

# Capsular Contracture in Implant-Based Breast Reconstruction: Examining the Role of Acellular Dermal Matrix Fenestrations

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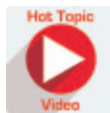
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**Background:** Acellular dermal matrices have been proposed to decrease the incidence of capsular contracture in implant-based breast reconstructions. The authors have modified acellular dermal matrices with fenestrations to facilitate greater pole expansion and improve contour. The effect of fenestrations on the ability of matrices to suppress capsule formation, however, has not been examined.

**Methods:** A retrospective review of all fenestrated acellular dermal matrix–assisted, implant-based breast reconstructions performed by the two senior authors, with a minimum of 1-year follow-up after permanent implant placement, was completed. Patient demographics, details of extirpative and reconstructive procedures, and complications were examined. Capsular contractures were scored according to the Baker grading scale and compared to those reported in the literature.

**Results:** Thirty patients (50 breasts) underwent fenestrated acellular dermal matrix–assisted reconstruction, with mean follow-up times of 3.3 and 2.6 years after expander placement and implant exchange, respectively. Seven patients (23 percent) had a body mass index greater than 30 kg/m<sup>2</sup>, three (10 percent) were active smokers, and six breasts (12 percent) were irradiated. Complications included one infection (2 percent), six cases (12 percent) of incisional superficial skin necrosis, and one (2 percent) tissue expander extrusion. Zero breasts had clinically significant Baker grade III/IV capsular contracture. The average Baker grade was 1.1.

**Conclusions:** Fenestrated acellular dermal matrices decrease capsular contracture to rates similar to what is seen with nonfenestrated matrices. Further research is necessary to determine whether this observation is a result of decreased need for inferolateral acellular dermal matrix coverage to achieve these effects or modified physical interaction of acellular dermal matrices with surrounding soft tissues. (*Plast. Reconstr. Surg.* 136: 629, 2015.)

**CLINICAL QUESTION/LEVEL OF EVIDENCE:** Therapeutic, IV.

**B**reast reconstruction after mastectomy has increased significantly over the past decade, with implant-based procedures constituting the majority of reconstructive efforts.<sup>1,2</sup> Despite advances in surgical technique and implant devices, capsular contracture remains a frequent complication after breast reconstruction (2.8 to 15.9 percent),<sup>3–5</sup> and often requires reoperation.

To date, the exact mechanisms of capsular contracture and the appropriate prevention and treatment remain largely unknown. Several theories

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for the development of capsular contracture exist, although no single theory is universally accepted. Infection, whether clinical or subclinical, and the subsequent periprosthetic inflammation receives the strongest support by the available literature as the mechanism behind this phenomenon.<sup>6-8</sup> Indeed, the use of dilute antibiotic irrigants during implant placement has led to a decrease in the incidence of capsular contracture following cosmetic breast augmentation and reconstruction.<sup>9</sup> However, a significant number of patients still suffer from contracture after reconstruction, with a reported incidence up to 15.9 percent in large prospective studies.<sup>3-5</sup>

Acellular dermal matrices have recently emerged as a potential tool available to the surgeon to both prevent and treat capsular contracture. Their widespread use in direct-to-implant and two-stage breast reconstruction can be traced to several cited functional benefits, including improved soft-tissue coverage<sup>10,11</sup>; decreased time to complete expansion in two-stage reconstructions<sup>12,13</sup>; and improved aesthetic results because of better accentuation of the inframammary fold, definition of the lateral mammary contour, and projection of the lower pole.<sup>11,13-15</sup> Functioning as an interface between the implant and the soft tissues of the chest wall, acellular dermal matrices may decrease the inflammatory process around the inert material of the implant, suppressing the process of capsule formation.<sup>16</sup> Clinical studies have demonstrated promising results, reporting significantly lower rates of capsular contracture in two-stage breast reconstruction using acellular dermal matrices, although these studies are often limited by sample size and follow-up duration.<sup>12,15,17-19</sup>

The senior authors have been using acellular dermal matrices in implant-based breast reconstruction over the past 8 years. Longitudinal fenestrations have been added as a means of facilitating acellular dermal matrix expansion under the weight of the implant and during the filling process, creating a more ptotic and natural appearing inferior pole. We have previously demonstrated that this technique improves intraoperative fill volumes, decreases the number of postoperative expansions, and improves the expansion rate.<sup>13</sup> The effects of acellular dermal matrix fenestration on capsular contracture, however, have not been studied. Although this fenestration technique exposes more chest wall soft tissue to the breast prosthesis, which in theory challenges the beneficial effect of acellular dermal matrix to prevent capsular contracture, we hypothesize that the placement of fenestrations in the matrix may physically disrupt collagen deposition and fibrosis

and the subsequent formation of painful capsular contractures. The purpose of this study was to review the authors' experience with fenestrated acellular dermal matrix breast reconstruction as it pertains to capsular contracture formation.

