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ORIGINAL SCIENTIFIC PRESENTATION

Immediate Single-Stage Reconstruction of the Breast Utilizing FlexHD and Implant Following Skin-Sparing Mastectomy

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Introduction: Primary reconstruction of the breast is the standard of care for patients undergoing a mastectomy for breast cancer. Surgical techniques involving immediate implant reconstruction following skin-sparing mastectomy can offer improved patient self-image and enhanced aesthetic outcomes compared with other techniques. The use of an acellular dermal matrix (ADM) as a supporting material has been shown to further improve cosmetic results. Here, we describe a technique that allows for primary reconstruction of the breast mound with implant after a skin-sparing mastectomy in a single procedure using a new form of ADM known as FlexHD.

Materials and Methods: A total of 50 patients (85 breast reconstructions) over a period of 20 months underwent immediate reconstruction with this method using a silicone gel mammary implant. The surgical approach and complications for each patient were documented. In some patients, biopsies were obtained 2 and 6 months after initial placement of FlexHD (at the time of expander replacement) for pathologic and histologic evaluations.

Results: All reconstructions were completed in a single-stage procedure. The technique resulted in positive aesthetic outcomes and patient satisfaction with few complications and low postoperative pain. Infections were more frequently observed following bilateral mastectomy and in patients who had previous radiation therapy or were smokers. Fibroblast migration and neovascularization of the ADM were observed at 2 months with full incorporation into native tissue at 6 months.

Conclusions: Our experience suggests that single-stage breast reconstruction with FlexHD is a preferred approach to the primary reconstruction of the breast after mastectomy.

It has been estimated that during 2010, the number of new cases of breast cancer totaled 209,060, with a total of 40,230 deaths as a result.¹ Approximately two thirds of patients with breast carcinoma will undergo breast conservation surgery, and one third will undergo mastectomy.² The most basic of the many decisions facing the patient lies in choosing a mastectomy versus an operation that will allow for breast conservation.

Contemporary management of breast cancer requires a multidisciplinary approach. The initial oncologic management lies in the hands of the breast surgeon along with a team composed of radiologic, oncologic, and reconstructive specialists. Once the decision is made to proceed with mastectomy, and particularly with the skin-sparing approach, there are several options available to the patient in the surgical armamentarium. Autologous myocutaneous flaps such as the latissimus dorsi flap or the transverse rectus abdominis myocutaneous (TRAM) flap in the form of pedicled or free flaps are an option but are subject to the morbidity and limitations inherent to those procedures. These include more technically challenging reconstructions usually requiring longer operative times, lengthier hospitalizations, and extended recoveries.³ The complication rates from TRAM reconstruction have been reported in the range of 16% to 28%, with even greater variability in patients who undergo reconstruction prior to radiotherapy.^{4,5} The comparative cost between an autologous flap and an implant-based reconstruction is also in favor of the latter. However, when taking into

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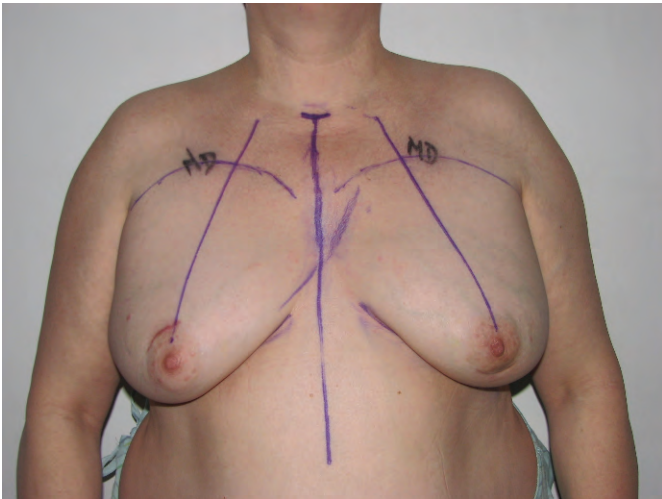


Figure 1. Anteroposterior (AP) preoperative markings. AP view showing preoperative markings including lines through the meridian of the breast; superior, medial, and lateral extents of the planned dissection; and the position of the inframammary fold.

account subsequent procedures required for implant reconstruction, such as the expansion process and expander exchange, this difference narrows.^{3,6}

An increasingly favored option in the treatment continuum is an immediate implant reconstruction by the plastic surgeon with a simultaneous procedure for symmetry on the contralateral breast.⁷ Many studies have shown the psychological benefits of achieving symmetry after breast reconstruction. These include an increase in patient satisfaction with the aesthetic result and the perception of sexual attractiveness.⁸⁻¹¹ In addition, there is a decrease of anxiety and depression after a primary reconstruction versus a staged procedure, a delayed approach, or no reconstruction.^{12,13}

