Journal of Plastic, Reconstructive & Aesthetic Surgery (2019) 72, 401–409

JPRAS
An International Journal of Surgical Reconstruction
www.JPRASurg.com

# Immediate breast reconstruction in high-risk cases using an anatomically shaped permanent expandable implant

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Received 19 August 2018; accepted 28 October 2018

**Summary** *Background:* Anatomically shaped permanent expandable implants are dual-chambered devices, which allow their postoperative expansion for the adjustment of volume. Their use is optional when 1-stage immediate breast reconstruction (IBR) direct to permanent implant is not feasible. The aim of this study is to present one center's long-term experience with the anatomical Becker expandable implant in a large series of patients who underwent either IBR or a salvage procedure for IBR with the device.

*Methods:* The records of 141 patients (a total of 161 breasts) who underwent IBR with the Becker implant were retrospectively reviewed. Patient demographics and surgical outcomes were analyzed. Indications for this procedure included reduced skin envelopes, compromised skin flaps, salvage procedures, and single-stage procedures in patients with major comorbidities.

*Results:* One hundred twenty-three devices (76%) involved IBR and 38 devices (24%) were salvage cases after direct-to-implant IBR. The device was used in a previously radiated breast in 36 cases (22%). Long-term follow-up demonstrated that 99 devices (61.5%) had been exchanged or removed and that only 62 devices (38.5%) remained as permanent implants. Removal of the device was associated with prior breast radiation and advanced age.

*Conclusions:* The use of the Becker device in high-risk IBR cases had a low retention rate as a permanent implant. Favorable indications for the use of this device in IBR cases include contralateral breast augmentation and patients with major comorbidities, which demonstrated a higher retention rate. Other indications for high-risk IBR cases could probably benefit using a 2-stage tissue-expander and implant technique.



## Introduction

Breast reconstruction is being increasingly carried out after mastectomy and has been shown to lessen the deleterious effects of mastectomy on self-image and psychosocial well-

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https://doi.org/10.1016/j.bjps.2018.10.030
1748-6815/

being.[1-8] This improved psychological outlook is more pronounced when the breast reconstruction is performed at the time of mastectomy (i.e., immediate breast reconstruction [IBR]) than delayed reconstruction. In addition, surgical esthetic outcomes favor IBR over delayed reconstruction, and it has been conclusively shown to be oncologically safe as well.[1-8] This has led to an increase in its application, even though the procedure is challenging in terms of surgical complexity and high patient expectations. Implant-based reconstruction has become routine in IBR that involves 1-stage direct-to-implant or 2-stage expander-implant reconstruction.[1-8]

In direct-to-implant IBR, or the "one-step" approach, a permanent implant is introduced after the mastectomy, usually with a mesh (biologic or synthetic) support. This approach allows for a single-stage reconstruction of the breast mound, thereby avoiding further surgeries under general anesthesia, reducing healthcare costs, and lowering overall morbidity.[9-17] It ultimately became the preferred approach for IBR in the authors' practice.

However, some patients are not suitable for this approach. They include women with a limited skin envelope (previous breast surgery, breast asymmetry, or mastectomy with excessive skin excision), those with a compromised skin flap (flawed surgical technique, active smoking, or previous radiation), those who desire large-sized breasts, and those requiring salvage procedures (due to skin necrosis or infection). For such cases, the default procedure for implant-based reconstruction is the insertion of tissue expanders and a 2-staged breast reconstruction.

Anatomically shaped permanent expandable implants are dual-chambered devices with an outer high-cohesive silicone gel chamber and an inner saline-filled chamber with a filling tube attached to a remote valve.[18] The device has "soft" expansion capabilities for volume and soft tissue envelope adjustments. The MemoryGel™ Siltex™ Contour Profile™ Becker™ 35 Cohesive II (Mentor Worldwide LLC, Santa Barbara, USA) and the Natrelle® Biocell® Style 150 anatomical tissue expander (Allergan, Dublin, Ireland) are currently the only devices available on the market.

