

# Robotic Prophylactic Nipple-Sparing Mastectomy with Immediate Prosthetic Breast Reconstruction: A prospective Study of 138 Procedures

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## Abbreviations:

NSM: nipple sparing mastectomy;  
BC: breast cancer;  
RNSM: robotic nipple-sparing  
mastectomies;  
IBR: immediate breast reconstruction;

## Rezumat

*Mastectomia profilactică robotică cu preservarea mamelonului cu reconstrucție mamară protetică imediată: un studiu prospectiv de 138 de proceduri*

**Context:** Chirurgia robotică a sânului este o procedură emergentă cu rezultate preliminare încurajatoare. Scopul acestui studiu este de a evalua fezabilitatea și siguranța mastectomiei robotice cu preservarea mamelonului (MRPM) cu reconstrucție mamară protetică imediată (RMPI).

**Metode:** Acesta este un studiu prospectiv care include din decembrie 2015 până în ianuarie 2020 toate operațiile MRPM cu RMPI, la paciențele cu ptoză moderată și cupa A, B sau C. Criteriul principal de evaluare a fost rata de necroză majoră. Punctele finale secundare au fost rata de conversie, complicațiile postoperatorii (infecții, hematom, expunerea implantului), rezultatele estetice și calitatea vieții.

**Rezultate:** Studiul include un număr de 79 paciențe la care s-a practicat 138 mastectomii robotice cu preservarea mamelonului cu reconstrucție mamară protetică imediată. Paciențele au fost urmărite pe o perioadă medie de 28 de luni. 2 proceduri au necesitat conversie. S-au înregistrat două cazuri de necroză majoră (1,4%). Au fost observate 9 infecții de plagă chirurgicală (6,5%), dintre care 4 au fost tratate prin înlocuirea implantului iar 5 au dus la pierderea implantului. Pierderea implantului a fost înregistrată în alte 4 cazuri: 2 din cauza necrozei majore și 2 din cauza capsulei periprotetice. În total, s-au pierdut un număr de 9 implanturi (6,5%). Rezultatele estetice au fost în mare parte foarte satisfăcătoare, iar calitatea vieții nu a fost afectată de mastectomie.

Received: 10.03.2021  
Accepted: 20.04.2021

**Concluzii:** Mastectomie robotică cu preservarea mamelonului cu reconstrucție mamară protetică imediată a fost asociată cu rate scăzute de necroză majoră. Aceasta este o procedură sigură și reproductibilă care permite reconstrucția sânelui fără cicatrici vizibile.

**Cuvinte cheie:** mastectomie robotică, reconstrucție mamară, chirurgie minim invazivă, mastectomie cu preservarea complexului areolo-mamelonar, chirurgie profilactică

## Abstract

**Background:** Robotic breast surgery is an emergent procedure with encouraging preliminary results. The aim of this study is to assess the feasibility and the safety of robotic nipple sparing mastectomy (RNSM) with immediate prosthetic breast reconstruction (IPBR).

**Methods:** This is a prospective study including from December 2015 to January 2020 all RNSM surgeries with IPBR, in patients with moderate ptosis and A B or C cup. The primary endpoint was the rate of major necrosis. Secondary endpoints were conversion rate, postoperative complications (infections, hematoma, implant exposure), aesthetic results and quality of life.

**Results:** 79 patients underwent 138 RNSM with IPBR. The average follow-up was 28 months. 2 procedures required conversion. Two cases of major necrosis occurred (1.4%). 9 surgical site infections were observed (6.5%), 4 infections could be treated with implant replacement. Unfortunately, 5 others resulted in implant loss. 4 other implant losses occurred: 2 due to major necrosis, and 2 due to periprosthetic capsula. In total, 9 implants were lost (6.5%). Esthetical results were mostly very satisfying and quality of life was not affected by the mastectomy.

**Conclusions:** RNSM with IPBR was associated with low rates of major necrosis. It is a safe and reproducible procedure that allows breast reconstruction without visible scar.

