Original Article

Single stage, direct to implant pre-pectoral breast reconstruction

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Background: Given the current trends in skin preservation during mastectomy, improved biofilm reduction algorithms, and advancements in tissue bioengineering and perfusion assessment, acellular dermal matrix (ADM)-reinforced single stage, direct to implant insertion in the pre-pectoral space has become a viable alternative to two-stage expander-based, sub-pectoral reconstruction.

Methods: The authors performed a retrospective review of their pre-pectoral cases evaluating outcomes for all single stage, direct to implant procedures. Outcomes reviewed included hematoma, seroma, infection, device loss or change, animation deformity and revisional procedures such as fat grafting. The anterior tenting surgical technique is also reviewed.

Results: The authors have carried out 305 direct to implant pre-pectoral breast reconstructions using an anterior tenting technique with low complication rates and superior clinical and functional outcomes. The benefits of this technique include less patient discomfort, no need for postoperative expansion, virtually no subjective negative impact on upper extremity function and elimination of animation deformity. Longer-term follow-up demonstrates maintenance of the integrity and quality of the reconstructions over time.

Conclusions: The authors consider single stage, pre-pectoral direct to implant breast reconstruction to be a state-of-the-art breast reconstruction technique and have found it to be safe and reproducible. This technique is their primary choice for immediate implant-based reconstruction following mastectomy.

Keywords: Breast reconstruction; pre-pectoral; prepectoral; direct to implant; single stage

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Introduction

While the breast is a pre-pectoral structure and breast restoration intuitively should occur in the same space, sub-pectoral breast reconstruction has been the mainstay of implant-based reconstruction for the last half century. While early implant-based breast reconstruction was attempted in the subcutaneous plane, device placement in the sub-pectoral location was favored to reduce the high rates of capsular contracture, infection, and implant loss seen after subcutaneous insertion (1-13). Sub-pectoral reconstruction continues to be in vogue to circumvent perceived concerns regarding implant visibility, palpability and failure.

Since the early days of implant-based breast reconstruction, the scientific evidence surrounding capsular contracture implicates bacterial contamination at time of implant insertion with biofilm formation (6,8,13). The advent of biofilm reduction techniques resulted in a significant reduction in capsular contracture rates, potentially minimizing one of the principal reasons for placing the implant beneath the muscle (14-16). Tissue expanders have been used routinely for two-stage breast reconstruction to recover skin domain lost after mastectomy

since the late 1970s (9). However, as skin sparing and nipple sparing techniques became standard mastectomy approaches, the need for expansion has become somewhat redundant (17,18). Additionally, total sub-muscular coverage in the setting of expander-based breast reconstruction had been conceived to some extent to control expander position at the time of mastectomy. This was largely replaced by the introduction and subsequent adoption of lower pole coverage with acellular dermal matrices (ADM) (19,20). ADMs not only provided tissue reinforcement, but also better pocket control, and shape without the compressive effects of total sub-muscular coverage (21,22). Furthermore, expanders allow for controlled stepwise increases in volume, thereby reducing the risk of compressing the mastectomy flap's delicate vascular supply. Immediate unsupported direct-to implant reconstructions with placement of the final prosthesis in the pre-pectoral position raise concerns regarding undue weight and tension on the mastectomy flap impeding tissue perfusion as well as subsequent thinning of the overlying mastectomy skin. ADM-reinforced direct-to-implant reconstruction offloads direct pressure on the mastectomy flaps with the weight being taken almost entirely by the ADM, mitigating these concerns. Moreover, perfusion assessment was, at best, an inexact science during the beginnings of implant-based breast reconstruction but has matured into a promising and reliable technology. Surgeons previously were reliant on clinical assessment and use of fluorescein. The advent of indocyanine green laser-induced fluorescence angiography was a turning point in mastectomy skin flap perfusion assessment and multispectral near infrared reflectance imaging is further improving perfusion assessment (23,24).

While two-stage sub-pectoral implant reconstruction gave reasonable results, it was apparent on critical appraisal, that patients experience significant physical limitations secondary to sub-pectoral implant placement. Most patients exhibit some degree of animation deformity during activity, particularly during adduction of the humerus (12,25-27). Sub-pectoral implant placement may also have more serious morbidity. Partial and complete loss of normal muscle fiber architecture has been documented when evaluating biopsies with electron microscopy after sub-pectoral tissue expansion and breast reconstruction (28). Additionally, although the evidence is conflicting and studies are limited in sample size, there are reports of significant reductions in function and strength amongst patients with sub-pectoral implants (25,29-34). Subcutaneous fat grafting has been used extensively in both surgeons' practices (AK Antony, G Jones) in an effort to re-establish a gliding plane and ameliorate the disfigurement from animation deformity with limited success (35). Changing the position of reconstruction from the sub-pectoral to the pre-pectoral plane offers the opportunity to negate these effects, eliminating the distortion seen with sub-pectoral implant positioning (6,12,36-40). With the limitations imposed by sub-pectoral breast reconstruction, and the confluence of scientific achievement, improvement in surgical technique and advances in technology, successful pre-pectoral direct to implant breast reconstruction has become a reality.