The apparent advantages of these devices in IBR include the single-stage procedure and the ability to adjust the size of the implant postoperatively for enhanced breast symmetry. This represents a major advantage in patients receiving postmastectomy radiotherapy, as the final volume of the device can be adjusted after completion of the radiotherapy. Disadvantages of the device include relative breast firmness once the final saline inflation has been completed, and the esthetic outcome (e.g., limited lower pole expansion and upper pole fullness). The use of a Becker implant-based reconstruction has a learning curve, with device-specific complications of up to 6% filling port failure and up to 15.7% port flip-over complications.[18-21] Such sequelae may require secondary surgical port repositioning to permit expansion. These expanders are nevertheless associated with fewer complications than integrated valve expanders.[21]

Previous publications on breast reconstruction with Becker implants demonstrated a high percent of device exchange. Chew et al. reported that more than 68% of patients who had undergone breast reconstruction with Becker implants had their device removed within 5 years from surgery.[22] Sindali et al. showed even higher numbers, with just a 25% rate of retention of the device after postmastectomy reconstruction.[23] These findings are far less favorable than the reported percentages for the removal of permanent breast implants, which range between 14% and 21% in 5 and 9 years, respectively, after implant insertion.[24-26] In contrast, the INAMED R95 study reported implant replacement or removal for any reason to be only 23% and 28% of the patients at 3 and 5 years, respectively.[27]

The aim of this study is to present one center's long-term experience with the anatomical Becker expandable implant in a large series of patients who underwent either direct-to-implant IBR or a salvage procedure for IBR with the device. We analyzed the different indications for the use of the device, the complication rates, and the surgical outcomes, including the need for additional surgical procedures and device exchange.

## Patients and methods

### Study design

The records of patients who underwent IBR with the anatomical Becker implant (Mentor Becker 35) between January 2008 and October 2016 at the Tel Aviv Sourasky Medical Center (TASMC) or at the private clinic of the senior author (YB) were retrospectively reviewed. After approval was obtained from the TASMC institutional review board, data on demographic characteristics, oncologic findings, hospital admissions, and postoperative outcome and complications were collected and evaluated. The Becker implant filling rates and final outcome were documented, including additional operative procedures. All patients were followed up postoperatively by the plastic and breast surgeons and by the institutional oncologists for at least 1 year after surgery.

The use of the Becker implant had 4 main indications:

1. Reduced skin envelope due to previous breast surgery, wise pattern skin-reducing mastectomy, or patients with a large contralateral breast (native or simultaneous breast augmentation).
2. Compromised skin flaps as a result of surgical technique, active smoking, or previously radiated skin.
3. Salvage procedure of a direct-to-implant IBR due to infection, skin necrosis, or wound dehiscence/implant extrusion.
4. One-stage procedure in patients with major comorbidities. This group included patients for whom we preferred to minimize the surgical procedures because of relatively advanced age coupled with major comorbidities such as diabetes, hypertension, and ischemic heart disease.

### Surgical technique

All candidates for IBR were discussed at the institutional multidisciplinary breast team conference. The patients accepted for surgery were marked in the standing position before undergoing the procedure, and an intravenous prophylactic antibiotic was administered preoperatively during anesthesia. The mastectomy was performed by the breast

surgeon in a skin-sparing, nipple-sparing, or skin-reducing mastectomy pattern. The breast was removed, marked, weighed, and sent for pathologic evaluation. The breast skin flaps were meticulously inspected and evaluated for tissue viability and the likelihood of accommodating a permanent implant. The contralateral breast was simultaneously adjusted when needed, and it underwent breast augmentation, mastopexy, breast reduction, or combinations.

Once the decision was made to reconstruct the breast using a Becker implant, the free lateral border of the pectoralis major muscle was split and a sub-pectoral pocket was dissected with separation of the inferior-medial insertion of the muscle. The muscle was released from the lower breast pole, and an acellular dermal matrix (ADM) mesh was introduced at the lower and lateral breast poles to provide full device coverage. In cases of skin-reducing mastectomy, the inferior skin of the Wise pattern was de-epithelialized and used to cover the lower pole of the device instead of an ADM.[28] In all of the cases, the device was positioned in a subpectoral plane, with no cases of prepectoral device placement.

Once the pocket was ready and the device size had been chosen, the package was opened in a sterile manner and the large port was connected to the device after rinsing it with an antibiotic solution. It was then prepared by aspirating the air from the saline chamber using a 23-gauge butterfly needle inserted through the remote port and then partially filling it with saline solution. A subcutaneous tunnel was then dissected laterally and inferiorly from the implant pocket to accommodate the port. The partially filled implant was then placed in the pocket, with the port insertion through the tunnel, thus ensuring that the port was firmly anchored to avoid overturning. The ADM was sutured snugly to the inferior edge of the pectoralis muscle and lateral breast border to avoid malrotation of the device. The inferior mastectomy skin flap was draped over the lower part of the Becker implant. Two drains were introduced: one was placed in the lower pole of the submuscular plane and the other was placed in the upper pole of the subcutaneous plane. The skin was closed in a layered fashion, thus ensuring minimal skin tension upon closure. The saline filling was adjusted accordingly.

