions, and to ascertain the satisfaction levels of both patients and surgeons.

Takeaways

Question: The reconstruction of the nipple-areola complex (NAC) is a crucial step for completing breast restoration with patient satisfaction.

Findings: We used prosthetic devices for NAC reconstruction and examined the safety of these devices associated with ease of implantation and patient satisfaction levels. Ninety percent of the patients expressed satisfaction or high satisfaction with the appearance and balance of the new NAC. The prosthetics enhanced the overall body self-image and self-regard of all the study participants.

Meaning: This straightforward, noninvasive, affordable medical device (FixNip) deserves consideration as a reconstructive option for all patients seeking breast reconstruction, promoting full body integrity.

MATERIALS AND METHODS

Patients and Technique

The NAC prosthetic device was implanted in 40 consecutive patients who met the inclusion criteria of being female patients undergoing immediate or delayed breast reconstruction (autologous or implant-based) following mastectomy with NAC excision. Patients who had undergone bilateral NAC excision were also included. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study protocol was approved of by the local ethics committee (CET AOU delle Marche). Written informed consent was obtained from all subjects and approved by the local ethics committee (CET AOU delle Marche). The application of the NAC prosthesis took place upon the completion of the wound healing process, typically around 1 month postsurgery. In cases where patients required adjuvant radiotherapy, the application of the NAC prosthesis was delayed until after the completion of this treatment. The NAC prostheses used in this study were a silicone implant (FixNip, GC Aesthetics, Caesarea, Israel) specially designed for aesthetic improvement of the female nipple with softer feel and natural appearance (Fig. 1). The implant includes a nitinol frame designed to provide mechanical structure that is fully covered by the silicone and has no contact with the breast tissue. It is important to note that the FixNip prosthesis is CE marked and ISO13485 certified, including compliance with European and international standards for medical devices. However, it lacks US Food and Drug Administration approval, which should be considered for applicability of this study in different regulatory environments. Upon signing the informed consent form approved by the local ethics committee during their initial visit, patients would have an ultrasound of the skin to evaluate its thickness. If the thickness was adequate (range 0.3–0.5 mm), they underwent surgery to implant the NAC prosthesis. The methodology for preoperative markings is illustrated in Figure 2A. All markings were completed while the patient standing in front of a mirror. Once the position of the new NAC was established, the upper pole of the neo-areola was marked on the breast mound using a permanent marker, followed by positioning a circular areola marker with the diameter of the new areola. An incision of 2 cm was made in the breast skin, usually in correspondence with the previous scar of mastectomy (Fig. 2B). A subcutaneous pocket was created (Fig. 2C);