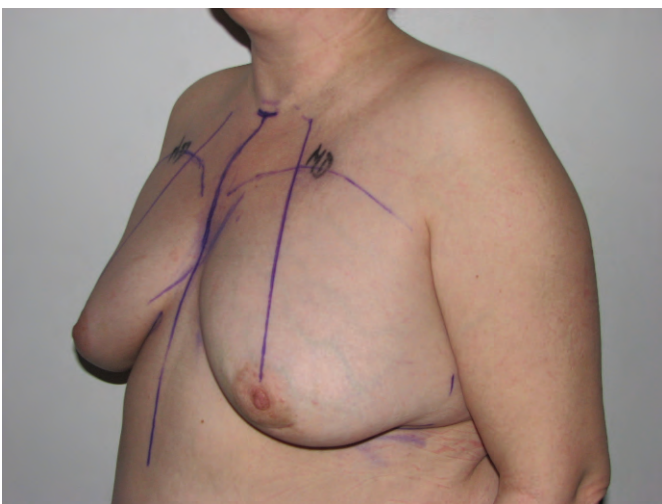


Figure 2. Lateral preoperative markings. Oblique view of preoperative markings, drawn while patient is standing.

Immediate breast reconstruction with the placement of a subpectoral gel implant has a high satisfaction rate among patients but poses its own set of problems. The first is the lack of definition of the lateral border of the breast, which is a notable defect created when the mastectomy extends beyond the natural borders of the breast. This increases the risk of gradual lateral displacement of the gel implant with time. Second, patients who have insufficient skin for coverage of the implant or a limited retropectoral space must undergo expansion. This is a process that is time-consuming for the surgeon and uncomfortable for the patient. Third, in thin patients, the implants are often visible and show rippling on the skin surface. Implant extrusion through the mastectomy skin envelope has also been described as a complication. The addition of acellular dermal matrix (ADM) as a supporting, pliable hammock counteracts many of these limitations and improves the cosmetic result significantly.¹⁴

FlexHD is a new ADM material described by the manufacturer as a human-derived matrix with excellent strength and resistance to stretching. We analyzed the clinical results of 50 patients who received FlexHD for immediate breast reconstruction over a 20-month time period. Data points such as aesthetic result, patient satisfaction, and complications were recorded and analyzed. Patients who had a complication were further stratified based on known risk factors such as smoking and previous radiation therapy to the breast.

Materials and Methods

Planning for the procedure is done in concert with the oncologic surgeon, who has done an appropriate preoperative radiologic and pathologic evaluation. After consent has been obtained for breast reconstruction with implant or expander and placement of allograft material, preoperative marking consists of marking the midline, inframammary fold (IMF), and lateral extent of the breast (Figures 1 and 2). In the initial portion of the procedure, a skin-sparing mastectomy with or without a sentinel lymph node biopsy or axillary dissection is performed by the oncologic surgeon. Our surgeons use a “box to X” incision (developed by Drs Cahan and Palaia), allowing for increased surgical exposure and camouflage of the incision in the course of the areolar reconstruction (Figure 3).

At the completion of the mastectomy and axillary procedure, the reconstructive team takes over. Using a lateral opening created in the fascia, a plane is developed between the pectoralis major muscle (PMM) and