The Becker implant size was selected according to the footprint dimensions of the breast and the expected breast volume according to the contralateral breast size and shape. The final implant filling was performed on an outpatient basis. On reaching the final volume and completing the oncologic treatment, we assessed the reconstructed breast shape, size, softness, and symmetry. In consultation with the patient, we decided whether or not to remove the Becker port or exchange it for a permanent implant or autologous tissue. Nipple reconstruction, when relevant, was offered at the same time. Patients who underwent postmastectomy radiation therapy were assessed at least 6 months after completing the therapy.

### Statistical analysis

Statistical analysis was performed by SAS for windows version 9.4 (SAS Institute Inc., Cary, NC, USA). A $p$ value of 0.05 was considered significant.

**Table 1** Patients' demographics*.

| | $N = 141$ | % | Mean |
|---|---|---|---|
| Age, years (range) | | | 47 (25–78) |
| Smoking | 26 | 18.5 | |
| BRCA carrier | 21 | 15 | |
| BSO | 16 | 11.5 | |
| Other malignancy | 4 | 3 | |
| DM | 6 | 4.5 | |
| HTN | 17 | 12 | |
| IHD | 2 | 1.5 | |
| Hypothyroidism | 7 | 5 | |
| Morbid obesity (BMI > 35) | 1 | 0.7 | |
| Previous radiation therapy | 36 | 22.4 | |

BRCA Carrier, BRCA mutation carrier; BSO, bilateral salpingo-oophorectomy; DM, diabetes mellitus; HTN, hypertension; IHD, ischemic heart disease; BMI, body mass index.

* Some patients had more than one comorbidity.

Continuous variables were reported as means and standard deviations or as median and interquartile range depending on their distribution (normal or abnormal, respectively). Categorical variables were reported as their relative frequencies. Normality was determined using the Kolmogorov–Smirnov test.

Univariate analysis was performed to examine an association of all potential demographic and clinical predictors with the following outcome measures: removing or replacing the device, and major complications. Continuous variables that followed a normal distribution were analyzed using a two-sample Student $t$ test. Variables that did not follow a normal distribution were analyzed using the two-sample Wilcoxon test, and the Pearson chi-square test was used to examine associations with regard to categorical variables.

## Results

One hundred forty-nine patients received a total of 169 Becker implants for IBR between 2008 and 2016. Twenty patients (13.5%) had bilateral Becker implant insertion. Eight patients with unilateral reconstruction were lost to follow-up, hence leaving 141 patients and 161 Becker implants with full follow-up documentation. Patient demographics and comorbidities are summarized in Table 1. The average patient age of the cohort was 47 years (range 25–78 years). Twenty-six patients (18.5%) were active smokers, and 21 patients (15%) tested positive for BRCA gene mutation.

The indications for the use of Becker implants are summarized in Table 2. One hundred twenty-three devices (76%) involved IBR, and 38 devices (24%) were used in salvage cases after direct-to-implant IBR. The device was used in a previously radiated breast in 36 cases (22%). The ADM used for reconstruction was AlloDerm (LifeCell, Branchburg, NJ, USA) in 72 cases (59%), SurgiMend (Integra LifeSciences, Plainsboro, NJ, USA) in 22 cases (18%), and FlexHD Pliable (Mentor Worldwide LLC, Santa Barbara, USA) in 3 cases (2%). The remaining 26 cases (21%) did not have an ADM as part of their skin-reducing mastectomy and were performed with a

**Table 2** Indications for the use of the Becker implant device.

| Indication | $N = 161$ | % | Subtype* |
|---|---|---|---|
| Reduced skin envelope | 68 | 42 | Previous breast surgery ($n = 28$)<br>Wise pattern skin-reducing mastectomy ($n = 14$)<br>Large contralateral breast ($n = 20$)<br>Contralateral breast augmentation ($n = 36$) |
| Compromised skin flaps | 51 | 32 | Surgical technique (n = 9)<br>Active smoking ($n = 26$)<br>Previously radiated breast ($n = 36$) |
| Salvage procedure | 38 | 24 | Skin necrosis ($n = 14$)<br>Wound dehiscence/implant extrusion ($n = 25$)<br>Infection ($n = 7$) |
| Major comorbidities | 4 | 2 | |

* Some cases had more than one subtype indication.