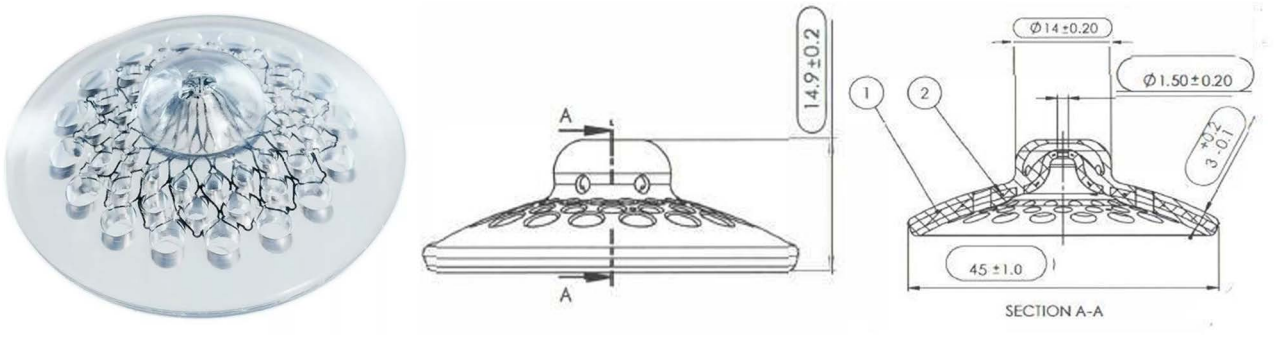

Fig. 1. The FixNip nipple reconstruction implant is an implantable solid silicone hypodermic implant intended to be placed under the skin in the subcutaneous fat for the cosmetic enhancement of the female nipple areola. It consists of a "flower-shaped" nitinol frame with a solid silicone cover that allows anchoring of the implant to adjacent tissue, a softer feel, and encapsulation of the nitinol frame. Appearance and some technical details of the medical device are shown. Base diameter: 45.0 ± 1.0 mm, thickness: 3.0 mm −0.1 mm/+0.2 mm, projection diameter: 14.0 ± 0.20 mm, projection hole diameter: 1.5 ± 0.20 mm, and height: 14.9 ± 0.20 mm. © GC Aesthetics. Used with permission.

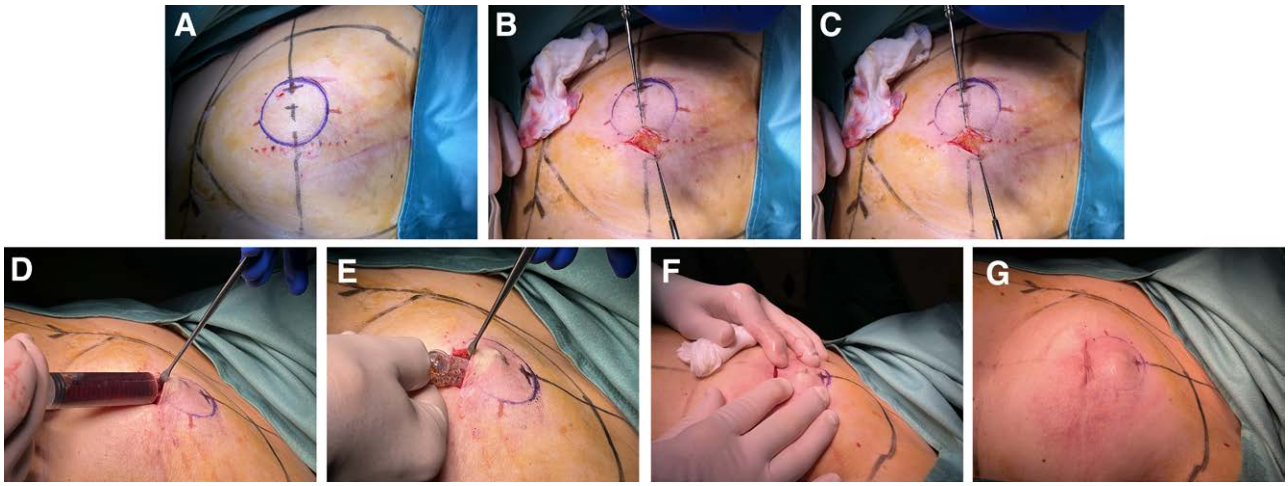

Fig. 2. Nipple-areola reconstruction after a monoliteral mastectomy with immediate reconstruction. A, Preoperative markings are applied to the breast mound. B, Two-centimeter incision on the skin with a scalpel on the previous scar. C, Creation of the subcutaneous pocket with a suitable thickness. D, Irrigation of the pocket with a solution consisting of 500 mL of NaCl solution, 50 mL of betadine, 1 g cefazolin, 1 g gentamicin (Adams modified solution). E, Implantation of the FixNip prosthesis in the subcutaneous pocket. F–G, Pocket closure and immediate postoperative result.

the pocket was irrigated (Fig. 2D) with a solution consisting of 500 mL of NaCl solution, 50 mL of betadine, 1 g cefazolin, and 1 g gentamicin (Adams modified solution)[15]; and the implant was inserted (Fig. 2E). The FixNip prosthesis was placed in the subcutaneous fat layer, and the incision was sutured closed (Figs. 2F, G). Following the reconstruction of the NAC, a protective dressing was applied, consisting of a layer of Vaseline gauze and foam dressing encased in an occlusive film. This process took place in the outpatient clinic. The dressing was changed seven days after the operation and replaced with a protective breast pad. Sutures were removed during an office visit 15 days postoperation.

