

Immediate Breast Reconstruction (IBR) With Direct, Anatomic, Extra-Projection Prosthesis

102 Cases

Jorge M. Fernandez Delgado, MD,* Jose R. Martínez-Méndez, MD,* Javier de Santiago, MD,†
Gines Hernández-Cortes, MD,† and César Casado, PhD*

Abstract: There are different methods described until now for immediate breast reconstruction. Despite the use of autologous flaps considered by many authors, implants are considered as an option by others. A prospective study of 102 clinical cases was designed, including a 1-year follow-up in which glands were reconstructed by immediate breast reconstruction (IBR) with direct, extra projection, anatomic prostheses located in a submuscular pocket after a skin-sparing mastectomy. The prosthesis coverage was made by the muscle in its upper two thirds and by using the skin from the mastectomy in its lower third. The cosmetic results obtained were evaluated according to the volume, form, and symmetry achieved using a linear numeric analogical score. This evaluation had an averaged value of 2.79 ± 0.8 in our scale from poor (0) to excellent result (4). The overall rate of complications was 15.7% of the cases, with seroma being the most frequent. In conclusion, this preliminary study demonstrates that immediate breast reconstruction with a direct, extra projection, anatomic prosthesis is a good alternative. Nevertheless, more long-term studies with a higher number of patients and using an SF-36 for patient satisfaction are needed to confirm these results.

Key Words: immediate breast reconstruction, anatomical prostheses, skin-sparing mastectomy, breast cancer

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According to today's medical publications, breast cancer has become the most frequent tumor seen in women. Approximately 20% of patients in our center have undergone a mastectomy in combination with radiotherapy, hormone therapy, and other treatments such as chemotherapy. Indications and design have evolved since 1991, when Toth and Lappert¹ coined the term *skin-sparing mastectomy* (SSM).

Today, this technique includes the removal of the nipple-areola complex, previous biopsy incisions, entire mammary gland and the recumbent skin as well, if the tumor is found near the surface, while at the same time conserving the rest of the skin covering the gland.²

Kroll et al³ discovered 1 recurrence in 100 patients during a 23-month follow-up, while other authors have previously published lengthy series in which no significant statistical difference was found between the incidence of local recurrence (7% to 11%) after undergoing either a classic or skin-sparing mastectomy.^{4,5}

Immediate breast reconstruction (IBR) has become a much more viable option for avoiding unpleasant physical and mental effects caused by the resulting deformity from a mastectomy. Furthermore, symmetrical results are obtained in the majority of patients, thanks to new reconstructive techniques such as expanders, expander/implants, prostheses, and the design development of autologous flaps. Favorable cosmetic results were also achieved using these techniques. For patients who have undergone this type of reconstruction, the most important benefits were both social and psychologic.⁶

Currently, reconstruction using flaps (TRAM/DIEP) is considered by numerous authors to be the first-choice technique,⁷ although their application may not be possible due to the anatomic characteristics of some patients or simply because the patient has rejected this option. In the majority of cases, expanders are used, especially on those occasions when it is necessary to use implants or expander/prostheses, while direct prostheses are applied much less frequently. In 1983, Asplund⁸ reported the use of round, submuscular implants for breast reconstruction after modified radical or simply mastectomy. Anatomic implants first appeared in 1995,⁹ and they had been used for IBR.¹⁰ They continued to evolve until the appearance of new, extra projection, special gel implants in 2002, which provided new devices for augmentation and reconstructive mammoplasty. These devices improved especially the lower-pole projection.

Our technique consists of immediate, postmastectomy, breast reconstruction using extra projection, anatomic, cohesive gel prostheses placed in a superior submuscular layer and inferior subcutaneous layer. The objective of this study was to show, based on our experience, the results and complications using extra-projection prostheses in IBR after an SSM.

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From the *Plastic Surgery and Burns Department and †Gynecology Department, La Paz Hospital, Madrid, Spain.

Reprints: Jose R. Martínez-Méndez, MD, Plastic Surgery and Burns Department, La Paz Hospital, Pso. Castellana, 261, 28034 Madrid, Spain.
E-mail: josemartinez77@telefonica.net.

