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Robotic Nipple-Sparing Mastectomy for the Treatment of Breast Cancer: Feasibility and Safety Study

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Abstract

Background—We previously devised and reported on an innovative surgical technique of robotic nipple-sparing mastectomy and immediate robotic breast reconstruction. Here we describe the outcome of the first 29 such consecutive procedures performed on breast cancer patients to assess feasibility, reproducibility and safety.

Methods—The following morbidity factors were tested: operation time, conversion rate to open technique, length of hospitalization, registration of complications for 1 year postoperatively and their characterization as either minor, major, or multiple, depending on clinical severity and treatment required.

Results—The total duration of the final robotic surgeries of our series was around 3 hours, showing a very rapid learning curve. The conversion rate due to technical problems was 2 of the 29 procedures (6,9%). No major complications, including hematoma, seroma, skin or nipple-areola injury or necrosis or infection were observed for any case. Two patients had a small degree of blistering from internal electrocautery in the breast skin flap, both of which resolved in one week without any specific therapy. No systemic complications were observed.

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Competing Interests:
The authors declare that they have no conflict of interest.

Conclusion—The low conversion rate to open surgery, the rapid learning curve and the low rate of post-operative complications observed in this preliminary series lead us to endorse a prospective study aimed at evaluating patient satisfaction.

Keywords

Breast cancer; robotic mastectomy; nipple-sparing mastectomy; conservative mastectomy; risk-reducing surgery; breast reconstruction; robotic surgery; cancer BRCA

Introduction

The application of robotic technology in various specialties has exerted a significant impact on surgical techniques and on the postoperative outcome of patients over the past decade. Robotic surgery is today considered a valid option for radical prostatectomy, radical cystectomy, colorectal surgery and hysterectomy, with the majority of cases being dedicated to oncologic procedures [1–3]. Despite the lack of a natural cavity needed for endoscopic viewing, applications of robotic surgery have also recently emerged for superficial organs such as in the fields of thyroidectomy [4], oropharyngeal surgery [5], and plastic and reconstructive surgery [6,7].

Technical innovations have made it feasible to conduct endoscopic nipple-sparing mastectomy which has been reportedly well-tolerated, safe, and associated with greater patient satisfaction [8]. Furthermore, several clinical trials have now been conducted to provide follow-up data regarding the oncological success of endoscopic breast surgery [8,9]. However, the manual control of a two-dimensional endoscopic in-line camera produces an inconsistent optical window around the curvature of the breast skin flap and the internal mobility is limited. Moreover, the dissection angles during endoscopic mastectomy seem inadequate because rigid-tip instruments are working almost in parallel through a single access [8–13]. Because of such technical limits the endoscopic approach to breast surgery has not been significantly adopted in clinical practice.

In October 2015 Toesca et al. [14,15] were the first to describe the surgical technique of single small hidden axillary scar robotic nipple-sparing mastectomy (RNSM) and immediate robotic breast reconstruction (IRBR) with implant.

The aim of this project is to study an innovative technique to improve aesthetic results and patient satisfaction removing the entire breast glandular tissue without disruption to the appearance of the breast, thereby overcoming the limitations so far experienced with mini-invasive endoscopic technique.

After the early phase of innovation in which we devised the surgical technique, in this article we describe the outcome of the first 29 consecutive RNSM and IRBR procedures performed at the European Institute of Oncology and assess feasibility, reproducibility and safety.

Patients and Methods

Patients Selection (Inclusion and Exclusion criteria)

Patients were prospectively selected from June 2014 to May 2016.

At the beginning, for the first three patients, in order to exercise caution regarding the oncological safety of the new application of this procedure, we selected female BRCA mutation carriers with a previous history of breast cancer surgery who had decided to receive a delayed contralateral risk-reducing nipple-sparing mastectomy and immediate reconstruction with implant. Once we had ascertained the complete removal of the gland during the first procedures, we decided to extend the indication to breast cancer patients. The RNSMs were offered to selected patients with clinically negative axillas and tumors less than 4 cm in diameter in any of the four quadrants, multicentric breast cancer, or cases of intraductal neoplasia. In addition, tumors had to be situated greater than 1 cm from the nipple areola complex. This was assessed either by clinical examination or breast imaging, mammogram, ultrasound or magnetic resonance imaging when necessary.