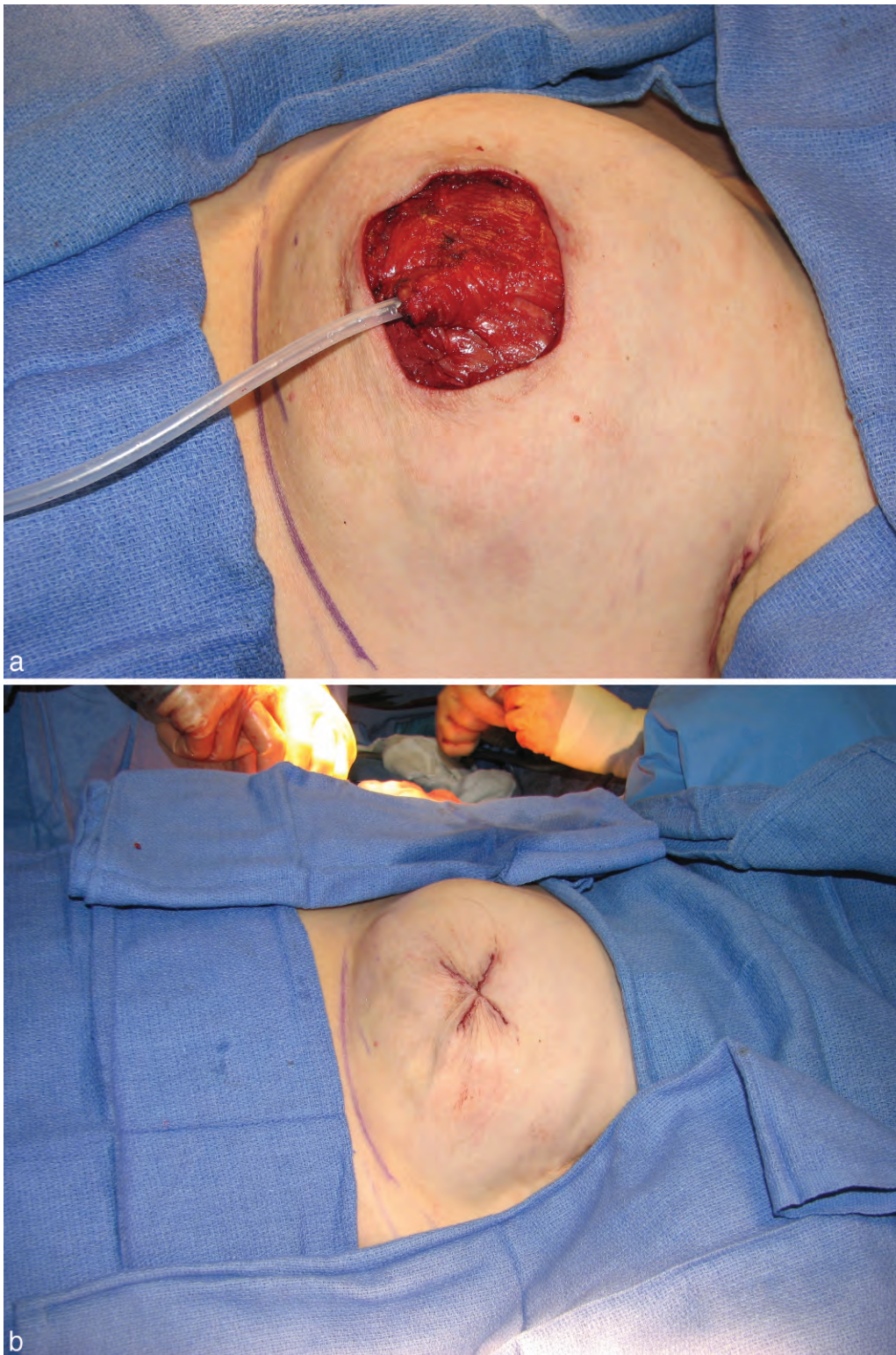


Figure 3. Box to X incision. (a) In the Box to X incision, the areolar complex is excised using a square-shaped incision, offering full exposure to the breast and underlying musculature. (b) After closure of the incision, an x-shaped scar is defined.

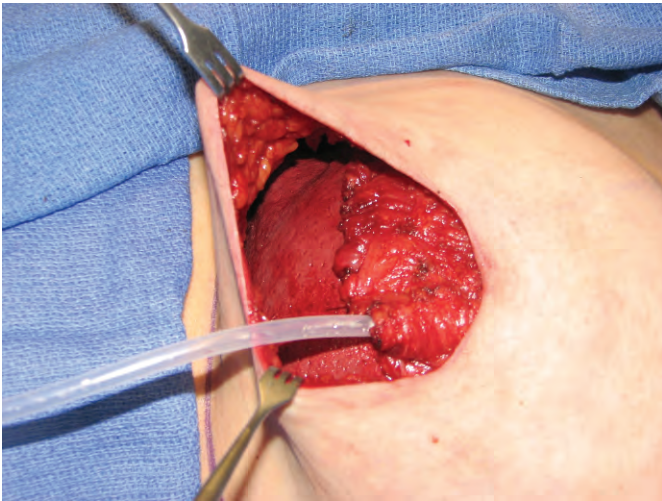


Figure 4. Sizer with allograft in place. FlexHD is shown sutured to the lateral cut margin of the pectoralis major muscle.

chest wall, taking care to preserve as many perforator vessels as possible. The limits of dissection extend to the anterior axillary line laterally (as marked preoperatively) and the IMF inferiorly. The dissection is extended upward to about 2 cm below the clavicle and to the level of the ipsilateral sternal margin medially. The upper lateral portion of the PMM is left intact at the site of transition from the serratus anterior and pectoralis minor muscles. Using the preoperative mapping outline for borders on the skin surface as a guide, a line is then drawn with a sterile marker within the incision to delineate the medial margin of the serratus anterior muscle and the IMF. A 4 × 16-cm-thick

