

AlloDerm Performance in the Setting of Prosthetic Breast Surgery, Infection, and Irradiation

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Background: The performance of AlloDerm (LifeCell Corp., Branchburg, N.J.) in the setting of prosthetic breast reconstruction, infection, and radiation therapy has not been well documented. The purpose of this study was to review the author's experience with AlloDerm-assisted prosthetic breast surgery and determine the tolerance in the setting of infection and irradiation.

Methods: A total of 361 women and 476 breasts underwent reconstruction or revision with prosthetic devices. Of these, 76 women and 100 breasts underwent reconstruction using AlloDerm assistance.

Results: The incidence of postoperative infection was 5.85 percent (22 of 376) when prosthetic devices were used without AlloDerm and 5 percent (five of 100) when prosthetic devices were used with AlloDerm. Radiation therapy was a factor in 23 of 100 breasts reconstructed with AlloDerm. Adherence of AlloDerm was noted in 100 percent (23 of 23) and infection was noted in 8.7 percent (two of 23). The timing of irradiation (before or after AlloDerm insertion) did not affect the adherence or the infection rate. The overall incidence of seroma was 5 percent, the incidence of skin necrosis was 3 percent, and the incidence of incisional dehiscence was 4 percent.

Conclusions: This study demonstrates that prosthetic breast surgery using AlloDerm is safe and well-tolerated. AlloDerm viability has been demonstrated in the setting of infection and radiation therapy. The risk of prosthetic breast infection in the setting with AlloDerm is no different from in the setting without AlloDerm. Local complications such as dehiscence, skin necrosis, and seroma formation can occur in accordance with radiotherapy. (*Plast. Reconstr. Surg.* 124: 1743, 2009.)

Infection following breast reconstruction with tissue expanders and implants remains a concern, with a reported incidence that ranges from 1 to 6 percent.^{1,2} This incidence has remained relatively constant over the years. Numerous factors that may predispose to prosthetic infection such as diabetes mellitus, advanced age, tobacco use, chemotherapy, and lymph node dissection have been studied, but the only one that has demonstrated a significant association is radiation therapy.¹ Previous studies have demonstrated an increased complication rate in the setting of prosthetic breast reconstruction and radiation therapy.^{3,4} This is most likely attributable

to the decreased vascularity of the surrounding soft tissues in the setting of a prosthetic device, creating a milieu that is more susceptible to infection.

Over the past 5 years, the use of acellular dermal matrices to assist with prosthetic breast recon-

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struction has gained increased acceptance and popularity.⁵⁻¹² The most commonly used acellular dermal matrix is AlloDerm (LifeCell Corp., Branchburg, N.J.). The benefits of AlloDerm in the setting of prosthetic breast reconstruction are becoming better understood and appreciated; however, questions about infection and its ability to tolerate radiation remain. This stems in part from its aseptic classification and its mechanism of action regarding revascularization, recellularization, and tissue integration in both the irradiated and the nonirradiated host. Several studies have reported the incidence of infection as an independent variable, with an incidence that ranges from 0 to 8.3 percent, but none has studied infection as an isolated variable⁵⁻¹⁰ (Table 1).

The purpose of this study is severalfold. The first is to provide an update regarding infectious complications following prosthetic breast reconstruction. The second is to compare the infection rate in women who had AlloDerm-assisted prosthetic breast surgery to those who did not have AlloDerm-assisted prosthetic breast surgery. The third is to evaluate the performance of AlloDerm in the setting prosthetic breast reconstruction and no radiation therapy, preoperative radiation therapy, and postoperative radiation therapy. Pertinent questions include whether AlloDerm predisposes to infection; how AlloDerm behaves in the setting of superficial or deep space infection; whether AlloDerm and radiation therapy is associated with increased infection, delayed healing, or seroma formation; and finally whether AlloDerm adherence depends on the timing of radiation therapy with regard to the reconstruction.

PATIENTS AND METHODS

Between July of 1997 and September of 2008, a total of 361 women underwent completion of the process of breast reconstruction using prosthetic devices. Completion, for the purposes of this study, is defined as removal of a tissue expander and insertion of a permanent implant and completion of adjuvant therapies (i.e., chemotherapy

and radiation therapy) when delivered. Of these, 115 women had bilateral reconstruction, making the total number of breasts reconstructed 476. The mean age of these women was 48.2 years (range, 17 to 77 years).

Within the group of 361 women are two subsets. The first includes a group of women that had prosthetic breast reconstruction without AlloDerm ($n = 285$), and the second includes a group of women that had prosthetic breast reconstruction or revision with AlloDerm ($n = 76$). Within the first group, immediate and delayed prosthetic reconstruction following mastectomy was evaluated. Revision and augmentation patients were not included. Of the 76 women in group 2, 24 had bilateral procedures, totaling 100 breasts. The time interval for these AlloDerm-assisted prosthetic procedures was from March of 2006 to September of 2008. The mean age was 46 years (range, 23 to 69 years). The specific indications for the reconstruction or revision are listed in Table 2. AlloDerm was used for immediate breast reconstruction following mastectomy in 60 women, on a delayed basis following mastectomy in seven women, in three women for revision augmentation, and in six women for revision reconstruction. The indications for using AlloDerm were based on the author's experience and included ideal compartmentalization of the device, optimal intraoperative expansion, and an overall improvement in aesthetic outcomes. Mean follow-up for this arm of the study was 17 months (range, 6 to 37 months). Evidence of revascularization and recellularization was made by clinical observation and not histologic analysis.