Patients with skin or nipple-areolar infiltration or erosion were also excluded from this procedure. To minimize the risk of learning-curve-related complications and technical problems, we selected patients with low risk factors for systemic or local perioperative complications [16]. All the patients had no associated comorbidities, a body mass index of less than 25 kg/m2 and were classified as low risk for anesthesia.

The RNSM was not performed in patients who were found to have ptosis of grade >2, oversized breasts, or diabetes, those who were heavy smokers or obese, and those who had undergone previous radiation therapy for any reason (eg. mantle radiation therapy) or previous mammoplasty. Those characteristics were considered as exclusion criteria due to their associated high risk of skin flap necrosis and/or infections.

Methodological Approach

The protocol for this prospective development study was discussed with the scientific directorate board before patient recruitment begun, describing patient selection principles, operative methods, and outcomes to be measured. The protocol and ongoing results were periodically discussed in the internal breast surgeon’s institution for approval. Before the operation, all patients gave their signed informed consent for RNSM and IRBR according to the established regulations.

Technical modifications during the assessment of surgical technique were meticulously recorded to allow understanding of possible effect on outcomes. Learning curves were recorded and analyzed and clear sequential outcome of all cases was reported.

To evaluate feasibility, safety and reproducibility, the following morbidity factors were tested: operation time, number of conversions to open technique, length of hospitalization and number of complications.

The study entailed the recording of complications for one year postoperatively and characterized them as either minor, major, or multiple, depending on clinical severity and treatment required. Major complications included reoperations, rehospitalizations or implant loss. Minor complications include subcutaneous emphysema due to carbon dioxide insufflation, minor infections, necrosis, and delayed wound healing.

Data were collected on patient age, body mass index (BMI), breast cancer characteristics (biology), tumor size, location, type and grade, nodal status, receipt of adjuvant chemotherapy, radiation and hormonal therapy for future oncological outcome analysis.

Surgical Technique

The surgical technique was the same in both the prophylactic and therapeutic groups, with thin 5-mm flaps beneath the nipple-areola complex, and intraoperative frozen sections performed on a biopsy of the retroareolar ducts in the therapeutic cases. If neoplasia was identified both intraoperatively as well as on permanent final pathology, the nipple-areola complex was removed.

The surgical technique has been previously described and no substantial variations were made [14,15]. Twenty-five procedures were carried out using the da Vinci Xi Surgical System® (Intuitive Surgical, Sunnyvale, CA) except for five procedures completed with the da Vinci Si Surgical System® (Intuitive Surgical, Sunnyvale, CA).

A 3 cm-long extra-mammary axillary incision was made along the midaxillary line in the axillary fossa so as to be hidden by the arm. The subcutaneous flap was dissected with electrocautery under direct vision in a 3 cm area. We then obtained a working space for the introduction of the single port in order to overcome the blind spots and commence the mastectomy (Fig. 1). Since there is no specific port for robotic mastectomy, we chose a sterile, single-patient access system device studied for laparoscopic surgery (Access Transformer OCTO™; Seoul, Korea) consisting of 4 plastic 5–12 mm access for the camera and instruments, gas valve and silicon gas pipe.

The robot was docked with the cart on the contralateral side of the operation and the robotic arms nearly parallel with the floor, positioned with the elbows opened as much as possible to avoid conflicts during dissection. The port was connected to an insufflator to keep the pressure at 8 mm Hg. The endoscopic view was observed through a 0° 12-mm-diameter rigid camera (Intuitive Surgical®, Sunnyvale, CA) installed between the two operative arms to enable a central view.

Dissection was performed with a 5 mm monopolar cautery with cautery spatula tip (Intuitive Surgical®, Sunnyvale, CA) used on the right robotic arm.

Traction and counter-traction, along with maintaining excellent exposure and stretching out the tissue, was performed with a 8 mm Cadiere Bipolar Forceps (Intuitive Surgical®, Sunnyvale, CA) fitted on the left robotic arm.

The assistant was at the operating table to check, through the transillumination of the skin flap, the position of the tip of the instruments during dissection to coordinate the first

surgeon. The RNSM required a superficial dissection of the gland, moving from the axillary toward the nipple areola complex (NAC); it then continued below the NAC up to the breast fold along the lateral, inferior and internal margins.