Ultrasonography

Preoperatively, 3 months, 6 months and 12 months after surgery, patients underwent a new ultrasound to assess skin thickness and before undergoing aesthetic tattooing. Ultrasound examinations were performed by the same experienced observer. The equipment used during the study was Samsung RS85 with 14- or 18-MHz linear array transducers (Samsung Healthcare, Samsung Medison Co., Ltd) using a coupling gel, and ensuring no pressure was applied on the study zone.

Patient Satisfaction

To evaluate NAC satisfaction, a BREAST-Q questionnaire[16] was administered to patients before and after surgery (6 and 12 months). Additionally, a tailored questionnaire was administered postsurgery for both patients and surgeons, assessing tolerance and biocompatibility; documenting any dermatological or systemic reactions such as erosions, erythema, or infections; and evaluating aesthetic satisfaction including general appearance, color, texture, shape, dimension, relief, elasticity, finesse, details, and symmetry.

Statistical Analysis

Continuous variables were reported as either the means and SD or median and interquartile ranges according to their distribution, as assessed by the Shapiro-Wilk normality test. Categorical variables were reported as percentages. Differences in patients' quality of life, according to BREAST-Q scores, before and after the treatment were tested by *t* test for paired samples or Wilcoxon signed-rank test (according to their distribution). The statistical variables, produced by the questionnaires, are all on a discrete scale that can be analyzed as numerical data by assuming a fixed distance between scores and using the median as the best measure of central tendency.

We performed a preliminary power analysis to estimate the maximum sample size necessary to detect an effect size (ie, the standardized mean difference between the BREAST-Q scores before and after treatment) equal to 0.45. With a sample size of 41 pairs of data, the analysis achieves a power of 80% in rejecting the null hypothesis that the effect size is equal to 0. (**See figure, Supplemental Digital Content 1,** which displays the sample size number with respect to the effect size based on power of 80% and a significance level [alpha] of 0.05 using a 2-sided Wilcoxon signed-rank test for paired data, **http://links.lww.com/PRSGO/D729**.) This result is based on a significance level (alpha) of 0.05 and utilizes a 2-sided Wilcoxon signed-rank test for paired data. All the statistical values equal to or smaller the 0.05 were considered statistically significant. The analysis was conducted using the R statistical software (version 4.1.3; March 10, 2022).

RESULTS

The average age of the 40 patients included in the study was 63 years (31–77 years). Five patients were smokers (12.5%). Comorbidity included 1 case of diabetes (2.5%) and 10 cases of hypertension (25%). A significant

portion of the patients underwent adjuvant therapy as part of their breast cancer treatment, including radiation therapy (n = 15, 37.5%), chemotherapy (n = 11, 27.5%), and antihormone therapy (n = 25, 62.5%). In all instances, radiation and chemotherapy were administered before the NAC reconstruction, whereas antihormone therapy continued postmastectomy, both before and after the NAC reconstruction. Unilateral NAC reconstruction was performed on 32 patients (80%), whereas 8 patients (20%) underwent bilateral reconstruction, accounting for a total of 46 reconstructed breasts. Twenty-seven women (83%) underwent monolateral skin-sparing mastectomy followed by immediate reconstruction using an expander or silicone implant in combination with an acellular dermal matrix if reconstruction was performed prepectoral (10, 34%), and 5 women (17%) underwent delayed breast reconstruction using a flap taken from the patient's back. Moreover, 6 women (75%) underwent bilateral skin-sparing mastectomy followed by immediate reconstruction using an expander, and 2 women (25%) underwent delayed breast reconstruction using a flap taken from the patient's back. Table 1 presents the demographic data and preoperative characteristics (including the ultrasound thickness) of the patients. The median interval from mastectomy to NAC reconstruction was 24 months (ranging from 12 to 48 months). Preoperatively, ultrasound examination evaluated the appropriate thickness of the skin over the breast prosthesis (skin thickness > 3 mm) and the stiffness of the periprosthetic tissue using the shear-wave elastosonography with dual live imaging with confidence mapping (Fig. 3A). Additionally, at 6 and 12 months, ultrasound examinations analyzed the correct integration of the FixNip medical device into the subcutaneous tissue, assessing the position and integration of the prosthesis (Figs. 3B, C). The follow-up ultrasound images showed that the position of the implanted prosthesis remained stable, and there was increased firmness due to tissue integration into the prosthesis's hole. Furthermore, follow-up ultrasounds focused on evaluating periprosthetic structures, fluid presence, tissue inhomogeneities, liponecrosis, and subcutaneous tissue thickness over the top of the FixNip medical device.