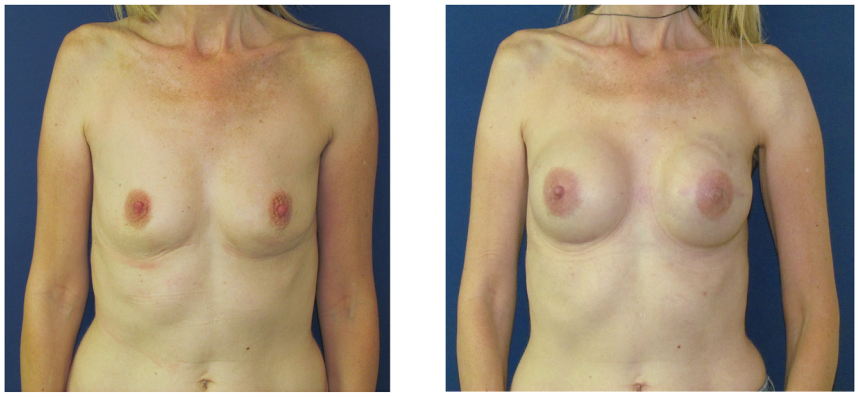

**Figure 1** A 44-year-old patient with left multifocal breast cancer (*Figure* 1A). She received neoadjuvant chemotherapy before surgery. She then underwent left skin-sparing mastectomy and immediate reconstruction with a 290 cc Becker implant and acellular dermal matrix (ADM) and right augmentation 200 cc (moderate-plus profile). One year after surgery, completing nipple-areolar complex (NAC) reconstruction (*Figure* 1B).

**Table 3** Surgery, device characteristics, and follow-up data.

| | Mean | Range | SD |
|---|---|---|---|
| Mastectomy weight (g) | 494 | 115-1500 | 324.6 |
| Becker size (cc) | 433 | 190-685 | 119.8 |
| Hospitalization, days | 6 | 1-35 | 4.9 |
| Device volume after surgery compared to total volume (%) | 60% | 35-100 | 15.5% |
| Device volume after surgery compared to mastectomy weight (%) | 72% | 15-160 | 29.1% |
| Device follow-up, mo ($N = 161$) | 33 | 0.5-111 | 30.9 |
| Device follow-up, mo (retained devices, $N = 62$) | 66 | 13-111 | 22.8 |
| Device follow-up, mo (removed/replaced devices, $N = 99$) | 14 | 0.5-68 | 13.2 |

SD, standard deviation; g, grams; mo, months.

de-epithelized lower pole flap. ADM was not used in salvage cases. Figures 1-3 demonstrate cases of Becker device usage due to reduced skin envelope: contralateral breast augmentation (Figures 1 and 2) or Wise pattern skin-reducing mastectomy (Figure 3).

The average mastectomy weight was 494 g, and the average Becker volume was 433 cc (Table 3). The average device volume after surgery was 60% of the total device volume. Follow-up was concluded with either the removal or the exchange of the Becker implant or in October 2017 to allow for a minimum follow-up of one year (Table 3).

The postoperative complications are listed in Table 4. The major ones were defined as complications that required revision surgery for reconstruction salvage, while the minor ones were treated conservatively or eventually led to an elective late exchange of the device due to capsular contracture, malrotation, or breast asymmetry (Figure 2). Device removal included all cases of device explantation without replacement. The causes of device removal ($n = 25$) were infection ($n = 13$), wound dehiscence ($n = 7$), skin necrosis ($n = 3$), and involved tumor margins ($n = 2$). Device failure included one case of saline leak after port removal