The operation proceeded with the deep layer dissection. The plane started along from the posterior of the gland on the major pectoral fascia in which the breast tissue was pulled up to create a sufficient working space along the major pectoral fascia. The dissection of the last attachment from the inferior breast fold was completed, thus fully mobilizing the gland for extraction. The specimen was then removed entirely en-bloc through the 3 cm axillary skin incision.

The monoport was repositioned and submuscular pocket was dissected medially and inferiorly reaching the inframammary fold and sternum, taking care to completely release the pectoralis major muscle from the thorax wall, allowing for adequate muscular distension. At the same time pectoralis major muscle attachment to the skin flap was spared in order to guarantee an adequate implant cover. All the reconstructive procedure was conducted robotically with the same intruments.

The implant (Allergan Inc; Irvine, California) was inserted manually; drains were manually placed in both submuscular and subcutaneous planes and the subcutaneous and cutaneous suture was performed by the classical technique.

The entire operation was carried out involving a 3 cm hidden axillary incision.

Results

Clinical and Pathologic Characteristics

A total of 24 women between June 2014 and July 2016 underwent 29 RNSMs and IRBR for either prophylaxis or the treatment of breast cancer.

Eight procedures were carried out for breast cancer risk reduction. All of these were conducted on patients with a family history of breast cancer and who were positive for a BRCA mutation. Fifty percent of this portion underwent delayed contralateral risk reduction RNSM and IRBR with implant; the rest were bilateral procedures.

Eighteen women received therapeutic RNSMs, representing 62% of the total number of procedures. There were 9 cases (37,5%) of ductal carcinoma in situ (DCIS) and 9 cases (37,5%) of invasive carcinoma.

Among the 9 invasive cancers, 7 were stage I out 2 that were stage II. No stage III or IV patients were enrolled.

The median tumor size was 1.7 cm ranging from 0 (for pathologycal complete response) to 3,2 cm. A sentinel node biopsy was performed in all cases of therapeutic mastectomies and was positive in only 2 cases and axillary dissection was performed with the open technique from the same 3 cm long incision at the end of the robotic procedure. None of the patients having prophylaxis received an axillary staging. Two women had carcinoma or DCIS at the

nipple-areola complex specimen histology necessitating removal of the nipple-areola complex. One of these was at the final histology so removal was conducted in a second operation.

Among diseased patients, at a median follow-up of 8 months (range 1–14 months), there were no reported local recurrences or metastatic disease.

All patients out of 7 received a unilateral procedure with contralateral augmentation according to bilateral symmetry needs. Five patients receive a bilateral robotic mastectomy. All patients underwent reconstruction with an implant except for 4 who had tissue expanders. Weight of resected tissue range between 200 and 300 g.

Duration of Surgery

The setting-up time, which includes the positioning of the patient, the initial axillary skin incision, port placement and docking of the robot, was reduced gradually from about 1 hour and 30 minutes for the first case to 30 minutes for the final cases (Figure 1). The duration of the RNSM ranged from 5 hours for the first case when the technical procedure was set up, to 1 hour and 30 minutes for the last patients. After removal of the gland from the surgical cavity, before starting the reconstructive phase, the robot arms had to be replaced, which took an additional 30 minutes. The reconstructive time of robotic implant placement ranged from 2 hours for the first operation to 1 hour for the last operation. In summary, the total length of time of the first robotic surgery was 7 hours for the first case and around 3 hours for the last cases.

Conversion Rate and Perioperative outcomes

The first case was converted to an open technique near the end of the procedure to reduce the time of surgery. The last part of the gland (around 20% of the breast), located in the lower-inner quadrant, was dissected using traditional scissors, without the need to enlarge the surgical incision, partly under endoscopic view. Another case was converted because of nipple-areola complex positivity, toward the end of the robotic procedure. In this case the patient received a double incision, one on the axilla (3 cm in length) and another peri-areolar incision. In the last converted case the axillary incision was made too posteriorly to a mid-axillary line, rendering optical vision difficult around the curvature of the breast dome in the inner quadrants. There was no conversion to the open technique for the other 23 procedures.