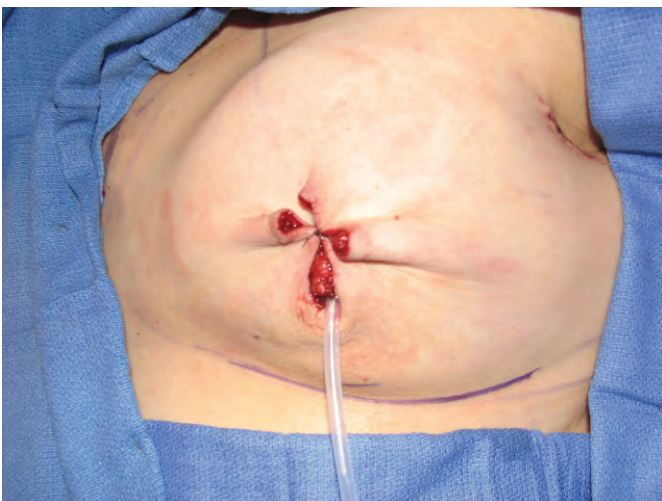


Figure 5. Sizer with skin reapproximated. The skin has been loosely reapproximated with the sizer in position to allow for comparison to the opposite breast and for any refinements to be made.

(0.8/1.7 mm) segment of FlexHD (Musculoskeletal Transplant Foundation, Edison, NJ) ADM is then placed parallel to the inferior edge of the PMM. The lower border of the FlexHD is sutured to the chest wall along the IMF, and the suture line is extended superolaterally along the medial border of the serratus anterior muscle, as marked. A Marcaine pain pump (I-Flow Corporation, Lake Forrest, Calif) is inserted percutaneously and placed in the subpectoral space. A sizer is then inserted through the lateral opening underneath the PMM and inflated to obtain the desired size, with respect to the opposite breast. The lateral border of the FlexHD is loosely sutured to the opening in the PMM (Figures 4 and 5). Once tested for appropriate size, shape, and placement, the lateral tacking sutures are removed, and the sizer is exchanged for a permanent silicone gel implant (Johnson & Johnson Corporation, New Brunswick, NJ). After the implant is inserted, the inferior border of the PMM is completely divided with cautery, and the FlexHD is sutured to the cut margin of the PMM, inferiorly and laterally, completely covering the implant. Two #10 Jackson-Pratt drains are inserted percutaneously; one is placed at the IMF between the FlexHD and skin flap and the other on the lateral aspect of the reconstruction toward the axilla. The placement of a drain directly over the ADM is thought to reduce the risk of a seroma and consequent dead space, thus increasing the likelihood of incorporation to the surrounding biologic layers. The skin is closed with absorbable sutures and the drains sutured in place and removed 5 days later.

Earlier in our series, where expanders had been placed at the initial reconstruction, biopsies were obtained during secondary surgery at the time of the expander replacement for a permanent gel implant, and they underwent a pathologic and histologic evaluation. The specimens were taken at 2 and 6 months

Complication Rate in 50 Patients

Complication	Number/ Percentage	Outcome
Hematoma	0/0	
Allograft dehiscence	1/2	Reoperation
Infection	6/12	Removal of implant
Seroma requiring drainage	10/20	Resolved with time
Implant extrusion	0/0	
Deep venous thrombosis	0/0	1 negative Doppler for pain
Pulmonary embolus	0/0	
Death	0/0	