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MATERIALS AND METHODS

One hundred two skin-sparing mastectomy patients were selected over a period of 12 months (October 2002 to October 2004) for immediate reconstruction using McGhan 410 XP anatomic prostheses. Patients' ages ranged from 26 to 57 years old, with an average age of 45.6 years. In every case, mastectomies were done by oncologic surgeons (gynecologists or general surgeons) doing the surgical approach following the marks drawn previously by a reconstructive plastic surgeon. Selection criteria (Table 1) were the following: first and most important were the oncologic needs. This type of reconstruction was done only on patients with invasive ductal carcinoma in stages I and II and with the possibility of use skin-sparing mastectomy techniques. Patients needing radiotherapy were excluded.

Patients were informed of the possible reconstructive options, and the intervention was done only in cases in which the patients were sufficiently motivated to undergo this type of surgery and with the use of prosthesis. During the study, patients receiving chemotherapy (50%) were not excluded.

A model was chosen from the McGhan 410 XP, Mentor, or Polytech range in 99 unilateral cases and in 3 bilateral cases (Table 2). Patients were offered the possibility to adjust the form and position of the opposite breast if necessary to obtain the best possible symmetric result during the same surgical intervention.

Surgical Technique

Skin-sparing mastectomies were done in all cases. An elliptical excision was made to include the gland, the nipple-areola complex, previous biopsy scar (if present), and recumbent skin if the tumor was superficial. The incision was made such that the resulting scar would not be visible on the patient's cleavage, allowing her to dress normally. Special attention was paid by the oncologic and plastic surgeons regarding the thickness of the cutaneous flaps during the intervention to guarantee excellent implant coverage quality. Subcutaneous fat and subdermal plexus were conserved to insure skin vascularization in every case. The entire gland, including the anterior pectoral muscle fascia, was removed. An axillary lymphadenectomy was necessary in 67 cases (66%). This technique was made using the same approach in the 50%; however, the remaining cases needed a second incision. An aspirative drain was used in every case, one in the implant pocket and another in the axillary area when the lymphadenectomy was made.

The McGhan 410 XP implant (anatomic and with extra projection) was used in the majority of the patients, using 6 times de Mentor profile, and in 1 patient with a bilateral

TABLE 2. Devices Used During This Study

Device	No.
McGhan XP range	94
MX	80
165 g	1
205 g	3
225 g	1
255 g	5
290 g	2
320 g	5
325 g	23
370 g	25
410 g	2
420 g	3
425 g	4
445 g	6
LX	14
195 g	2
270 g	3
310 g	5
330 g	4
Mentor	6
275 g	6
Polytech	2
325 g	2

The first company that sold this type of prosthesis in our country was McGhan, with the 410 XP range. Later, other companies distributed similar devices with extra projection. We begun to use them, obtaining similar results, but we are not able to compare the different devices, because of the low number of cases in the latest groups.

reconstruction the Polytech devices. The model was selected according to the patient's nature (height and constitution) and breast's values (base and height of the breast to be reconstructed).

The plastic surgeon designed the submuscular pocket after the oncologic surgeon's intervention, along with a carefully done hemostasia. The intervention was done according to the one described by Spear and Spittler¹¹ by resituating the greater pectoral muscle. This was accomplished by unattaching the inferior portion until the medial zone, where the superficial attachment was maintained. Next, a cavity was completed with the same dimensions as the prosthesis.

The prosthesis was then placed in a submuscular position. A cover was made in its superior two thirds by the muscle and the remaining inferior third by the cutaneous flap created during the mastectomy. The use of the prosthesis was rejected if the inferior flap was not thick enough, due to the risk of cutaneous vascular damage and implant extrusion. It was necessary in some cases to lower the submammary fold to gather skin from the abdomen and reduce final suture tension. An aspirative drain was placed, and the cutaneous and subcutaneous layers were closed after attaching the major pectoral muscle to the lower dermis of the inferior cutaneous flap.