**Key words:** robotic mastectomy, breast reconstruction, minimal invasive surgery, nipple-sparing mastectomy, prophylactic surgery

## Introduction

Nipple sparing mastectomy (NSM) is today considered as a valid procedure for prophylactic mastectomy and an acceptable option for breast cancer (BC) therapeutic mastectomy (1,2). An increasing number of women are choosing mastectomy for risk reduction. Consequently, the demand to improve cosmetic results in breast reconstruction is rising steadily.

However, NSM is technically challenging because of exposure difficulties. Surgical approach is therefore crucial since oncologic safety and reconstruction success depend on it. Indeed, exposure problems could lead to incomplete resection or surgical complications such as cutaneous necrosis (3). Moreover, peri-

areolar or radial incisions are associated with nipple-areola complex deformation or malposition (4,5).

Endoscopic nipple-sparing mastectomy procedure has been developed to overcome these complications (6–8). However, using rigid endoscopic instruments with a two-dimensional endoscopic camera is highly technically challenging and has thus not led to the popularity of this technique (9). Using robotic surgery in nipple-sparing mastectomies can enable enhanced exposure which allows for improved preservation of the vasculature to the mastectomy flap. The insufflation provided by robotic surgery replaces the need for retraction which decreases the subsequent damage caused by aggressive retraction on the mastectomy flap.

Robotic surgery has been largely developed in oncologic surgery, with satisfactory outcomes. These experiences lead us to start breast robotic surgery development (10–13).

Very few studies of robotic mastectomy were reported (14–17), with encouraging preliminary results.

The aim of this study was to report feasibility of robotic NSM with a large series of 138 procedures.

## Patients and Methods

This is a prospective descriptive monocentric study. Robotic nipple-sparing mastectomies (RNSM) and immediate breast reconstruction (IBR) were performed by one surgeon during 4 years (from December 2015 to January 2020).

### Patient Selection

Patients had to meet the following criteria: breast cup size A, B or C (based on bra size) and ptosis grade  $\leq 2$  (Regnault ptosis scale) (otherwise a skin-reducing nipple-sparing mastectomy was indicated). Patients with high risk of cutaneous necrosis were excluded: strong tobacco intoxication ( $> 1$  pack per day), uncontrolled diabetes mellitus, history of breast surgery or breast radiation. A breast imaging (ultrasound, mammography, or MRI scan) was done during the preceding 6 months. All indications were validated in multidisciplinary meetings. Before the procedure, every patient provided signed informed consent for RNSM with IPBR according to the established regulations.

### Design

The study was performed in accordance with the Good Clinical Practice guidelines and the Declaration of Helsinki. The institutional review board at Gustave Roussy, an ethics committee, and health authorities approved the study protocol.

The primary study endpoint was the rate of major necrosis (mastectomy skin flap or NAC necrosis that requires surgery). Secondary endpoints included the conversion rate to open

technique, post-operative complication rate (hematoma, infection, implant exposure), esthetical results and quality of life.

Esthetical results were evaluated by the patient herself and by the surgeon at 6 and 12 months after surgery, and also by four independent plastic surgeons, from pictures taken 6 months after surgery (frontal, profile, and three quarter). Quality of life was studied comparing pre-operative and 12-months post-operative BREAST-Q results.

### Surgical Procedures

All procedures were performed with the da Vinci<sup>®</sup> XITM (Intuitive Surgical<sup>®</sup>, Sunnyvale, CA). A lateral-thoracic approach is associated with a high vertical scar of 3-5 cm, located within the footprint of the bra, with a sub-centimeter vertical scar, located 8-9 cm below the previous incision. These incisions are located 6-7 cm behind the lateral-mammary fold.

Patients' installation was dorsal decubitus, with arm overhead (90 degrees abduction and internal rotation, elbow at 90 degrees). Infiltration with a saline solution containing 1mg/mL of adrenaline was used to reduce bleeding and to facilitate subcutaneous dissection of the gland. Subcutaneous dissection was then performed as far as possible with scissors. Before inserting ports, we ensured that dissection was confluent between the two incisions to allow insertion of the instruments under endoscopic vision. The upper incision was closed, and three 8-mm diameters ports were inserted and fixed with stitches to the skin incision. Robot docking was guided by the target sign, which had to be aligned with both the skin incision and the nipple. Carbon dioxide insufflation (8 mmHg, 10 L/min) created an adequate working space for the robot. The 30° camera (Intuitive Surgical<sup>®</sup>, Denzlingen, Germany) was introduced first in the middle port to allow non-traumatic insertion of the monopolar-curved scissors and the bipolar grasping forceps (Intuitive Surgical<sup>®</sup>, Sunnyvale, CA). Subcutaneous dissection of the gland was completed in a lateral to medial direction, up to the limits of the gland. Then,

