

# An 8-Year Experience of Direct-to-Implant Immediate Breast Reconstruction Using Human Acellular Dermal Matrix (AlloDerm)

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**Background:** The advent of skin- and nipple-sparing mastectomy in conjunction with the use of human acellular dermal matrix to provide lower pole coverage has made direct-to-implant immediate breast reconstruction following mastectomy feasible. The purpose of this study was to evaluate long-term complications associated with this technique.

**Methods:** All human acellular dermal matrix–assisted direct-to-implant immediate reconstructions performed over an 8-year period were included in this analysis. Patient charts were reviewed for type of mastectomy (oncologic or prophylactic), incision type, complications during follow-up, length of follow-up, rate and type of revision surgery in breasts without postoperative complications, contralateral procedures, and adjuvant radiotherapy.

**Results:** A total of 466 breasts (260 patients) were reconstructed; 68 percent were prophylactic and 32 percent were oncologic cases. Twenty-one breasts (4.5 percent) received radiotherapy. Mean implant size placed was  $412.8 \pm 24.7$  cc (range, 150 to 600 cc). Mean follow-up was  $28.9 \pm 21.3$  months (range, 0.3 to 97.7 months). The overall complication rate was 3.9 percent (implant loss, 1.3 percent; skin breakdown/necrosis, 1.1 percent; hematoma, 1.1 percent; human acellular dermal matrix exposure, 0.6 percent; capsular contracture, 0.4 percent; and infection, 0.2 percent). Type, incidence, and overall rate of complications did not differ significantly between prophylactic and oncologic breasts. Irradiated breasts had a fourfold higher rate of complications. In 354 breasts with more than 1 year of follow-up (mean,  $36.7 \pm 18.6$  months; range, 12.1 to 97.7 months), there were no long-term complications.

**Conclusions:** Human acellular dermal matrix–assisted direct-to-implant breast reconstruction following mastectomy is safe and reliable, with a low overall long-term complication rate. The low incidence of capsular contracture supports the growing body of evidence that human acellular dermal matrix mitigates capsular contracture. (*Plast. Reconstr. Surg.* 127: 1, 2011.)

Over the past decade, immediate implant reconstruction has become an accepted approach for the management of patients with breast cancer; on average, 15 to 20 percent of breast reconstructions annually were performed with this technique.<sup>1–4</sup> The feasibility of this approach is largely attributable to the preservation of the native skin envelope by means of skin-sparing or nipple-sparing mastectomy, which is usually sufficient to cover an implant during an immediate

reconstruction. As it is not judicious to cover the implant with subcutaneous tissue alone, the implant is often placed subpectorally with serratus anterior muscle elevated for total muscle coverage or in a dual-plane with the mastectomy flap covering the lower pole of the breast. The latter, however, often results in inadequate pectoralis major muscle coverage of the implant at the inferolateral border. This, in turn, may re-

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sult in a higher risk of exposure, thinness of skin, and loss of control of the inframammary fold. Several approaches have been used to provide alternate soft-tissue coverage of the implant at the lower pole, including recruiting the serratus anterior, rectus abdominis sheath, obliques major, and pectoralis minor<sup>5</sup>; recruiting deepithelialized skin<sup>6</sup>; recruiting the rectus abdominis fascia and the external oblique fascia<sup>7</sup>; and, more recently, using human acellular dermal matrix (AlloDerm; LifeCell Corp., Branchburg, N.J.)<sup>8-13</sup> and polyglycolic mesh.<sup>14</sup>

In 2001, the first use of human acellular dermal matrix for breast surgery was performed by the lead author (C.A.S.) in immediate breast reconstruction. In 2006, we reported our initial experience of successfully using human acellular dermal matrix to provide lower pole coverage of the implant during immediate implant reconstruction postmastectomy in 49 patients (76 breasts).<sup>9</sup> Durable breast reconstruction with good symmetry and a low complication rate (5.2 percent) was demonstrated with the use of human acellular dermal matrix. Complications included one instance of fold thickening at the suture line between the human acellular dermal matrix and the pectoralis major muscle, two instances of superficial skin epidermolysis of the mastectomy flaps over the human acellular dermal matrix, and one instance of full-thickness skin flap necrosis with resultant exposure of the human acellular dermal matrix. All complications were resolved without further consequences. There were no instances of capsular contracture during an average follow-up period of 18 months (range, 3 to 52 months).<sup>9</sup> Since our initial report, there have been three reports with the use of human acellular dermal matrix in immediate implant reconstruction, testifying to the safety and good outcomes with this technique.<sup>11-13</sup> However, the mean follow-up period was relatively short (<2 years) and patient population size was small in these studies, including our 2006 study (Table 1). As with any new technique, to ascertain the benefit of human acellular dermal matrix in immediate implant reconstruction, extensive experience and long-term

safety data are needed. The purpose of this study was to review our 8-year experience with using human acellular dermal matrix in immediate implant reconstruction in 260 patients, representing 466 reconstructions, and to evaluate the long-term complications associated with this technique.