## PATIENTS AND METHODS

An institutional review board–approved, retrospective chart review identified all patients who underwent implant-based breast reconstruction using allograft performed by the two senior authors (K.Z.P. and G.A.W.) at our institution from 2008 to 2014 (institutional review board no. 2014-1107). Operative dictations were used to further isolate all occasions on which the allograft product was fenestrated at the time of reconstruction. Furthermore, only those patients with a minimum follow-up of 1 year after their permanent implant placement were included in this analysis. Patients who had undergone previous breast surgery (i.e., augmentation or mastopexy) or those undergoing delayed reconstruction were excluded from the study.

Allograft fenestration, tissue expander placement, and implant exchange were performed as described previously by Martin et al.<sup>13</sup> Briefly, strategically placed longitudinal fenestrations were created in the acellular dermal matrices, with the goal of achieving optimal overlap between fenestrations in adjacent rows. During inset, the allograft is sutured to the pectoralis major muscle superiorly, laterally to the serratus anterior fascia, and inferiorly at the inframammary fold. The expander or silicone implant (direct-to-implant scenario) is then placed in a partial subpectoral pocket with the allograft acting as a sling supporting its weight. The skin envelope is then closed in a tension-free manner. A single drain is left in the prepectoral, subcutaneous space and removed when drainage is less than 25 cc/day for 48 hours. After completing tissue expansion, patients undergo implant exchange, often with subsequent nipple reconstruction.

Strict aseptic technique is used when handling allogenic and alloplastic materials. Both acellular dermal matrices and tissue expanders/implants are soaked in triple-antibiotic solution (50,000 units of bacitracin, 1 g of cefazolin, and 80 mg of gentamicin per 500 cc of normal saline) on removal from their packaging and are henceforth handled by the senior surgeon donning a clean pair of gloves. The breast pocket is irrigated with the triple-antibiotic solution, and the skin is re-prepared with Betadine Solution (Purdue Products, Stamford, Conn.) before tissue expander or implant placement. Postoperatively, patients who remain overnight receive

**Table 1. Patient Demographics**

	Value (%)
No. of patients	30
Total no. of breasts	50
Age, yr	
Mean	46.0
Range	26–69
BMI, kg/m <sup>2</sup>	
Mean	26.4
Range	19.1–42.6
No. of obese patients (BMI >30)	7 (23.0)
Smoking status	
Active smoker	3 (10.0)
Former smoker	1 (3.3)
Diabetes mellitus	0 (0.0)

BMI, body mass index.

prophylactic intravenous antibiotics with transition to an oral regimen on discharge, which is continued until the drains are removed.

Patient demographics including patient age, body mass index, active or prior tobacco use, and comorbid conditions were extracted from inpatient and outpatient records. The type of mastectomy performed and any history of chemotherapy or radiation therapy were also recorded. Reconstruction details included the type of allograft [AlloDerm (LifeCell Corp., Branchburg, N.J.), AlloMax (Bard, Inc., Warwick, R.I.), or FlexHD (Musculoskeletal Transplant Foundation, Edison, N.J.)], the tissue expander size, intraoperative fill volume, outpatient fill volumes, and time to full expansion. The status of the capsule was evaluated by the two senior authors during postoperative follow-up visits and scored according to the Baker grading scale.<sup>20</sup>

## RESULTS

Thirty patients (50 breasts) were identified for inclusion in the study (Table 1). The mean age was 46 years (range, 26 to 69 years). Seven patients (23 percent) were obese (body mass index >30 kg/m<sup>2</sup>), three (10 percent) were smoking at the time of tissue expander placement, and one patient (3.3 percent) quit smoking within 3 months before surgery. No patients had any significant cardiovascular disease or cardiovascular disease equivalents, including diabetes.

