Efficacy of Acellular Dermal Matrices in Revisionary Aesthetic Breast Surgery: A 6-Year Experience

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Abstract

Background: Augmentation mammoplasty and augmentation mastopexy are associated with a substantial primary and secondary revision rate. Capsular contracture (CC), implant malposition, ptosis, asymmetry, and rippling are the main reasons for revisionary surgery in these patients. Traditional corrective techniques have not been completely reliable in preventing or treating these complications. Recently, acellular dermal matrices (ADM) have been used to assist with revisionary surgery with promising results.

Objective: The authors review their 6-year experience using ADM for revisionary surgery in aesthetic patients and evaluate long-term outcomes with this approach.

Methods: Patients who underwent revisionary breast augmentation or augmentation mastopexy with ADM in conjunction with standard techniques over a 6-year period between October 2005 and December 2011 were retrospectively reviewed. Only patients with at least 1 year of follow-up were included in the analysis.

Results: A total of 197 revisions were performed (197 patients). Reasons for revision included CC (61.8%), implant malposition (31.2%), rippling (4.8%), ptosis (4.8%), implant exposure (1.6%), and breast wound (0.5%). The mean ± SD follow-up period was 3.1 ± 1.1 years (range, 0.1-6.1 years). The complication rate was 4.8%, including Baker grade III/IV CC (1.6%), infection (1.6%), implant malposition (0.5%), hematoma (0.5%), and seroma (0.5%). Most (98%) revisions were successful, with no recurrence of the presenting complaint.

Conclusions: The use of ADM in conjunction with standard techniques for the reinforcement of weak tissue in revision augmentation and augmentation mastopexy patients appears to be effective.

Level of Evidence: 4

Keywords

breast revision surgery, acellular dermal matrices, revision augmentation, capsular contracture, implant malposition, rippling, ptosis

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subpectoral to neosubpectoral in patients who already have their implants in the subpectoral position) in conjunction with capsulotomy or capsulectomy, implant replacement (change from saline to silicone implants or change to newer forms of silicone implants in patients who already have silicone implants), and the use of capsular flaps for creation and reinforcement of the breast pocket. Although these corrective techniques may help to ameliorate the presenting condition, the high rate of reoperation in revision augmentation patients is a clear indication that the procedures are not completely effective in correcting or mitigating the risk of recurrence.

More recently, regenerative acellular dermal matrices (ADM) have been adopted into aesthetic surgery to provide soft-tissue reinforcement in revision augmentation, mastopexy, and reduction mammoplasty patients, based on the benefits of these matrices in reconstructive patients. In reconstructive patients, ADM products have been successfully used to provide lower breast pole reinforcement and have been shown to be associated with low rates of complications and low rates of observed CC. In 2009, we reported on our initial experience using different types of ADM for revisionary surgery in 78 consecutive augmentation or augmentation mastopexy patients during an approximately 2-year period (between October 2005 and January 2008), with at least 1 year of follow-up after revisionary surgery. We showed that ADM can be effectively used in revisionary cases to improve lower pole support, stabilize the breast pocket, and minimize the rate of recurrent CC.

The purpose of this study is to review our 6-year experience with ADM in revision augmentation or revision augmentation mastopexy patients and to evaluate long-term outcomes associated with the use of ADM in revisionary surgery.

METHODS

A retrospective chart review was performed for consecutive patients who underwent revision augmentation or revision augmentation mastopexy using an ADM between October 2005 and December 2011. Only patients who had a minimum of 12 months of follow-up were included in this analysis. Over a 73-month study period, 197 ADM-assisted revisionary surgeries were performed in 197 patients. Of these patients, 186 (94.4%) had at least 12 months of follow-up and were included in this analysis. Patients who underwent revisionary surgery following postmastectomy breast reconstruction were excluded from this analysis.

Patient charts were reviewed and the following data were collected: patient age at time of ADM-assisted revisionary surgery, medical comorbidities, indications for ADM-assisted revisionary surgery, time to ADM-assisted revisionary surgery from initial or last revision augmentation or augmentation mastopexy, number of prior revisionary surgeries, original implant location (subpectoral or subglandular), type of implant used for ADM-assisted revision, type of ADM used, length of follow-up, pre- and postoperative Baker classification, and any other postoperative complications. Clinically significant CC requiring revision was defined as a Baker grade III or IV. The preoperative and postoperative Baker classification of CC was analyzed by type of ADM used for revisionary surgery.