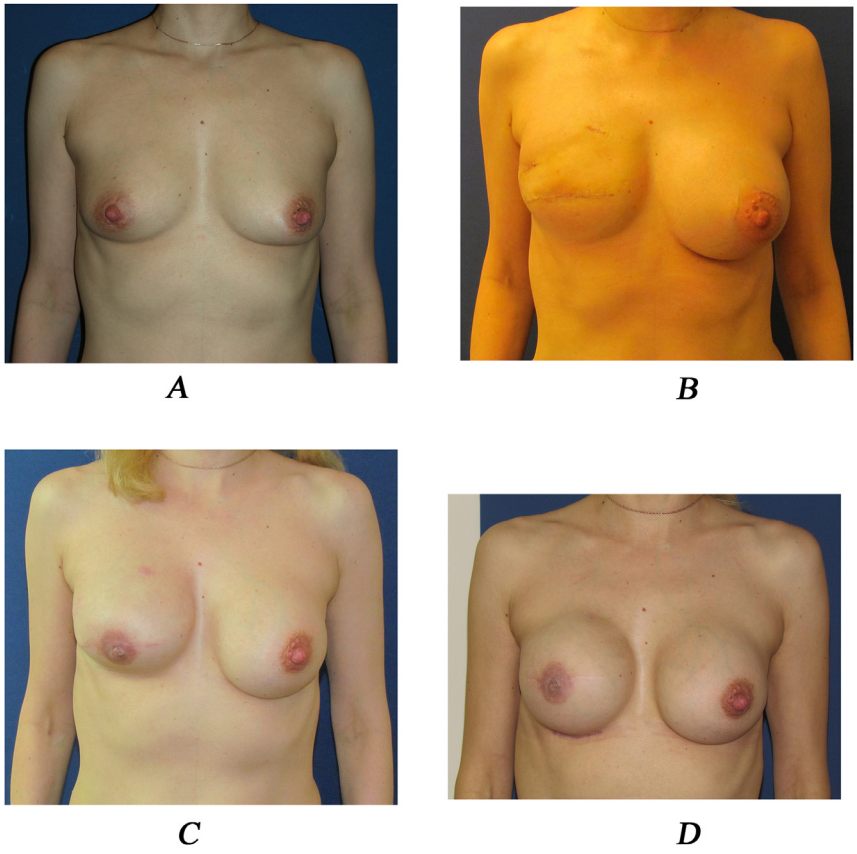


**Figure 2** A 32-year-old patient with right multifocal breast cancer (*Figure* 2A). She underwent right skin-sparing mastectomy and immediate reconstruction with a 365 cc Becker implant and acellular dermal matrix (ADM) and left augmentation 225 cc (moderate-plus profile). The patient, 3 weeks after surgery before fully inflating the Becker device (*Figure* 2B). The surgical outcome at 1 year after surgery with nipple-areolar complex reconstruction, thus demonstrating breast asymmetry with malposition of the device (*Figure* 2C). She underwent right exchange of the device to a permanent implant (420 cc, full profile) (*Figure* 2D).

**Table 4** Postoperative complications per device.

| | Devices ($N = 161$) | (%) |
|---|---|---|
| Major complications | | |
| Infection | 4 | 2.5 |
| Skin necrosis | 4 | 2.5 |
| Wound dehiscence | 2 | 1.2 |
| Hematoma | 2 | 1.2 |
| Device removal | 25 | 15.5 |
| Total | 37 | 23 |
| Minor complications | | |
| Infection | 15 | 9.3 |
| Skin necrosis | 9 | 5.6 |
| Seroma | 4 | 2.5 |
| Capsular contracture | 10 | 6.2 |
| Asymmetry* | 5 | 3.1 |
| Device failure | 2 | 1.2 |

* Asymmetry - Volume/shape discrepancy or device malposition.

and one case of silicone chamber leak, and both cases resulted in device exchange. Device malposition included 2 cases of malrotation of the anatomic implant. The complications were calculated per device, totaling only one complication per device.

Stratification of the risk factors revealed that there were various risk factors that correlated to major complications, device removal, and device exchange (Table 5). Major complications were related to larger intraoperative volume inflation of the device ($p = 0.031$). Inflating the Becker device's volume to more than 60% of its total volume emerged as the cut-off point related to the occurrence of a major complication ($p = 0.05$). Major complications were also related to compromised skin flaps ($p = 0.011$) as an indication for the use of the Becker device. None of the other indications for the use of the device, including reduced skin envelope, salvage procedure, and major comorbidities, correlated to major complications. Among the compromised skin flaps cases, only smoking ($p = 0.04$) correlated to major complications as a stand-alone risk factor. Previous breast radiation therapy as a stand-alone risk factor was not a statistically significant for major complications ($p = 0.2$), but it correlated significantly to major complications if combined with other risk factors ($p = 0.022$).