Cancer diagnoses and details related to the ablative surgery and neoadjuvant and/or adjuvant therapies are summarized in Table 2. The majority of mastectomies were skin-sparing (84 percent), seven (14 percent) were nipple-areola sparing, and one (2 percent) was a complete mastectomy. Thirteen patients (43 percent) received neoadjuvant chemotherapy and four patients (13.3 percent) received adjuvant chemotherapy. Two patients received

**Table 2. Cancer Type and Treatment**

	No. (%)
Cancer diagnosis	
Infiltrating lobular	1 (2)
Infiltrating ductal	11 (22)
DCIS	10 (20)
Phyllodes tumor	2 (4)
Prophylactic	
Contralateral side	20 (40)
BRCA-positive	6 (12)
Mastectomy type	
NSM	7 (14)
SSM	42 (84)
Modified radical mastectomy	1 (2)
Neoadjuvant chemotherapy	13 (26)
Adjuvant chemotherapy	4 (8)
Radiation therapy	6 (12)

DCIS, ductal carcinoma in situ; NSM, nipple-sparing mastectomy; SSM, skin-sparing mastectomy.

**Table 3. Reconstruction Characteristics**

	Value (%)
Bilateral	20 (66.7)
Acellular dermal matrix product	
AlloDerm	39 (78.0)
AllerMax	6 (12.0)
FlexHD	5 (10.0)
TE characteristics*	
Size, cc	504.7 ± 172.8
Intraoperative fill, cc	286.8 ± 173.7
Total fill, cc	532.1 ± 174.7
Intraoperative fill/total fill, %	54.4 ± 23.0
No. of postoperative expansions	3.2 ± 1.8
Time to full expansion, days after TE placement	54.3 ± 39.6
Follow-up after first stage, yr	
Mean	3.3
Range	1.3–6.1
Follow-up after implant exchange, yr	
Mean	2.6
Range	1.0–5.8

TE, tissue expander.

\*Values for tissue expander characteristics are presented as mean ± SD.

both neoadjuvant and adjuvant chemotherapy. Six breasts (12 percent) were irradiated postoperatively.

During the first stage of reconstruction, AlloDerm (78 percent), AlloMax (12 percent), or FlexHD (10 percent) was used as an allograft (Table 3). One patient (two breasts) underwent a direct-to-implant reconstruction. Tissue expanders were filled intraoperatively to an average of 54.4 percent of the total fill volume, and were expanded a mean of 3.2 times postoperatively over a period of 54.3 days until after expander placement. Patients were followed for an average of 3.3 years (range, 1.3 to 6.1 years) and 2.6 years (range, 1.0 to 5.8 years) after expander placement and implant exchange, respectively.

Complications during the follow-up period are summarized in Table 4. One patient (2 percent)

**Table 4. Complications**

	No. (%)
Infection	1 (2)
Seroma	0 (0)
Superficial skin necrosis (incisional)	6 (12)
NAC necrosis	0 (0)
TE extrusion	1 (2)

NAC, nipple-areola complex; TE, tissue expander.

**Table 5. Capsular Contracture (Baker Grade)\***

	No. (%)
I	46 (92)
II	4 (8)
III	0 (0)
IV	0 (0)

\*Mean Baker grade  $\pm$  SD, 1.1  $\pm$  0.3.

developed an infection that occurred concomitantly with expander extrusion and required explantation of the expander, with replacement at a later date. The mean Baker grade for all 50 breasts was 1.1, with no patients with grade III/IV capsular contractures (Table 5). Of the four breasts (8 percent) that were Baker grade II capsular contracture, two had received postoperative irradiation and none had a clinically identifiable infection or hematoma within the breast pocket. The relationship between Baker grade and postoperative radiation exposure was not significant [chi-square (Yates) (1,  $n = 50$ ) = 2.68,  $p < 0.05$ ].

## DISCUSSION

Acellular dermal matrices have been increasingly used in alloplastic breast reconstruction.<sup>21,22</sup> Aside from increased soft-tissue coverage and improved aesthetics, the recent literature has also supported a decreased incidence of capsular contracture in acellular dermal matrix–assisted prosthetic breast reconstruction.<sup>12,15,17–19</sup> Furthermore, acellular dermal matrices have emerged as a potential treatment for clinically significant capsular contracture.<sup>23–25</sup> The senior authors have modified the matrices with strategically placed fenestrations as a means of increasing the support of the tissue expander or implant within a rapidly expanding pocket and ultimately improving the aesthetic result. This technique, however, leaves certain areas of the implant exposed to the soft tissue of the chest wall, prompting the question of whether modifying acellular dermal matrices with fenestrations alters the capabilities of the allograft to act as an anti-inflammatory, anti-capsule formation agent.