Surgical Procedures

The surgical procedure performed was based on the indication for revisionary surgery. There were 3 main reasons for revisionary surgery in this patient cohort—reinforcement of the breast pocket for the correction of implant malposition (bottoming out, synmastia, and lateral malposition), reinforcement of thinned soft tissue for the correction of rippling, and reinforcement of capsulectomy for treatment of CC. Regardless of the type of surgical procedure, implant replacement with a pocket change was performed in all cases. If the original implant was subcutaneous, a subpectoral plane change was performed, and if the original implant was subpectoral, a neosubpectoral pocket was created. To minimize contamination during surgery, all pockets were irrigated with triple antibiotic solution, and all new implants were bathed in the same solution before insertion into the new pocket. In addition, all patients were prescribed perioperative antibiotics.

Six different ADM products were used for revisionary surgery in this patient cohort: AlloDerm (LifeCell, Branchburg, New Jersey), Strattice (LifeCell), FlexHD (processed by the Musculoskeletal Transplant Foundation [MTF], Edison, New Jersey, for Ethicon, Inc, Somerville, New Jersey), DermaMatrix (processed by MTF for Synthes CMF, West Chester, Pennsylvania), SurgiMend (TEI Biosciences, Boston, Massachusetts), or NeoForm (processed by RTI Biologics, Inc, Alachua, Florida, for Mentor Corporation, Santa Barbara, California). In the correction of implant malposition, the ADM was placed and sutured at the lateral, inferior, or medial implant border (depending on the type of implant malposition) to reinforce the breast pocket. In the correction of rippling, the ADM was placed over regions of thin tissue to provide additional soft-tissue reinforcement. In the correction of CC, a pocket change was performed in conjunction with a total capsulectomy if the original capsule was subglandular, or with partial anterior capsule excision and residual capsule obliteration or total or partial capsulectomy if the original capsule was subpectoral. The ADM was placed and sutured at the inferior or medial border of the breast to reinforce the capsulectomy.

RESULTS

Of the 186 patients included in the final study, 159 (85.5%) had at least 2 years and 93 (50%) had at least 3 years of follow-up. Most (88.7%) had an initial augmentation, and 11.3% had an initial augmentation mastopexy (Table 1). The original implants were placed subpectorally in 74.7% and subglandularly in 25.3% of patients. The
majority of patients (66.1%) had no prior revisionary surgery. At the time of ADM-assisted revisionary surgery, the mean ± SD age of patients was 40.8 ± 9.5 years (range, 24-66 years), and nearly all had no existing comorbid conditions. One patient was a current smoker, and another had undergone massive weight loss. Two patients had a past history of tobacco use. The most frequent reasons for ADM-assisted revisionary surgery were reinforcement of capsulectomy for treatment of CC (Baker grade III or IV) in 61.8%, reinforcement of breast pocket for the correction of implant malposition in 31.2% (including bottoming out in 17.7%, synmastia in 6.5%, and lateral malposition in 4.8%), reinforcement of thinned soft tissue for the correction of rippling in 4.8%, and correction of ptosis in 3.8% (Table 2).

During ADM-assisted revisionary surgery, 120 patients (64.5%) received silicone gel implants (51 smooth and 69 textured implants), and 66 patients (35.5%) received cohesive gel implants. In the majority of patients, revisionary surgery was performed with the assistance of Strattice (51.6%) or AlloDerm (30.6%) (Table 3). The mean ± SD follow-up period after ADM-assisted revisionary surgery was 3.1 ± 1.1 years (range, 1.0-5.5 years). During this period, complications occurred in 9 patients (4.8%), including CC in 3 patients (1.6%), infection in 3 patients (1.6%), and implant malposition, hematoma, and seroma in 1 patient each (0.5% each) (Table 4). The 3 cases of infection occurred in patients who had AlloDerm, Strattice, and FlexHD. Implant malposition, hematoma, and seroma occurred in patients who had received AlloDerm. The seroma formation occurred as a consequence of double-layering AlloDerm.

