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# Acellular Dermal Matrix in Cosmetic Breast Procedures and Capsular Contracture

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## Abstract

Prevention and treatment of capsular contracture after breast augmentation is a controversial and oftentimes vexing problem. While there are traditional methods of addressing this condition, acellular dermal matrix materials offer a new and promising modality that is gaining momentum in the field of plastic surgery. In this article, the author examines the etiology and pathophysiology of capsular contracture and review the existing literature on acellular dermal matrix in breast surgery related to capsular contracture.

## Keywords

breast enhancement, breast enlargement, capsular contracture, neopeitoral pocket, primary or secondary or revision breast augmentation, revision or secondary surgery, implants

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There are perhaps no other topics in aesthetic breast surgery as controversial as the techniques for the prevention and treatment of capsular contracture (CC) associated with implants. Over the last five decades, numerous modalities have been proposed for the prevention of CC, such as the submuscular placement of implants, textured implants, pocket irrigation with steroids, pocket irrigation with antibiotics and/or Betadine, the avoidance of drains, cautery in lieu of blunt pocket dissection, the minimization of implant handling and/or touching of breast skin on insertion, and the inframammary as opposed to periareolar approach for implant placement. Techniques utilized by surgeons for the treatment of CC have included closed capsulotomy, open capsulotomy, and capsulectomy associated with implant exchange, pocket site change, treatment of the affected breast with ultrasound, and the oral ingestion of high-dose vitamin E, montelukast, and zafirlukast.

Although published data available for these prevention techniques are hardly definitive, it is clear that there has been a dramatic decrease in the incidence of CC in published reports studying one or several of the aforementioned methods. The treatment of CC, especially when it is recurrent, has been studied far less. Recent laboratory and clinical findings associated with decreased CC rates in the presence of acellular dermal matrix (ADM) materials in

revisionary breast surgery are exciting, pointing to a new addition to the treatment options for CC. As clinical data involving large series of patients are still emerging, this area of research is certainly worthy of further investigation.

## THE CLINICAL STUDY OF CC

The incidence of CC and the timing of risk have been the subject of controversy. Manufacturer-reported data of pathologic (Baker<sup>1</sup> Grade III or IV) CC rates with saline and silicone implants have ranged from 10% to 30% over a three- to five-year period.<sup>2-4</sup> Large clinical studies have documented long-term CC rates of up to 30% in primary breast augmentation.<sup>5</sup> In the setting of breast reconstruction, radiation therapy is a clear risk factor for CC, with a reported incidence of up to 73%.<sup>6-10</sup> Meta-analyses of shell

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characteristics strongly suggest the protective effect of textured versus smooth implants, with the relative risk of pathologic capsule formation in smooth implants being three to five times that of textured implants when both are placed in the subglandular plane.<sup>11,12</sup> Drawbacks of textured implants have included higher rates of deflation and higher rates of rippling and wrinkling.<sup>13</sup> In considering implant positioning options (submuscular placement vs subglandular placement), a retrospective multicenter analysis of more than 500 patients found that subglandular placement increased the risk of CC almost eightfold.<sup>14</sup> Possible explanations for the decrease in occurrence of CC incidence with submuscular placement includes the separation of the implant from breast tissue and possible sources of infectious organisms, as well as the massaging effect derived from continuous muscular contractions.

In a study of 3495 implants in 1529 women undergoing cosmetic, reconstructive, and revisionary surgery over a 25-year period in a single practice, Handel et al found that the longer implants were in place, the greater the cumulative risk of developing CC became.<sup>13</sup> Hematoma was found to significantly increase the relative risk of contracture (2.19 times). The most common indication for reoperation in patients studied (56%) was found to be CC. Baker Grade III or IV contracture rates were found to be approximately 2% after primary breast augmentation, 5% after breast reconstruction, and 4% after revisionary breast augmentation. However, the percentage of patients remaining contracture-free at 10 years was much lower in all groups (79% in the primary breast augmentation group, 63% in the reconstruction group, and 58% in the revisionary procedure group), suggesting that contracture is a progressive phenomenon and that the longer any group of patients is followed, the greater the cumulative risk of developing CC. Handel's findings suggest that the risk of contracture persists for many years after implantation and that multifactorial causes for CC may contribute to acute events, such as bacterial contamination, as well as to the chronic effect of implants on adjacent breast tissue. Other well-designed studies of CC confirm the propensity for acute and chronic effects of silicone implants. Prantl et al found that 58% of contracture occurred within the first 11 months after implantation, 17% within three years, and 25% after five years.<sup>15</sup>