Table 1. Demographic and Preoperative Characteristics of Patients

Demographic Characteristics	
Age, y, median (range)	63 (31–77)
Comorbidities, n/N (%)	
Smokers	5/40 (12.5)
Diabetes mellitus	1/40 (2.5)
Hypertension	10/40 (25)
Breast reconstruction, n/N (%)	
Unilateral	32/40 (80)
Immediate	27/32 (83)
Delayed	5/32 (17)
Bilateral	8/40 (20)
Immediate	6/8 (75)
Delayed	2/8 (25)
Medical therapy, n/N (%)	
Adjuvant therapy	5/40 (12.5)
Radiotherapy	15/40 (37.5)
Chemotherapy	11/40 (27.5)
Hormone therapy	25/40 (62.5)
Preoperative characteristics	
Ultrasonography, n/N (%)	
0.3–0.5 cm thickness	8/40 (20)
0.5–1 cm thickness	22/40 (55)
>1 cm thickness	10/40 (25)
Main interval between breast reconstruction and NAC reconstruction, mo	24 (12–48)
Main interval between NAC reconstruction and tattoo, mo	12 (6–24)
Postoperative characteristics, n/N (%)	
Completed follow-up	36/40 (90)
Complications	4/40 (10)
Nickel allergy	1/4 (25)
Prosthesis intolerance	1/4 (25)
Incorrect implantation	2/4 (50)
Tattooing, n/N (%)	30/40 (75)

A total of 36 patients completed pre- and post-FixNip implant questionnaires within the study periods. Compared with preimplant scores (72 ± 12.25), there was a statistically significant increase in the mean "satisfaction with nipple" score (77 ± 12.50) postsurgery ($P < 0.001$), but also in "psychosocial well-being," (72 ± 7.25 versus 79.5 ± 2.50), "sexual well-being" (58 ± 11.25 versus 68.±11.5), and "physical well-being chest" (73 ± 12 versus 75.5 ± 13.50) (Table 2). Moreover, the mean post-FixNip implant scores in "satisfaction with breast," "psychosocial well-being," and "sexual well-being" exceeded the published normative mean scores in these domains. (**See figure, Supplemental Digital Content 2,** which displays the mean BREAST-Q reconstruction scores: pre- versus post-FixNip versus normative data. $P > 0.05$ for "satisfaction with breast mound," "psychosocial well-being," "sexual well-being," and "physical well-being-chest," and $P = 0.001$ for "satisfaction with nipple," **http://links.lww.com/PRSGO/D730**.) By stratifying the 4 questions asked to the patients and then the pre- and postimplant differences within the 2 subgroups (patients undergoing prosthetic implant after immediate reconstruction and patients undergoing prosthetic implant after delayed reconstruction), the results show that the scores are not all significant, except for the question "psychosocial well-being." (**See figure, Supplemental Digital Content 3,** which displays the satisfaction with nipple BREAST-Q survey responses: proportion of patients who answered "satisfied" or "very satisfied" presurgery, post- FixNip implant [6 months] and post tattooing [12 months], **http://links.lww.com/PRSGO/D731**.) In the comparison of raw BREAST-Q scores for "satisfaction with nipple" before, after FixNip implantation (6 months) and after tattooing (12 months), a Wilcoxon signed-rank test examining the proportion of patients indicating they were "satisfied" or "very satisfied" revealed there was a notable increase in the proportion of patients reporting being satisfied with the position (45% versus 70%, Z = −2.89, $P = 0.002$) and symmetry (50% versus 70%, Z = −2.27, $P = 0.002$) of the new NAC and most frequently very satisfied with nipple projection (45% versus 86%, Z = −3.1, $P < 0.001$). (**See figure, Supplemental Digital Content 4,** which displays