the gland was separated from the pectoralis major muscle in a lateral to medial direction. The robot was undocked and the ports were removed. The gland was then extracted, oriented, and sent for pathological examination. A drain was placed through the inferior infracentimetric scar. The anatomical implant was inserted in a prepectoral position. Finally, the implant pocket was closed laterally to avoid any secondary malposition of the prosthesis (*Fig. 1*).

### Statistics

Categorical variables are summarized in frequency tables, with the counts and percentages of patients in each category. For continuous variables, summary statistics include number of patients, mean and range (Excel). For the comparison of means, we used a Student test.

## Results

### Patients

From December 2015 to January 2020, a total

of 79 women underwent 138 RNSM with IPBR (*Table 1*). For 75% of patients, it was a bilateral prophylactic mastectomy. The weight of resected tissue ranged between 87 and 590 g. Mean follow-up was 28 months.

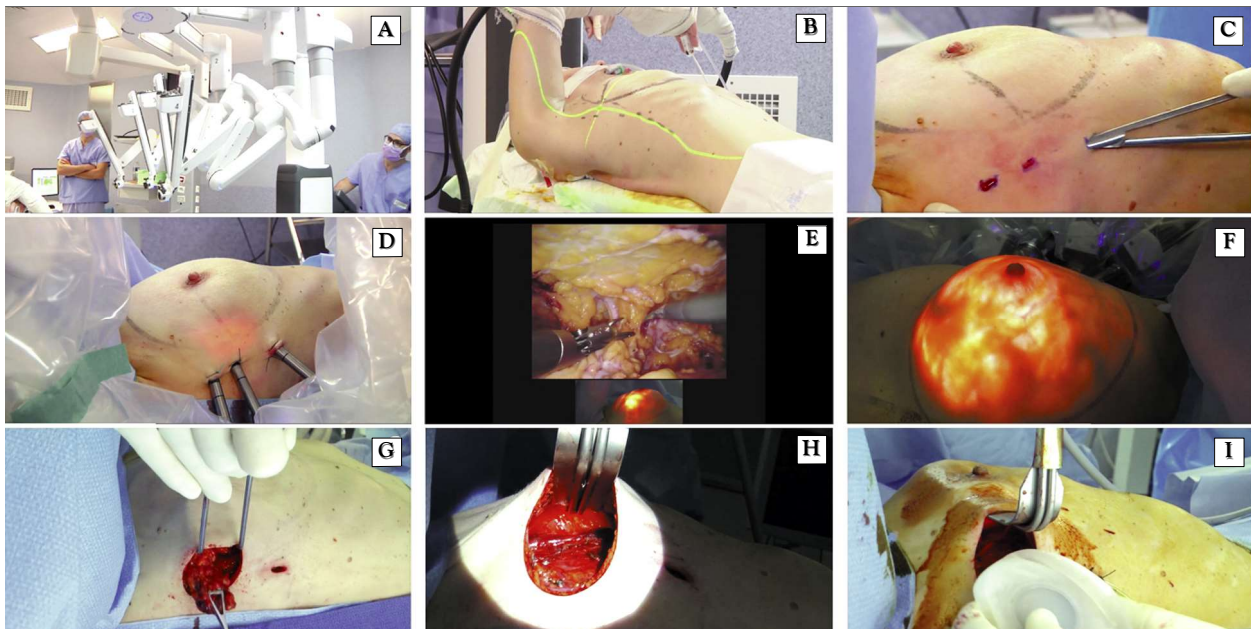
### Operating Time

Operating time decreased considerably over time: from 214 to 85 minutes per breast. Docking time has been reduced from 47 to 5 minutes. Mastectomy length could vary from 20 to 83 minutes, depending on breast volume and surgeon's experience).