In this study, we reviewed the long-term complications associated with both one- and two-stage fenestrated acellular dermal matrix breast

reconstruction, with a specific focus on the incidence of capsular contracture. Overall, complication rates were low. Infection (2 percent) and seroma (0 percent), which have previously been reported to be much higher in acellular dermal matrix–assisted breast reconstructions (infection rates of 8.9 to 28.9 percent and seroma rates of 9.7 percent), were rare or nonexistent in our cohort.<sup>26–28</sup> We believe that this is likely a result of improved fluid drainage from the subpectoral to the prepectoral subcutaneous pocket through the fenestrations, reducing “dead space” with more expansion, and better effacement of the allograft to the soft-tissue envelope. The incidence of capsular contracture was low throughout the follow-up period, which was on average 2.6 years following implant exchange. Zero breasts with grade III/IV capsular contracture were identified in our study population. Of the four breasts with grade II capsular contracture, two (50 percent) received radiation therapy, which has been demonstrated to increase the degree of capsular contracture in two-stage reconstructions, regardless of acellular dermal matrix use.<sup>29,30</sup> Whether matrices are efficacious in decreasing capsular contracture in the irradiated field remains to be determined. They have been shown to limit the histologic changes seen around implants after irradiation, and preliminary studies have shown favorable clinical and histologic results.<sup>31,32</sup> In contrast, larger series have suggested that irradiation significantly decreases the ability of acellular dermal matrices to suppress capsule formation.<sup>33,34</sup>

Capsular contracture following implant-based reconstruction using the nonfenestrated acellular dermal matrix as an inferolateral sling is observed less frequently than in reconstructions that do not use allograft. One of the larger studies comparing capsular contracture rates between 337 immediate acellular dermal matrix (208 breasts) and non-acellular dermal matrix (129 breasts) reconstructions reported clinically significant contracture in 3.8 percent of breasts in the matrix group at 29 months after implant exchange.<sup>35</sup> Other studies have demonstrated an even lower incidence of capsular contracture, comparable to what was seen in our review. A prospective series of 58 breasts by Spear et al. had one breast (1.7 percent) with Baker grade III/IV capsular contracture 3 months after implant exchange.<sup>15</sup> Bindingavele et al., Becker et al., and Namnoum all identified zero capsular contractures in their cohort of immediate two-stage reconstructions, with a mean follow-up period ranging from 6.7 to 21 months.<sup>12,17,19</sup>

In this study, we observed a comparable or lower incidence of capsular contracture than what

is reported in the literature for nonfenestrated acellular dermal matrix–assisted two-stage breast reconstruction. By fenestrating the matrix, we believe that improved expansion and resultant effacement with the soft-tissue envelope along with enhanced fluid egress from the subpectoral pocket is achieved, all the while preserving the inherent and beneficial anti-inflammatory properties of the allograft. Fenestration decreases the overall contact surface area between the implant and allograft. Given that our cohort experienced an equally impressive rate of capsular contracture as that reported in the literature for acellular dermal matrix–assisted breast reconstruction, the role of allograft in decreasing capsule formation must be further elucidated.<sup>16</sup>

The exact mechanism behind the ability of acellular dermal matrices to suppress capsule formation is still a subject of debate, particularly as the cause of capsular contracture is still not well understood. However, the theory that matrices control the inflammatory periprosthetic milieu fits well with the leading hypothesis behind capsule formation; namely, that a local inflammatory reaction leads to subsequent fibrosis and contracture.<sup>6–8</sup> *In vitro* studies have shown differential induction of specific inflammatory mediators, such as vascular endothelial growth factor and interleukin-1 $\beta$ , interleukin-6, and interleukin-8 between the various acellular dermal matrices, which is hypothesized to affect their *in vivo* performance, integration, fibroblast activation, and ability to suppress a chronic inflammatory state.<sup>36</sup> These findings are supported by clinical investigations in which histologic analysis of biopsy specimens obtained from partial subpectoral acellular dermal matrix reconstructions revealed that the biointegrated matrix had decreased fibrosis, fibroblast cellularity, and chronic inflammatory changes compared with the native subpectoral capsule.<sup>16</sup>

Although the anti-inflammatory role of acellular dermal matrices is becoming fairly well established, the extent of implant coverage necessary to achieve these benefits is still not well understood. Animal studies have shown that implants wrapped completely in allograft have reduced inflammation and cell proliferation, and decreased myofibroblast cells and capsule thickness.<sup>37–39</sup> Clinical studies have supported these results. Cheng et al. treated 10 cases of grade III/IV capsular contracture and four cases of recalcitrant capsular contracture with complete coverage of implants with allograft, with encouraging results.<sup>23</sup>