Device removal correlated to various risk factors (Table 5). Previous radiotherapy was the main risk factor for device removal, both as a single variable and in combination with other risk factors ($p = 0.008$ and $p < 0.001$, respectively). Advanced age was also related to device removal ($p = 0.006$). Patients who received Becker implants due to simultaneous contralateral augmentation

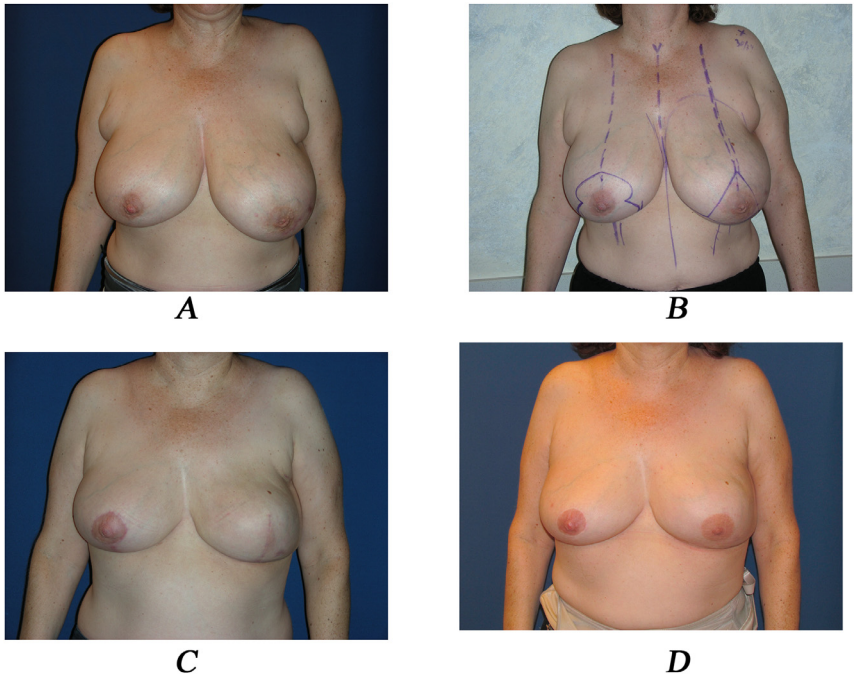


**Figure 3** A 48-year-old patient with left multifocal breast cancer (*Figure* 3A). She underwent left skin-reducing mastectomy (Wise pattern) and immediate reconstruction with a 685 cc Becker implant and left right breast reduction. Preoperative marking (*Figure* 3B). The patient, 8 weeks after surgery (*Figure* 3C). The surgical outcome at 1 year after surgery with nipple-areolar complex reconstruction (*Figure* 3D).

**Table 5** Risk factors for major complications, device removal, or exchange.

| Variable | Major complications *P* Value | Device removal *P* Value | Device exchange *P* Value |
|---|---|---|---|
| Age | 0.1 | 0.006 | 0.61 |
| DM | 0.87 | 0.25 | 0.32 |
| HTN | 0.68 | 0.32 | 0.48 |
| IHD | 0.56 | 0.53 | 0.29 |
| Hypothyroidism | 0.27 | 0.23 | 0.044 |
| Obesity (BMI) | 0.68 | 0.66 | 0.45 |
| BRCA mutation carrier | 1 | 0.62 | 0.05 |
| Other malignancy | 0.41 | 0.63 | 0.55 |
| Smoking | 0.04 | 0.25 | 0.18 |
| Compromised skin flaps | 0.011 | 0.2 | 0.70 |
| Previous RT | 0.2 | 0.008 | 0.95 |
| Previous RT + other risk factors | 0.022 | <0.001 | 0.81 |
| Setting - immediate BR vs. salvage | 0.07 | 0.61 | 0.27 |
| Mastectomy weight | 0.17 | 0.48 | 0.32 |
| ADM type | 0.27 | 0.83 | 0.10 |
| Contralateral augmentation | 0.09 | 0.017 | 0.38 |
| Becker size | 0.55 | 0.73 | 0.50 |
| Percent of device inflated in OR | 0.031 | 0.15 | 0.2 |
| Percent inflated device-60% cut-off | 0.05 | 0.09 | 0.48 |
| Postmastectomy RT | NA | 0.53 | 0.1 |

DM, diabetes mellitus; HTN, hypertension; IHD, ischemic heart disease; BMI, body mass index; RT, radiation therapy; ADM, acellular dermal matrix; OR, operating room.