The opposite breast was adjusted in 64% of cases (65/102). Of those cases in which the appropriate reconstructive technique was chosen, 2 were breast reductions by inferior pyramedial pedicle, 27 were mastopexies using the

TABLE 1. Inclusion Criteria

Inclusion Criteria
Oncologic (invasive ductal carcinoma stage I or II)
No multifocal or multicentral carcinoma
Sufficient cutaneous coverage after skin-sparing mastectomy
Adequate quality of soft tissue
No previous or subsequent radiation therapy
Patient motivation

same pattern as the reduction, and 38 were mastopexies by deepithelialization of a superior semilunar to the nipple-areola complex.

The patient remained in the hospital for 3 days after the intervention, and at the end of that time, the aspirative drain was removed. Treatment with antibiotics was maintained for 5 days.

The last reconstruction phase was carried out 2 to 3 months after implant placement or after completing chemotherapy. It was done by an outpatient surgery using local anesthetic and according to the technique described by Bogue et al.¹² This procedure consisted in a local superior-based flap for the nipple and a local skin autograft taken from the same site for the areola.

The cosmetic results of reconstructive surgery were evaluated using pre- and postoperative photographs. The volume, shape, symmetry, and level of the submammary fold obtained were compared with the normal breast by 2 plastic surgeons blinded to the purpose of the study, using a linear numeric analogue score.¹³ The average value was calculated for each case. The final result was classified as poor (0–1), fair (1.1–2), good (2.1–3), or excellent (3.1–4).

RESULTS

Any problem that occurred during the patient's recovery was considered a complication, including cutaneous irritation with or without necrosis, hematomas, seromas, infections, prosthesis extrusion, or recurrence (Table 3). The overall rate of complications was 15.7% (16/102). No infections were observed in our patients. There were 10 cases of local cutaneous flap necrosis surrounding the scar, which was attributed to the probable excess of tension. Eight of these cases were resolved with minor treatment. Seromas were seen as the second most frequent complication in this series (5/102). In 2 cases, the seroma was associated with cutaneous necrosis. In those cases, both implants were removed due to prosthesis exposure through the skin necrosis. A second reconstruction was performed 8 months later, involving the placement of an expander in one case and using a latissimus dorsi musculocutaneous flap in the other. All cases of seroma were produced in patients who had suffered lymphadenec-

TABLE 3. Complications in Our Series

Complications	No.	%
Seromas	5	4.9
Cutaneous necrosis	10	9.8
Cutaneous necrosis + seroma + prosthesis exposure	2	1.9
Infection	0	
Hematoma	0	
Recurrence	1	1

The overall rate of complications was 15.7% (16/102). The most frequent complication was cutaneous necrosis (5/102). In 2 cases, the necrosis was accompanied by seroma. In all the cases that had a seroma, the devices were explanted because of the exposure of the prosthesis. All cases of exposed prosthesis were due to other complications.

TABLE 4. Cosmetic Results

	No.	%
Poor	7	7.1
Fair	23	23.2
Good	53	53.5
Excellent	16	16.2
Total	99	100

A scale of 4 degrees was used: 1, poor; 2, fair; 3, good; and 4, excellent. Three patients were excluded because their photographs were incomplete. Two blinded plastic surgeons evaluated the pre- and postoperative photographs from 99 patients. The averaged evaluation was 2.79 ± 0.8 .

tomy through the same incision. In this situation, the axillary lymphatic drainage would have contacted the implant.

A local recurrence of breast cancer was reported in only 1 case. Until now, no hematomas have been found, thanks to drains and a carefully done hemostasia. No capsular contracture has been reported.

For the cosmetic results analysis, pre- and postoperative photographs were used. Three patients were excluded from the cosmetic rating because their photographs were incomplete. The remaining 99 cases were recorded. Each category was evaluated and then was averaged (Table 4). With the scale described above, 69.8% of patients had a good or excellent esthetic result. Only 7 cases were recorded as a poor result. The averaged evaluation was 2.79 ± 0.8 (Figs. 1–3).