In summary, the conversion rate due to technical problems was 2 out of the 29 procedures (6.9%).

No major complications, including hematoma, seroma, skin or nipple-areola injury or necrosis or infection were observed for any case. In the first case we observed a biceps brachii temporary strength reduction which resolved spontaneously and had probably arisen as a result of a prolonged stretch positioning of the head on the operating table.

The 3rd and 8th patient had a small blistering from internal electrocautery in the breast skin flap, both of which resolved in one week without the need for any specific therapy (Figures 2 and 3).

The amount of blood lost during surgery has not been measured because the lack of significant bleeding. No robotic aspirator was used.

No systemic complications were observed. Nor was there any development of subcutaneous emphysema due to carbon dioxide insufflation. Patients were all discharged on the second postoperative day.

Discussion

Oncological safety of skin-envelope preservation has been clearly demonstrated by many studies in which skin-sparing mastectomy and nipple-sparing mastectomy are reported to have a local recurrence rate similar to that of modified radical mastectomy (5–6%) [17–22]. The main issue regarding this new robotic surgical approach is whether preservation of the skin envelope (nipple-areola complex included) amplifies the local recurrence rate. There are in fact many studies which report that different kinds of skin incision do not influence local recurrence rate and that breast skin removal is not necessary when clinically negative [17–22].

In this scenario, we have to consider that after completion of surgical and adjuvant treatment, breast cancer survivors or BRCA mutation carrier women have to cope not only with the fear of future disease recurrence but also with an altered body image that affects their everyday life. In view of the high cure rate of breast cancer, cosmesis and emotional well-being are important, and the availability of new technologies should be of service in this objective.

Total glandular excision is especially important in women with multicentric disease, invasive cancers with extensive intraductal component, or pure extensive ductal intraepithelial neoplasia. In those patients who have small and medium-size breasts, mastectomy is sometimes inevitable to achieve clear margins. Mini-invasive mastectomy could offers a solution for complete excision of mammary tissue, including all ducts in the nipple, with a good aesthetic result.

The minimal incision hidden in the axilla, the great respect for anatomical structures during skin and subcutaneous flap detachment lead to high trophism, vitality and unchanged color of the nipple-areola complex. In our opinion, this minimally invasive approach might reduce changes in the woman’s body image, thereby increasing patient satisfaction (Figure 4 and 5).

At the moment, the early phase of our study is focused on the development of a new technique and the description of its outcomes is not aimed at assessing its effectiveness against current standards but to demonstrate its feasibility, reproducibility, surgical and oncological safety. In our opinion this method is sufficiently developed to warrant full evaluation in further cases. In these first 26 procedures, surgeons and patients reported a high degree of satisfaction that will be evaluated by means of specific questionnaires during our ongoing project.

From a technical point of view, the use of the da Vinci Xi® (Intuitive Surgical, Sunnyvale, CA) system with respect to the classical technique offers certain advantages such as robotic

optical 3D vision with a tenfold image magnification and a better intense lighting view of the proper surgical dissection plane. This enhances the difference in contrast of colors of different structures, thereby highlighting blood vessels, lymphatic vessels, adipose lobules, the crests of Duret, Cooper's ligaments, the mammary gland itself and the skin. Sharpness and clarity of image, associated with a high precision of movement of the instrument, greater stability due to tremor abolition and greater accuracy, permit a better detachment of the gland from its suspensory ligaments. Furthermore, the robotic instruments have 7 degrees of freedom of motion at the tips. Not only does this allow for increased precision in controlling small vessels and maintaining a consistent plane, but it also allows negotiation around the curvature of the breast skin cupola which has been reported as being a limitation of endoscopic instruments [23]. Certainly, with the goal of removing the gland by a small axillary incision, we decided to apply this technique to small breast, avoiding enlargement of the scar. No data from large breast are available at the moment.

Although all patients were treated at a tertiary referral center which is also a teaching hospital, this series suggests that RNSM and IRBR could be adopted if the robotic device is available as long as the surgeon adopting the approach has sufficient experience with standard procedures. At the beginning the whole team had to adjust every single surgical movement to set up a technique never described before but in the future the learning curve could be faster since subsequent surgeons will be able to draw upon the experience and expertise already gained and avail themselves of teaching, courses, and publications.