Two of the 3 cases of postoperative CC occurred in patients who had received SurgiMend and 1 in a patient who had NeoForm (Tables 4 and 5). All 3 cases of CC were Baker grade III. There was no incidence of CC in patients who had received Strattice, AlloDerm, FlexHD, or DermaMatrix, although more than 50% of patients who received Strattice, AlloDerm, or FlexHD had an original indication for CC for revisionary surgery (Table 5). At final follow-up, 94.6% of patients were assessed as having a soft breast, classified as a Baker grade I CC (Table 6). Clinical results are shown in Figures 1 through 8.
Reliable methods for revisionary surgery in augmentation mammoplasty patients are an unmet need in breast aesthetic surgery. Current data from the literature indicate an approximately 2-fold higher rate of revisionary surgery in revision augmentation patients compared with primary augmentation patients. In an effort to improve revisionary surgery outcomes, ADM has been used to provide the much-needed reinforcement of soft tissue, which is often lacking in augmentation patients.5,23 Preliminary data, including our data published in 2009,23 indicate that the addition of ADM may provide a means for effectively reinforcing capsulectomy for the treatment of CC, reinforcing the breast pocket for the correction of implant malposition (bottoming out, synmastia, lateral malposition), and reinforcing thinned soft tissue for the correction of rippling. In this study, we extended our preliminary findings using a larger patient population with a longer follow-up period. In addition, as several different ADM products were available in the market for breast reconstruction (AlloDerm, Strattice, SurgiMend, NeoForm, FlexHD, and DermaMatrix), we also investigated whether there were any potential differences between products with respect to clinical outcomes, particularly the risk of CC.

Thinning of breast parenchyma and the overlying soft tissues is often seen in augmentation patients as a consequence of having large implants. Thinned tissue, in turn, may contribute to implant palpability, rippling, ptosis, implant malposition (bottoming out, synmastia, lateral malposition), and implant extrusion.24-26 In our patient cohort, approximately a third of the patients collectively had implant malposition, rippling, or implant exposure as a presenting complaint. In these patients, ADM was used to support the newly created implant pockets as well as to supplement weak tissue presenting as rippling. After revisionary surgery, none of these patients experienced a recurrence of the presenting complaint during the follow-up period. The only complications were seroma formation in a patient who had revisionary surgery for rippling, which was attributed to double-layering of AlloDerm, and infection in a patient who had revisionary surgery for synmastia. Although double-layering is a procedure often performed in our practice, surgeons should be aware of the risk of seroma formation with this technique and should take the necessary precautions to prevent its occurrence (eg, proper drain placement and drainage).

Capsular contracture is the most frequent reason for revisionary surgery in augmentation patients, and it is also the most frequent and challenging complication.3,4 Data from implant manufacturers indicate a cumulative CC rate of 10% to 15% in primary augmentation and approximately 20% in revision augmentation patients over a 6-year period. In our patient cohort, CC Baker grade III to IV was the presenting symptom in approximately 62% of patients.

Observed CC rates noted in the literature with the use of an ADM, particularly AlloDerm, are low (0%-4.4%).12-22 These observations were the impetus for using ADM for the reinforcement of weak tissue following a capsulectomy in the treatment of CC in breast augmentation patients. In our patient cohort, there were 3 incidences of CC after ADM-assisted revisionary surgery during a mean follow-up period of 3.1 years, for an overall CC rate of 1.6%. This rate is comparable to the 0% to 4.4% rate reported in breast reconstruction patients during a follow-up period of 0.6 to 2.4 years.12-22 All 3 cases of postrevisionary CC occurred in patients who had an initial presenting complaint of CC; thus, corrective surgery was not successful in preventing recurrence in these cases. Of note, these 3 patients were part of the first 78 patients evaluated in our 2009 publication, wherein we had

### Table 4. Postoperative Complications

<table>
<thead>
<tr>
<th></th>
<th>AlloDerm</th>
<th>Strattice</th>
<th>FlexHD</th>
<th>SurgiMend</th>
<th>NeoForm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total complications</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Implant malposition</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Seroma</td>
<td>1*</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Infection treated with antibiotic</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

*Due to double-layering.