DISCUSSION

Breast cancer has become one of the most common types of malignant tumors in women of all ages. Mastectomy and all its variable forms is one of the popular ways of treating breast cancer today. The skin-sparing mastectomy, first described in 1991,¹ has become the technique of choice in lower stages. Numerous series have been published in which the recurrence rate was compared between the traditional method and skin-sparing mastectomy. Carlson and Bostwick^{13a} published in 1997 a series of 435 consecutive cases treated by mastectomies and immediate reconstruction. Two groups were divided according to the oncologic technique used. Three hundred twenty-seven cases received skin-sparing mastectomies as opposed to 188 who received conventional mastectomies. The recurrence rate reached 7% in the first group compared with 9.5% in the second. In the same year, Kroll⁴ and collaborators published a review of 372 cases in stages T1 and T2 treated with skin-sparing mastectomies and immediate reconstruction. There was only 6.2% local recurrence in the 372 cases reviewed. Medical publications that support these results over recent years confirm that this type of surgery (skin-sparing) is as efficient in controlling cancer as a traditional mastectomy.^{14,15} This technique, as described by Bostwick, offers other benefits such as the ability to do the reconstruction at the same time as the surgery commonly referred to today as IBR.

Immediate reconstruction is considered to be a tremendous advance in the treatment of breast cancer. It offers documented psychological benefits,¹⁶ as well as permitting

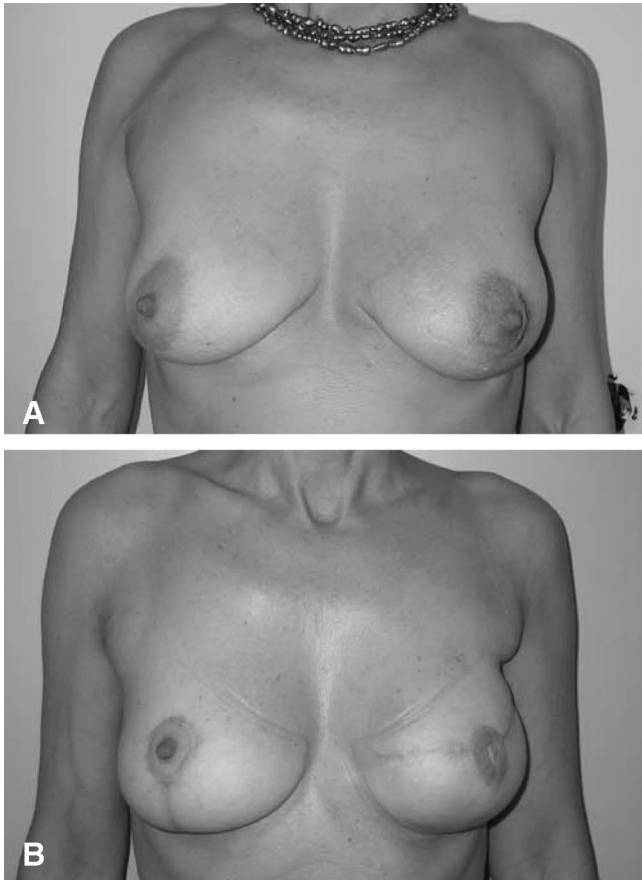


FIGURE 1. An in situ ductal carcinoma was diagnosed in this 50-year-old woman. After a preoperative study, a skin-sparing mastectomy was done by the gynecologist surgeon. The breast was reconstructed immediately using an extra-projection prosthesis, type MX-410 g. In the contralateral gland, a mastopexy with a pyramedial pedicle was used to reach the symmetry. In the figure, preoperative (A) and 1-year postoperative (B) photographs are presented.

similar oncologic management, while at the same time generating very acceptable cosmetic results.

Khoo and collaborators¹⁷ published a study whose results showed that IBR was more cost-effective than delayed reconstruction. Many authors consider that reconstruction using autologous tissues provides the best long-term results,¹⁸ and some even consider flaps transferred microsurgically from the abdominal wall to be the best technique.^{7,19} Nevertheless, not all centers have the necessary infrastructure to make flaps microsurgically. Furthermore, it has to be taken into account that they are aggressive techniques that cannot be done on every patient, and on occasion the patient rejects this type of treatment.²⁰ Spear et al²¹ recently published a study about the costs of reconstruction using a TRAM flap as opposed to using a prosthesis. The use of implants is definitely favored in this series because costs and the use of hospital resources are clearly diminished. In our series, an IBR using a direct prosthesis signifies a reduction of surgical time, length of hospital stay, and, most important, costs while obtaining similar cosmetic results.

