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ORIGINAL ARTICLE

Multicenter Study on Breast Reconstruction Outcome Using Becker Implants

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Abstract The use of tissue expanders and implants is the simplest option for breast reconstruction following mastectomy. In the 1980s, Hilton Becker introduced a round, inflatable breast implant that could be used as a permanent implant. Since then, the original implant has been improved in both design and architecture. The new Becker device consists of an anatomical implant composed of 35% cohesive silicone gel in the outer chamber and 65% normal saline in the inner chamber. This multicenter study describes our experience with the new anatomical Becker implants in a large series of patients, in both immediate and delayed breast reconstruction. We reviewed the clinical records of 204 patients who underwent a breast reconstruction with an anatomical Becker-type implant in the sub-muscular position between November 2004 and December 2006. Data on the patients' characteristics, indications for reconstruction, operative technique, device size used, complications, and need for further operations were collected and analyzed. A total of 248 breast reconstructions were performed in 204 patients. One hundred forty-three patients (70%) underwent an immediate reconstruction; in the remaining 61 cases (30%), the breast reconstruction was performed later. The patients' age ranged from 26 to 66 years, with a median age of 47.5 years. The implant was placed unilaterally in 160 women (78.5%) and bilaterally in the remaining 44 (21.5%). Complications occurred in 85 cases (34.2%), in both the immediate and delayed reconstruction groups, and were related to wound healing, bleeding, seroma, and problems with the inflatable expanders. Iatrogenic implant rupture was documented in one case (0.4%). Inflation was impossible in 7 cases (2.8%) as a result of valve obstruction (3 cases, 1.2%) and valve displacement (4 cases, 1.6%). Implant malposition was the most troublesome complication; indeed, 34 patients (13.7%) complained of device malposition. Capsular contracture was assessed in all the patients. Significant capsular contracture (Baker grade III and IV) was detected in 6 cases (2.4%) at the follow-up approximately 1 year after surgery. Breast reconstruction with permanent inflatable expanders is widely acknowledged as a useful technique for breast cancer patients undergoing simple or modified radical mastectomy. The use of this device eliminates the need to replace a temporary tissue expander with a breast implant, thus avoiding a second operation. Although we believe autologous tissues afford the best method of reconstruction in the majority of patients, the results of our study show that expander implant placement may yield a reasonable reconstruction.

Keywords Breast reconstruction · Anatomical Becker's implant · Permanent inflatable expanders

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Introduction

The use of tissue expanders and implants is the simplest option for breast reconstruction following mastectomy. In the 1980s, Hilton Becker introduced a round, inflatable breast implant that could be used as a permanent implant to replace temporary tissue expanders [1–3]. The use of this implant eliminates the need for a second operative procedure to remove the expander and replace it with another breast implant. This permanent round implant was composed of an outer silicone chamber, comprising 25 or 50% of the implant, and a saline fillable inner lumen that could be adjusted by means of a tube attached to a small remote valve [1, 2]. Through improvements in both design and architecture, the original implant has evolved into the Becker implant we know today.

The new Becker device consists of an anatomical implant composed of 35% cohesive silicone gel in the outer chamber and 65% normal saline in the inner chamber. Traditional permanent implants are usually round rather than anatomically contoured to match the natural breast shape [1, 2, 4]; anatomical permanent expander implants may have the further advantage of providing a better breast shape than that provided by unshaped implants or expanders.

The aim of this multicenter study is to describe our experience with the new anatomical Becker implants in a large series of patients who underwent either immediate or delayed breast reconstruction. We focus on the use-related problems we encountered, the complications, and the cases in which a second surgical procedure may be required.

Materials and Methods

We reviewed the clinical records of 204 patients who underwent a breast reconstruction with an anatomical Becker-type implant in the sub-muscular position between November 2004 and December 2006. All the patients were admitted to the Plastic Surgery Departments of the "La Sapienza" University of Rome, the University of Sassari, or the University of Perugia.