### Table 5. Preoperative and postoperative capsular contracture rate

<table>
<thead>
<tr>
<th>Acellular Dermal Matrix Group</th>
<th>Capsular Contracture, n/N (%)</th>
<th>Preoperative</th>
<th>Postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strattice</td>
<td>51/96 (53.1)</td>
<td>0/96 (0)</td>
<td></td>
</tr>
<tr>
<td>AlloDerm</td>
<td>45/57 (78.9)</td>
<td>0/57 (0)</td>
<td></td>
</tr>
<tr>
<td>FlexHD</td>
<td>10/19 (52.6)</td>
<td>0/19 (0)</td>
<td></td>
</tr>
<tr>
<td>SurgiMend</td>
<td>6/8 (75)</td>
<td>2/8 (25.0)</td>
<td></td>
</tr>
<tr>
<td>NeoForm</td>
<td>3/4 (75)</td>
<td>1/4 (25)</td>
<td></td>
</tr>
<tr>
<td>DermaMatrix</td>
<td>0/2 (0)</td>
<td>0/2 (0)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>115/186 (61.8)</td>
<td>3/186 (1.6)</td>
<td></td>
</tr>
</tbody>
</table>

*Baker grade III or IV.

### Table 6. Preoperative and Postoperative Baker Classification of Capsular Contracture

<table>
<thead>
<tr>
<th>Baker Classification</th>
<th>Preoperative, n/N (%)</th>
<th>Postoperative, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>56/118 (47.4)</td>
<td>176/118 (94.6)</td>
</tr>
<tr>
<td>II</td>
<td>23/116 (19.5)</td>
<td>14/116 (12.1)</td>
</tr>
<tr>
<td>III</td>
<td>100/118 (85.2)</td>
<td>3/118 (2.5)</td>
</tr>
<tr>
<td>IV</td>
<td>14/118 (12)</td>
<td>0/118 (0)</td>
</tr>
</tbody>
</table>

DISCUSSION

Reliable methods for revisionary surgery in augmentation mammoplasty patients are an unmet need in breast aesthetic surgery. Current data from the literature indicate an approximately 2-fold higher rate of revisionary surgery in revision augmentation patients compared with primary augmentation patients. In an effort to improve revisionary surgery outcomes, ADM has been used to provide the much-needed reinforcement of soft tissue, which is often lacking in augmentation patients.5,23 Preliminary data, including our data published in 2009,23 indicate that the addition of ADM may provide a means for effectively reinforcing capsulectomy for the treatment of CC, reinforcing the breast pocket for the correction of implant malposition (bottoming out, synmastia, lateral malposition), and reinforcing thinned soft tissue for the correction of rippling. In this study, we extended our preliminary findings using a larger patient population with a longer follow-up period. In addition, as several different ADM products were available in the market for breast reconstruction (AlloDerm, Strattice, SurgiMend, NeoForm, FlexHD, and DermaMatrix), we also investigated whether there were any potential differences between products with respect to clinical outcomes, particularly the risk of CC.

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Figure 1. (A, C, E) This 41-year-old woman had previously undergone breast augmentation with saline implants placed in a subglandular pocket and presented with capsular contracture with overlying ptosis. (B, D, F) Sixteen months after revision augmentation mastopexy (inverted T), which included total capsulectomy, a site change, lower pole reinforcement with an acellular dermal matrix, and replacement of existing implants with round silicone gel implants.
Figure 2. Revision surgery interventions of the patient shown in Figure 1. (A) Total capsulectomy and explantation of saline implant. (B) Site change from subglandular to dual-plane pocket (arrow in new pocket). (C) Tailor tacking of breast mound with sizer in place with patient at 90-degree position. (D) Lower pole reinforcement with an acellular dermal matrix (arrow on ADM).

Figure 3. The patient in Figures 1 and 2 is shown immediately after revisionary surgery (A) and demonstrating the softness of her breasts at 28 months following surgery (B).
Figure 4. (A, C, E) This 32-year-old woman had previously undergone multiple revision breast augmentations and presented with bilateral implant malposition. (B, D, F) Thirty-two months after revision augmentation, which included the development of a neopectoral pocket, lower pole reinforcement with an acellular dermal matrix, and replacement of existing implants with form-stable, highly cohesive gel anatomic implants.
reported no incidence of CC at a mean follow-up of at least 1 year.\textsuperscript{23} But with longer follow-up, complications of CC have surfaced in these patients. This reinforces the need for longer-term follow-up to arrive at a better estimation of complications as well as recurrences after revisionary surgery. In the present study, about 86\% of patients had at least 2 years of follow-up and 50\% at least 3 years of follow-up.