**Table 6** Outcome of Becker device.

| | $N = 161$ | % |
|---|---|---|
| As a permanent implant | 62 | 38.5 |
| Removed | 25 | 15.5 |
| Exchanged | 68 | 42.3 |
| Scheduled for exchange | 6 | 3.7 |

had a lower risk for device removal (protective factor, $p = 0.017$).

Device exchange correlated to being a BRCA mutation carrier ($p = 0.05$) (Table 5). Patients with hypothyroidism had a lower risk for device exchange (protective factor, $p = 0.044$). Radiotherapy, either before surgery or after surgery, had no significant correlation to device exchange ($p = 0.95$ and $p = 0.1$, respectively). Ten patients developed capsular contracture (grades 3-4), and they all underwent device exchange with the exception of 1 patient who is scheduled for future exchange. Capsular contracture correlated significantly to postmastectomy radiotherapy ($p = 0.005$) but not to previous radiotherapy ($p = 0.87$).

Other variables including Becker implant size, mastectomy weight, ADM type, diabetes, hypertension, ischemic heart disease (IHD), or obesity had no statistical correlation to major complications, device removal, or exchange ($p =$ NS for all) (Table 5). Furthermore, salvage procedure as an indication for Becker device did not correlate to major complications, device removal, or exchange ($p = 0.07$, $p = 0.61$, and $p = 0.27$, respectively).

Analysis of the long-term outcome of the Becker implants revealed that 62 devices (38.5%) stayed as permanent implants. Of the remaining 99 devices (61.5%), 68 (42.3%) were exchanged for another device, 25 (15.5%) were removed, and 6 devices (3.7%) are scheduled for future exchange (Table 6). As for the timing of device removal/exchange, 19 devices were operated on (15 removed and 4 exchanged for an expander or deflated new Becker) within 2 months from surgery. By the end of the first postoperative year, 9 devices were surgically removed and 34 were exchanged for a permanent implant. Long-term device follow-up (i.e., more than 1 year after surgery) findings showed that 30 additional devices had been exchanged and 1 had been removed. Six additional patients are scheduled for future device exchange.

## Discussion

IBR using an anatomically shaped permanent expandable implant has several advantages in selected indications, particularly in cases of mismatches between the skin envelop and the breast volume. The apparent advantages of these devices in IBR include a single-stage procedure and the ability to adjust the size of the implant postoperatively to enable gradual stretching of the skin flaps and to enhance breast symmetry (Figures 1-3). The alternative to this technique is the traditional 2-stage breast reconstruction using a temporary tissue expander in the first stage, thus committing to a second operation. The disadvantages of the Becker device are cost per unit, the relative device stiffness, and the poorer esthetic outcome than a nonexpandable permanent implant. The cost of a Becker device is approximately US$1300 per unit compared to that of US$730 for an anatomical tissue expander and that of US$820 for an anatomical implant. Thus, while IBR using a Becker implant as a permanent device is initially cost effective, it would cost more than a 2-stage tissue expander reconstruction if the device is subsequently exchanged for a permanent implant.

The aim of this study was to analyze the long-term experience with the Becker implant and to stratify the outcome data of the device for complex IBR cases. This series is the largest single-surgeon study to date with the application of the Becker implant for IBR and the inclusion of a long-term follow-up (mean 5.5 years) for evaluating the reliability, efficacy, and cost-effectiveness of the device.

The outcome of this study was that the Becker device was exchanged or scheduled for exchange in 74 cases (46%), and removed in 25 cases (15.5%). Follow-up at 3 years after surgery showed that only 45.3% (73 devices) of the patients retained the device, and that only 38.5% (62 devices) of the patients had retained the device at the end of the follow-up period (Table 6). These results are comparable to those of similar studies, which reported a retention rate of 24.9% in the postmastectomy subgroup at 10 years[23] and a 5-year postinsertion retention rate of less than 30% for the oncological and risk-reducing mastectomy groups.[22] Analysis of the reliability of the device revealed that the percent of technical device failure was low, with only 2 devices (1.2%) having failed during the study period, and both were exchanged for permanent implants.