Surgical Technique

In both the immediate and delayed groups of breast reconstruction, all the patients were marked preoperatively. With the adjustable expander implant, immediate reconstruction was performed in one stage. After the general surgeon had removed the breast, the free lateral border of the pectoralis major muscle was split and raised to create as much cleavage as possible, which was in turn extended by raising the serratus anterior laterally to enable the serratus muscle sheet and fascia to be drawn forward to provide lateral implant cover. The inferior pectoralis major muscle was detached from the ribs and raised either together with the abdominal fascia or together with the deep subcutaneous layer above the abdominal fascia so as to provide complete coverage of the implant. The implant was then placed in the pocket, with the port exiting inferiorly or laterally in a subcutaneous pocket. The inferior mastectomy skin flap was stretched over the lower part of the anatomical expander implant to accentuate the lower pole of the reconstructed breast. The implant was positioned to maintain optimum symmetry. Two or three drains were used in immediate reconstructions: one placed in the submuscular plane, one in the subcutaneous plane, and the third, if required, in the axilla (Figs. 1, 2, 3).

In delayed breast reconstructions, a portion of the scar of the original mastectomy was removed and sent for pathologic examination, the old mastectomy incision was reopened, and the sub-muscular pocket was dissected. Only one drain was used in delayed reconstructions.

The appropriate size of the expander implant for each patient was selected according to the transverse breast width, which was measured at the preoperative assessment. The implant was prepared by aspirating any air from the saline bladder by means of a 23-gauge butterfly needle inserted through the remote port, and then partially filling the bladder with saline. The partially filled implant was positioned and the pocket closed. The implant was then further filled with saline to comfortably fill the pocket, as close to maximum as possible. Final implant fill was performed on an outpatient basis.

Data on the patients' characteristics, indications for reconstruction, operative technique, device size used, complications, and need for further operations were collected and analyzed.

Results

A total of 248 breast reconstructions were performed in 204 patients over a 2-year period (November 2004–December 2006) for the reasons shown in Table 1. The patients' age ranged from 26 to 66 years, with a median age of 47.5 years (immediate: range = 26–61 years; delayed: range = 35–66 years). None of the patients received radiation.

A Siltex Contour Profile Becker 35 implant (Mentor Corporation, Santa Barbara, CA) was used in all patients. One hundred forty-three patients (70%) underwent an immediate reconstruction in which the anatomical Becker device was implanted at the time of the mastectomy; in the remaining 61 cases (30%), the breast reconstruction was performed in a second procedure. The Becker implant was