### PATIENTS AND METHODS

All patients who chose an implant-based reconstruction, between December of 2001 and January of 2010 in the authors' practice, were offered the direct-to-implant option, even if postoperative irradiation was anticipated. The decision to perform human acellular dermal matrix–assisted implant reconstruction was made preoperatively, before mastectomy, during patient evaluation based on mastectomy type (skin-sparing or nipple-sparing). The decision was confirmed intraoperatively in patients who had adequate skin envelope (quantity and quality) (Fig. 1). In patients who had received prior radiotherapy, the quality of the skin and muscle envelope was assessed; if the quality was poor, a flap procedure was recommended. Only patients who underwent human acellular dermal matrix–assisted immediate implant reconstruction were included in this retrospective follow-up analysis. Patients who underwent delayed reconstructions, immediate two-staged tissue expander/implant reconstructions, reconstructions with Becker expandable implants, and flap procedures were excluded from the analysis.

The surgical technique of human acellular dermal matrix–assisted immediate breast reconstruction with implants has been described previously.<sup>9</sup> Briefly, after mastectomy, with either a nipple-removing incision or inframammary approach, a retropectoral pocket is created that extends from the lateral border of the pectoralis major muscle to the second rib superiorly, to the sternum medially, and to the level of the contralateral inframammary fold inferiorly. An implant, with size and type (silicone or saline) according to patient preference, is then inserted into the newly created retropectoral pocket, and the overlying pectoralis major muscle is brought over to cover the superior portion of the implant.

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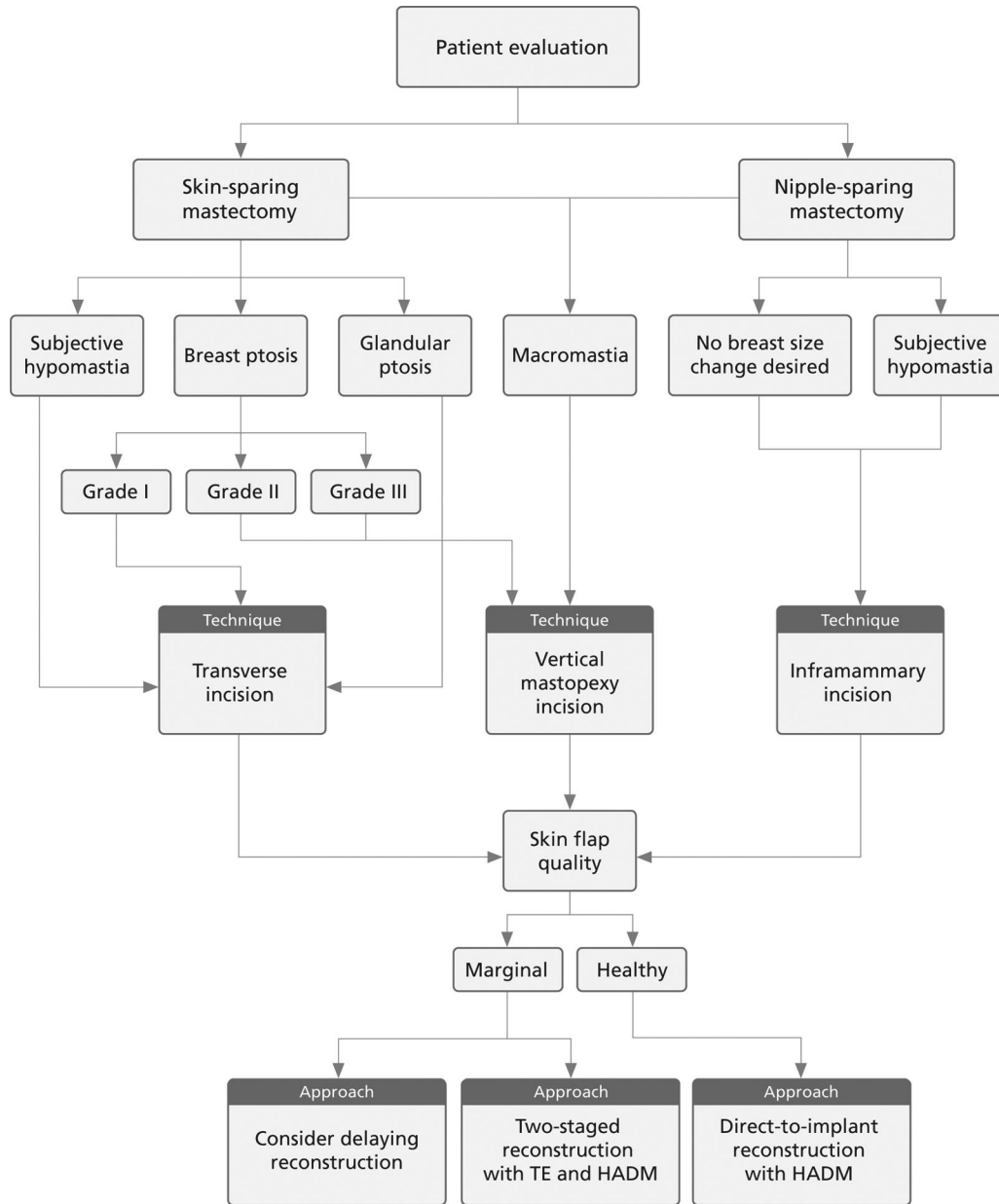
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**Table 1. Published Series of Immediate Implant Reconstruction with Human Acellular Dermal Matrix Support**