The specific details of breast reconstruction using prosthetic devices with and without the assistance of AlloDerm have been described previously.^{6-9,11,13} In all reconstructions, the prosthetics devices were placed in the "dual-plane" position, with the upper two-thirds of the device under the pectoralis major muscle and the lower third of the device under either the lower mastectomy skin flap or the AlloDerm. The salient points with regard to AlloDerm-assisted prosthetic reconstruction are that the volume of intraoperative tissue expansion was sufficient to establish total contact between the AlloDerm and the lower mastectomy skin flap. Tissue expanders were generally filled to 40 to 70 percent of capacity when AlloDerm was used and 10- to 20 percent of capacity when AlloDerm was not used. The endpoint for intraoperative expansion was based on the contact point between the upper and lower mastectomy skin flaps, as the device was expanded such

Table 1. Infection Data from Six Studies in Which Prosthetic Devices and AlloDerm Were Used

Reference	No. of Breasts	No. of Infections (%)
Margulies et al., 2005 ⁵	50	2 (4)
Gamboa-Bobadilla, 2006 ⁶	12	1 (8.3)
Salzberg, 2006 ⁷	76	0 (0)
Zienowicz and Karacaoglu, 2007 ⁸	30	0 (0)
Breuing and Colwell, 2007 ⁹	67	2 (3)
Preminger et al., 2008 ¹⁰	45	3 (66)

Table 2. Indications, Number of Subjects, Timing of Chemotherapy, and Timing of Radiation Therapy of the 100 Patients with AlloDerm

Indication	No. of Patients	No. of Breasts	Chemotherapy		Radiation Therapy	
			Preoperatively	Postoperatively	Preoperatively	Postoperatively
Prophylactic mastectomy	6*	28*	0	0	0	0
DCIS	14	14	0	0	1	0
Stage 1	21	21	1	8	2	2
Stage 2	24	24	8	12	5	6
Stage 3	6	6	5	1	1	5
Stage 4	1	1	0	1	0	1
Phyllodes tumor	1	1	0	0	0	0
Revision augmentation	3	5	0	0	0	0
Total	76	100	14	22	9	14

DCIS, ductal carcinoma in situ.

*28 is the total number of mastectomies; 6 is the number of mastectomy patients who did not *also* have a breast removed because of cancer.

that no undue tension was placed on the flaps. This is especially important in the case of thin skin flaps with compromised vascularity. The number of postoperative expansions that were performed in the non-AlloDerm group ranged from three to eight (mean, 5.5), whereas the number of postoperative expansions in the AlloDerm group ranged from two to five (mean, three). The antimicrobial irrigation protocol consisted of two phases. The first irrigation consisted of a dilute povidone-iodine solution (20%) followed by bacitracin irrigation. All povidone-iodine was washed away from the periprosthetic space by the bacitracin. The irrigation was initiated when the prosthetic device with or without the AlloDerm was in the mastectomy pocket. Closed suction drains were placed at the level of the inframammary fold above and below the AlloDerm and retained for 1 to 3 weeks. The endpoint for removal was when drain output was less than 30 cc/day. All patients received intraoperative antibiotics and were continued on postoperative oral antibiotics for as long as the drains were in place.

Adjuvant therapies were initiated either before or after the prosthetic breast reconstruction (Fig. 1). These included chemotherapy and radiation therapy. When chemotherapy was initiated before surgical management, mastectomy and prosthetic reconstruction usually occurred 1 month later. Radiation therapy was usually initiated 1 month after mastectomy and reconstruction. Postoperative expansion was usually initiated 2 weeks after the reconstruction and was terminated before the radiation template design. Expanders were not deflated during the radiation therapy treatments but were left inflated. The specifics regarding chemotherapy protocols and radiation therapy dosimetry are not reviewed in this article; however, the therapeutic strategies com-

plied with current standards for treatment. Radiation treatments were administered at various facilities and dosimetry records were not available. Comparisons are made based on indication for reconstruction, tumor stage, chemotherapy (preoperative and postoperative), and radiation therapy (preoperative, postoperative, and both preoperative and postoperative).

Other variables that may affect outcomes are reviewed briefly. The prosthetic devices used in this study include Mentor (Santa Barbara, Calif.) and Allergan/Inamed (Irvine, Calif.). All reconstructive procedures were performed by the author (M.Y.N.). The mastectomies were performed by eight different breast surgeons and two different institutions. Data on body mass index are not included in this review.

RESULTS

Comparisons between prosthetic breast reconstruction with and without AlloDerm assistance are provided in Table 3. When no AlloDerm was used, the overall incidence of infection was 5.85 percent (22 of 376), compared with an overall incidence of 5 percent (five of 100) when AlloDerm was used. The incidence of prosthesis removal was 5.32 percent (20 of 376) when no AlloDerm was used and 2 percent (two of 100) when AlloDerm was used. Table 4 lists the characteristics of the five women who developed postoperative infections following use of AlloDerm.