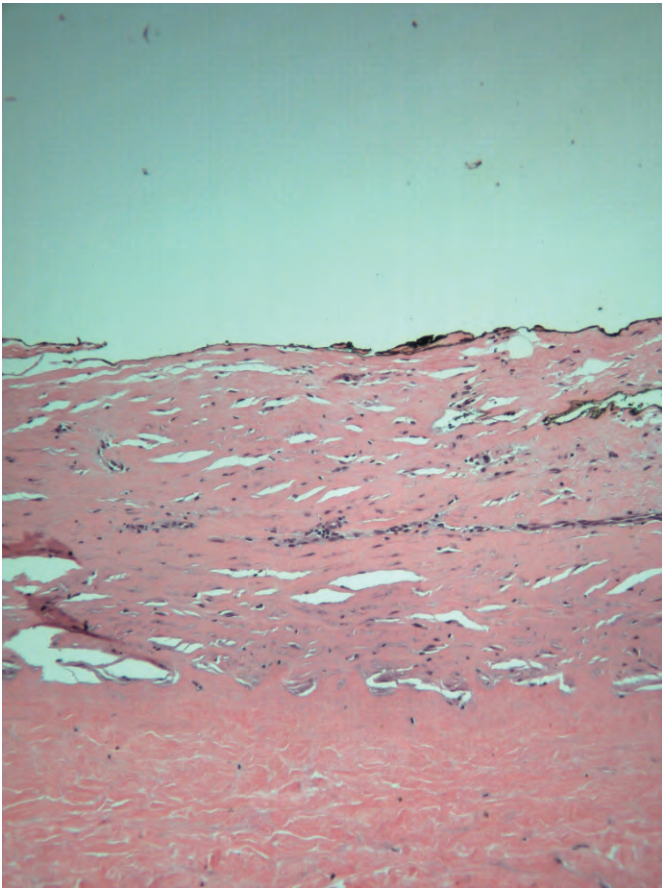


Figure 6. *Fibroblasts and collagen ingrowth. Hematoxylin and eosin staining of removed FlexHD showing fibroblast and collagen ingrowth into the acellular dermal matrix at 2 months.*

after the initial placement of the FlexHD. A hematoxylin and eosin staining method was used to visualize the neocapsular architecture.

Results

Patient data were collected during a period of 20 months (October 2008 to May 2010). These procedures were performed by the Northern Westchester Hospital Institute of Aesthetic Surgery and Medicine surgical group. The surgical approach and complications were documented (Table). Reported postoperative pain was minimal due in part to less dissection on the lateral aspect of the pocket at the junction of the pectoralis major with the serratus anterior muscle fibers and the placement of a submuscular Marcaine pain pump. All reconstructions were completed in a single stage, reducing total operative time compared with both autologous reconstruction and staged implant reconstruction.

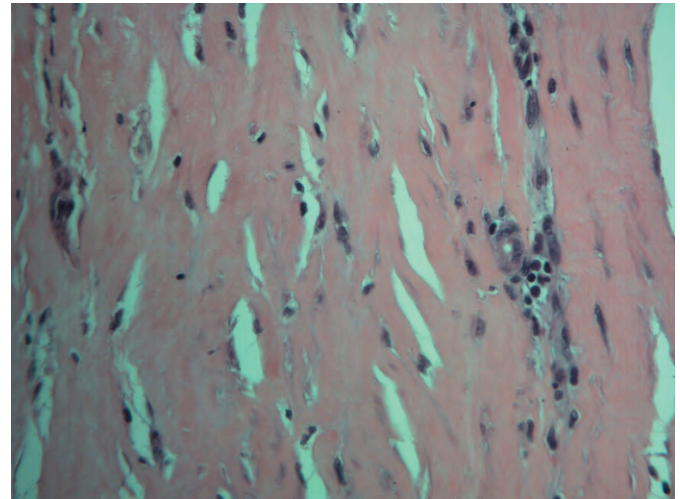


Figure 7. *Fibroblast and leukocyte ingrowth. Hematoxylin and eosin staining of removed FlexHD showing fibroblast and leukocyte ingrowth into the acellular dermal matrix at 2 months.*

Fibroblast migration as well as neovascularization were seen as early as 2 months (Figures 6–8), demonstrating cellular infiltration and formation of collagen fibrils in addition to new vascularity. Histologic follow-up at 6 months revealed vascular and cellular ingrowth into the implanted alloplastic sling with full incorporation into the native tissues (Figure 9).

The aesthetic outcomes were highly satisfactory to patient and surgeon (Figures 10–13). Complications of this technique (Table) included infection requiring removal of the implants in 6 of 50 patients (12.0%), or 11 of 85 breast implants (12.9%). Of note, 5 of 6 patients who required removal of their implants

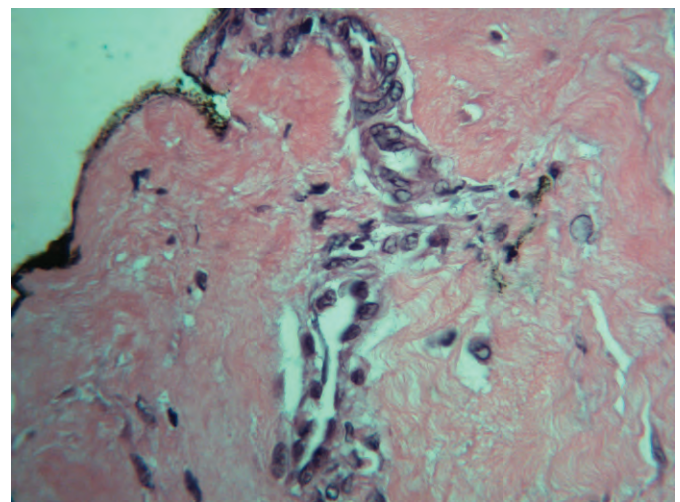


Figure 8. *Neovascularization. Hematoxylin and eosin staining of removed FlexHD showing neovascularization of the acellular dermal matrix at 2 months.*