The low conversion rate to open techniques (7.6%), the rapid learning curve, and the low rate of post-operative complication observed in this preliminary study encourage the continued evaluation of this new technique.

There is significant cost related to purchasing the robot and yearly maintenance, and many studies focus on how this impacts surgery on a per-case basis. Since this is the only study published on robotic mastectomy, no bibliography on cost analyses is available in literature. However, in a large hospital with high robot utilization, the robot purchase and maintenance costs are no different than the purchase of any other durable technology. The marginal cost of using the robot for nipple sparing mastectomy and immediate breast reconstruction is the additional operating room time and the cost of the instruments. The sharp reduction of the operating time we observed during the learning curve might at least partially overcome the issue of operating room time. A cost analysis is currently in progress.

Conclusions

Despite superficial organs not being the best target for robotic surgery, we safely performed RNSM and IRBR with implant. In this feasibility and safety study we report a better field of vision during operation and a minimally-invasive approach with an anatomically more respectful mastectomy.

Robotic mastectomy is a form of conservative mastectomy entailing complete removal of the breast parenchyma, not only in combination with preservation of the breast-skin envelope and the nipple-areola complex, but also avoiding any visible scar on the breast dome.

The technique itself is not simple, but with some experience, is both reliable and reproducible with a relatively brief learning curve.

Here this technique was tested on patients with small breast size and high cosmetic expectations.

Although more cases are needed, the encouraging preliminary results of the first 29 operations lead us to recommend a prospective randomized study aimed at evaluating patient satisfaction.

Acknowledgments

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All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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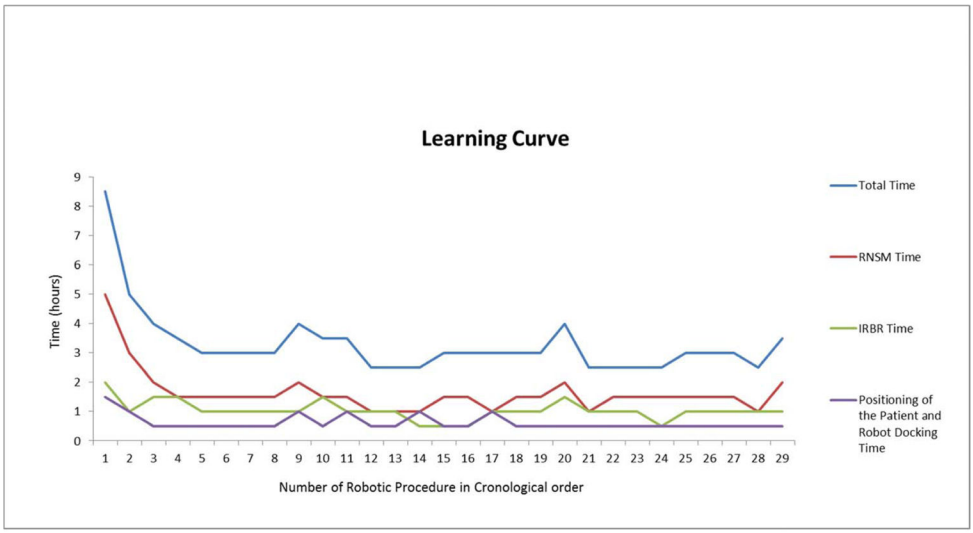

Figure 1.
Learning Curve

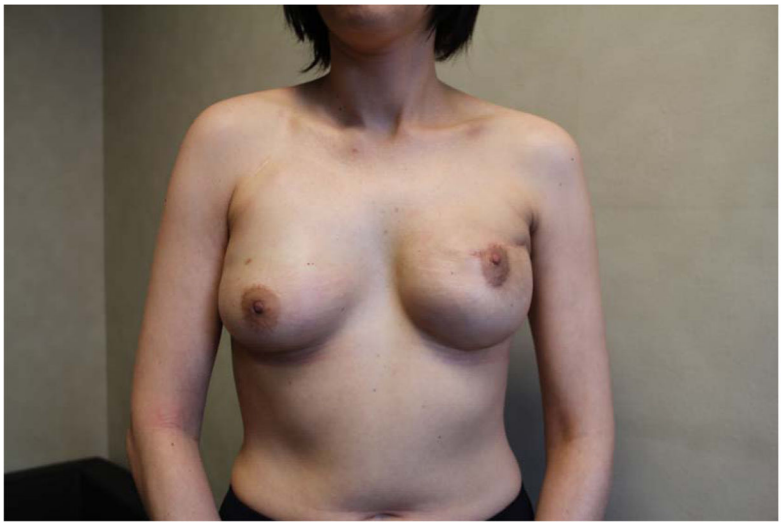

Figure 2.