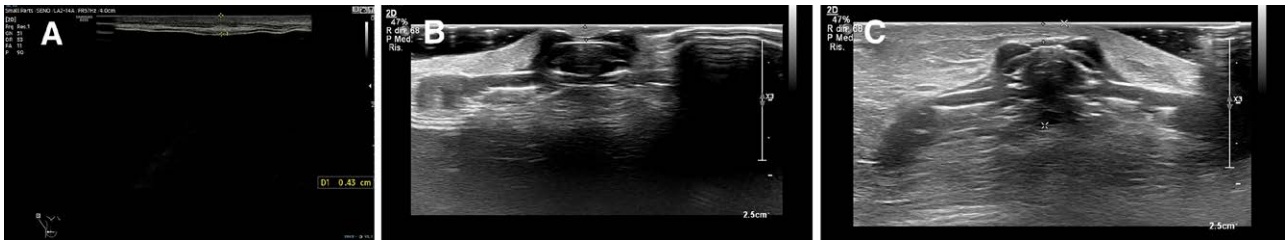

Fig. 3. Ultrasound examination. Preoperatively (A), we evaluated the idoneous thickness of the skin over the breast prothesis (skin thickness > 3 mm). At 6 months (B) and at 12 months (C), we analyzed the correct integration of the medical device FixNip into the subcutaneous tissue.

Table 2. Breast-Q Questionnaire, Pretreatment and Posttreatment

	Time to Treatment		
Characteristic	**Pre, N = 36***	**Post, N = 36***	***P*†**
Satisfaction with breast mound	72.00 (12.25)	77.00 (12.50)	<0.001
Psychosocial well-being	72.00 (7.25)	79.50 (2.50)	<0.001
Sexual well-being	58.00 (11.25)	68.00 (11.50)	<0.001
Physical well-being chest	73.00 (12.00)	75.50 (13.50)	<0.001

*Median (interquartile range).
†Wilcoxon signed-rank test with continuity correction.

the stratification of BREAST-Q reconstruction score in patients undergoing prosthetic implantation after immediate reconstruction and in patients undergoing prosthetic implantation after delayed reconstruction. A, The "satisfaction with breast mound" score with no significant differences pre- and postimplantation in the 2 subgroups. B, The "psychosocial well-being" score with a significant pre- and postimplantation statistic in both groups. C, The "sexual well-being" score with a significant statistic only in the immediate reconstruction group compared with the delayed group. D, The "physical well-being chest" score with no significant differences pre- and postimplantation in the 2 subgroups, **http://links.lww.com/PRSGO/D732**.)

All patients except 4 (90%) were satisfied and very satisfied with the tolerance and biocompatibility of NAC prosthesis. Moreover, regarding retrospective thoughts and willingness to undergo NAC reconstruction procedure, the 90% of patients reported "definitely agree" when asked if they would hypothetically undergo the procedure again knowing what they know now. Respondents also strongly agreed with the statements "I would encourage other women in my situation to have nipple-areola reconstruction surgery." When asked about aesthetic satisfaction, general appearance, color, femininity, and tolerance, the majority of patients reported that the sensation in the new nipple was apparently perceptible with adequate projection and an increase in their sensation of femininity or sexuality. The highest satisfaction rate was with the thickness, texture, and color. (**See figure, Supplemental Digital Content 5,** which displays the graphic representation of the survey results. A, For surgeons. B and C, For patients, **http://links.lww.com/PRSGO/D733**.)