### PHYSIOLOGIC AND PATHOLOGIC MECHANISMS FOR CC

Numerous theories exist regarding the development of pathologic CC. Histologically, capsules are found to consist of tightly-woven collagen fibers. Excessive capsule formation is likely mediated via an inflammatory process and, specifically, myofibroblast formation associated with wound contraction.<sup>16</sup> The microbiological theory postulates that infectious organisms present within the periprosthetic space cause subclinical infections and chronic

inflammation. This biofilm is generally not significant enough to cause an implant infection, but it does predispose the patient to contracture. Well-designed studies have confirmed high rates of bacterial colonization of Baker Grade III and IV capsule specimens and little to no colonization for Grade I and II.<sup>17</sup> Other studies have found a direct correlation between greater capsular thickness and an increased number of silicone particles and silicone-loaded macrophages in the peri-implant capsule when silicone implants are placed.<sup>16</sup>

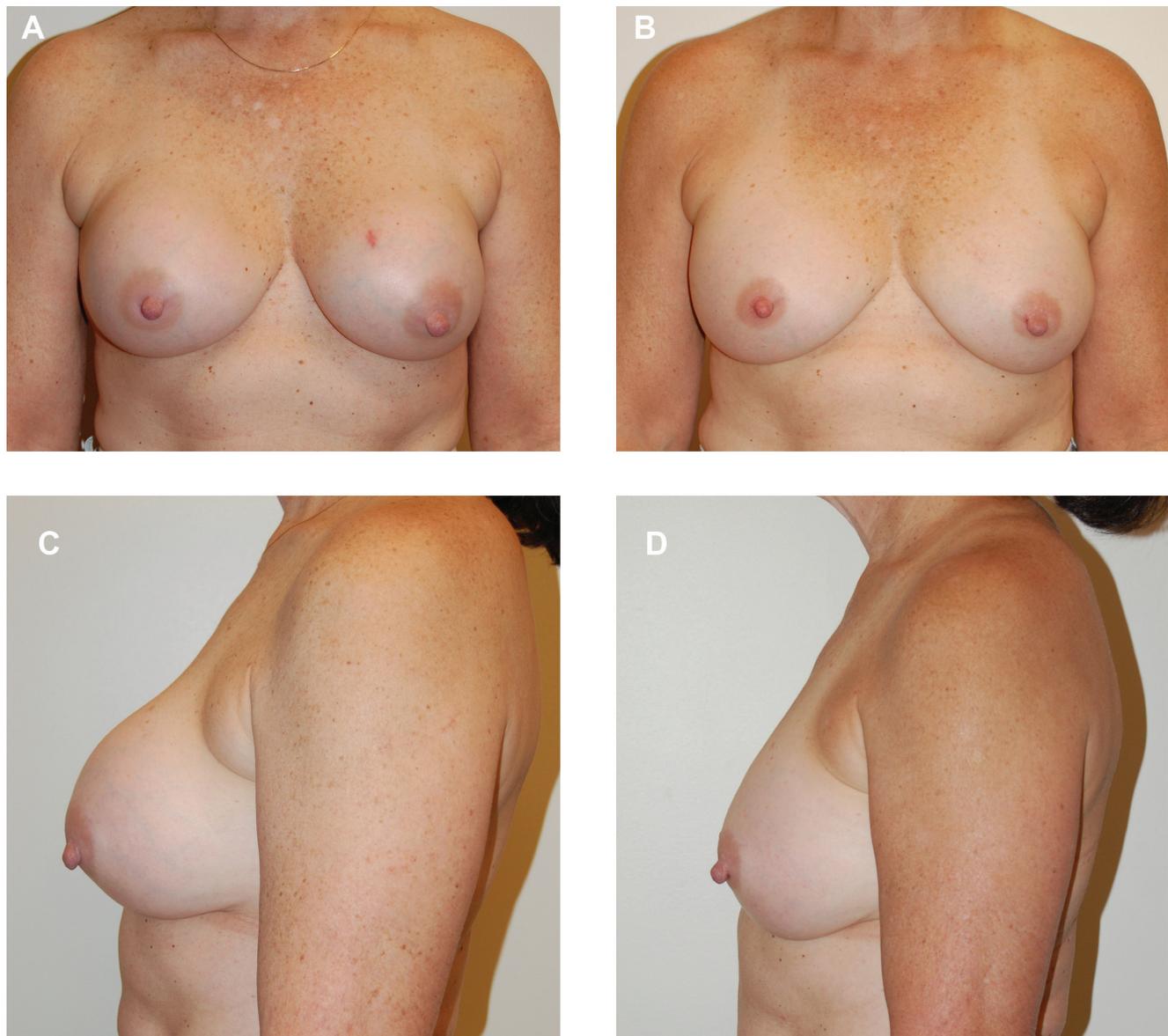
### CLINICAL DATA ON PREVENTION TECHNIQUES FOR CC