Methods

Surgical technique

After completion of the mastectomy, the key to deciding to proceed with single stage reconstruction is based entirely on adequacy of mastectomy skin flap perfusion with a temporary sizer in place. In our collective experience, intraoperative skin flap perfusion is of primary importance in decision-making and supplants skin flap thickness. Fat grafting can be performed later as an adjunctive procedure to augment the mastectomy flaps if needed. Perfusion assessment is determined using either multispectral near infrared imaging with the Kent KD203 handheld device (Kent Medical Imaging) (G Jones), or, indocyanine green dye laser-induced fluorescence imaging (SPY, Stryker) (AK Antony). If skin perfusion is adequate with the appropriate temporary sizer in place, a decision is made to proceed with single stage direct-to-implant reconstruction in the pre-pectoral plane. If perfusion is marginal, an under-filled expander can be inserted, or the reconstruction delayed.

Both surgeons prefer an anterior tenting technique (G Jones, AK Antony). If skin perfusion is adequate, the mastectomy pocket and skin is prepared with betadine solution (16,41) A sheet of 16 cm × 20 cm thick ADM (AlloDerm, Allergan Inc.) is prepared according to manufacturer protocol and is sutured to the anterior surface of pectoralis major using the anterior tenting approach (42-44). Using 2-0 PDS, suturing is performed from 12 to 5 o'clock and 12 to 7 o'clock leaving an inferior access window for implant insertion (G Jones). Alternatively, interrupted 2-0 vicryl sutures can be placed to anchor the ADM and then 2-0 PDS is sutured to reinforce the medial and lateral border, again leaving an inferior window for access (AK Antony). The prepared pocket is re-checked with a sizer in place to ensure correct shape and position of

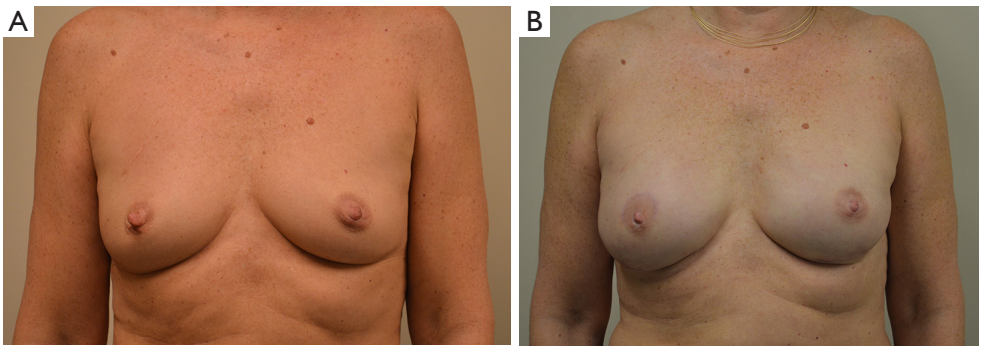

Figure 1 Pre- and post-operative view of a 55-year-old woman with right breast carcinoma. (A) Pre-operative view; (B) post-operative view 1 year following bilateral nipple-sparing mastectomies with immediate single stage pre-pectoral breast reconstruction.

the reconstruction. The sizer is removed and the pocket and chest are re-prepped with betadine or chlorhexidine/alcohol solution. The surgeon changes gloves and the implant is inserted using a Keller funnel to ensure no contact between the implant and the skin in an effort to minimize biofilm formation (15,16,45). The inferior ADM pocket is closed with 2-0 PDS sutured to the chest wall in a gentle curve to shape the inframammary fold. Closure of the skin is performed over 1–2 channel drains (G Jones) or 2 channel drains, one placed in the axilla and the other around the construct (AK Antony). AK Antony has implemented a strict drain protocol with maintenance of the drain until drainage is less than 20–25 cc/daily for 2 days; 1st drain removal typically occurs at post-operative day (POD) 10 and two ipsilateral drains are never removed simultaneously. Tegaderm occlusive dressing is used to cast the skin to optimize skin and nipple position and reduce shearing forces between the skin and ADM.

