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# A Breast Prosthesis Infection Update: Two-Year Incidence, Risk Factors and Management at Single Institution

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## ORIGINAL ARTICLE

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## A breast prosthesis infection update: Two-year incidence, risk factors and management at single institution

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## Abstract

**Background:** Infection following augmentation and prosthetic-based breast reconstruction can cause significant physical and psychological distress for patients. It may delay adjuvant therapies and compromise aesthetic outcomes. The aim of this study is to identify modifiable risk factors for infection and identify common bacterial isolates to achieve optimal outcomes for patients. **Methods:** A retrospective cohort study was performed for patients undergoing implant-based breast reconstruction over a 2-year period. In each case, we documented demographics, co-morbidities, complications and antibiotic use. We reviewed treatments, infectious species cultured where applicable and all outcomes. **Results:** A total of 292 patients met the inclusion criteria. Fifty-five patients (19%) developed an infection. Univariate analysis showed a significantly increased infection rate with longer operative times ( $P = 0.001$ ) and use of tissue expanders ( $P = 0.001$ ). Multiple logistic regression analysis confirmed drain use and elevated body mass index (BMI) as risk factors (odds ratio [OR] 2.427 and 1.061, respectively). After controlling for BMI, smoking status and radiation, we found an increased odd of infection with allograft use (OR 1.838) and a decreased odd with skin preparation using 2% chlorhexidine gluconate in 70% isopropyl (OR 0.554), though not statistically significant. Forty of 55 patients with infections had cultures, with 62.5% of isolates being Gram-positive species and 30% Gram-negative species. The median time to clinical infection was 25 days. Implant salvage with surgical interventions was achieved in 61.5% of patients. **Conclusions:** This study identified judicious use of drains and efficiency in the operating room as modifiable risk factors for infections following implant-based breast reconstruction. Prospective trials to analyse techniques for infection prevention are warranted. Implant salvage following infection is a possible end-point in the appropriate patient.

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## Full Text

## Introduction

One in eight women will develop invasive breast cancer over the course of their lifetime. About 35–40% of those diagnosed annually will be treated with a total mastectomy, and more of these patients are pursuing breast reconstruction in recent years. In 2013, over 95,000 reconstructive breast procedures were performed, 75,000 of which were expander-implant-based reconstructions. Infections following augmentation and implant-based breast reconstruction cause significant physical and psychological distress for patients. It delays adjuvant therapies and leads to compromise of aesthetic outcomes. Breast implant infections also pose a significant financial burden on the health-care system. Olsen et al. found that infections after breast operations are associated with a cost over \$4,000 per patient.[1] Implant infection following breast reconstruction is not an uncommon event; rates cited in the literature range from 2.5% to 16.5%. Implant infection following breast augmentation is much less common with rates of 1%–2.5%.[2],[3],[4],[5],[6],[7],[8],[9]

Identification and modification of risk factors for infection leads to better counselling for patients and undoubtedly improves outcomes. Previously described risk factors for the development of implant infections following reconstruction include: Elevated body mass index (BMI), use of drains, smoking, medical co-morbidities, the use of acellular dermal matrix (ADM), concurrent procedures, chemotherapy, radiation therapy and immediate reconstruction. However, there is much variability in the literature as to which factors are the most significant.[2],[3],[4],[8] Historically, the most common bacterial isolates have been staphylococcal species, but there has been a recent rise in Gram-negative infections.[9] A better understanding of the most common causative species involved allows reconstructive surgeons to approach the treatment of these patients in a rational and evidence-based manner.

The management of implant-associated infection varies depending on severity. Less severe cases can be treated with outpatient oral antibiotics, while more severe cases necessitate inpatient admission and intravenous antibiotics. The most severe cases result in a failure of reconstruction and implant loss.[7] Attempts for reconstructive salvage, defined as the ability to keep an implant after infection, have also become more popular in recent years.[4],[8] The purpose of this study is to identify modifiable risk factors for implant infections, identify the most common causative bacterial isolates, and to analyse and compare success rates for both surgical and conservative management strategies. Our overall goal is to devise a rational and evidence-based approach to the treatment of these patients.