Study	No. of Patients	No. of Reconstructions	Mean Follow-Up (Months) (Range)
Salzberg, 2006 <sup>9</sup>	49	76	18 (3–52)
Breuing and Colwell, 2007 <sup>11</sup>	30	54	19.4 (not reported)
Zienowicz and Karacaoglu, 2007 <sup>12</sup>	24	30	18 (15–24)
Topol et al., 2008 <sup>13</sup>	23	35	9.5 (1–24)



**Fig. 1.** Clinical decision making in direct-to-implant breast reconstruction with human acellular dermal matrix (HADM). TE, tissue expander.

Adequate lateral coverage is usually not attained, requiring coverage with an appropriate size sheet of rehydrated human acellular dermal matrix. Through separate stab incisions, two suction drains are positioned, one in the retropectoral and the other in the subcutaneous spaces. The human acellular dermal matrix is secured to the elevated lateral border of the pectoralis major muscle, to the serratus fascia laterally without muscle elevation, and to the inframammary fold inferiorly. Skin incision closure is then performed, completing the reconstruction.

Patient charts were reviewed for type of mastectomy (oncologic or prophylactic), incision type, complications during follow-up, length of follow-up, rate and type of revision surgery in breasts that had no postoperative complications, contralateral procedures, and adjuvant radiotherapy. The rates of complications were compared between oncologic and prophylactic patients. Patients with Baker grade 1 or 2 capsules were defined as free of contracture, whereas patients with Baker grade 3 or 4 capsules were considered to have significant contracture. All postoperative

evaluations were performed independently by three physicians (C.A.S., A.Y.A., and E.C.-T.).

Categorical data are presented as percentages and continuous data are presented as mean ± SD. Statistical comparisons were performed using Fisher’s exact test for categorical data and the *t* test continuous data; all tests were two-sided. Results were considered to be statistically significant for values of *p* < 0.05.

**RESULTS**

A total of 260 patients (466 breasts) underwent human acellular dermal matrix–assisted immediate implant reconstruction during the 8-year study period. Approximately 68 percent of the mastectomies were prophylactic (318 of 466) and 32 percent were oncologic (148 of 466). Twenty patients [21 breasts (4.5 percent)] received adjuvant radiotherapy; 11 breasts were irradiated before reconstruction and 10 breasts were irradiated after reconstruction. The mean implant size placed was 412.8 ± 24.7 cc (range, 150 to 600 cc).

Patients were followed for an average of 28.9 ± 21.3 months (range, 0.3 to 97.7 months) from the time of surgery. During this period, 18 breasts had complications, for an overall complication rate of 3.9 percent (Table 2). Implant loss was the most frequent complication in this series, occurring in five patients [six breasts (1.3 percent)], followed by skin breakdown/necrosis [five breasts (1.1 percent)], hematoma [five breasts (1.1 percent)], and human acellular dermal matrix exposure [three breasts (0.6 percent)]. Four of the implants lost were secondary to skin breakdown/necrosis, one was secondary to infection, and one was caused by cancer recurrence along the mastectomy scar. Treatment of the infected breast entailed implant removal, pocket irrigation with antibiotic solution, and implant replacement

followed by intravenous antibiotic administration to the patient. All cases of hematoma were resolved by surgical drainage without further sequelae. One patient with bilateral hematoma had a history of factor deficiency. There were three cases of human acellular dermal matrix exposure in this series caused by skin necrosis. The exposed human acellular dermal matrix was closed over without further consequences. There were two instances of Baker grade 3/4 capsular contracture (0.4 percent), one in a prophylactic and the other in an oncologic breast; both occurred during the first year of follow-up. In both cases, corrective surgery involving a capsulectomy followed by implant removal and replacement was performed. At 21 months and 31 months after corrective surgery, both patients remain contracture free. Of note, all complications in the 18 breasts occurred within the first 12 months of reconstruction and were thus early complications. There were no long-term or late complications beyond 1-year of follow-up. A total of 197 patients (354 breasts) had a minimum of 1-year follow-up (mean, 36.7 ± 18.6 months; range, 12.1 to 97.7 months).