### Conversions

Two procedures (1.4%) were converted to an open technique: the first one because of a bleeding from an internal mammary perforator that could not be controlled endoscopically. The second conversion was due to exposure difficulties with a large fatty breast. Post-operative complications (*Table 2*).

We noted 2 cases of major skin flap or NAC



**Figure 1. Surgical procedure:** Presentation of the robot Da Vinci Xi® (A) - Position of the patient (B) - After infiltration and realization of three 8 mm incisions, dissection subcutaneous as far as possible with scissors (C) - Placement of the 3 ports and insufflation (D) - Continuation of the dissection with robotic instruments (E, F) - Extraction of the gland through an incision (< 5 cm) joining the 3 ports incisions (G) - Placement of the prosthesis (H, I)

**Table 1.** Patient characteristics (N = 79) and mastectomy characteristics (N = 138)

|   |                 |
|---|-----------------|
| Age, years, median (range)                    | 37.4 (23 - 56)  |
| BMI, kg/m <sup>2</sup> , median (range)       | 21.16 (17 - 34) |
| Chest size, number of patients (%)            |                 |
| 75 cm   | 2 (2.5)         |
| 80 cm   | 3 (3.8)         |
| 85 cm   | 19 (24.1)       |
| 90 cm   | 41 (51.9)       |
| 95 cm   | 9 (11.4)        |
| 100 cm  | 2 (2.5)         |
| NA  | 3 (3.9)         |
| Cup size, number of patients (%)              |                 |
| A   | 11 (13.9)       |
| B   | 47 (59.5)       |
| C   | 21 (26.6)       |
| Regnault ptosis scale, number of patients (%) |                 |
| 0   | 46 (58.2)       |
| 1   | 23 (29.1)       |
| 2   | 5 (6.3)         |
| pseudoptosis                                  | 3 (3.8)         |
| Missing                                       | 2 (2.5)         |
| Pinch test, number of patients (%)            |                 |
| < 1cm   | 22 (27.8)       |
| [1 ; 2 cm]                                    | 37 (46.8)       |
| > 2 cm  | 4 (5.1)         |
| NA  | 16 (20.3)       |
| Smoking history                               |                 |
| Current                                       | 2 (2.5)         |
| Past  | 6 (7.6)         |
| Bilateral surgery (%)                         | 59 (74.7)       |

**Table 2.** Operating data and post-operative follow-up

|                                |                   |
|--------------------------------|-------------------|
| Number of patients             | 79                |
| Number of mastectomies         | 138               |
| Gland weight (g)               | 206 (87 - 590)    |
| Drain removal (day)            | 6.6 (3 - 12)      |
| Conversion                     | 3 (2.2)           |
| Complications:                 | 22 (15.9)         |
| Necrosis                       | 2 (1.5)           |
| Hematoma requiring reoperation | 4 (2.9)           |
| Infection                      | 9 (6.5)           |
| Implant loss:                  | 9 (6.5)           |
| - Infection:                   | 5 (3.6)           |
| - Necrosis:                    | 2 (1.5)           |
| - Periprosthetic capsula:      | 2 (1.5)           |
| Seroma                         | 7 (5.1)           |
| Operating time (h)             | 4.4 (2.57 - 7.18) |
| Follow-up (months)             | 28.2 (3 - 52)     |

Unfortunately, five infections led to implant loss.