Preventing CC from developing in the first place is vastly preferable to attempts at treatment, since the morbidity, emotional toll, and financial costs of this condition can be considerable. A number of reports have documented low rates of CC with techniques that minimize handling of implants, utilize antibiotic irrigation solutions, rely on cautery as opposed to blunt dissection, and involve placement of implants in the submuscular or dual-plane position. A retrospective study of 3002 aesthetic augmentation mammoplasty procedures, performed by 12 surgeons over six years with a minimum of two-year follow-up, recorded a CC rate of 0.5% (Baker Grade III or IV). Interestingly, all CC instances occurred after five postoperative years. Analysis of surgical techniques found that placement of drains increased the risk of capsule formation fourfold and that blunt dissection increased the rate of CC sevenfold.<sup>18</sup>

Over the last decade, antibiotic irrigation solution has become an increasingly standardized regimen for many surgeons. In a prospective study of 335 patients over six years with a mean follow-up of more than three years, implants and breast pockets were bathed in a simple antibiotic irrigation regimen of 50,000 U of bacitracin powder, 1 g of cefazolin, and 80 mg of gentamicin in 500 mL of normal saline. This study showed a rate of pathologic CC in primary breast augmentation patients below 2%. Breast reconstruction patients in this study had a 9.5% rate of Grade III or IV contracture.<sup>19</sup>

### CLINICAL DATA ON TREATMENT MODALITIES FOR CC

Pathologic CC is generally considered to require surgical intervention for treatment. Closed capsulotomy techniques have been largely abandoned secondary to the risk of hematoma, shell rupture with silicone leakage, and high recurrence rates. Reports of capsulectomy, implant exchange, and pocket site change have yielded the best results in recurrence rates. In a study by Spear et al of 85 patients with Grade III or IV contracture over a seven-year period, these interventions yielded a 100% "cure" rate of CC.<sup>20</sup> A complication rate of only 3.5% was recorded;