Two-month postoperative outcome of the third patient. Comparison between RNSM for contralateral delayed risk reducing surgery (right side) and classical open technique (left side). It is still visible a small blistering from internal electrocautery in the upper quadrant.

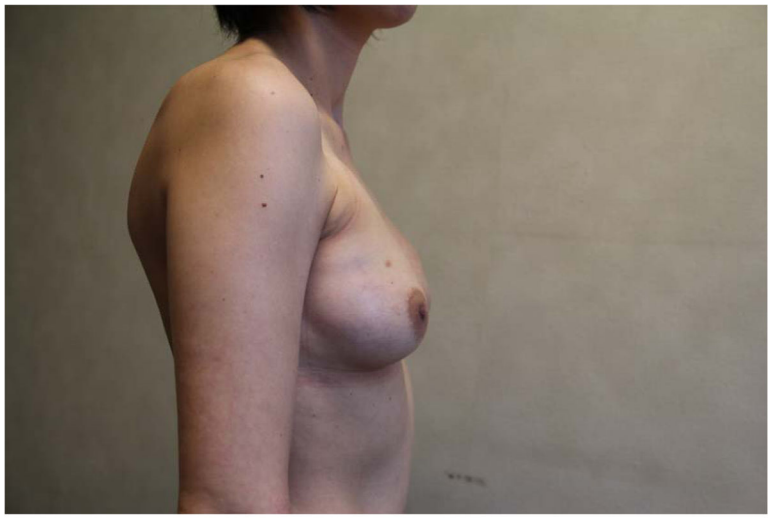

Figure 3.

Two-month postoperative outcome of the third patient. Lateral view. The 3 cm incision remain hidden in the axilla. It is still visible a small blistering from internal electrocautery in the upper quadrant.