## Methods

This study received approval from the sponsoring institution's Institutional Review Board, a committee which reviews research protocols to ensure ethical research standards and patient safety. Patients were identified by performing a search by Current Procedural Terminology codes for those who underwent prosthesis-based breast reconstruction over a 2-year period at a single institution. The codes included were 19325: Mammoplasty augmentation with implant; 19328: Removal of intact mammary implant; 19357: Breast reconstruction with tissue expander; 19340: Insertion of the breast prosthesis, immediate; 19342: Delayed insertion of breast prosthesis; and 19330: Removal breast prosthesis. Three hundred and twelve patients were identified. After inclusion criteria were applied and procedures confirmed in operative notes, 292 patients were included in the study. The exclusion criteria included patients under the age of 18 years and those in an active state of confinement in a detention system.

To assess patient characteristics and factors that may influence infection rates we documented the following data points demographics and co-morbidities (age, smoking status, BMI, medical history, American Society of Anaesthesiologists (ASA) classification, prior radiation and perioperative chemotherapy); surgical procedures (augmentation vs. reconstruction, immediate vs. delayed reconstruction, use of autograft or allograft, tissue expander vs. implant placement, additional lymph node dissection, operative time, skin preparation and pocket irrigation); and perioperative protocols (drain use, perioperative use of antibiotics).

For the purpose of this study, we defined infection as any documentation of breast 'cellulitis', 'erythema', with accompanying warmth, swelling, purulent drainage or pain requiring intravenous or oral antibiotic treatment in the outpatient or inpatient setting. We also defined infection as patients with documentation reporting a diagnosis of implant 'infection' requiring outpatient or inpatient antibiotic therapy, as well as patients with culture-positive swabs of the implant pocket during a re-operation for dehiscence or mastectomy flap necrosis.

Within the infected cohort, we documented the species of bacteria cultured, inpatient versus outpatient treatment, success or failure of outpatient treatment, and time to infection. In addition, we looked at the concomitant presence of additional complications including implant exposure, seroma, haematoma and wound dehiscence. Operative interventions undertaken to treat infections were recorded. We compared the demographics and outcomes between patients who developed an infection and those who did not.

Nominal categorical variables were compared using Chi-square and Fisher's exact tests, as appropriate. Continuous variables were tested for normality using the Shapiro–Wilk test for normality along with histograms. Normally distributed continuous variables were compared using t-tests; otherwise, Mann–Whitney U-tests were used. Univariate odds ratios (ORs) were calculated using logistic regression models. Statistical significance was defined as a  $P < 0.05$ .

A multiple logistic regression model was used to find predictors of infection among the reconstruction cases. A full model was created with main effects for all pre- and peri-operative variables that were found to have univariate  $P < 0.2$  in their relationship with infection. Then, a backwards elimination procedure was applied where variables were removed one at a time if and only if doing so reduced the model's Akaike's Information Criterion (AIC) since a lower AIC implies a better fit to the data. Prior studies have suggested that smoking status, BMI and radiation exposure may contribute to increased rates of infection.[10],[11] To see if graft type and surgical prep had an effect on infection rates independent of these known risk factors, two separate logistic regression models were fit to the data. One model looked at the effect of graft type controlling for smoking status, BMI and radiation exposure, while the other looks at the effect of surgical prep controlling for smoking status, BMI and radiation exposure. Goodness of fit of the logistic regression models was tested using the Hosmer–Lemeshow test. Multicollinearity among the predictors was assessed using generalised variance-inflation factors. The assumption of linearity in the logit was tested for continuous predictors using the Box-Tidwell transformation. All statistical analyses were performed in R programming language, version 3.4.3 (R Core Team; Vienna, Austria).

## Results

A total of 292 patients were included in the study after the inclusion and exclusion criteria were applied. Fifty-five patients developed an implant infection for an infection rate of 18.8%. All of the infections were in the reconstructive cohort, with a 0% complication rate in the cosmetic augmentation group (32 cases total). The median time from implant placement to infection was 25 days (range 6–448 days).

### Patient characteristics and risk factors

The mean age was 48 years (range 18–79 years). Older age did not correlate with the development of an implant infection. The mean BMI was 28 kg/m<sup>2</sup> (range 17.7–46.8 kg/m<sup>2</sup>). Elevated BMI was a statistically significant risk factor for the development of an infection ( $P = 0.001$ ). ASA class, diabetes and smoking status were not found to be statistically significant predictors of infection [Table 1].