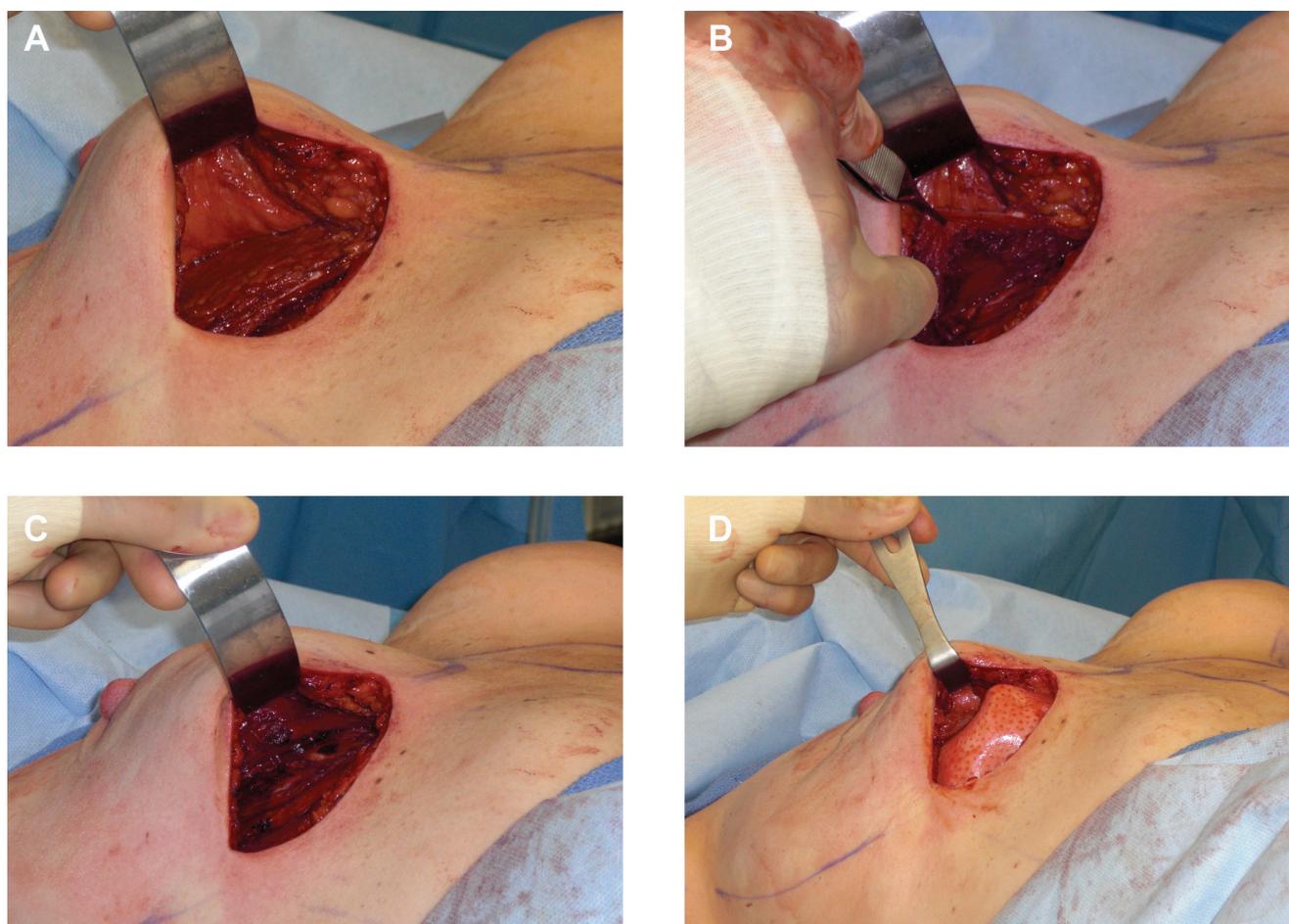


**Figure 1.** (A, C) This 53-year-old woman had undergone bilateral subglandular breast augmentation with silicone implants 23 years before presentation. She sustained left breast trauma during a fall, and an ultrasound was performed confirming extracapsular silicone implant rupture. She complained of progressive pain and left breast distortion and was found to have Baker Grade IV capsular contracture on the left. (B, D) Fourteen months after bilateral explantation and capsulectomy, during which an intact right breast implant and left extracapsular rupture were confirmed. Her procedure included submuscular pocket conversion and placement of 10- × 16-cm sheets of acellular dermal matrix (Strattice; LifeCell Corporation, Branchburg, New Jersey) with new 304-cc silicone implants.

these cases were due to implant malposition in a handful of patients requiring reoperation.

Nonsurgical modalities, including oral administration of leukotriene antagonists such as zafirlukast, have been found to be potentially useful in decreasing the inflammatory process around implants in animal and human models.<sup>21,22</sup> Since

hepatic dysfunction is a rare but serious complication associated with leukotriene antagonists, the risks may outweigh the benefits of this treatment option.<sup>23</sup> Though no peer-reviewed studies have been published to date in the plastic surgery literature on ultrasound technology for the treatment of CC, it has been anecdotally reported for over 30 years.<sup>24</sup>