The characteristics of the patients with regard to tumor stage, timing of chemotherapy, and timing of radiation therapy are listed in Table 2. Indications for use of AlloDerm included mastectomy for cancer in 66 breasts, prophylactic mastectomy in 28 breasts, revision augmentation in five breasts, and phyllodes tumor in one breast. Of the 66 women with breast cancer, chemother-

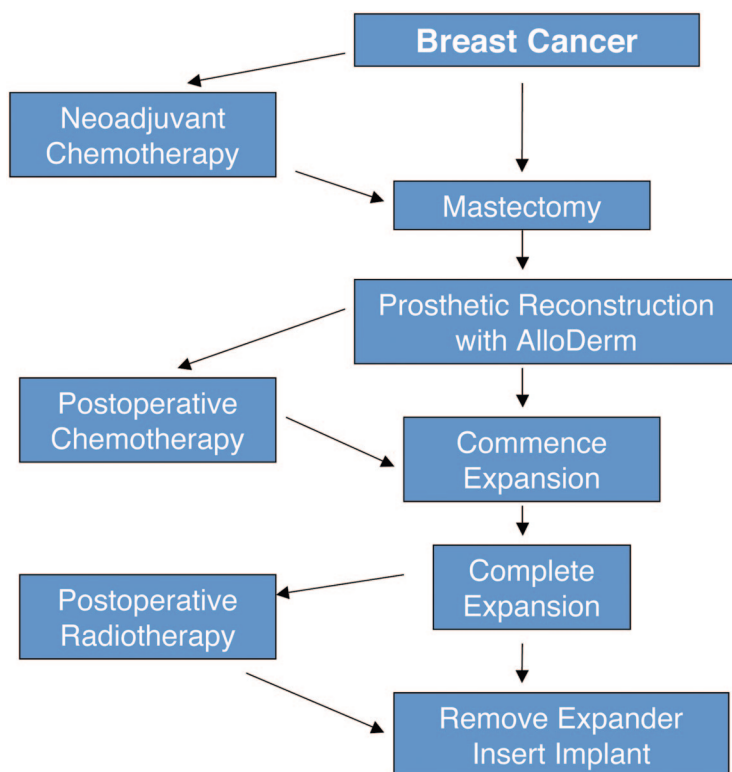


Fig. 1. Flow chart highlighting the adjuvant therapies in relation to the prosthetic breast reconstruction.

Table 3. Comparison of the Incidence of Infection in Women with Prosthetic Breast Reconstruction with or without AlloDerm

Factor	Implant without AlloDerm (%)	Implant with AlloDerm (%)
Women	285	76
Implants	376	100
Infection	22/376 (5.85)	5/100 (5)
Remove implant	20/376 (5.32)	2/100 (2)
Remove AlloDerm	NA	1/100 (1)

NA, not applicable.

apy was necessary in 36 (55 percent) and was delivered preoperatively in 14 (38.9 percent) and postoperatively in 22 (61.1 percent). Radiation therapy was necessary in 23 women (34.8 percent) and was delivered before AlloDerm in nine (39.1 percent), after AlloDerm in 13 (56.6 percent), and before and after AlloDerm in one (4.3 percent).

The incidences of infection, seroma, skin necrosis, and incisional dehiscence as they relate to radiation therapy are listed in Table 5. As stated, infection occurred in five breasts. The infection was superficial in two women and deep in three women. Of the three deep space infections, two required removal of the implant and one did not. The AlloDerm was removed in one of the three

deep space infections that occurred 2 weeks postoperatively. The AlloDerm was not adhered in this case. The AlloDerm was adhered and not removed in the remaining two deep space infections that occurred at 2 and 9 months postoperatively. Infection occurred in three of 77 breasts (3.9 percent) that received no radiation therapy, one of nine breasts (11.1 percent) that received pre-AlloDerm radiation therapy, one of 13 breasts (7.7 percent) that received post-AlloDerm radiation therapy, and no breast that received both preoperative and postoperative radiation therapy. A seroma occurred in five of 100 breasts, of which two were in nonirradiated breasts, one was in a preoperatively irradiated breast, and two were in a postoperatively irradiated breast. In contrast, a seroma occurred in nine of 376 breasts (2.4 percent) following prosthetic reconstruction without AlloDerm. Skin necrosis occurred only in women having immediate breast reconstruction only [three of 77 breasts (3.9 percent)]. Skin necrosis was not observed in any woman who had radiation therapy. Incisional dehiscence was observed in four breasts: one in the setting of no radiation therapy, two following preoperative radiation therapy, and one in the sole breast that received preoperative

Table 4. Characteristics of the Five Women Who Developed Postoperative Infections

Patient	Age (yr)	Tumor	Time to Infection	TE Volume	Tobacco Use	Organism	Chemotherapy	Radiation Therapy
1	46	II lobular	9 mo	650	No	<i>Staphylococcus epidermidis</i>	Postoperatively	Postoperatively
2	67	I ductal	2 wk	400	No	<i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i>	None	None
3	33	DCIS	1 wk	200	No	None	None	None
4	36	I ductal	1 wk	350	No	None	None	Preoperatively
5	37	II ductal	2 mo	450	No	<i>S. aureus</i>	Postoperatively	None

TE, tissue expansion; DCIS, ductal carcinoma in situ.

Table 5. Morbidities That Occurred with or without Radiation Therapy

Factor	No. of Breasts	No. of Infections	No. of Seromas	No. of Skin Necroses	No. of Incisional Dehiscences
No RT	77	3	2	3	1
RT preoperatively	9	1	1	0	2
RT postoperatively	13	1	2	0	0
RT preoperatively and postoperatively	1	0	0	0	1

RT, radiation therapy.

and postoperative radiation therapy. Of the 23 women who had radiation therapy in the setting of AlloDerm, all demonstrated either total [21 of 23 (91 percent)] or nearly total [two of 23 (9 percent)] adherence of the AlloDerm. In the two cases of nearly total adherence, the nonadhered AlloDerm was located in the lateral portion of the breast, occurred in women who had radiation therapy following AlloDerm insertion, and was excised to the point of adherence.