Of the 3 patients who had postoperative CC, 2 received SurgiMend and 1 received NeoForm. It is particularly remarkable that 53.1\%, 78.9\%, and 52.6\% of patients who had received Strattice, AlloDerm, and FlexHD, respectively, had preoperative CC, and none of these patients had a recurrence during the follow-up period. The small number of patients who received SurgiMend and NeoForm in this study precludes any statistical analyses of the observed difference in the incidence of recurrent CC between the ADM products. Larger studies will be needed to assess for differences in CC rates between the ADM formulations. Given that ADM differ in product characteristics, it is conceivable that these may translate to differences in revascularization, recellularization, and/or foreign body inflammatory response, which may play a role in CC. In fact, an in vitro study has demonstrated differences in inflammatory response between ADM (AlloDerm, FlexHD, and AlloMax [Bard Davol, Warwick, Rhode Island]).\textsuperscript{27} Of the ADM products investigated, AlloDerm had the lowest inflammatory response, as measured by cytokine expression, to human peripheral blood mononuclear cells. Whether the differences in inflammatory response translate into better in vivo ADM performance was not investigated in this study.

The precise etiology of CC has yet to be established, but it is known that inflammation at the cellular level may result in the formation of pathologic CC.\textsuperscript{28} Furthermore, foreign body inflammatory response has been directly correlated to capsule thickness and the Baker score.\textsuperscript{29} The low rate of CC with certain ADM may be related to their ability to reduce the foreign body inflammatory response, as shown in a human histological study using AlloDerm.\textsuperscript{30} In this study, significantly reduced levels of granulation tissue formation, vessel proliferation, chronic inflammatory changes, capsule fibrosis, fibroblast cellularity, and foreign body giant cell inflammatory reaction were noted in biopsies of integrated AlloDerm obtained during second-stage implant exchange from patients who underwent AlloDerm-assisted tissue expander reconstruction compared with biopsies obtained from native capsules. These data suggest that AlloDerm inhibits inflammatory changes that are required for the inception of capsule maturation and thus may provide an explanation for the observed low rate of CC with its use.

Although the cause of the inflammatory response can be multifactorial, current evidence strongly suggests that the primary cause is likely to be subclinical infection with either biofilm-forming or non–biofilm-forming bacteria.\textsuperscript{28} Furthermore, recent data from an in vivo study have substantiated this by demonstrating a causal link between subclinical infection, biofilm formation, and CC in a porcine model.\textsuperscript{31} Thus, aseptic techniques must be an integral part of revisionary surgery, irrespective of the use of ADM, to minimize breast pocket contamination and the subsequent development of CC.

In this study, 98\% of revisions were successfully managed with no recurrence of the presenting complaint during a 3-year mean follow-up period. Although we did not have a control group of patients who underwent revisionary surgery with traditional techniques, the recurrence rate in the published literature is on the order of 30\% to 40\% within 6 years after revisionary surgery using traditional techniques.\textsuperscript{3,4} Furthermore, in this study, the use of ADM was associated with a low overall postoperative complication rate (4.8\%, including recurrences).

**CONCLUSIONS**

The use of ADM for the revision of breast augmentation and augmentation mastopexy complications in conjunction with standard techniques is effective, with minimal postoperative complications. In the majority of patients in this series, the presenting complaints of implant malposition, CC, and rippling were effectively corrected with no evidence of recurrence during the follow-up period. The ADM products may thus represent an important addition to the current techniques in breast augmentation surgery for the treatment of complications.

**Disclosures**

Allen Gabriel, MD, and G. Patrick Maxwell, MD, are paid consultants for LifeCell Corporation, the manufacturer of products discussed in this article.
Figure 6. (A, C, E) This 41-year-old woman had previously undergone multiple attempts at correction of her bilateral implant malposition and severe animation deformity. (B, D, F) Twenty-five months after revision augmentation through an inframammary fold incision, which included the development of a neopectoral pocket, lower pole reinforcement with an acellular dermal matrix, and replacement of existing implants with textured gel implants.
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REFERENCES