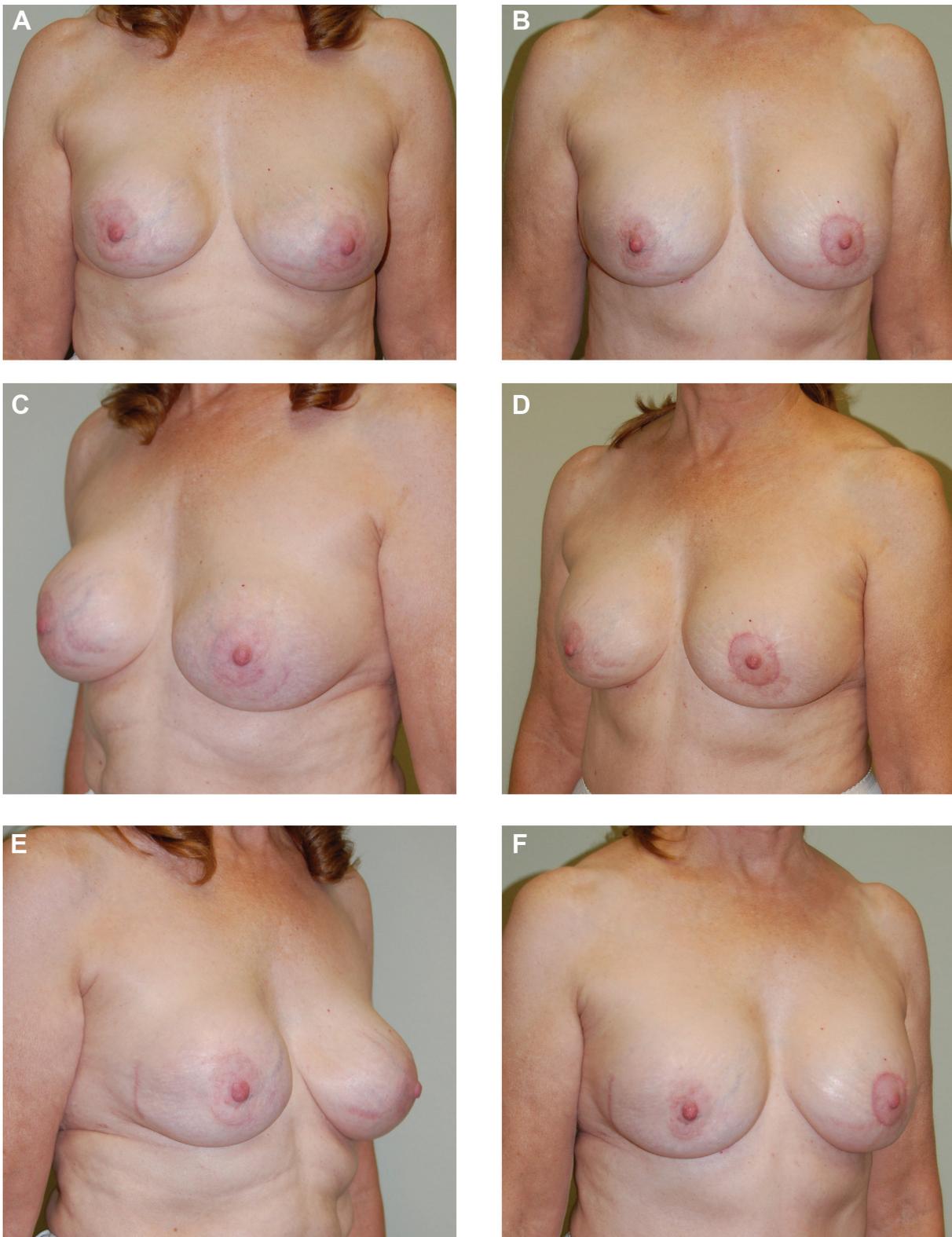
**Figure 2.** The patient in Figure 1 is shown intraoperatively. The patient's implants were converted from a subglandular to a submuscular position, with the addition of an ADM sling to enable the pectoralis major to accept the desired volume. (A) Original subglandular plane. (B, C) The submuscular plane is raised. (D) The ADM sling supports the inferior pole of the new implant in a submuscular position.