A comparison of complications in oncologic breasts and prophylactic breasts indicated no significant differences in the type, incidence, or overall rate of complications (Table 2), although there were two times more complications in oncologic breasts. The most frequent complications were implant loss<sup>4</sup> and skin breakdown<sup>3</sup> in oncologic breasts, whereas hematomas<sup>4</sup> were the most frequent complications in prophylactic breasts (Table 2).

Of the 21 oncologic breasts that were irradiated, three had complications, for an overall complication rate of 14.3 percent in irradiated breasts. The complications included skin breakdown in two breasts, with implant loss in one and implant

T2

**Table 2. Complications during the Follow-Up Period**

	Total No. of Breasts (%)	No. of Oncologic Breasts (%)	No. of Prophylactic Breasts (%)
No.	466	148	318
Complications (total)*	18 (3.9)	9 (6.1)	9 (2.8)
Implant loss/explanted	6 (1.3)	4 (2.7)	2 (0.6)
Skin breakdown or necrosis	5 (1.1)	3 (2.0)	2 (0.6) (unilateral)
Hematoma	5 (1.1)	1 (0.7)	4 (1.3)
HADM exposure	3 (0.6)	1 (0.7)	2 (0.6)
Capsular contracture (Baker grade 3/4)	2 (0.4)	1 (0.7)	1 (0.3)
Infection (requiring intravenous antibiotics)	1 (0.2)	1 (0.7)	0
Implant exposure	1 (0.2)	1 (0.7)	0
Implant malposition	1 (0.2)	1 (0.7)	0

HADM, human acellular dermal matrix.

\*Breasts with more than one complication were counted once.

T3

malposition in one breast, without evidence of capsular contracture (Table 3).

F2-4

The postoperative course was uneventful in 244 patients (93.8 percent), representing 448 breasts (96.1 percent). The outcome of three representative patients is shown in Figures 2 through 4. Of patients without postoperative complications, 37 (15.2 percent) underwent elective revision surgery that were performed in 42 breasts (9.4 percent). The most frequent reason for revision surgery was implant exchange for larger sizes (34 of 42 breasts) (Table 4). In addition, five patients (five breasts) underwent contralateral breast augmentation. Of note, there was no evidence of breast cancer occurrence in any patient who had undergone a prophylactic nipple-sparing mastectomy.

T4

### DISCUSSION

This study is a follow-up to our initial experience and includes 260 patients (466 reconstructions), representing the largest series of patients who had undergone immediate human acellular dermal matrix–assisted implant reconstruction following mastectomy. Furthermore, this series includes patients who were followed for a maximum of 97.7 months (average, 28.9 months), the longest reported to date. The overall complication rate in the present study was 3.9 percent, which is lower than the rate reported in short-term follow-up (average, 10 to 20 months) studies of human acellular dermal matrix–assisted immediate implant reconstructions (5.2 to 11 percent).<sup>9,11–13</sup> Our result confirms that the use of human acellular dermal matrix in immediate implant reconstruction is a safe procedure with low complication rates. Furthermore, in a cohort of our patients followed for more than 1 year (average, 36.7 months), there were no late complications, a finding that attests to the long-term safety of this procedure.

A drawback of immediate reconstruction is the risk of skin necrosis and associated implant loss. Skin necrosis is, in fact, considered the main complication of skin-sparing mastectomy, because the resection of a maximum of glandu-