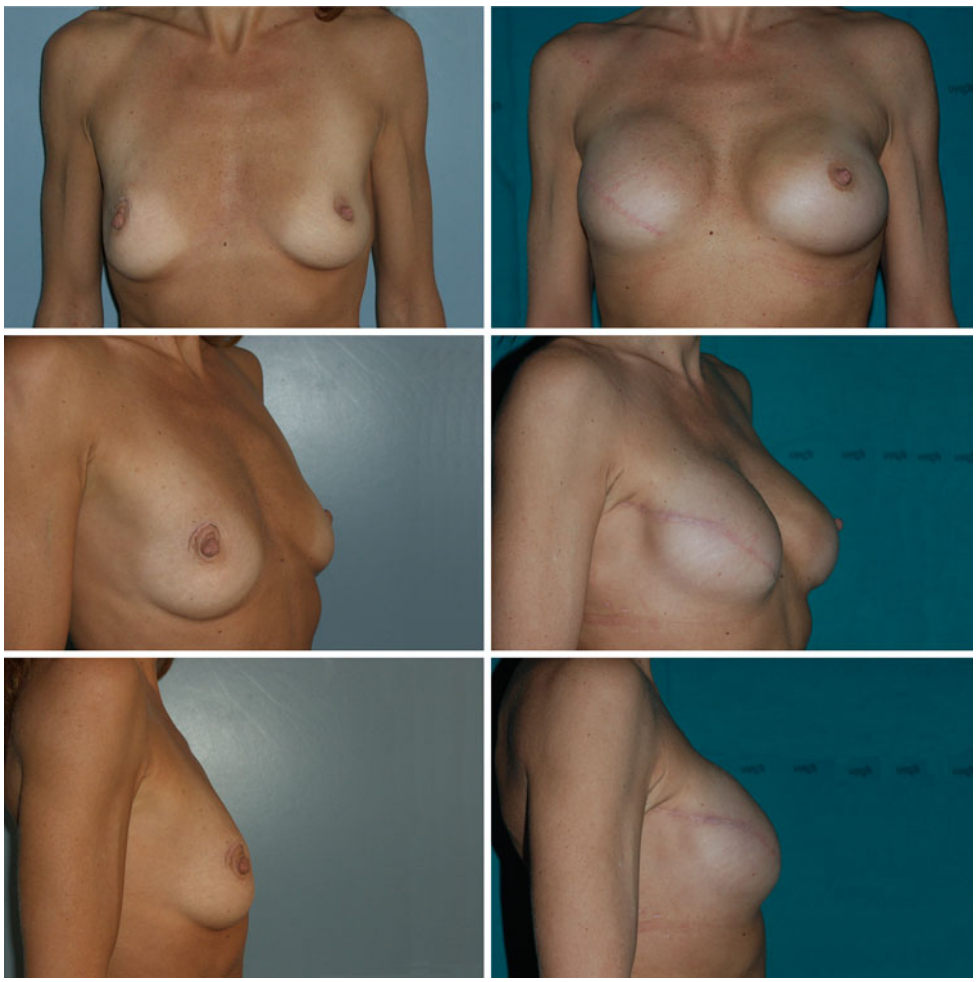

Fig. 1 Bilateral immediate breast reconstruction. *Right* Preoperative frontal, oblique, and lateral views. *Left* One-year postoperative frontal, oblique, and lateral views of the same patient

placed unilaterally in 160 women (78.5%) (immediate: 119; delayed: 41) and bilaterally in the remaining 44 (21.5%) (immediate: 24; delayed: 20). Breast reconstruction was performed using the Becker implant alone in all the patients but one (0.5%), in whom the device was associated with a latissimus dorsi (LD) flap (Poland's syndrome).

The size of the devices used ranged from 145 to 685 cc, with a mean volume of 344.71 cc and a mode of 365 cc (72n). One hundred two implants were filled to recommended fill volume and 146 were overfilled (from 20 to 40 cc of saline, mean = 25.5 cc). These implants were successively deflated to achieve breast symmetry. No implant was under-filled. Table 2 shows the contralateral breast adjustment offered to achieve symmetry, which was indicated in 82 cases (40%) (immediate: 60 cases; delayed: 22 cases).

The breast reconstruction was accompanied by a contralateral procedure immediately after the reconstruction in 20 cases (10%) (immediate: 12 cases; delayed: 8 cases). The contralateral breast adjustment was not performed in 78 cases (38.5%) (immediate: 59 cases; delayed: 19 cases), while 44 patients (21.5%) (immediate: 24, and delayed: 20) underwent bilateral reconstruction.

One hundred forty-two patients (70%) underwent a single surgical procedure, 20 adjusted immediately (10%) (immediate: 12 cases; delayed: 8 cases), 78 not adjusted (38.5%) (immediate: 59 cases; delayed: 19 cases), and 44 bilaterally reconstructed (21.5%) (immediate: 24, and delayed 20). The second stage of the procedure in patients in whom a delayed readjustment was performed consisted of removing the dome, reconstructing the nipple–areola complex, and adjusting the contralateral breast as requested.

Post-operative complications, including those related to the implant, are listed in Table 3. Complications occurred in 85 cases (34.2%), in both the immediate (57 cases) and delayed (28 cases) reconstruction groups, and were related to wound healing, bleeding, seroma, and problems with the inflatable expanders.

Implant rupture, which was iatrogenic (accidental needle injection during seroma aspiration), was documented in one case (0.4%). Inflation was impossible in 7 cases (2.8%) due to valve obstruction (3 cases, 1.2%) and valve