### CLINICAL DATA ON ADM BREAST SURGERY

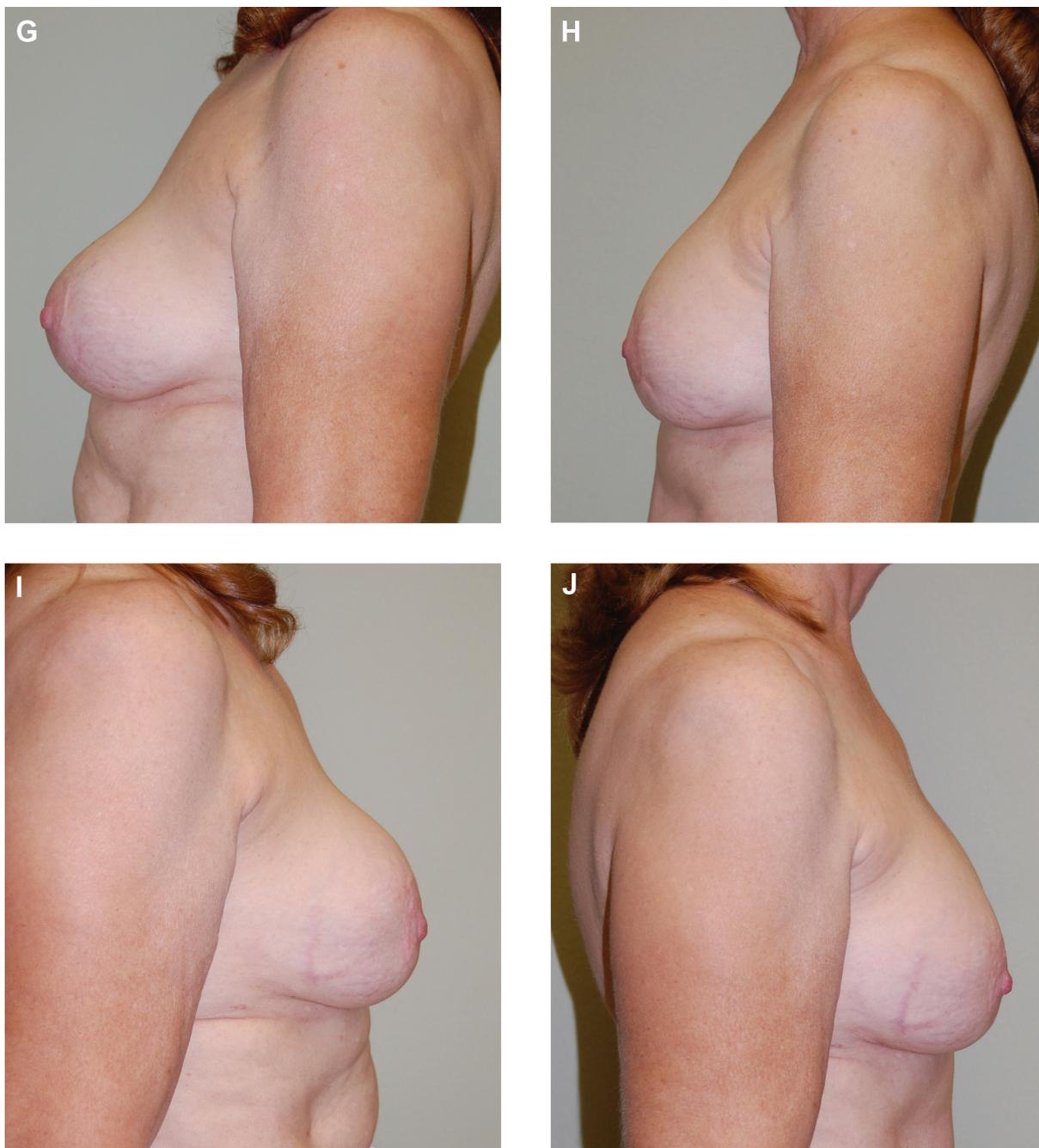
Data available on the prevention and treatment of CC with ADM products have been largely derived from clinical studies yielding low rates of CC with ADM products in revisionary breast surgery and breast reconstruction. However, the enthusiasm for ADM as a preventative modality should be tempered by similarly low reported rates of CC with the other previously-described techniques. Furthermore, when placed during breast reconstruction, high rates of other reported complications, such as seroma formation, postoperative infection, and mastectomy flap skin necrosis, must be considered with ADM products. Though there is a relative dearth of clinical studies examining complication rates with ADM products for aesthetic breast surgery, numerous studies have examined complications associated with ADM products in breast reconstruction. In a study of 283 patients undergoing breast reconstruction over a six-year period by

seven surgeons, the relative risk of major infection with ADM products (8.2%) was found to be 12-fold greater, the risk of seroma formation (14.1%) fourfold greater, and the risk of mastectomy major skin flap necrosis (20.5%) fivefold greater than when a tissue expander or implant was placed without ADM.<sup>25</sup> CC was not an evaluated endpoint in this study. An increased risk of complications with ADM products in breast reconstruction was noted in a study of 153 breast reconstructions; the rate of infection requiring expander removal was 7.2%, and the seroma rate was 7.2%.<sup>26</sup>