Results

Jones outcomes

One hundred and ninety-four breasts in 140 patients were operated upon with longest follow-up of 3.8 years. Successful outcome was achieved in 93.3% of cases (*Figure 1*). The most common complications were minor contour deformities at 44.3%, seromas 5.2%, and cellulitis in 5.7% patients. Explantation for any reason occurred in 6.7% of cases. There were no major full thickness skin necrosis requiring debridement and closure in the operating room. Partial thickness cutaneous blistering was treated conservatively with topical therapy in 4.1%. Minor rippling was present in 15% of cases and fat grafting was performed to soften minor contour deformities in 38%. There was 0% capsular contracture in non-radiated patients and 0% animation deformity. Long-term revision for implant size change occurred in 7.2% of cases.

Antony outcomes

One hundred and sixty-three pre-pectoral reconstructions were carried out in 94 patients; of these, 111 (68%) were pre-pectoral direct to implant breast reconstructions (PP DTI). Longest follow-up was 3.6 years (mean follow-up of 15.1 months). Pre-pectoral tissue expander reconstruction was performed in lieu of direct-to-implant reconstruction for patient preference (the patient preferred to be more involved in the expansion process and determination of the final volume achieved) or if substantial size increase was planned in a smaller breasted patient. Successful outcome was achieved in 100% of PP DTI cases (*Figure 2*). The most common complications were minor contour deformity treated with fat grafting (13.5%), downsizing to TE with subsequent exchange for permanent implant (1.8%), hematoma (0.9%), and capsular contracture (0.9%). There were no seromas (0%), infections (0%), or device loss (0%). Revision for implant size change occurred in 1.8% of cases. Animation deformity occurred in 0% of cases.

Discussion

Renewed interest in pre-pectoral reconstruction has emerged since Sigalove *et al.* first presented their amalgamated results of 353 reconstructions in 207 patients, of which 89% were two-stage pre-pectoral reconstruction (35). Pre-pectoral breast reconstruction remains predominantly tissue

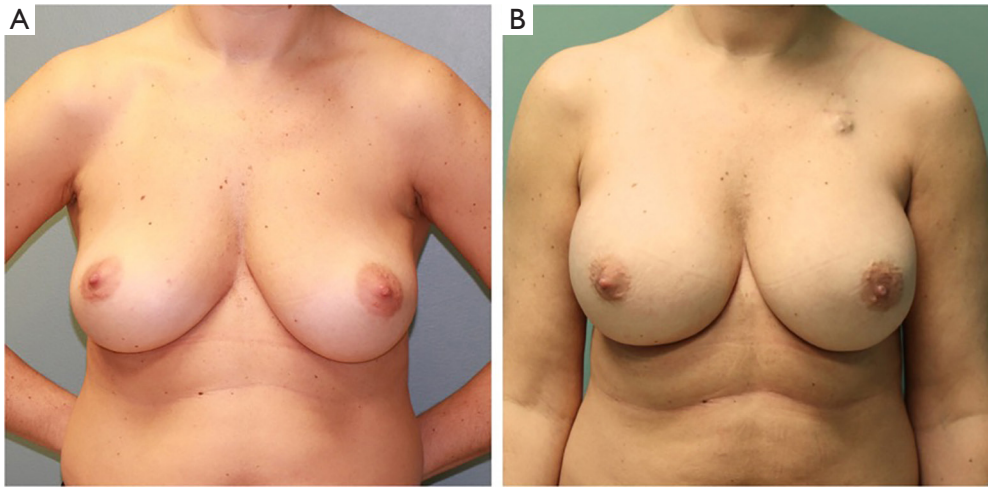

Figure 2 Pre- and post-operative view of a 44-year-old woman with right breast cancer. (A) Pre-operative view; (B) post-operative view 1 year following bilateral nipple-sparing mastectomies with immediate single stage pre-pectoral breast reconstruction.

expander based (35,46-53). There is a rising interest in single stage, direct-to-implant pre-pectoral reconstruction and recent studies report favorable data on this state-of-the-art breast reconstruction modality (54-57). However, direct to implant breast reconstruction remains a smaller fraction (less than 15%) of implant-based reconstruction likely for concerns of high revision rates and the steep learning curve (58-60).

Direct-to-implant reconstruction has become more viable as a reconstructive option with modern mastectomy techniques that preserve ever increasing amounts of skin, fully realized with nipple sparing mastectomy (17,18). Two stage breast reconstruction was conceived when significant skin resection was carried out at the time of mastectomy. Expansion was the preferred method to restore skin surface area for the insertion of an adequate volume implant. As newer skin- and nipple-preserving mastectomy approaches have been adopted, the need for expansion has exponentially decreased. Additionally, the release of the fascial constraints of the breast at mastectomy often results in the breast skin envelope being capable of accommodating a similar, or even larger, sized implant than the original breast volume.