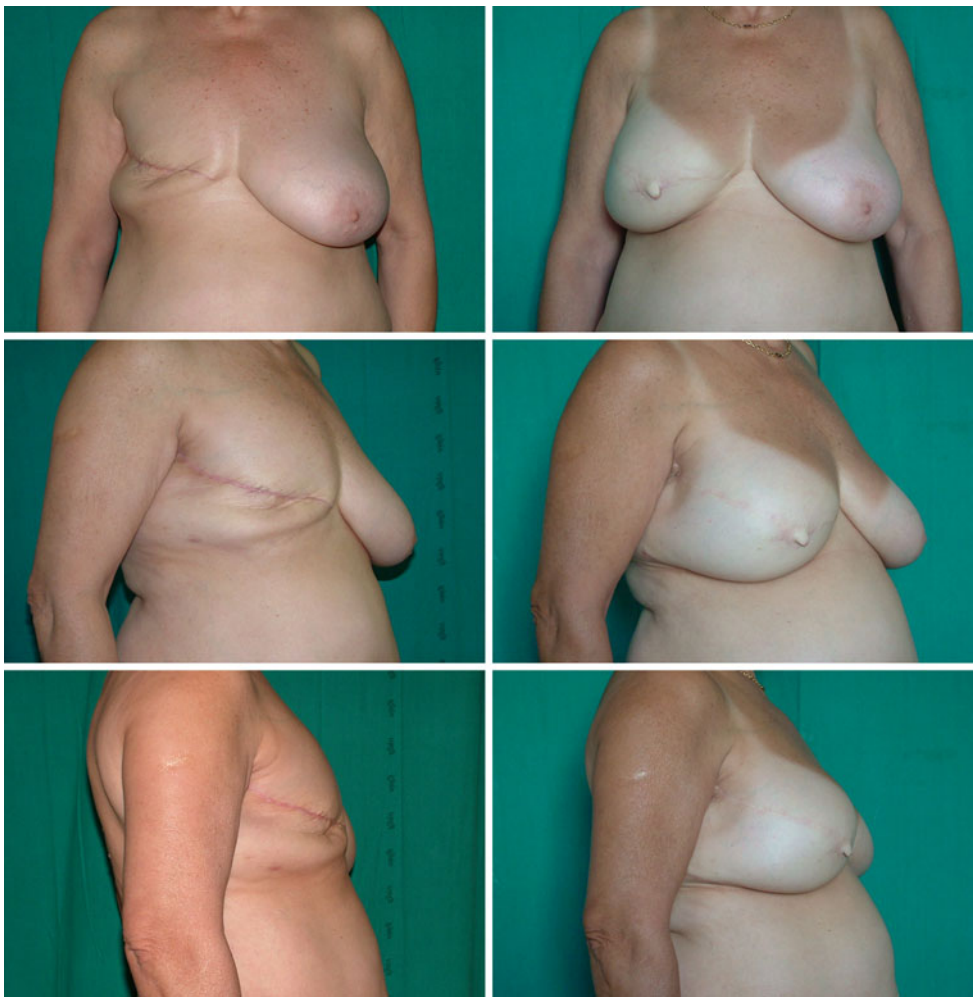

Fig. 2 Delayed right breast reconstruction. *Right* Preoperative frontal, oblique, and lateral views. *Left* Two-year postoperative frontal, oblique, and lateral views of the same patient