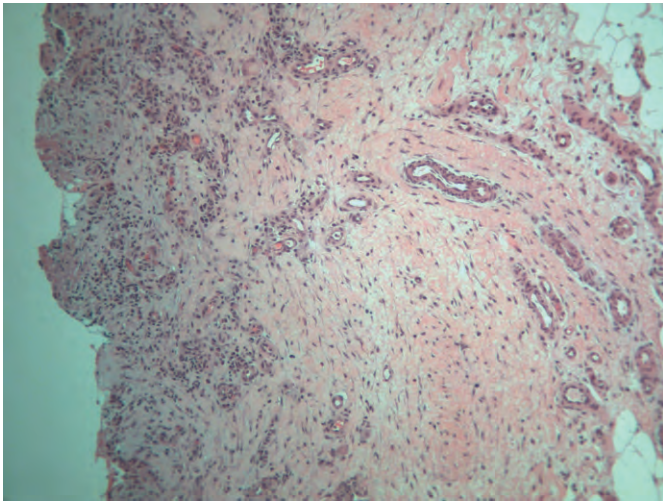


Figure 9. Establishment of allograft and neovascularization. Hematoxylin and eosin staining of removed FlexHD showing cellular replacement of the matrix at 6 months.

underwent bilateral mastectomy and reconstruction, reflecting a complication rate of 5 of 35 patients (14.3%), compared with the 1 of 15 patients who had unilateral reconstructions (6.7%). With further analysis of the 6 patients who required implant removal (failed reconstruction), 4 of the 6 (66.7%) were smokers, compared with a total of 8 smokers in the entire group (16%). There were also 4 patients who had previous radiation therapy in the infection group (66.7%), compared with a total of 9 patients in the entire cohort who had previous radiation therapy (18%). Two of the 6 patients had both smoking and previous radiation therapy as risk factors. Patients had drains in place for an average of 4.5 days following surgery, and the seroma rate was 20%. There was no correlation between persistent seroma and infection requiring removal of the implant. There were no hematomas requiring reoperation or drainage, and there were no documented deep vein thromboses, pulmonary emboli, or deaths in our series of patients. Overall aesthetic results were good, complications requiring implant removal were less than 13%, and patient satisfaction with the single-surgery approach was high.

Discussion

The use of ADM as an adjunct in immediate breast reconstruction with or without expansion is an accepted and widely used method.^{14,15} Its use for the coverage of soft-tissue defects has been well documented. These include cleft lip and palate reconstruction, abdominal wall defect repairs, and the closure of intraoral defects,

among many other uses.¹⁶⁻¹⁹ The application of the ADM in breast reconstruction is performed by creating a pocket in the retropectoral plane and creating a supportive sling on the inferolateral portion of the dissection, which serves as inferior and lateral support for the implant.²⁰ This allows reestablishment of the IMF and the redefinition of lateral mammary limits that are undermined during the mastectomy procedure. In the case of patients who for any number of reasons may require expansion, this can be accomplished in less time because of the larger retromammary pocket created by the additive area of the PMM and the ADM. This procedure carries less morbidity, an improved self-image, and benefits in cost.

One form of ADM known as FlexHD presents several advantages over its analogues. The first is that since it is stored in 70% ethanol, it is available for immediate use without requiring rehydration. FlexHD is reported to have excellent tensile strength, pliability, and appropriate elasticity, and it seems to retain these properties weeks after the initial surgery. This has been corroborated during secondary surgeries. Its biologic incorporation into local tissues has been analyzed histologically, showing full-thickness neovascularization as early as at 6 weeks in 1 of our cases. The fact that this implant is harvested from a human rather than a porcine source has had advantages for us in terms of patient acceptance.

Immediate breast reconstruction using FlexHD was successful in yielding a single-stage durable repair with few complications and high patient satisfaction. The complication rate in patients who underwent bilateral mastectomy and reconstruction is higher than unilateral surgery, a finding consistent with other reports in the literature. Whether this reflects the additional operative time or some difference in technique is not clear. Our data also clearly confirm the well-documented knowledge that smoking and previous radiation therapy significantly increases the risk of infection and removal of the implant in patients undergoing breast reconstruction with implants. If the 15 patients with increased risk secondary to smoking or previous radiation therapy were eliminated from our study (15 patients with 4 complications), the complication rate would drop to 2 of 35 patients (5.7%), a favorable number compared with historical controls in the literature. Based on our data, we have modified our approach and no longer offer the option of immediate implant reconstruction in patients with a history of smoking or previous radiation therapy to the breast. For this patient population, our first choice



Figure 10. Unilateral reconstruction and augment mastopexy. (a) Preoperative view of patient scheduled for right mastectomy and left augment mastopexy. (b) Right breast reconstruction with 500-mL Mentor smooth round moderate plus silicone implant and FlexHD and left augmentation mastopexy with 200-mL Mentor moderate plus silicone implant at postoperative month 3.