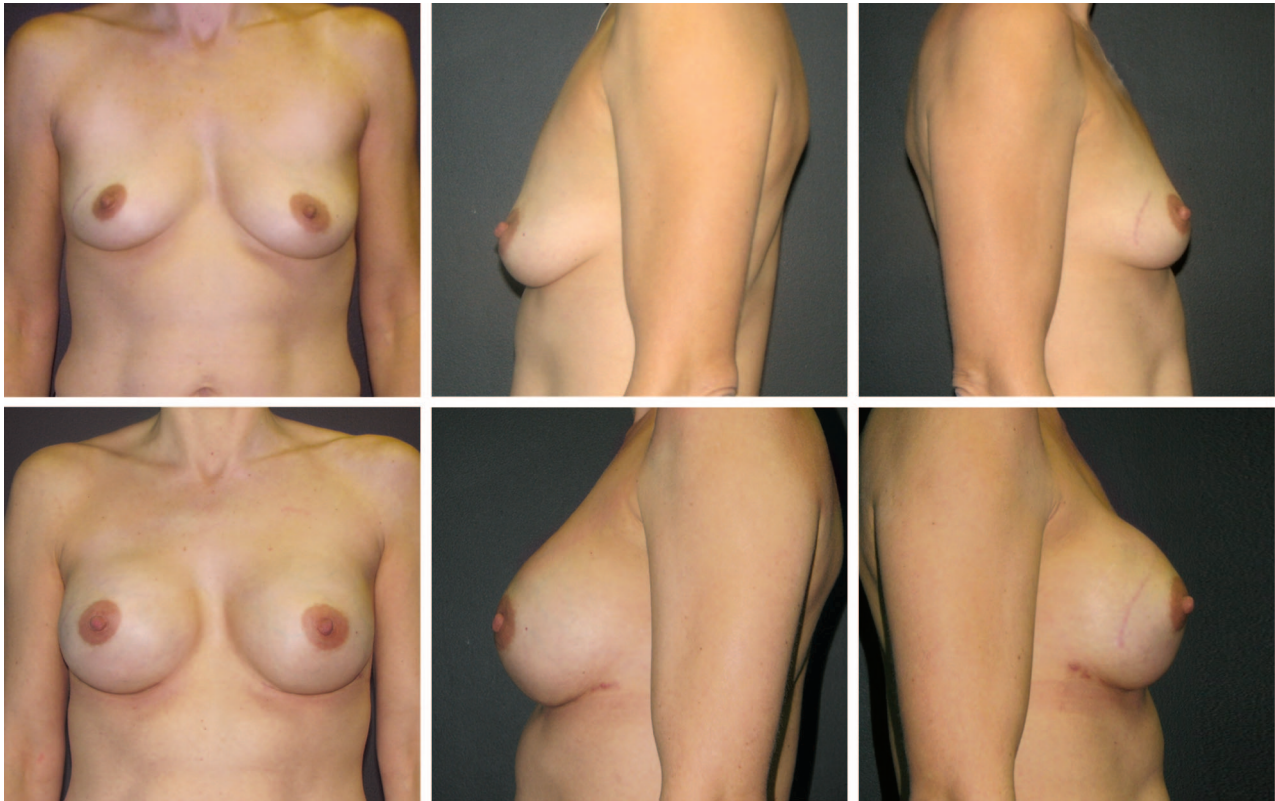
lar tissue inevitably leaves an extremely thin skin envelope. Skin flap ischemia, ranging from epidermolysis to full-thickness flap necrosis, has been reported in 5 to 27 percent of patients undergoing conventional immediate implant-based reconstruction (i.e., without human acellular dermal matrix support).<sup>15–18</sup> Skin necrosis may subsequently lead to muscle or implant exposure, which in turn may lead to implant loss. The rate of implant loss in patients undergoing conventional immediate implant-based reconstruction has been reported to range from 5 to 11 percent (including implant loss caused by dehiscence, infection, capsular contracture, and skin necrosis).<sup>15,16,18–20</sup> Compared with the rates of skin necrosis and implant loss associated with conventional immediate implant reconstruction, our rates are much lower (<1.5 percent). Even in oncologic breasts, where there is a greater tendency for the skin to be compromised, our rates of skin necrosis and implant loss were less than 3.0 percent. By providing an additional soft-tissue layer at the breast lower pole, human acellular dermal matrix cushions and supports the breast implant, reinforcing the overlying skin. Consequently, the use of human acellular dermal matrix may help to minimize the rate of skin breakdown and implant loss, considered to be the main pitfall of immediate implant reconstructions.

Although there is growing appreciation of the benefits of using human acellular dermal matrix in implant-based reconstructions, two questions remain with the use of this tissue matrix—its ability to resist infection and its ability to confer any protection against the effects of radiotherapy. As human acellular dermal matrix recellularizes, revascularizes, and fully incorporates within the host tissue following implantation, it has the potential to overcome an infectious insult.<sup>21</sup> Nonetheless, it takes time for human acellular dermal matrix to recellularize and revascularize, providing a window whereby infections can establish.<sup>7</sup> Moreover, human acellular dermal matrix is classified as aseptic rather than sterile, raising concerns about the potential for infections. Most published series

**Table 3. Complications in Irradiated Breasts**

	Total Irradiated Breasts (%)	Irradiation before Reconstruction (%)	Irradiation after Reconstruction (%)
No.	21	11	10
Complications (total)*	3 (14.3)	1 (9.1)	2 (20.0)
Skin breakdown	2 (9.5)	0	2 (20.0)
Implant loss	1 (4.8)	0	1 (10.0)
Implant malposition	1 (4.8)	1 (9.1)	0

\*Breasts with more than one complication were counted once.