Figures 2 through 9 illustrate four cases of postoperative infection following breast reconstruction with tissue expanders and AlloDerm. Figures 2 and 4 show a nonirradiated superficial infection, Figure 5 shows a nonirradiated deep space infection, Figures 6 and 7 show an irradiated deep space infection, and Figures 8 and 9 show AlloDerm adherence following preoperative and postoperative radiation therapy without any associated infection. These cases were selected to highlight the performance of AlloDerm in these various settings.

DISCUSSION

In 2003, we reported our findings regarding the incidence of infection following breast reconstruction with tissue expanders and implants.¹ Of the 130 women in the study, none had placement of AlloDerm. Of the 168 reconstructed breasts, 10 became infected (6 percent). Infectious agents included *Staphylococcus aureus* and *Serratia marcescens*. Infected tissue expanders were removed at a mean time of 123 days after insertion (range, 14 to 333 days), and permanent implants were removed at a mean time of 91 days after insertion

(range, 63 to 118 days). A significant association ($p < 0.04$) was noted between implant infection and radiation therapy. The odds ratio for infection was 4.88 times greater for implants that were exposed to radiation therapy compared with those that were not. There was no significant association between implant infection and patient age, diabetes mellitus, tobacco use, tumor stage, timing of implant insertion, or chemotherapy.

In preparation for the current review, the number of women completing breast reconstruction with prosthetic devices was updated, and a comparative analysis was performed between those women who had and did not have AlloDerm. The results have demonstrated that the infection rate is essentially equal between the two groups (5.85 percent and 5 percent). The results have also demonstrated that prosthetic reconstruction in the setting of AlloDerm and radiation therapy is well tolerated and does not seem to predispose to infection. Of the five infections that occurred in the presence of AlloDerm, two [two of 24 (8.3 percent)] were in the setting of radiation therapy and three [three of 77 (3.9 percent)] were not. This ratio is actually less than the 4.88 factor that would be predicted based on the initial study.

There are several observations from this study that are useful for surgeons using AlloDerm in the setting of prosthetic breast surgery. The first is that AlloDerm does not appear to increase the risk of prosthetic breast infection based on the observed incidence of infection between the two arms. This is important because AlloDerm is classified as aseptic rather than sterile. To some surgeons, this

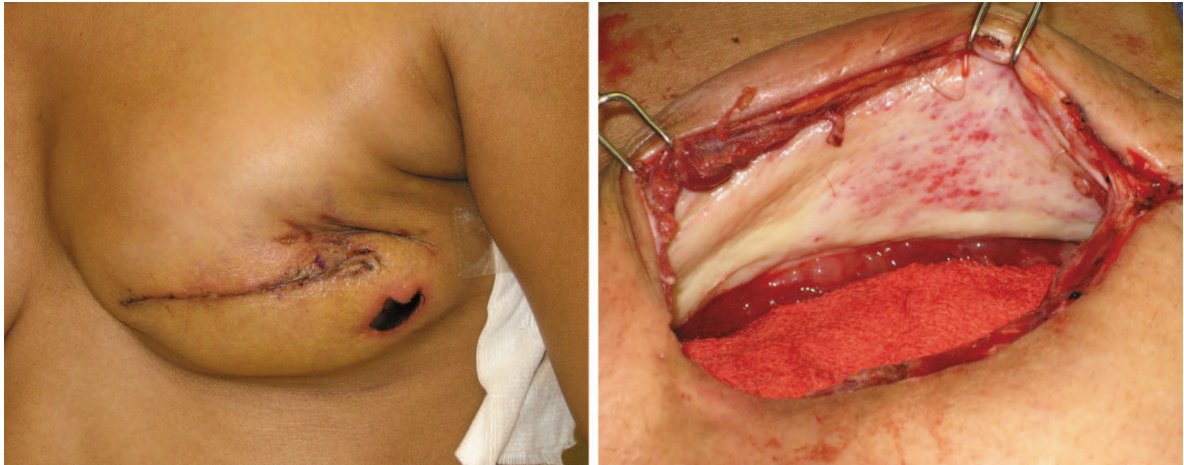


Fig. 2. (Left) Postoperative eschar formation following mastectomy and immediate reconstruction with a tissue expander and AlloDerm. (Right) A postoperative infection occurred 2 months postoperatively at the initiation of chemotherapy, requiring removal of the tissue expander. The AlloDerm was adhered, granulating, and not removed. The wound was irrigated, débrided, and closed over a closed suction drain.