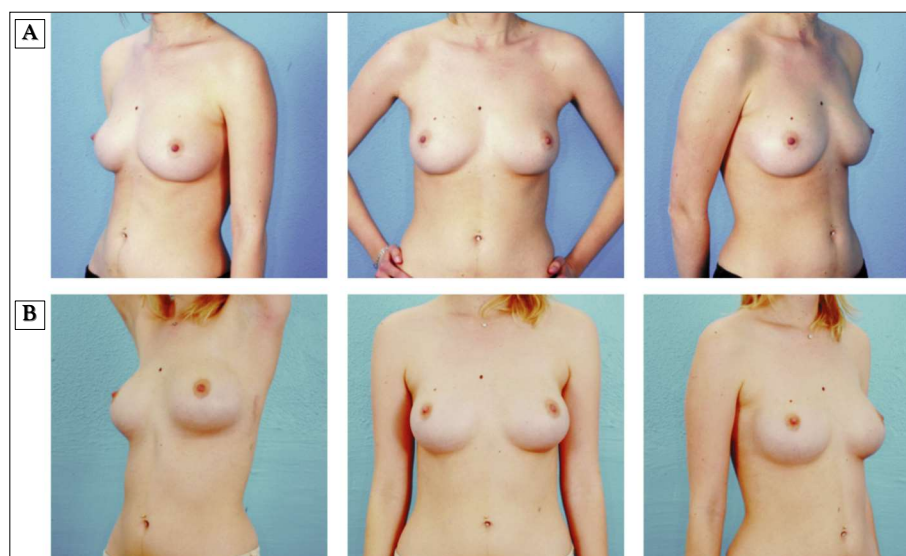
We reported 4 other implant losses: 2 following skin flap or NAC necrosis, and 2 due to severe periprosthetic capsula.

Finally, a total of nine implants were lost in our 138-patients cohort, corresponding to a rate of 6.5%.

### *Esthetical Results and Quality of Life*

necrosis, leading to a rate of 1.4% (2/138) (Table 2). Nine surgical site infections occurred (6.5%). Four infections were successfully managed with revision surgery to wash the implant pocket and to replace the implant.

The 12-month follow-up was available in 47 of 79 patients. Analysis of esthetical results by both surgeon and patient was consistent: satisfying or very satisfying for the vast majority (Table 3), (Fig. 2).



**Figure 2.** Preoperative (A) and postoperative (B) photos at one year after surgery

**Table 3.** Esthetical results evaluated by the patient herself and by the surgeon at 6 and 12 months after surgery: A very satisfying; B satisfying; C mixed result; D unsatisfactory

|                    | Patient | Surgeon |                        | Patient | Surgeon |
|--------------------|---------|---------|------------------------|---------|---------|
| Breast volume      |         |         | Position of the NAC    |         |         |
| A                  | 25      | 31      | A                      | 33      | 25      |
| B                  | 21      | 8       | B                      | 10      | 10      |
| C                  | 1       | 1       | C                      | 0       | 2       |
| D                  | 0       | 0       | D                      | 3       | 2       |
| Missing            | 0       | 7       | Missing                | 1       | 8       |
| Breast shape       |         |         | Appearance of the NAC  |         |         |
| A                  | 17      | 22      | A                      | 35      | 23      |
| B                  | 28      | 13      | B                      | 8       | 12      |
| C                  | 2       | 4       | C                      | 1       | 4       |
| D                  | 0       | 1       | D                      | 2       | 1       |
| Missing            | 0       | 7       | Missing                | 1       | 7       |
| Breast position    |         |         | Sensibility of the NAC |         |         |
| A                  | 26      | 22      | A                      | 6       | 5       |
| B                  | 18      | 14      | B                      | 17      | 15      |
| C                  | 2       | 4       | C                      | 14      | 16      |
| D                  | 1       | 0       | D                      | 4       | 1       |
| Missing            | 0       | 7       | Missing                | 6       | 10      |
| Breast texture     |         |         | Symmetry               |         |         |
| A                  | 11      | 17      | A                      | 20      | 22      |
| B                  | 30      | 19      | B                      | 19      | 10      |
| C                  | 4       | 3       | C                      | 6       | 6       |
| D                  | 2       | 1       | D                      | 1       | 1       |
| Missing            | 0       | 7       | Missing                | 1       | 8       |
| Breast sensibility |         |         | Overall impression     |         |         |
| A                  | 3       | 7       | A                      | 25      | 15      |
| B                  | 18      | 8       | B                      | 19      | 19      |
| C                  | 20      | 22      | C                      | 2       | 5       |
| D                  | 3       | 2       | D                      | 1       | 1       |
| Missing            | 3       | 8       | Missing                | 0       | 7       |

The four independent surgeons' evaluation (for the first sixty patients) showed excellent esthetical outcomes with a mean mark to 16/20.