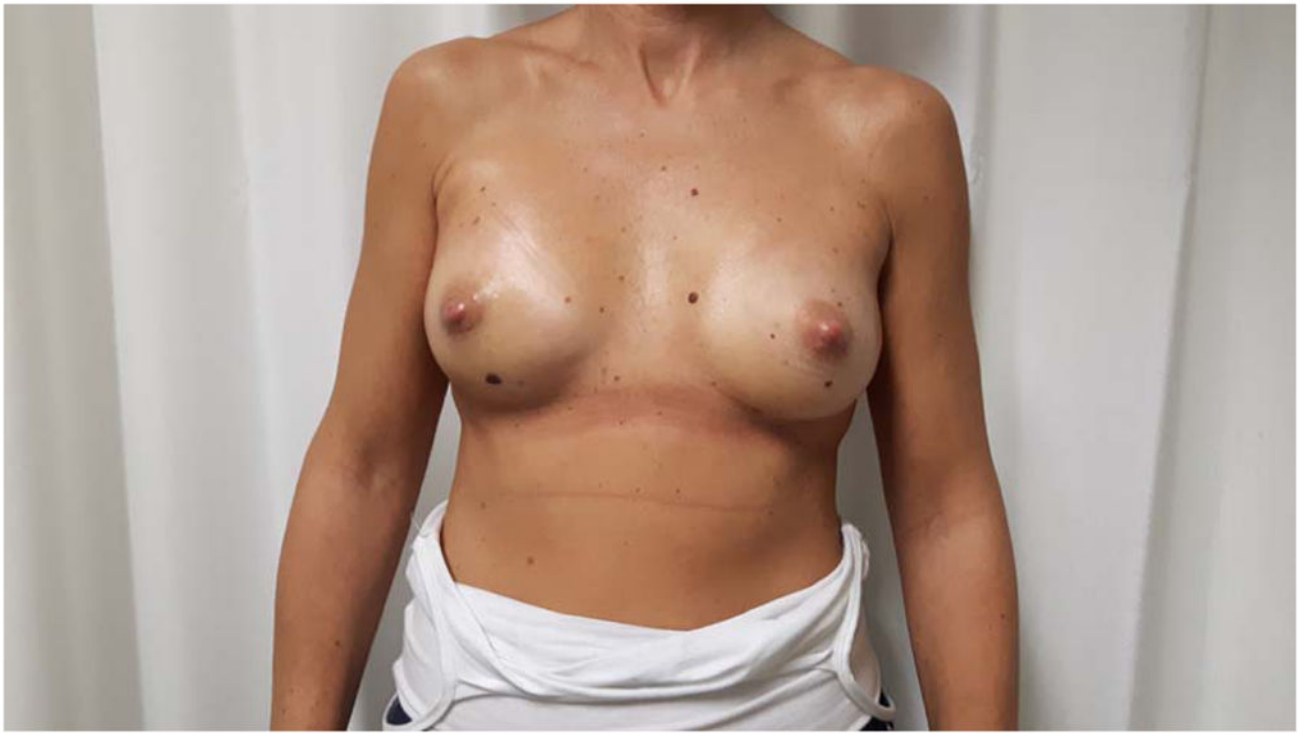

Figure 4.
14th Patient. Second post-opertive day of bilateral RNSM and IRBR.

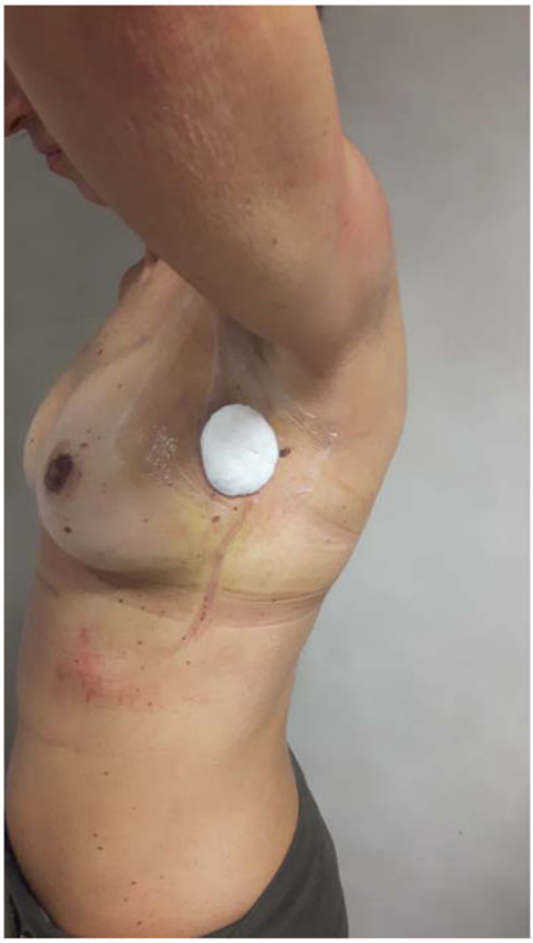

Figure 5.
14th Patient. One week of bilateral RNSM and IRBR. Lateral view.

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Table 1

Age (years) Median 42 (range 30–55)	**Women**	**Final Histology (Breast N°)**		**Genetic Test (Women N°=8)**	
		DCIS/LCIS	**Invasive (ductal/lobular)**	**BRCA1**	**BRCA2**
Monolateral mastectomy (N°)	19			N° of mutation carriers = 5	
- *Prophylactic*	4	-	-	-	3
- *Therapeutic*	15	9[*]	6	2	-
Bilateral Mastectomy (N°)	5			N° of mutation carriers = 3	
- *Prophylactic*	2	-	-	-	2
- *Therapeutic*	1	-	2[$]	-	-
- *Therapeutic + CPM*[#]	2[§]	1[£]	-	1	-

Legend:

[*] One patient had DCIS completely removed by VABB, negative final histology.

[#] CPM=contralateral prophylactic mastectomy.

[£] DCIS G2 left breast + CPM.

[$] Invasive ductal left breast, invasive lobular right breast.

[§] Left breast invasive cancer after neo-adjuvant treatment with cPR, negative final histology bilaterally + CPM