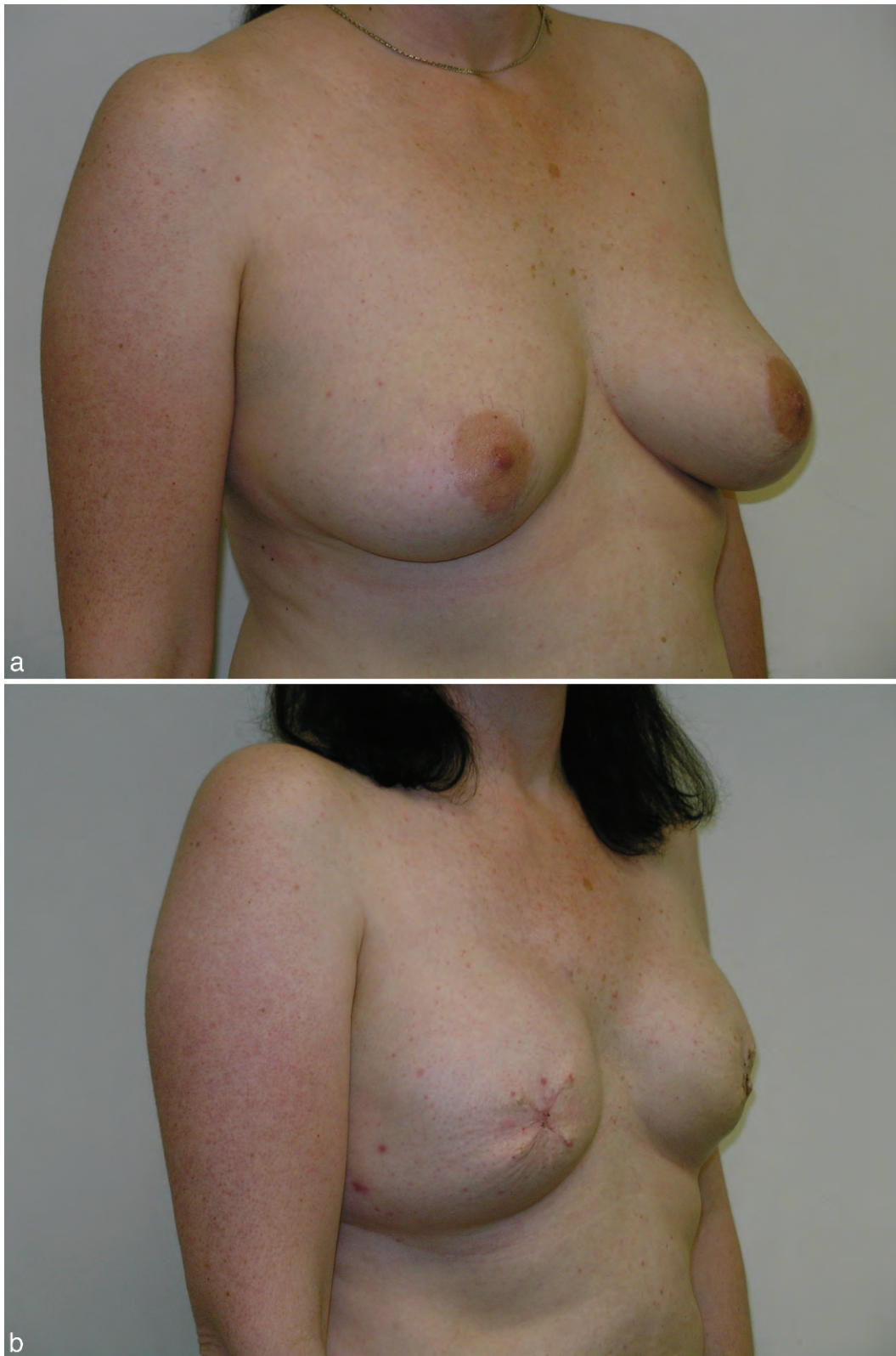


Figure 11. Bilateral reconstruction at 3 months. (a) Preoperative oblique view of bilateral mastectomy and reconstruction patient. (b) Bilateral breast reconstruction with 450-mL Mentor smooth round moderate plus silicone gel implants and FlexHD at 3 months postoperative, prior to planned nipple areolar reconstruction.