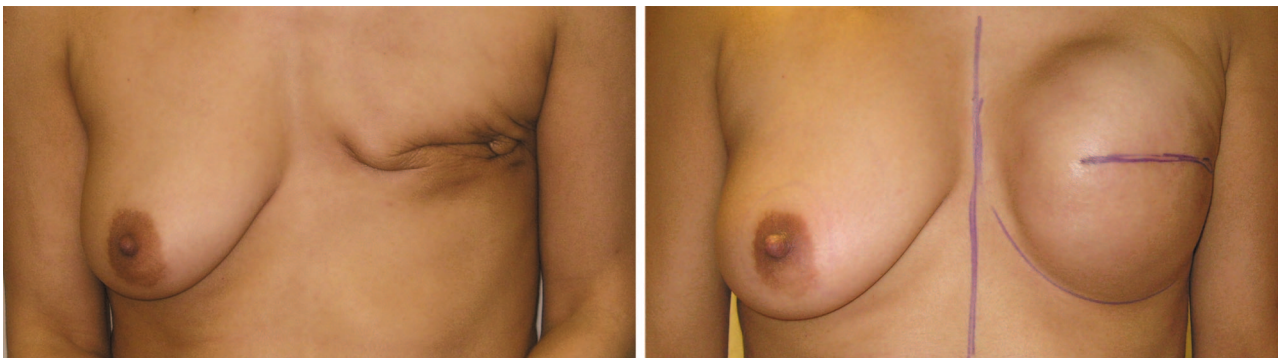


Fig. 3. (Left) After removal of the tissue expander, the chest was allowed to heal for 6 months. No radiation therapy was required. (Right) A second tissue expander was inserted and inflated over time.



Fig. 4. (Left) Intraoperative view of the retained AlloDerm at the time of removal of the expander and insertion of a permanent implant. (Right) Postoperative view following a contralateral augmentation mastopexy using a 300-cc device and the 550-cc permanent silicone gel implant at 1 year after the initial infection.

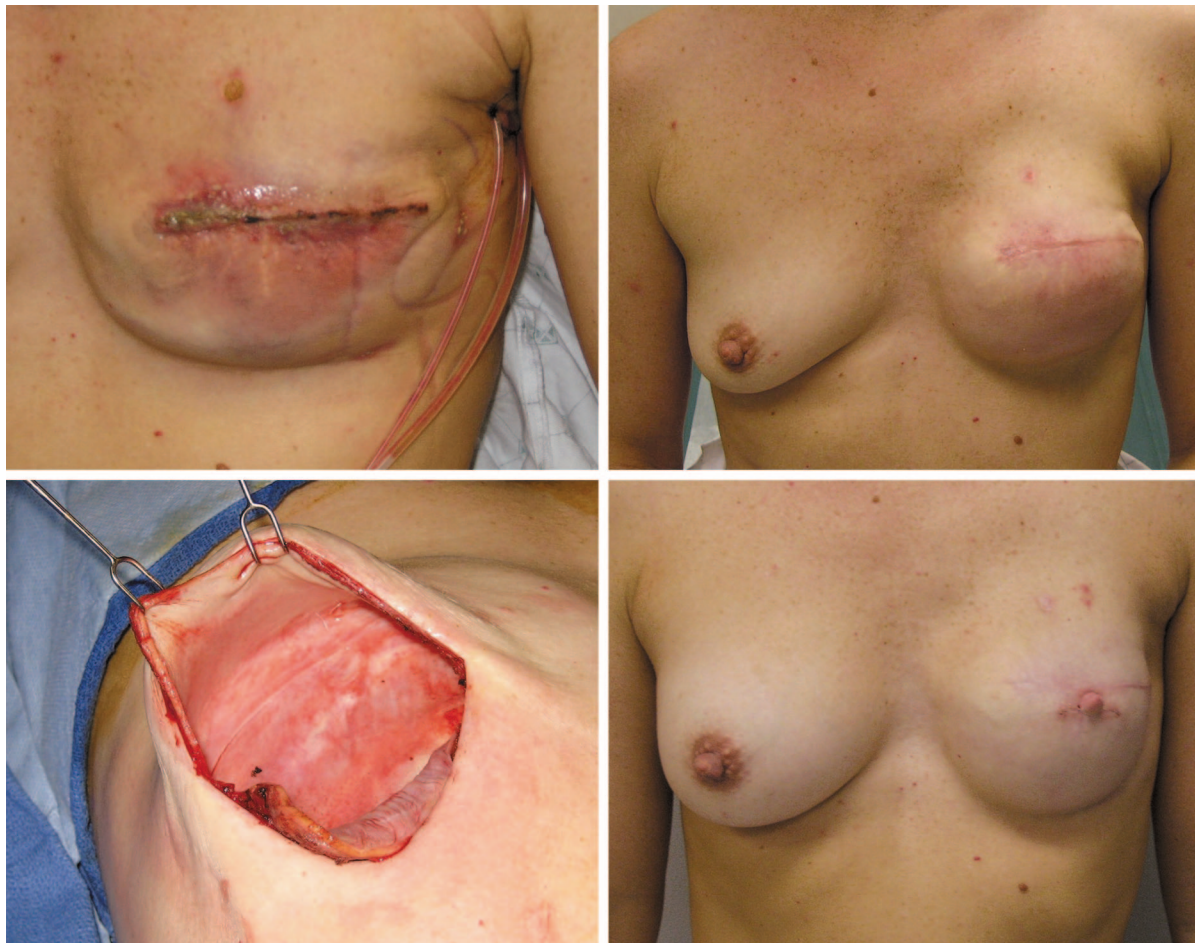


Fig. 5. (Above, left) Postoperative cellulitis occurring 1 week after mastectomy and immediate reconstruction using a tissue expander and AlloDerm. (Above, right) Resolution of cellulitis with intravenous antibiotics. No operative exploration was required, full expansion was completed, and no chemotherapy or radiation therapy was necessary. (Below, left) Intraoperative image of the AlloDerm and time of exchange 3 months later. The AlloDerm was adhered and viable without compromise from the previous overlying cellulitis. (Below, right) Postoperative view following breast and nipple reconstruction with no adverse sequelae at 6 months after initial infection.

fact is a concern; however, based on this study and several others, the incidence of periprosthetic infection is low and does not appear to be related to the AlloDerm.⁵⁻¹⁰ In the cases where AlloDerm integration was complete followed by a delayed periprosthetic infection, granulation tissue was visible on the AlloDerm. After superficial débridement and a period of quiescence, the AlloDerm was noted to maintain its presence and viability. It did not resorb or encapsulate. This observation confirmed that it was fully incorporated into the host with vascularity sufficient to eliminate a bacterial load. Quantitative analysis of the amount of bacterial clearance by incorporated AlloDerm has not been performed.