**Fig. 2.** Bilateral human acellular dermis–assisted breast reconstruction after nipple-sparing prophylactic mastectomy in a 38-year-old, *BRCA*-positive woman with prior biopsy. Preoperative views (*above*) and postoperative views at 6 months after breast reconstruction (*below*).

of implant-based reconstructions, however, have reported a low infection rate of 3 to 8 percent with the use of human acellular dermal matrix.<sup>9–11,20–24</sup> In addition, retrospective studies that have compared infection rates in implant-based reconstructions with or without human acellular dermal matrix support have also reported no difference in the infection rate between the two groups (2.2 percent versus 2.2 percent<sup>23</sup>; 8.0 percent versus 6.0 percent<sup>20</sup>; and 5.85 percent versus 5.0 percent,<sup>21</sup> respectively). Moreover, one of these studies reported that infections in human acellular dermal matrix–assisted reconstructions did not appear to be related to the human acellular dermal matrix, and the human acellular dermal matrix remained viable in this setting.<sup>21</sup> In contrast to these studies, two recent studies by Chun et al. and Lanier et al. have reported an increased rate of infections with human acellular dermal matrix–assisted implant-based reconstructions compared with those without human acellular dermal matrix support (8.9 percent versus 2.1 percent<sup>17</sup> and 28.9 percent versus 12.0 percent,<sup>18</sup> respectively). However, in the study by Chun et al., when native breast skin flap necrosis was eliminated as a potential contributing

variable for postoperative infection, the difference in infection rates was no longer statistically significant.<sup>17</sup> In the study by Lanier et al., which included other acellular dermal matrices (in 13 percent of cases), the increase in infection rate with acellular dermal matrix was found to be associated with breast sizes larger than 600 g but not with breast sizes smaller than 600 g,<sup>18</sup> underscoring the importance of appropriate patient selection for human acellular dermal matrix–assisted breast reconstruction. In our present study, there was only one incidence of infection, for an overall infection rate of 0.2 percent.

Implant-based reconstruction in the setting of adjuvant radiotherapy is associated with high complication rates—40 percent, with an extrusion rate of 15 percent—even with the latest prosthetic materials and modern radiation delivery techniques.<sup>25</sup> In animal studies, human acellular dermal matrix viability did not seem to be adversely affected by radiotherapy.<sup>26,27</sup> Whether clinically this translates into lower complications has yet to be established, although results from a small case series of five patients indicated an absence of capsular contracture and



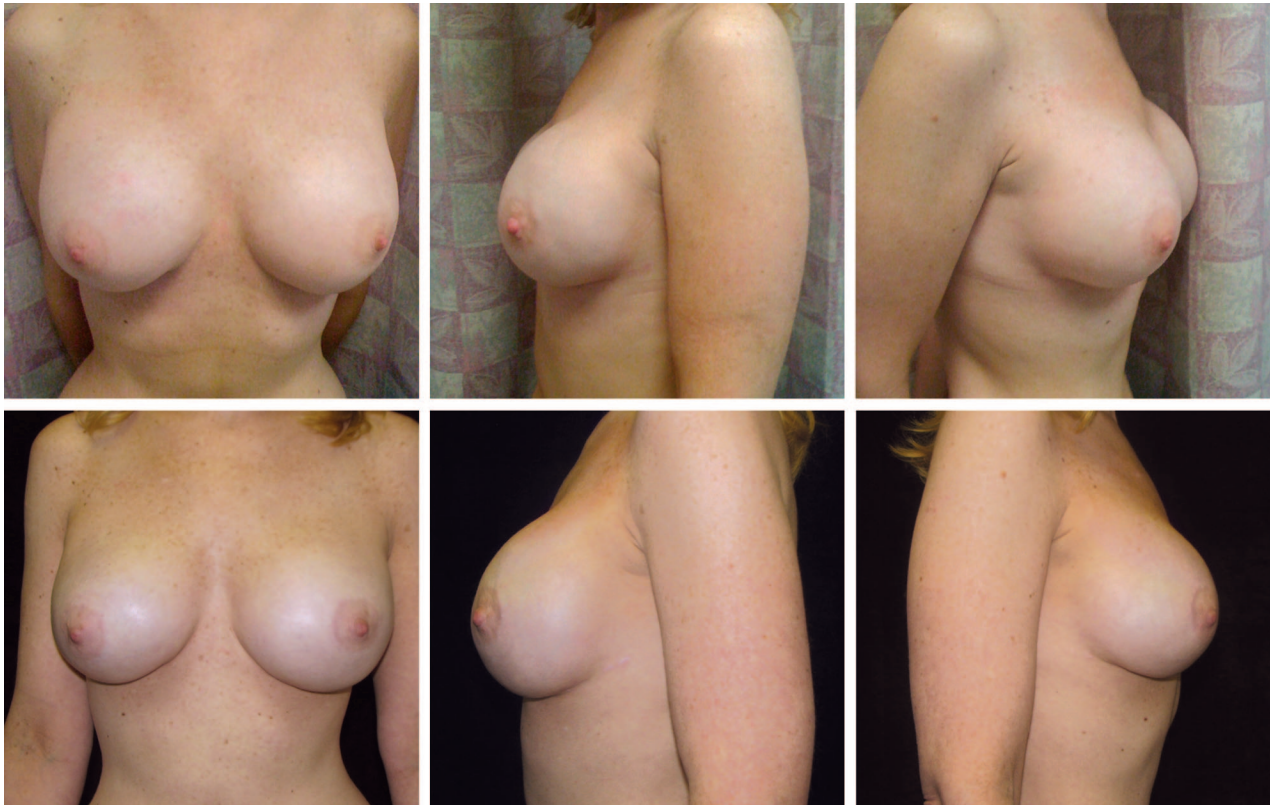
**Fig. 3.** Bilateral human acellular dermis–assisted breast reconstruction after right nipple–areola complex–sparing mastectomy and left total mastectomy in a 42-year-old woman with left breast cancer. Preoperative views (*above*) and postoperative views at 6 weeks after breast reconstruction (*below*).