Quality of life (sexual and physical well-being) evaluated 12 months after surgery was not affected by the mastectomy (*Table 4*).

## Discussion

This is a prospective study of the largest series of robotic nipple sparing mastectomy. In this series, 6.5% of procedures lead to an implant

loss: 5 losses following an infection, 5 losses caused by skin flap or NAC necrosis, and 2 losses due to severe periprosthetic capsula.

We reported here a very low rate of skin flap or NAC necrosis (1.5%). In our first preliminary series, and in Toesca's series, no case of necrosis occurred (15). The necrosis rate in the literature in open surgery is generally higher. Endara et al. noted a necrosis rate of 4.5%, not significantly different ( $p=0.12$ ) (18). In their series, Vita et al. reported a rate of 8.2% of skin flap or NAC necrosis, which is significantly higher than our necrosis rate ( $p=0.002$ ) (19). Piper et al. published a large meta-analysis including 27 studies, 3331 procedures, with a necrosis rate estimated at 9.5% (9.1% of superficial necrosis and 2% of major necrosis) (20).

We noted an infection rate of 6.5%, which is comparable to the values reported in the literature. Choi et al observed an infection

**Table 4.** Breast Q results

|  | Mean pre-operative score | Mean post-operative score |          |
|--|--------------------------|---------------------------|----------|
| Physical wellness<br>n = 40/79             | 22                       | 25,3                      | p = 0,13 |
| Quality of life and sexuality<br>n = 38/79 | 24                       | 24                        | p = 0,38 |

rate of 4.4% in their series of 160 mastectomies (9).

Lai et al. compared robotic NSM with conventional NSM (respectively 54 and 62 procedures); complication rates were 41% and 46.8% respectively, which is not significantly different (21). In a recent study, Houvenaeghel et al. reported 87 procedures of robotic NSM and 142 procedures of conventional NSM (17). Despite several significant higher rates of risks factors for complications in the robotic group, there was no significant difference for breast complications between the two groups, 21.8% and 27.5% for robotic NSM and conventional NSM groups, respectively. Lee et al. compared high-grade complication rates between open surgery and robotic surgery for this procedure (16). In their series, RNSM was associated with lower rates of high-grade post-operative complications (34.8% vs. 17.1%,  $p = 0.031$ ).

These first results are very encouraging. Necrosis rate with the robotic procedure does not seem higher than necrosis rate with open surgery, and might even be lower.

The major interest of robotic nipple sparing mastectomy is to enable complete gland resection without using retractors, through an incision leaving a satisfactory scar. Indeed, retractors could aggravate skin flap ischemia. In this procedure, working space is created by continuous carbon dioxide insufflation. Besides, the operator assistant checks that there is no pressure exerted on the skin flap. This could explain the very low necrosis rate with the robotic procedure. Moreover, there is no contact between the prosthesis and the scar, since the incision is outside the breast. This may reduce infection risk.

These complication rates will most likely continue to decrease with operators' experience. Houvenaeghel et al. reported a series of 100 robotic nipple sparing mastectomies. It underlines the importance of operator's and assistants' learning curve (14). Operating and docking times have been substantially reduced with the surgical team's experience. Toesca describes a short learning curve with operating times similar to those in open

surgery from the third procedure (15).

Esthetical results evaluated by the patient and the surgeon were mostly very satisfying and quality of life was not affected by the mastectomy. Nipple-sparing mastectomies are generally performed on young and healthy patients, as prophylactic surgeries. The scar on the breast could generate negative feelings. It could even be an obstacle to the acceptance of the surgery, in high-risk patients. This surgical procedure performed without visible scar could improve the experience of the patients.

## Conclusion

Robotic NSM is a safe and reproducible procedure that provides breast reconstruction without scar on the breast. The robotic nipple-sparing-mastectomy is at its early stages. These first results are very promising, but the surgical procedure will continue to improve with the experience of the operating team. The operating time and the complication rate will certainly decrease, in accordance with the learning curve. More studies and long-term data are needed to confirm the reduced rate of skin and NAC necrosis compared with the open technique, the oncological safety, and the esthetic stability of the result.

## Conflict of Interest

The authors declare no conflicts of interests.

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