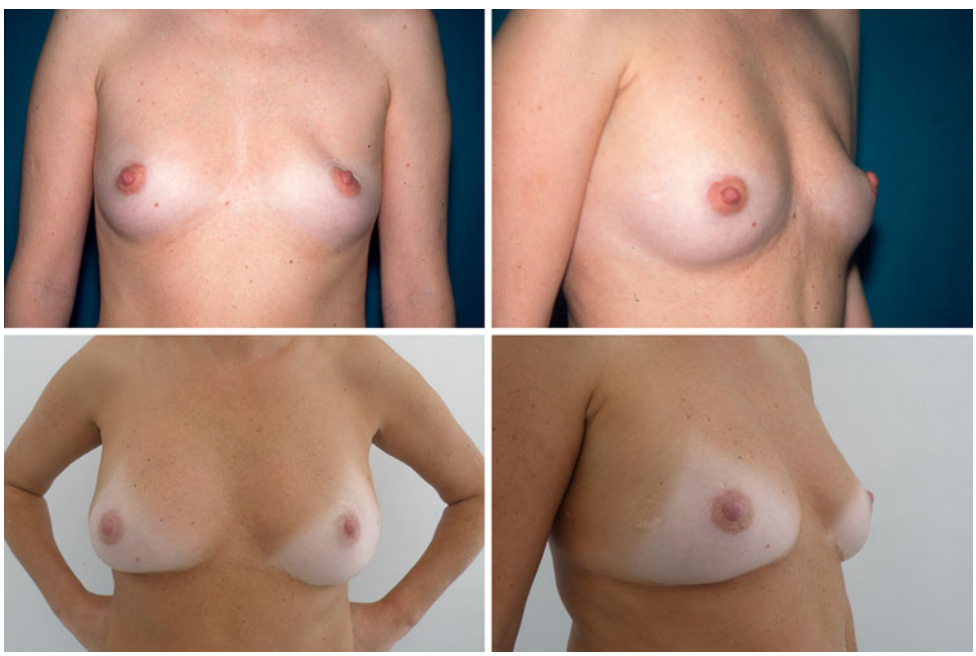

Fig. 3 Bilateral immediate breast reconstruction. *Right* Preoperative frontal and oblique views. *Left* One-year postoperative frontal and oblique views of the same patient

Table 1 Type of mastectomy performed

Type of mastectomy	*N*	%
Simple mastectomy	181	73.0
Adenomammectomy	28	11.3
Skin-sparing mastectomy	12	4.7
Skin-reducing mastectomy	26	10.5
Poland syndrome	1	0.5
Total	248	100

Table 2 Type of contralateral adjustment

Contralateral adjustment	*N*	%
Augmentation	16	8.0
Mastopexy	45	22.0
Reduction	21	10.0
No adjustment	78	38.5
Bilateral rec.	44	21.5
Total	204	100

Table 3 Complications

Complication	Immediate	Delayed	*N*	%
Pneumothorax	0	1	1	0.4
Bleeding	9	5	14	5.6
Seroma	9	3	12	4.8
Wound dehiscence	7	1	8	3.2
Infection	2	0	2	0.8
Valve obstruction	1	2	3	1.2
Valve displacement	2	2	4	1.6
Implant rupture	1	0	1	0.4
Implant malposition	22	12	34	13.7
Capsular contracture III–IV	4	2	6	2.4
Total	57	28	85	

displacement (4 cases, 1.6%). All the patients with valve problems underwent a second operation under local anesthesia to replace the filling port. Two devices became infected in the same patient and were removed. Implant malposition was the most troublesome complication; indeed, 34 patients (13.7%) complained of device malposition. Four of these patients declined any further surgery, while the remaining 30 patients underwent surgery to reposition the implant. Capsular contracture was assessed in all the patients. Significant capsular contracture (Baker grade III and IV) was detected in 6 cases (2.4%) at follow-up approximately 1 year after surgery [2–5]. We performed secondary surgery in 42 cases (16.9%): in 2 cases (0.8%) of bleeding, in 2 cases (0.8%) of infection, in the only case

Table 4 Reasons for secondary surgery

Reason for secondary surgery	Immediate	Delayed	*N*	%
Bleeding	1	1	2	0.8
Infection	2	0	2	0.8
Implant rupture	1	0	1	0.4
Valve problems	3	4	7	2.9
Malposition	21	9	30	12.0
Total	28	14	42	

(0.4%) of implant rupture, in 30 cases (12%) of implant malposition, and in all 7 (2.9%) cases of valve problems (Table 4). The follow-up ranged from 6 to 18 months.

Discussion

Breast reconstruction with permanent inflatable expanders is widely acknowledged as a useful technique for breast cancer patients undergoing simple or modified radical mastectomy. The use of this device eliminates the need to replace a temporary tissue expander with a breast implant, thus avoiding a second operation.

Thanks to new implant technology, breast reconstruction can be achieved in a single procedure and a few outpatient visits for expander inflation. Additional procedures may be required to obtain symmetry and nipple–areola complex reconstruction. Breast reconstruction using round Becker implants is well established. The ultimate surgical goal is to achieve a near-perfect result in a single procedure.

Few studies on shaped expander implants have been published. In 1998, Mahdi et al. [6] described their experience with immediate and delayed breast reconstruction procedures using the McGhan 150 device, with satisfactory results. In 2003, Gui et al. [7–9] described their experience with immediate breast reconstruction using the McGhan 150 permanent expander implant placed alone or in conjunction with a latissimus dorsi flap and their long-term results 2 and 5 years later.

Both early and more recent breast reconstruction is based on either traditional tissue expansion techniques, with a scheduled second procedure to replace the expander with a suitable fixed-volume, shaped saline or silicone prosthesis, or round permanent tissue expanders [1, 2, 10–22]. A thorough study of shaped Becker expander implants in breast reconstruction to our knowledge has not been conducted previously, nor has a clinical outcome analysis of the Becker 35 ever been published.