implant loss in irradiated breasts, with no histologic differences in human acellular dermal matrix biopsied from tissue expander/human acellular dermal matrix capsule taken from an irradiated and a nonirradiated breast.<sup>28</sup> Studies that compared complications in irradiated and nonirradiated breasts, however, have indicated a higher rate of complications in irradiated versus nonirradiated breasts. Spear et al. observed an 11-fold higher rate of total complications in irradiated versus nonirradiated breasts (45.5 percent versus 4.3 percent) after stage I human acellular dermal matrix–assisted tissue expander/implant reconstruction.<sup>29</sup> In our series, we noted a fourfold higher rate of complications in irradiated versus nonirradiated breasts. Nahabedian reported a higher incidence of infection (8.7 percent versus 3.9 percent), incisional dehiscence (13.0 percent versus 1.3 percent), and seroma (13.0 percent versus 2.6 percent) in human acellular dermal matrix–assisted implant-based irradiated versus nonirradiated breasts.<sup>21</sup> In all three studies, irradiated breasts constituted a small fraction of the total sample (<25). Further studies are needed to de-

cipher the potential benefits of human acellular dermal matrix in the setting of radiotherapy.

Capsular contracture is a common middle- to long-term complication associated with implant-based breast reconstructions. The risk of capsular contracture (Baker grade 3 or 4) after conventional implant reconstruction following mastectomy may increase with time and is on the order of 12 percent at 1 year and 30 percent at 5 years.<sup>30</sup> A capsular contracture rate of 13.7 percent was reported in the Mentor Core Clinical Study in reconstructive patients followed over a 6-year period,<sup>31</sup> whereas that reported by Allergan in their Core Clinical Study was 14.1 percent over a 4-year period.<sup>32</sup> Other published series have reported capsular contracture rates of 10 to 17 percent over a 3-year period.<sup>33,34</sup> In contrast, published series of human acellular dermal matrix–assisted implant-based breast reconstructions have reported a very low capsular contracture rate of 2 percent<sup>29</sup> or 0 percent<sup>9,11,12,24,35</sup> during a mean follow-up period of less than 2 years (Table 5). In our 8-year experience, we encountered only two instances of capsular contracture (0.4 percent),

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**Fig. 4.** Bilateral human acellular dermis–assisted breast reconstruction after nipple-sparing prophylactic mastectomy in a 36-year-old woman. Preoperative views (*above*) and postoperative views at 2 years after breast reconstruction (*below*).

**Table 4. Revisions in Breasts without Postoperative Complications**

Type of Revision	No. of Breasts (%)
Total	448
Implant exchange for size increase	34 (7.6)
Reduction for optimizing symmetry	1 (0.2)
IMF tacking for IMF deformity revision	2 (0.4)
Scar revision	2 (0.4)
Correction of implant malposition (asymmetry)	3 (0.7)
Total	42 (9.4)

IMF, inframammary fold.

both of which occurred during the first year after reconstruction. The low capsular contracture rate observed in human acellular dermal matrix–assisted implant-based reconstructions is remarkable. Collectively, these results lend support to the growing notion that the use of human acellular dermal matrix helps to minimize the risk of capsular contracture. Indeed, a histopathologic study showed decreased inflammatory response and subsequent decreased foreign body capsule formation in biopsy specimens taken from human acellular dermal matrix used

in breast reconstruction compared with biopsy specimens taken from native subpectoral capsules.<sup>36</sup> Furthermore, in animal models, human acellular dermal matrix has been shown to minimize capsule formation around implants.<sup>37,38</sup> Prospective studies, evaluating the rate of capsular contracture as an endpoint, are needed to confirm the observed reduced rate of capsular contracture in human acellular dermal matrix–assisted breast reconstructions.