All surgeons were satisfied with the appearance of the prosthesis (Fig. 4). (**See figure, Supplemental Digital Content 6,** which displays unilateral FixNip implant. A and B, Preoperative; C and D, 1-month follow-up; and E and F, 6-month follow-up, **http://links.lww.com/PRSGO/D734**.) (**See figure, Supplemental Digital Content 7,** which displays the unilateral FixNip implant. A and B, Preoperative; C and D, 6-month follow-up; and E and F, 6-month follow-up. Note how, already after 6 months from the intervention, the projection of the NAC is clearly visible through a shirt comparable to the contralateral NAC, **http://links.lww.com/PRSGO/D735**.) All patients with implanted prostheses have completed the follow-up period, except for 4 patients in whom we experienced complications that led to the removal of the implanted medical device. These complications can be attributed to 3 main reasons: (1) a patient's allergy to nickel, leading to inflammatory reaction and itching; (2) a patient's intolerance to the prosthesis, which they perceived as "foreign"; and (3) incorrect implantation of the prosthesis in 2 cases, resulting in the protrusion of the prosthesis through the overlying skin.

DISCUSSION

Breast reconstruction is a crucial part of breast cancer treatment,[17–20] aiming to achieve an oncologically safe resection while preserving or reconstructing the breast's aesthetic components. NAC reconstruction is essential for a successful and satisfying breast reconstruction.[12,21] Studies find it important for 96% of patients who underwent breast reconstruction.[7,13,22] Restoring the NAC is challenging but vital, often referred to as "the cherry on the cake" in reconstruction procedures. Among various NAC reconstruction methods available today,[23,24] patients showed higher satisfaction with surgical NAC reconstruction compared with tattooing.[25] The main sources of dissatisfaction with these techniques were the absence of nipple projection and discoloration

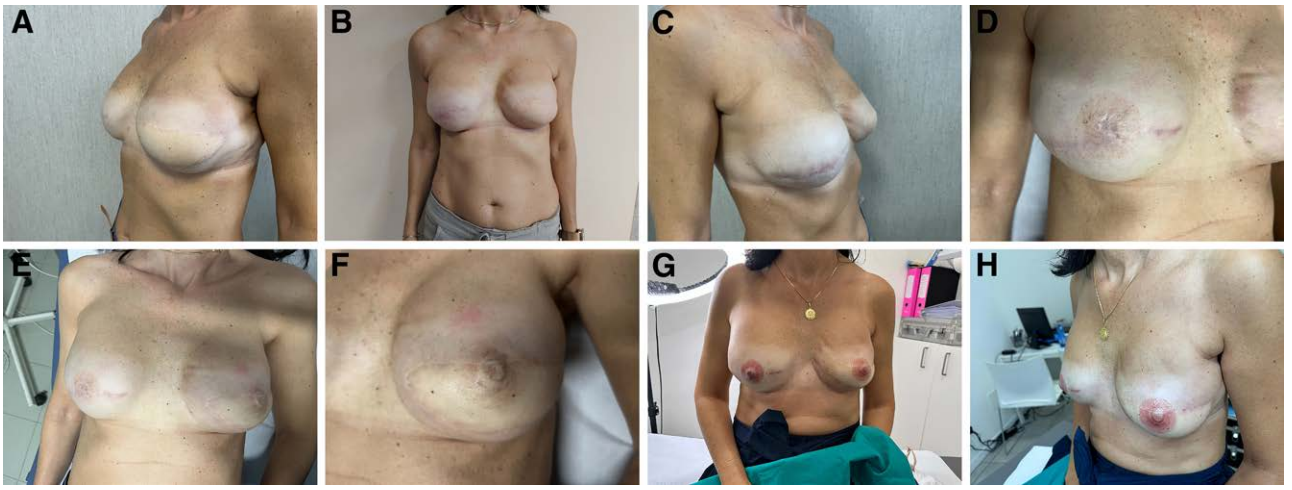

Fig. 4. Bilateral FixNip implant. A–C, Preoperative (left breast was reconstructed with a latissimus dorsi flap + prosthesis); D–F, 1-year follow-up; and G–H, 1-year follow-up after tattooing.