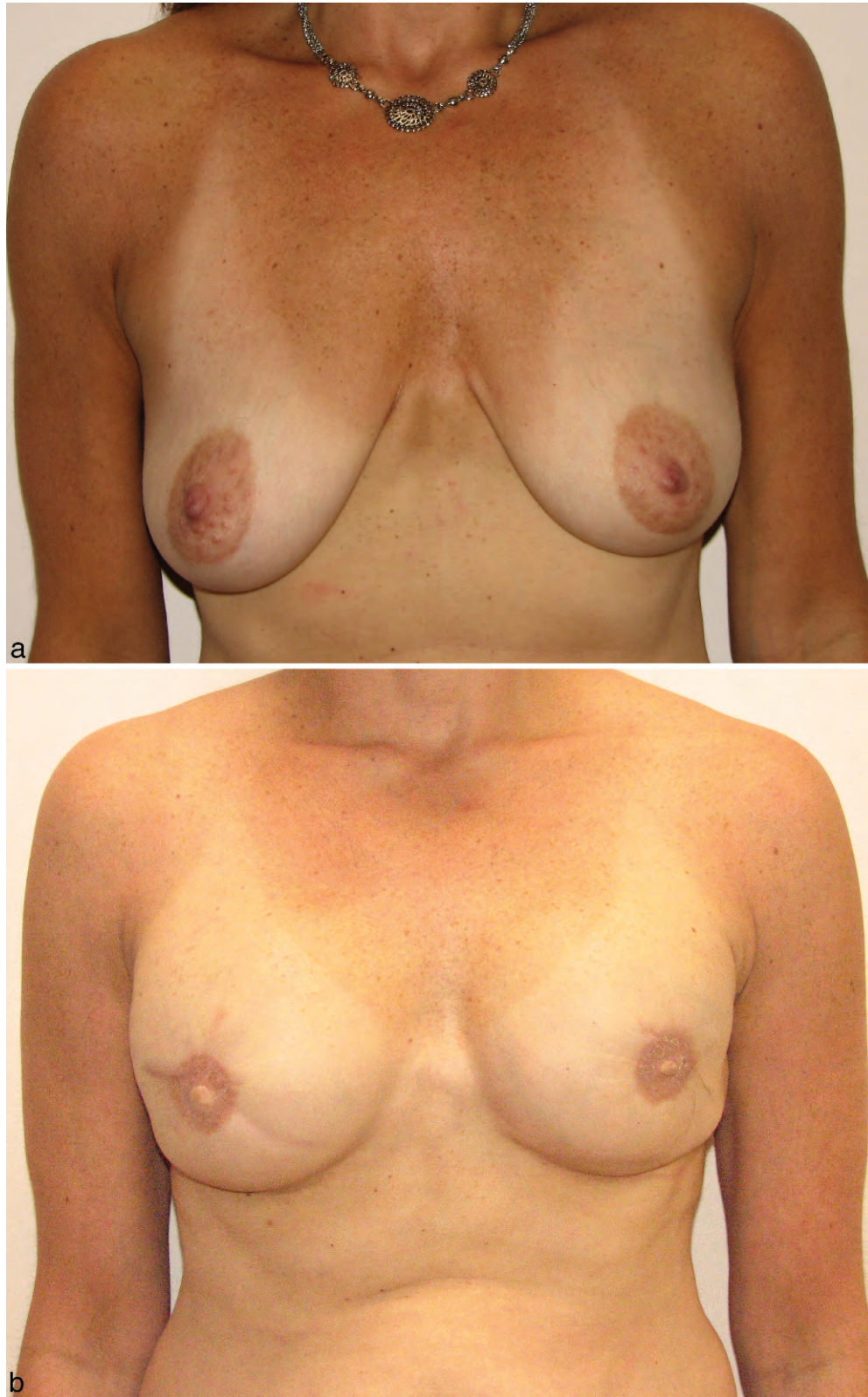


Figure 12. *Bilateral reconstruction at 6 months. (a) Preoperative view of patient scheduled for bilateral mastectomy. (b) Patient at 6 months postoperative from immediate bilateral reconstruction with 500-mL Mentor smooth round moderate plus silicone gel implants and FlexHD. Patient has also had nipple reconstruction and areolar tattoo.*



Figure 13. *Bilateral reconstruction at 3 months. Patient with tuberous breasts status post bilateral mastectomies and immediate reconstruction with 600-mL Mentor smooth round moderate plus silicone gel implants and FlexHD.*

would be autologous tissue reconstruction. In cases in which the patient is not a good candidate for autologous reconstruction or in which the patient understands the increased risk of infection and loss of the implant and still chooses implant reconstruction, we offer reconstruction with an expander and use a slow and deliberate approach to expansion.

Conclusions

Our experience suggests that single-stage breast reconstruction with FlexHD is a preferred approach for the primary reconstruction of the breast after mastectomy. As with other breast reconstruction techniques, careful patient selection for this technique is an important component of decreasing complications due to infections.

Financial Disclosure

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