Insertion of a definitive implant in one stage is predicated entirely on adequate skin perfusion to maintain tissue viability. Many surgeons express concerns about the thickness of skin flaps presented to them by oncologic surgeons. It is often assumed that skin thickness is the primary determinant of viability. However, our experience with perfusion assessment devices demonstrates that thin post-mastectomy skin flaps are typically well perfused even when fully extended after the primary implant insertion has occurred at the time of mastectomy. The eligibility of a patient for pre-pectoral reconstruction is based on skin perfusion, rather than flap thickness, and objective assessment with a tissue perfusion system is of critical importance to achieving successful outcomes (49). Pre-pectoral reconstruction has been safely performed in the setting of thin mastectomy flaps, provided flap vascularity is maintained (46). In correlating risk factors with outcomes, patient characteristics that compromise skin flap vascularity such as smoking, uncontrolled diabetes and radiation proved to be the most significant factors contributing to complications after the procedure (13,49). We feel it is safe to proceed if adequate skin perfusion is demonstrated with the temporary sizer in place and consider single stage, pre-pectoral direct to implant reconstruction to be a safe, reproducible technique.

Both surgeons were routinely performing direct-to-implant reconstruction in the sub-pectoral position before converting to pre-pectoral direct to implant reconstruction. While limited studies comparing pre-pectoral and sub-pectoral DTI reconstruction are available, these have been positive. Antony et al found in a comparison of 134 DTI reconstructions that transitioning to pre-pectoral direct to implant did not result in increased complications, degradation of aesthetic results (aesthetic blinded panel evaluation favored PP reconstructions) or an increase in revisional procedures (43). Cattelani *et al.* evaluated pre-pectoral breast reconstruction (pre-pectoral ADM-assisted direct to implant compared with submuscular

direct to implant and two-stage TE/I) and found less postoperative pain, faster recovery from postoperative upper extremity functional morbidity, higher aesthetic BREAST-Q scores as well as economic advantages in their series of 86 patients (57). Walia and colleagues also report significantly decreased postoperative pain in two stage pre-pectoral breast reconstruction patients without significant differences in BREAST-Q survey patient reported outcomes. However, there was a statistically significant increase in nipple ischemia amongst pre-pectoral patients (51). Finally, Baker *et al.* reported no significant difference in pain scores, early complications, or postoperative length of stay between direct to implant pre- and sub-pectoral breast reconstruction groups. However, more patients were dissatisfied with the amount of implant rippling in the pre-pectoral group (53).

At least three groups have looked at pre-pectoral breast reconstruction after post-mastectomy radiation therapy (PMRT) (55,56,61). Both Sigalove *et al.* and Elswick *et al.* found no statistically significant increased risk of adverse outcomes in pre-pectoral breast reconstructions that underwent PMRT based on short-term, retrospective data in 93 and 52 breasts respectively (55,61). More interesting is the results that follow from the study published by Sinnot and colleagues. These researchers found patients who underwent sub-pectoral breast reconstruction and receive PMRT actually had a greater rate of capsular contracture than patients that underwent pre-pectoral reconstruction (56).

The benefits of this technique include less patient discomfort, no need for post-operative expansion, less tissue flap edema, and virtually no subjective negative impact on upper extremity function. Additionally, animation deformity has been completely eliminated. Interestingly, fat grafting is required less frequently in our pre-pectoral patients compared to our sub-pectoral patients. This decreased rate of fat grafting is likely secondary to the elimination of animation deformity in pre-pectoral patients, and improved control over the medial aspect of the construct. Rippling perpendicular to the contraction of the pectoralis major muscle, and limitations in medial cleavage by the pectoralis major muscle are no longer an issue with pre-pectoral implant placement. The authors have been encouraged by the benefits seen from implementation of pre-pectoral direct to implant breast reconstruction in our practices and now routinely offer this modality to our patients as a primary reconstructive method.

Conclusions

Given the current trends in skin preservation during mastectomy, improved biofilm reduction algorithms, and advancements in tissue bioengineering and perfusion assessment, ADM-reinforced single stage, direct-to-implant insertion in the pre-pectoral space has become a viable alternative to two-stage expander-based, sub-pectoral reconstruction. We have experienced superior clinical and functional outcomes with minimal pain and enhanced convenience for the patient. Longer-term follow-up demonstrates maintenance of the integrity and quality of the reconstructions over time with extremely low rates of capsular contracture and complete absence of animation deformity. It is now the authors' primary choice for immediate implant-based reconstruction following mastectomy.

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Footnote

Conflicts of Interest: G Jones is a consultant for Allergan Medical. AK Antony is a consultant for Allergan Medical Inc. and Stryker Inc.

Ethical Statement: The study was approved by the Institutional Review Board of Rush University Medical Center (No. 16071402) and the University of Illinois College of Medicine at Peoria.

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