Another important observation regarding infection and AlloDerm is the occasional erythema

that occurs over the lower mastectomy skin flap overlying the AlloDerm. This can appear as a cellulitis and may prompt antibiotic treatment; however, this erythema is refractory to antibiotic therapy and is self-limiting. It is most likely an inflammatory response to the preservatives in which the AlloDerm is packaged. For this reason, it is recommended that the AlloDerm undergo two saline baths to remove the preservatives and to minimize this effect.

The use of povidone-iodine around prosthetic devices has been controversial. Reports of prosthetic delamination are anecdotal and associated with full-strength povidone-iodine that has been in prolonged and direct contact with the device. Another consideration is that full-strength povidone-iodine can be tissue-toxic and impair fibro-



Fig. 6. (Left) Cellulitis following mastectomy and immediate reconstruction with a tissue expander and AlloDerm 9 months after postoperative chemotherapy and radiation therapy. (Right) Operative exploration demonstrated an infected seroma (nonpurulent) in the presence of adhered and viable AlloDerm with superficial granulation tissue.

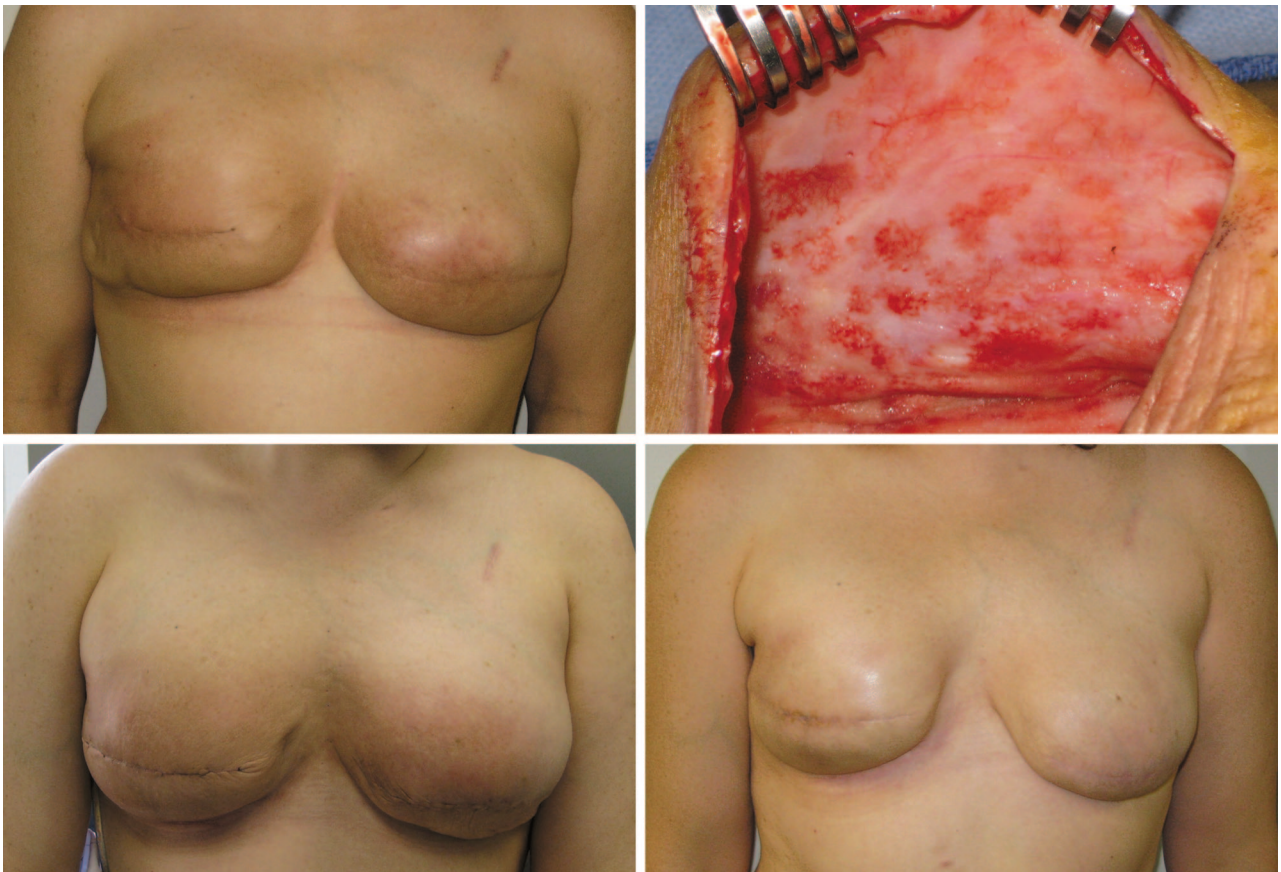


Fig. 7. (Above, left) Postoperative image following débridement, retention of AlloDerm, replacement of tissue expander, and intravenous antibiotics. There was no evidence of recurrent infection. (Above, right) Intraoperative view of the AlloDerm at the time of device exchange that occurred 5 months after the infection demonstrating AlloDerm adherence and revascularization (capillary network visible). (Below, left) Postoperative view at 1 month demonstrating no infection and good symmetry. (Below, right) Postoperative view at 7 months demonstrating no infection but progressive asymmetry. There was no recurrence of infection.