The relatively high percent of device exchange or removal after IBR can be attributed to the soft tissue coverage of the device. When using the Becker device in nonreconstruction cases or in reconstruction cases with autologous tissue, both with adequate soft tissue coverage, the retention rates of the device are relatively higher than that of IBR with implants.[29-31] As shown in other studies on congenital hypoplasia and asymmetry, the Becker implant retention rate was 75% at 5 years[22] and 46.8% at 10 years.[23] Additionally, in reconstruction mainly with a latissimus dorsi flap and Becker implants, there was only a 25.8% exchange rate during the course of an 18-year study period.[29] This supports the concept that an adequate soft tissue coverage of the Becker implant can lead to long-lasting single-stage breast reconstruction with the device. The current findings showed that there was a lower rate of device removal when the Becker implant was indicated due to a relatively reduced skin envelope, such as in simultaneous contralateral augmentation (Table 5).

The Becker device was used for true reduced skin envelope (resulting from previous surgery or a skin-reducing mastectomy), compromised skin flaps, and IBR salvage procedures for most of the cases in this study. These cases already have unfavorable conditions for IBR, with associated higher overall complication rates. The major complication rate was 23% (Table 4), and the risk factors for major complications were compromised skin flaps ($p = 0.011$) and smoking ($p = 0.04$), the latter being a stand-alone risk factor. Interestingly, salvage procedures cases for IBR and those for patients with previous radiotherapy as a single risk factor did not increase the risk for major complications. Nevertheless, previous radiotherapy was a dominant risk factor

both for device removal (alone or in combination with other risk factors) and for major complications when combined with other risk factors.

Device exchange was the predominant surgical procedure in this study. The only risk factor correlated with it was being a BRCA mutation carrier ($p = 0.05$) (Table 5). It is speculated that the patient's request for device exchange in cases of bilateral reconstructions with a unilateral Becker device was for reasons of symmetry and esthetics. Capsular contracture grades 3–4 was documented in 10 devices, all of which underwent device exchange with one exception, and that particular patient is scheduled for future exchange ($p = 0.005$). Even though all patients with capsular contracture had received postmastectomy radiotherapy, there was no direct correlation between that treatment and device exchange ($p = 0.1$). Moreover, radiotherapy before surgery did not correlate to either capsular contracture or device exchange ($p = 0.87$ and $p = 0.95$, respectively).

None of the other variables including Becker implant size, mastectomy weight, ADM type, diabetes, hypertension, IHD, and obesity had any significant correlation to major complications, device removal, or exchange ($p =$ NS for all) (Table 5). All 4 patients with a Becker indication of major comorbidities retained the device and did not exchange it.

Another interesting finding was the correlation between intraoperative device expansion and major complications. Larger intraoperative volume inflation of the device, with a cut-off point of more than 60% of the total volume, correlated to major complications ($p = 0.031$ and $p = 0.05$, respectively). Because the saline expandable chamber of the Becker device is 65% of the total implant volume, it is recommended that the device should not be inflated more than 25% of the total device volume (i.e., 40% of the total saline volume).

The essence of the current findings is that the Becker permanent expandable implant has a high rate of premature exchange and explantation when used for challenging high-risk IBR cases. It does not appear to meet the objective of providing a long-term single-stage alloplastic breast reconstruction for those patients. This is mainly due to inadequate soft tissue coverage and the poorer aesthetic outcome in a single-stage technique following mastectomy, rather than an intrinsic problem with the device itself. The use of a 2-stage tissue expander and implant technique can also be more cost-effective in these cases. The Becker permanent expandable implant device nevertheless has a place in IBR for selected cases, especially those in which there is a relatively reduced skin envelope, such as that observed in simultaneous contralateral breast augmentation. It is also indicated for patients with major comorbidities who desire IBR and a minimal one-staged surgical procedure.

Limitations of this study include its retrospective method and the radiation therapy, both before and after reconstruction, which was performed in a number of radiation centers with difference in treatment protocols.

## Conclusions

The Becker device evaluated in this study had a low retention rate (38.5%) as a permanent implant in high-risk IBR cases. Most of the devices were exchanged (42.3%), scheduled for exchange (3.7%), or removed (15.5%). Indications for the use of this device in IBR cases include contralateral breast augmentation and patients with major comorbidities. Other indications for high-risk IBR cases, including compromised skin flaps, salvage procedures, and reduced skin envelope in skin-reducing mastectomies and previous breast surgery, could probably benefit from the use of a 2-stage tissue expander and implant technique.

## Conflict of interest statement

No funding was provided for this paper. Dr. Barnea is a speaker for Johnson Medical. None of the other authors have financial interest or personal relationship to declare in relation to the content of this article.

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