Proponents of a two-staged tissue expander/implant reconstruction cite the possibility of performing revision surgery at the second stage, which would otherwise have to be performed as an additional operation in single-stage implant reconstructions. Nonetheless, two-stage procedures are still reported to be associated with revision rates of 10 percent after the second stage,<sup>39</sup> which is comparable to the revision rate of 9.4 percent observed in our series in breasts that did not have any postoperative complications.

Although low complication rates are achievable with human acellular dermal matrix–assisted immediate implant reconstruction, patient selection is an important factor. In our experience,

**Table 5. Capsular Contracture Rate in Published Series of Immediate Implant-Based Reconstruction with Human Acellular Dermal Matrix Support**

Study	No. of Patients	No. of Reconstructions	Mean Follow-Up (Months) (Range)	Capsular Contracture (%)
Salzberg, 2006 <sup>9</sup>	49	76	18 (3–52)	0
Breuing and Colwell, 2007 <sup>11</sup>	30	54	19.4 (not reported)	0
Zienowicz and Karacaoglu, 2007 <sup>12</sup>	24	30	18 (15–24)	0
Bindingavele et al., 2007 <sup>35</sup>	41	65	10 (7–21)	0
Spear et al., 2008 <sup>29</sup>	43	58	18.1 (6.7–31.6)	2 (grade 3)
Namnoum, 2009 <sup>24</sup>	20	29	21 (3–32)	0 (>grade 2)

human acellular dermal matrix–assisted immediate implant reconstruction is appropriate in patients who have adequate skin envelope in the postmastectomy setting. This procedure may be used both as an immediate intervention and as a delayed procedure with adequate skin tissue. All breast sizes, including large implant sizes of up to 650 cc and skin reduction pattern techniques are amenable to this procedure. Prior or planned future irradiation is not a contraindication, as demonstrated. Nonetheless, tissue expander/implant reconstructions still have a place in immediate reconstructions. In instances where the quality of the preserved skin envelope appears compromised, tissue expansion may be necessary to minimize the risk of skin necrosis. Tissue expansion using the same technique with human acellular dermal matrix could be substituted in these situations.

The surgical technique of inserting and suturing human acellular dermal matrix is not difficult to perform, nor does it augment operative time. On average, it takes approximately 2.5 to 3.0 hours to complete a human acellular dermal matrix–assisted bilateral reconstruction (inclusive of mastectomy), which is comparable to reconstruction without human acellular dermal matrix support. In fact, the use of human acellular dermal matrix may render the operation technically easier, as it obviates the need to recruit autologous muscle or tissue for lower pole coverage of the implant and may also consequently result in less postoperative pain.

Although the initial cost of human acellular dermal matrix (approximately \$36/cm<sup>2</sup>) may deter surgeons and patients alike from incorporating human acellular dermal matrix into their reconstructive options, the better aesthetic outcome and fewer complications (including a reduced risk of capsular contracture) associated with human acellular dermal matrix use may prove to be cost-effective in the long run. In our series, 96.1 percent of reconstructions had no postoperative complications. Furthermore, by avoiding a second exchange procedure (i.e., the second stage of a

tissue expander/implant reconstruction), the human acellular dermal matrix–assisted direct-to-implant procedure is also likely to contribute to an overall reduction in the cost of surgery.

The limitations of this study include its retrospective design and unblinded clinical evaluations of patients that were performed by the study authors. A prospective study comparing human acellular dermal matrix–assisted immediate implant reconstruction with the traditional approach using independent, blinded surgeons for the evaluation of complications is warranted to confirm the results of the present study.

## CONCLUSIONS

In this series of 260 patients (466 reconstructions) followed for a period of up to 8 years, we have shown that immediate human acellular dermal matrix–assisted implant reconstruction is a safe procedure and is associated with a low overall complication rate of 3.9 percent. Infection, skin necrosis, implant loss, hematoma, and capsular contracture all occurred at a rate of less than 1.5 percent. The low incidence of capsular contracture provides further support to the growing body of evidence that human acellular dermal matrix mitigates capsular contracture. Human acellular dermal matrix has also proven to have created a paradigm shift for cosmesis, as improved aesthetic outcomes is becoming the standard for breast reconstruction. As breast reconstruction techniques continue to improve, the ultimate goal of providing the postmastectomy patient with optimal results, in terms of both aesthetics and safety, appears to be a reachable goal.

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AQ: 4

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## AUTHOR QUERIES

### AUTHOR PLEASE ANSWER ALL QUERIES

1

AQ1: AUTHOR—Initials “C.A.S.” correct for “lead author”? If not, please supply the correct initials.

AQ2: AUTHOR—Sentence that begins “An implant”: Correct as edited? If not, please revise as needed.

AQ3: AUTHOR—Sentence that begins “In contrast”: the word “none” was edited to read “0 percent.” Correct as edited? If not, please revise as needed.

AQ4: AUTHOR—Ref. 28: Page number correct as edited, per listing on PubMed (PMID 19526050)? If not, please revise as needed.

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