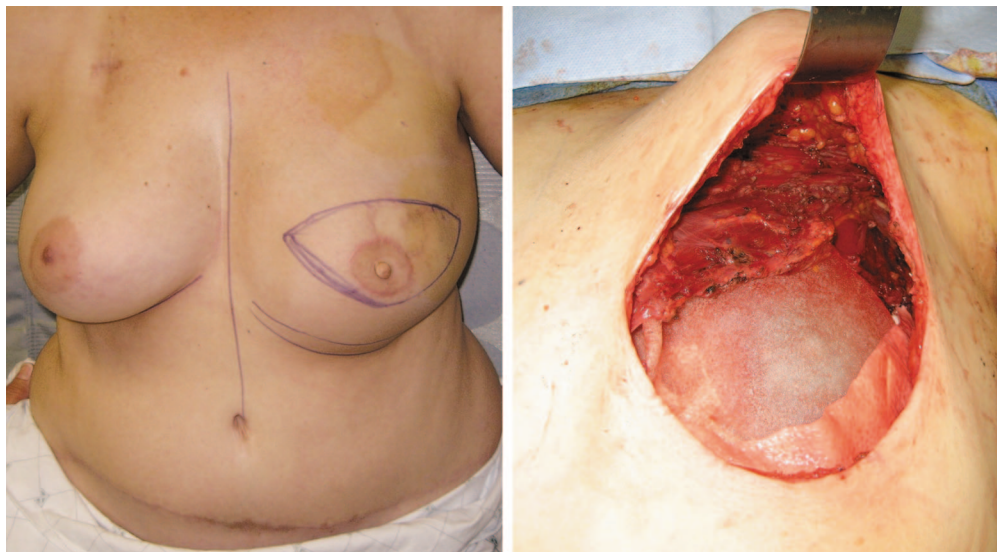


Fig. 8. (Left) Preoperative view following mastectomy and immediate reconstruction with a transverse rectus abdominis musculocutaneous flap. Postoperative radiation therapy was completed. Two years later, a recurrence was noted, necessitating a total flap removal. (Right) Intraoperative view demonstrating the relationship between the resected pectoralis major muscle, the 600-cc tissue expander, and the AlloDerm.

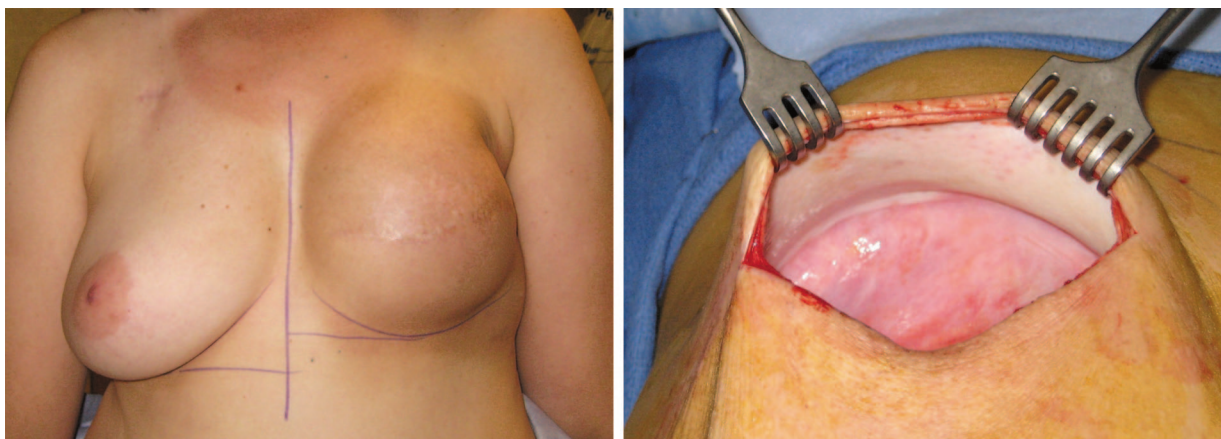


Fig. 9. (Left) After nearly total expansion, a second course of postoperative radiation therapy was initiated 1 month later. The radiation therapy was well tolerated, demonstrating excellent healing and tissue pliability. (Right) Intraoperative view demonstrating total adherence of the irradiated AlloDerm.

blast function. In this author's practice, povidone-iodine is used in a dilute form (20%). In this concentration, tissue toxicity and implant delamination have not been observed.

When analyzing postoperative infections, it is important to differentiate infectious complications from mechanical complications. Mechanical complications include delayed healing, incisional dehiscence, or mastectomy skin flap necrosis that is related to the vascularity of or tension on the remaining breast skin. It is not a primary infection. Thin mastectomy skin flaps may be prone to ne-

crosis because of the random nature of the vascularity and the length of the tissues. When confronted with these situations, there are several tips that may improve outcomes. These include débridement of the skin flaps to bleeding edges, limiting the degree of intraoperative expansion to minimize the pressure exerted on the tenuous skin flaps, and closure of the skin edges over pectoral muscle that may optimize wound healing.