associated with tattoos. Our study highlighted that NAC prostheses boast a high satisfaction rate, particularly regarding nipple position, symmetry, and projection, and moreover, regarding color after tattooing. Additionally, patients reported greater satisfaction and improved body image when using the NAC prosthesis. Other studies also indicate that the presence of the NAC enhances patients' overall well-being. The patients found the surgery very simple, as they underwent day surgery and local anesthesia, and also found good tolerance toward the prosthesis. With the exception of 2 patients who experienced (1) skin reaction and itching due to their nickel allergy and (2) nontolerability of the prosthesis, all the other patients did not complain of anything during the follow-up period and reported very high satisfaction rates, recommending these prostheses to other women. The novel contribution of this study is that NAC reconstruction improves the psychosocial and sexual well-being of patients undergoing breast mound reconstruction. Patients reported increased satisfaction with their appearance while unclothed in front of a mirror. The NAC may provide patients with a sense of normalcy by serving as a focal point for the breast. Moreover, women scored significantly higher on the psychosocial and sexual well-being scales after NAC reconstruction. All patients except 4 (90%) were satisfied or very satisfied with the appearance of the prosthesis. The highest satisfaction rate was with the color (100% satisfied). The thickness and texture were the least appreciated aspects, with a higher satisfaction rate. Similarly, previous studies have shown that NAC reconstruction increases satisfaction with the size, softness, and sexual sensitivity of the breast mound.[26,27] NAC reconstruction was associated with improved psychosocial well-being. Patients felt more confident in social settings, emotionally capable, emotionally healthy, of equal worth to other women, self-confident, feminine, accepting of their bodies, normal, like other women, and attractive. Similarly, preserving the nipple in nipple-sparing mastectomy has been shown to enhance patient psychosocial and sexual well-being.[28,29] It is speculated that these satisfaction parameters were mostly improved due to a more natural-looking breast, thus contributing to greater confidence and a sense of attractiveness during sexual activities, particularly among younger patients. Long-term nipple projection was found to be the most important factor for satisfaction. The majority of patients expressed willingness to undergo the procedure again if required and stated that they would encourage others to undergo NAC reconstruction and felt that it was important to complete the breast reconstruction process through NAC reconstruction. These responses suggest that, regardless of overall breast reconstruction satisfaction, women gain a sense of completion by undergoing NAC reconstruction as part of the total breast reconstruction process. Despite the numerous benefits of prostheses, it is important to acknowledge that there are also challenges and considerations to address when choosing this approach. Prostheses may require proper fitting and positioning to ensure a natural and harmonious result. Furthermore, it is essential to ensure that the prosthesis is comfortable to wear and securely fits the surrounding skin to avoid irritation or discomfort. The advent of innovative prostheses represents a significant advancement in the field of postmastectomy breast reconstruction and offers an effective and safe solution for many women affected by breast cancer. Ongoing research in this area is essential to identify best practices and ensure equitable access to high-quality reconstruction options for all patients. This study has several limitations that need to be addressed. First, the lack of a control or comparison group limits the ability to draw definitive conclusions about the effectiveness of the FixNip NRI prosthesis compared with other NAC reconstruction methods. Future studies should include control groups to enable comparative analyses. Additionally, the study's sample size is relatively small, although our results are statistically significant.

CONCLUSIONS

NAC reconstruction is a vital aspect of postmastectomy recovery that significantly impacts patients' quality of life and self-esteem. Prosthetic options offer a customizable and minimally invasive approach, yielding high satisfaction rates among patients. The findings underscore the importance of continuing innovation in NAC reconstruction techniques to enhance clinical outcomes and patient happiness. Future research should focus on optimizing the prosthetic materials and improving procedural techniques to mitigate complications. By prioritizing close collaboration between patients and healthcare providers and evaluating all available options thoughtfully, it is possible to achieve successful, individualized outcomes. The promising advancements in postmastectomy reconstruction, particularly with NAC prostheses, hold the potential to restore not only physical appearance but also the emotional and psychological well-being of patients.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

PATIENT CONSENT

Patients provided written informed consent for the use of their images.

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