Determining whether the efficacy of acellular dermal matrices in treating capsular contracture correlates with the extent of the implant adjacent to the allograft is less clear with regard to

the amount of allograft needed to suppress capsule formation in primary reconstruction. Using a primate model, Stump et al. demonstrated that decreased capsule formation occurred only where the acellular dermal matrix was in contact with the tissue expander, whereas areas without matrix coverage showed capsule formation similar to that of controls.<sup>40</sup> The clinical literature, however, has shown that partial coverage of implants with acellular dermal matrices, or the “dual-plane” technique, has been successful in decreasing rates of contracture, at least during the first few years after reconstruction, likely by interrupting the process of capsule formation in the area adjacent to the acellular dermal matrix.<sup>12,15,17,19,35</sup> There is a paucity of studies, however, examining the effects of further limiting the area of matrix coverage. By using fenestrations in our series, which leaves areas of the implant exposed, our results suggest that complete coverage of the inferolateral aspect of the implant by allograft may not be required for preservation of the intrinsic ability of acellular dermal matrices to suppress capsular contracture.

The cause of capsular contracture is undoubtedly multifactorial, suggesting that more than one compensatory mechanism may be required for the observed acellular dermal matrix–mediated capsule suppression. Moyer and Ehrlich demonstrated that collagen and fibroblasts organize in a unique helical structure in more severe cases of capsular contracture and suggest that failure of collagen fibers to organize as such may decrease the development of capsular contracture.<sup>41</sup> Furthermore, textured implants are known to have lower associated rates of capsular contracture compared with smooth implants because of disruption of the contractile forces around the implant.<sup>42</sup> We hypothesize that placement of fenestrations in the acellular dermal matrix may further disrupt fibroblast collagen deposition and interrupt the organizational development of capsules. Whether these modifications exerted such an effect and played a role in our observations remains to be confirmed, and will require biopsies and histologic assessment of both fenestrated and nonfenestrated integrated acellular dermal matrices.

The contribution of infection to the inflammatory milieu promoting capsular contracture must also be considered. Strong evidence has shown that infection and biofilm formation are associated with increased capsule formation.<sup>6,8,43</sup> This is especially important when considering reconstructions using acellular dermal matrices, which have been shown to increase the risk of infection.<sup>26,27</sup> Adams et al. demonstrated that using triple-antibiotic breast

irrigation significantly decreased rates of capsular contracture.<sup>9</sup> The authors adhere to this protocol as one aspect of an overall strict aseptic technique, as described in the Patients and Methods section of this article, which may contribute to our low infection rate. Additional factors may be the ability of fenestrations to improve drainage of fluid into the prepectoral subcutaneous pocket, along with decreased “dead space” with more rapid expansion, which we believe contributes to our low seroma rate. The improved fluid egress has also allowed us to use only one drain, which may decrease the introduction of bacteria.

As seen in the majority of the literature, short-term follow-up is a limiting factor, a parameter that is particularly important when considering capsular contracture. As acellular dermal matrices continue to be used in prosthetic breast reconstruction and techniques are further refined, future studies will be sought to differentiate whether allograft truly decreases capsule formation or merely delays the process in the short-term postoperative period. In addition, our study did not use a control population, as both senior authors have used fenestrations in all acellular dermal matrix–assisted breast reconstructions since developing the technique in 2008. It would not be possible to use an internal control whereby one breast was reconstructed using fenestrated matrix and the other without, as this would inherently lead to an asymmetrical result. Instead, we have observed that fenestrated acellular dermal matrix produces a comparable, if not improved, capsular contracture profile compared with peer-reviewed studies in the literature.

## CONCLUSIONS

As acellular dermal matrices find their place within the realm of alloplastic breast reconstruction, plastic surgeons will continue to better understand their benefits and limitations. The interaction between matrices and capsule formation has evolved in a similar fashion, as acellular dermal matrices were originally implicated as an important tool in the treatment of capsular contracture and later in their prevention. Although preliminary evidence suggests that matrices may indeed decrease rates of capsular contracture when used in primary breast reconstruction, much remains to be understood about the mechanisms behind these observations, the technique required to achieve these benefits, and the evaluation of the long-term results.

Fenestrated acellular dermal matrix has been previously demonstrated to improve functional

expansion and benefit the overall aesthetic outcome.<sup>13</sup> In this study, we demonstrate that the rate of capsular contracture observed in fenestrated acellular dermal matrix breast reconstruction is, at the very least, comparable to that of nonfenestrated acellular dermal matrix reconstructions. Whether this observation is a result of the modified physical interaction between the fenestrated acellular dermal matrix and the surrounding soft tissue remains to be supported by further evidence. Nevertheless, the results of this study further highlight that the balance between acellular dermal matrix coverage at the inferolateral pole and maintenance of the acellular dermal matrices' ability to suppress the periprosthetic inflammatory milieu and disrupt capsular contracture formation may be less stringent than previously thought.

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