A number of smaller clinical studies have documented a near-zero rate of pathologic CC when ADM products have been employed during breast reconstruction.<sup>27-34</sup> It is thought that ADM may serve as a barrier between the implant and the host defense mechanism, limiting the degree of inflammation and scarring. When ADM products are part of revisionary aesthetic breast surgery, a much lower rate of overall complications has been noted in several studies. Mofid and Singh evaluated 10 patients in a



**Figure 3.** (A, C, E, G, I) This 63-year-old woman had undergone subglandular silicone breast augmentation 33 years before presentation. She subsequently developed progressive bilateral Grade IV Baker CC. (B, D, F, H, J) Five months after bilateral capsulectomy, with removal of her ruptured silicone implants, bilateral pocket conversion to the submuscular plane with AlloDerm (LifeCell Corporation, Branchburg, New Jersey) 16- × 20-cm ultrathick acellular dermal matrix (half to each breast), placement of 340-cc silicone implants (Allergan Style 15; Allergan, Inc., Irvine, California), and a left circumareolar mastopexy.



**Figure 3. (continued)** (A, C, E, G, I) This 63-year-old woman had undergone subglandular silicone breast augmentation 33 years before presentation. She subsequently developed progressive bilateral Grade IV Baker CC. (B, D, F, H, J) Five months after bilateral capsulectomy, with removal of her ruptured silicone implants, bilateral pocket conversion to the submuscular plane with AlloDerm (LifeCell Corporation, Branchburg, New Jersey) 16- × 20-cm ultrathick acellular dermal matrix (half to each breast), placement of 340-cc silicone implants (Allergan Style 15; Allergan, Inc., Irvine, California), and a left circumareolar mastopexy.

retrospective study over eight years examining the placement of AlloDerm (human ADM; LifeCell Corporation, Branchburg, New Jersey) for the conversion of subglandular implants into the dual-plane position. No reported

cases of CC, infection, skin flap necrosis, or seroma were noted.<sup>35</sup> It is likely that the improved vascularity of the soft tissue envelope in revisionary breast cases (as compared to mastectomy reconstruction) affords a greater resistance

to infection, seroma formation, and skin flap necrosis. In a much larger study of 78 patients undergoing revisionary aesthetic surgery, Maxwell and Gabriel found no evidence of CC at 12 months.<sup>36</sup>

Two personal clinical examples of patients who underwent breast surgery with ADM materials are shown in Figures 1-3.

## SCIENTIFIC DATA ON ADM AND CAPSULE FORMATION

It is likely that clinical findings associating low CC rates with ADM products are related to the decrease in inflammation and inflammatory mediators secreted by monocytes and macrophages in association with these materials. In an in vitro study performed by Orenstein et al, AlloDerm was found to significantly inhibit IL-1, IL-6, IL-8, and vascular endothelial growth factor when placed in contact with human peripheral blood mononuclear cells.<sup>37</sup> In a rabbit animal model, a statistically significant 50% decrease in myofibroblast cell count and capsule thickness was found at 12 weeks in association with AlloDerm-wrapped silicone implants.<sup>38</sup> In a rat model, AlloDerm was found to diminish radiation-induced capsular formation at 12 weeks.<sup>39</sup> In a primate model at 10 weeks, AlloDerm was found to completely inhibit capsular formation and significantly decrease myofibroblast formation, presumably by serving as a barrier from the host and preventing the initiation of a foreign body reaction.<sup>40</sup> Biopsy studies and histological evaluation of human breast capsules at the time of implant exchange seem to confirm that granulated tissue formation, capsular fibrosis, fibroblast cellularity, and foreign-body giant cell inflammatory reactions are all decreased relative to controls when cadaveric ADM is employed.<sup>41</sup>

## CONCLUSIONS

CC in revisionary and reconstructive breast surgery is a troubling complication. Numerous technique modifications in breast surgery have been reported to result in a substantial decrease in rates of pathologic CC (eg, antibiotic irrigation solutions, submuscular positioning, minimizing the placement of drains, blunt dissection, and limited handling of implants). Though clinical data still have not emerged to demonstrate a definitive benefit to placing ADM products to prevent or treat CC, encouraging laboratory results have been published. At this point, practitioners must weigh the potential benefits of ADM products against the risk of complications that are known to occur when placing ADM during breast surgery.

## Disclosures

Dr. Mofid has served as a paid consultant for LifeCell Corporation (the manufacturer of the products discussed in this article). He is currently a paid consultant and speaker for Synovis Surgical Innovations.

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