Our study assesses breast reconstruction performed with the shaped Becker device, which consists of an anatomical permanent inflatable expander. In our study, the shaped permanent expander implant (Becker 35 device) was

inflated by at least 10% at the end of the operation. The median number of subsequent inflations and/or deflations performed on an outpatient basis was 7. In our experience, optimum breast shape is best achieved through expansion of the permanent expander on the operating table and then filling at outpatient visits.

This anatomical implant differs from previous Becker round implants in shape and size as opposed to volume and cup size, and thus allows more scope for breast shape [1, 2]. The design thus avoids the upper-pole fullness sometimes associated with dome-shaped prostheses and allows for a lower-sited nipple on the breast mound. This type of implant provides a more natural shape and affords a more precise placement of the implant. The implant can be placed while under-filled, thus decreasing tension, or over-expanded to reduce the capsular contracture rate and improve shape, while its size can be adjusted post-operatively to achieve symmetry more easily [4]. Indeed, the anatomical implant may even eliminate the need for contralateral mastopexy due to enhanced ipsilateral breast shape. Besides its anatomical design, the Becker 35 permanent expander implant has a textured surface designed to promote tissue adherence, which reduces the likelihood of implant migration and capsule contracture. Textured adjustable implants have to be filled to the recommended fill volume to prevent rippling.

The number of complications, especially implant malposition, was higher at the beginning of our series but gradually decreased as we gained more experience.

The main drawback of the Becker 35 permanent expander implant is the placement of the filling tube and the port. Since the implant is not round, the position of the port is not irrelevant. It is best placed inferiorly, at either the breast meridian or infero-laterally. Although the filling ports have proven to be very reliable, we have had problems caused by kinking of the connection tube and the consequent upside-down rotation of the port, which makes needle insertion and consequent expansion impossible; this drawback requires an outpatient surgical procedure to derotate the port or a second surgical procedure to remove the port. The valve displacement we observed in four cases probably was due to an excessively large pocket. The injection port should be placed in a snug pocket and sutured to prevent rotation; the fill tube should be trimmed so that it is tight. Morbidity associated with the port, such as pain, chafing and protrusion, has been reported [23].

Our rates of infection, hematoma, seroma, skin necrosis, implant loss, and implant failure are comparable to those reported in most other patient series in which permanent expander implants have been used.

At the 1-year follow-up visit, there was the same rate of capsular contracture as found in other series with different implants [24–29], though we believe that a longer follow-up period is required to more accurately assess the capsular contracture rate in our series.

In this study, 70% of the women were clinically assessed preoperatively to eliminate the need for contralateral readjustment to achieve a satisfactory aesthetic appearance after immediate breast reconstruction. Indeed, bilateral reconstruction was performed in approximately 21% of the patients, and contralateral breast symmetrization was performed during the operation in the remaining 10% of the patients.

In agreement with many other physicians, we believe that autologous tissue reconstruction with regional flaps or free tissue transfer is the gold standard in breast reconstruction [30, 31]. We also believe that many breast reconstructions performed using staged procedures with tissue expanders followed by implants look as good as, and are often comparable to, autologous tissue reconstruction in selected patients. Nevertheless, we believe that the Becker 35 expander implant also deserves its place in breast reconstruction.

There is no one-size-fits-all approach to breast reconstruction. Although we believe that autologous tissue is the best method of reconstruction in the majority of patients, it is not always possible, because of either the patient's anatomy or the patient's wishes. The results of our study show that expander implant placement and subsequent expansion may yield a reasonable reconstruction. We also feel that patient selection plays an important role in reducing the number of complications, achieving better aesthetic results, and improving patient satisfaction.

Conclusions

The crescent-shaped Siltex Contour Profile Becker 35 device affords a reliable and satisfactory outcome in selected patients. One-stage expander implant reconstruction is most appropriate and offers the best results in patients whose breast volume is moderate, who have minimal ptosis, and who need bilateral breast reconstruction, during which symmetry is more readily achieved. This breast reconstruction approach can, unlike the two-staged expander/implant reconstruction, be performed in one stage.

Conflict of interest None.

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