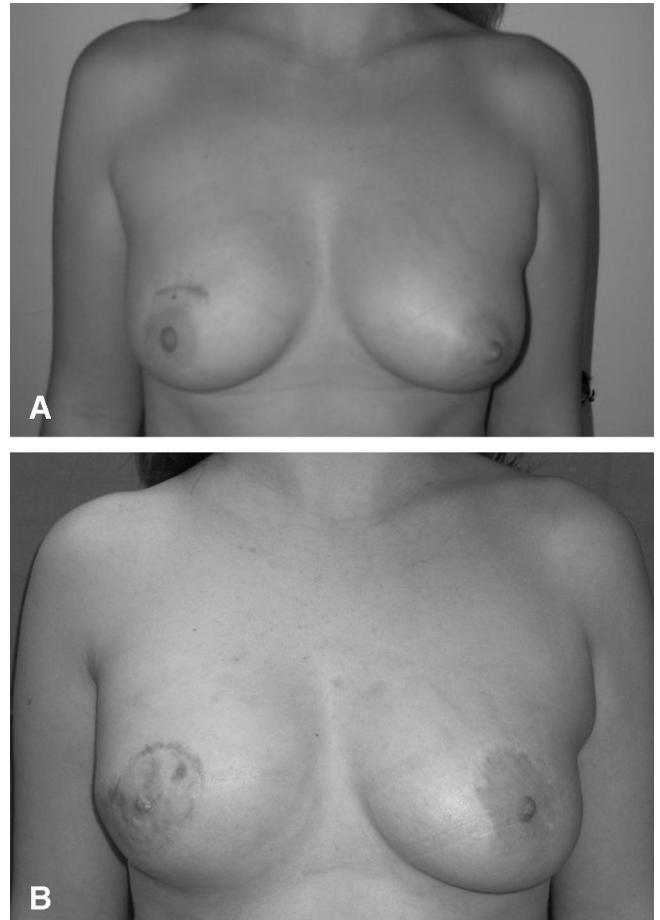


FIGURE 2. A right skin-sparing mastectomy with immediate breast reconstruction was the procedure made in this 32-year-old woman, after an in situ ductal carcinoma diagnosis. In this case, an extra-projection MX prosthesis weighing 410 g was selected. To obtain symmetry, a periareolar mastopexy was made at the contralateral breast. Photographs taken at the preoperative moment (A) and 1 month later (B) are shown.

Immediate reconstruction is also advantageous because patients do not usually require postsurgical adjuvant treatment with local radiation, except in the axillary region after a skin-sparing mastectomy. Chemotherapy is widely used in the treatment of breast cancer. Furey et al²² found no statistical difference in complications rates between a group of patients that received chemotherapy after mastectomy with IBR and another one who did not. However, Rey et al²³ found a higher rate of infections after high-dose chemotherapy than after conventional chemotherapy. Complementary chemotherapy was necessary in 50% of our cases, without causing a variation in the final rate of complications. There was only 1 recurrence in our cases, which is in concordance with current medical publications, based on the fact that the IBR after an SSM has good oncologic control of the breast cancer.

The use of the prosthesis in immediate reconstruction is nothing new. In fact, different authors reported the use of silicone- or saline-filled devices for this purpose. Today, they