The ability of AlloDerm to adhere to the mastectomy skin flaps and revascularize and recellularize in the setting of radiation therapy has been

demonstrated by this study. AlloDerm also appears to tolerate mild to moderate infections following tissue integration and revascularization. Intraoperative visualization and palpation demonstrated AlloDerm adherence in all cases of radiation therapy. Evidence of revascularization was supported by the erythematous appearance of the hair follicles and a visible capillary network. This observation is supported by two previous studies that have demonstrated that AlloDerm retains the ability to recellularize and revascularize following radiation therapy delivered either preoperatively or postoperatively.^{14,15} The main difference, when compared with AlloDerm adherence without radiation therapy, is that the process will take longer in the setting of radiation therapy.

Based on these cases, the author's protocol for managing periprosthetic infection in the presence of AlloDerm is as follows (Fig. 10). For any infection manifested by cellulitis, pain, and swelling of the breast, patients are admitted for intravenous antibiotics. The dilemma is to determine whether the infection is superficial (involving skin only) or deep (involving skin and periprosthetic space). If while on intravenous antibiotics the cellulitis resolves and the breast and patient improve clinically, operative exploration is negated or deferred.

However, if the clinical condition does not improve within 24 to 48 hours, patients are taken to the operating room for exploration. In the event of a seroma (infected or not), cultures are obtained, all nonadherent AlloDerm is excised, and the device is exchanged if clinically justified. In the event of purulence and nonadhered AlloDerm, the device and AlloDerm are removed and not replaced. In the event of purulence and adhered AlloDerm, the device is removed and not replaced.

Secondary complications such as delayed healing and dehiscence are also managed surgically. Whenever there is an incisional dehiscence, the first question should be whether this was attributable to a mechanical problem (tension, radiation effect) or infection. In the event of a dehiscence attributable to mechanical causes, the reconstruction can usually be salvaged by débridement of the skin edges and replacement of the device if exposed. AlloDerm will sometimes prevent exposure of the device and therefore replacement of the device may not be necessary. Seroma formation is usually managed by means of observation, because most seromas will resorb spontaneously. Careful needle aspiration or surgical drainage can be considered when refractory or when felt to pose an infection risk. In cases of radiation therapy where a seroma may develop, the resultant pressure can

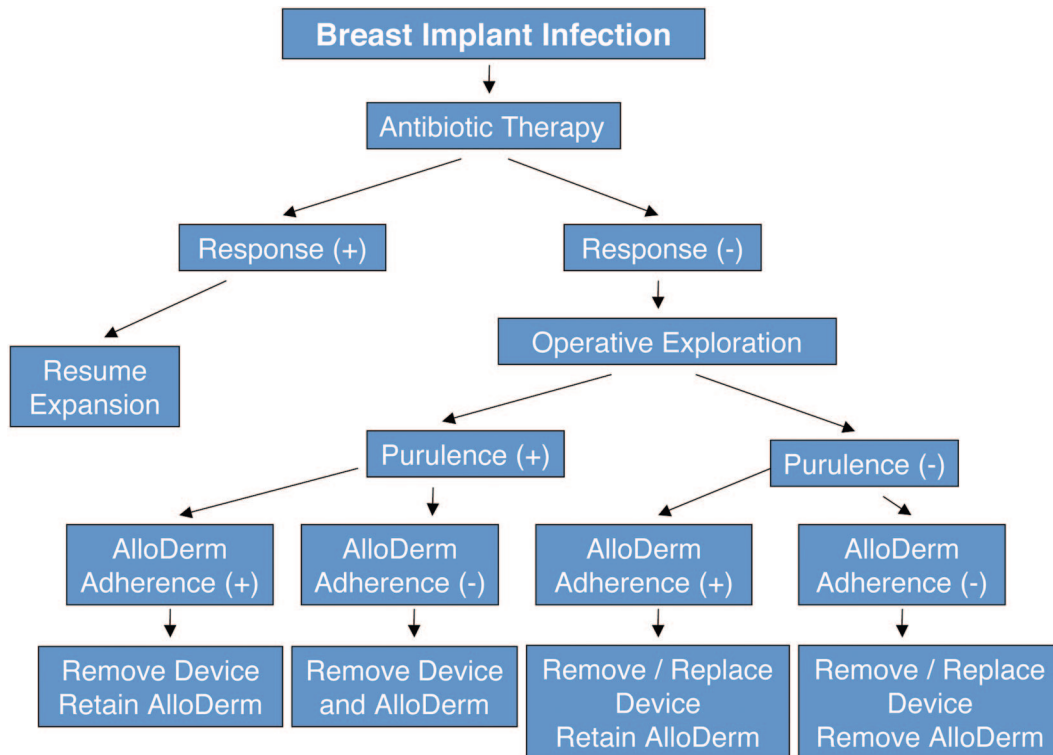


Fig. 10. Flow chart for prosthetic breast surgery with AlloDerm assistance.

cause a disruption of the suture line over time. In these situations, the skin edges are débrided, the device is exchanged when clinically justified, and closed suction drains are inserted.

CONCLUSIONS

In summary, the incidence of prosthetic infection following breast reconstruction with prosthetic devices remains between 5 and 6 percent in this author's practice. The use of AlloDerm does not appear to increase or decrease this risk. In the setting of radiation therapy, the incidence of infection, incisional dehiscence, and seroma formation increases slightly in accordance with that associated with the radiation. Delayed healing and skin necrosis were not observed in the women who had prosthetic reconstruction, AlloDerm, and radiation therapy.

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