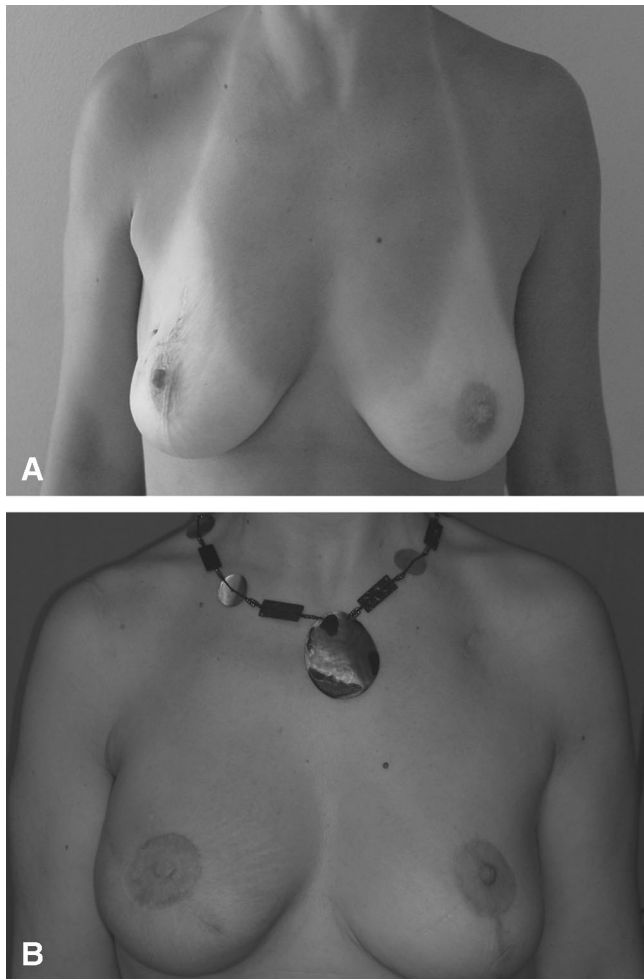


FIGURE 3. This 49-year-old woman was diagnosed with an in situ ductal carcinoma. An immediate breast reconstruction was made with an MX prosthesis weighing 325 g, after a skin-sparing mastectomy. A mastopexy with the same pattern as the previous cases was used in the contralateral gland to achieve symmetry. The photographs shown were taken 1 week after a biopsy (A) and 1 year after reconstruction (B).

are used frequently in different forms or sizes.⁶ Spear and Spittler¹¹ published a review about reconstruction using implants: prosthesis or expanders. The first case involved a technique which consisted of unattaching the major pectoral muscle from its inferior portion, creating a submuscular pocket for implant placement. Later, the pectoral muscle is anchored to the skin using a marionette suture while leaving an inferior third of the prosthesis in the subcutaneous layer. In our series, the surgical technique is basically the same, except a reabsorbable, monofilament suture was used instead of a marionette suture to anchor the lower dermis of the inferior flap. This type of closure leaves sometimes a mark on the skin which is later corrected quickly during the earliest postoperative period.

Until recently, only round or anatomic prostheses with a slight projection were available. When a breast reconstruc-

tion was made using these implants, a contralateral mammoplasty was needed to achieve symmetry because it was not possible to obtain a healthy breast shape with them. This has been one of the largest difficulties of the cosmetic result obtained using this technique.²⁴ Until 2002, the anatomic prosthesis was used for IBR by other authors. They had reported good esthetic results, with a very low complication rate.¹⁰ In 2002, the McGhan range 410 XP was marketed in Spain, featuring a greater inferior pole projection while maintaining the anatomic form of the prosthesis. This design is now widely distributed by other suppliers. The cosmetic result obtained has improved enormously because of this feature. This type of prosthesis was used in several of our cases with mild to moderate ptosis, achieving good cosmetic results, while in the majority of cases of severe or moderate ptosis, it was necessary to adjust the opposite breast to obtain a symmetrical appearance. In our series, the overall rate of complications is somewhat elevated, but this technique is safe if the rate of serious complications is considered.

In conclusion, a skin-sparing mastectomy has demonstrated until now that it provides a good oncologic control of breast cancer, which demonstrates it is a good base for performing an immediate reconstruction. In spite of the fact that many authors believe abdominal wall flaps are the technique of choice for breast reconstruction, it is not always possible to use them, either because they are contraindicated or the patient rejected them. The appearance of implants with extra projection and anatomic design has meant an improvement in the cosmetic results obtained from immediate reconstruction, markedly reducing surgical time when compared with the classic use of expanders. After analyzing our series, it can be concluded that the simplicity of the technique, reproducibility, low costs, good cosmetic results, and a reduced complication rate demonstrate the viability in the extra-projection prostheses' use in immediate reconstruction, adding this technique to the array of possibilities.

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