Operative duration had a statistically significant impact on the development of an infection, with longer operative times resulting in a higher infection rate ( $P = 0.021$ ). Tissue expanders were more likely to become infected than permanent implants ( $P = 0.001$ ). The timing of reconstruction did not have an impact on the development of an infection. Lymph node dissection was not associated with an increased risk of infection, nor was the use of allograft or autograft, the type of antibiotic used, perioperative chemotherapy or radiation therapy [Table 2]. The type of skin antiseptic used to prepare the skin and the initial fill volume also did not affect the implant infection rate [Table 3] and [Table 4]. The use of surgical drains with implant placement did have a statistically significant impact on the development of an infection ( $P = 0.032$ ). Further, increased hospital length of stay led to a statistically significant increase in implant infection rates ( $P = 0.001$ ).

Of the 55 patients, who developed an implant infection, 25 (45.4%) had an additional complication. These included seromas ( $n = 7$ ), skin flap necrosis ( $n = 5$ ), wound dehiscence with or without implant exposure ( $n = 12$ ), implant leaks ( $n = 2$ ) or a haematoma ( $n = 1$ ). The type of pocket irrigation had no effect on implant infection rates.

A backwards elimination stepwise procedure was used to develop a multiple logistic regression model for predicting infection among reconstructions and found BMI and drain used to be most predictive of infection. In this regression model, we observed that drain use was associated with a 2.4-fold increase (OR 2.427; 95% confidence interval [CI] 1.208, 5.252;  $P = 0.0171$ ) in the odds of an implant infection and a 1 unit increase in BMI was associated with a 6.3% increase (OR 1.061; 95% CI 1.014, 1.114;  $P = 0.0109$ ) in the odds of an implant infection [Table 5]. Two additional multiple logistic regression models were fit to investigate the relationships between graft type and surgical prep and infection after controlling for BMI, smoking status and radiation exposure. We observed an increased odds of infection with the use of allograft (OR 1.838), but it did not reach statistical significance ( $P = 0.1507$ ). Regarding surgical prep, there was an increased odds of infection with the use of isopropyl alcohol with 4% chlorhexidine and 4% chlorhexidine alone compared to povidone-iodine (OR 2.099 and 1.156, respectively). There was a decreased odds of infection for 2% chlorhexidine gluconate in 70% isopropyl alcohol alone compared to povidone-iodine (ORs 0.554). None of these reached statistical significance.

### Causative bacteria

Fifteen patients did not have wound cultures; thus, 40 cultures were analysed. In total, 62.5% of the isolates were Gram-positives, with 57.5% being staphylococcal species. Thirty percent were Gram-negatives [Table 6] for details of isolates]. There were three cases with no growth and three with mixed skin flora.

### Management of infections

Outpatient treatment with oral antibiotics was attempted in 40 of the 55 patients who developed an infection. Twenty of forty patients (50%) were successfully treated outpatient with complete resolution of their infection without admission or surgical intervention. Thirty-five of the fifty-five patients (63.6%) who developed an implant infection required an operation. Operative interventions included exploration and pocket lavage without explantation ( $n = 2$ ), implant removal and replacement with a new implant ( $n = 11$ ) and implant removal without replacement ( $n = 22$ ). Twenty patients (36%) with implant infections were successfully treated non-operatively with antibiotics alone [Table 4].

Implant salvage, or the continued presence of an implant after an operation (not necessarily the same implant) as defined by Nahebedian and Spear, was attempted in 13 patients. This was successful in eight of these 13 patients (61.5%). Five patients ultimately required implant removal.

## Discussion

The infection rate in the present study was 18.8%, which falls on the high end of the range cited in the literature. However, it should be

noted that our definition of infection was fairly broad when compared to that of other studies. For example, Francis et al.'s study on tissue expander infections found a rate of infection of 16.5%. Their definition of infection was any case where antibiotics were given in response to clinical signs of infection within 1 year from implant placed.[3] In contrast, Cordeiro and McCarthy study of 1521 tissue expanders found a much lower infection rate of 2.5%.[2] However, they defined infection as those patients who were re-admitted to the hospital. Feldman et al. cited an infection rate of 11%, but they limited their definition of infection as that occurring only within the 1st month following surgery.[12]

We did not find a statistically significant association between ADM and increased infection rates; however, there was a trend towards significance. Weichman and Chun did find a significantly increased infection rate with ADM use; however, Chun performed a follow-up study showing no difference when two drains were used, and the threshold for drain removal was decreased to 20 ml over 24 h rather than 30 ml over 24 h.[10],[13],[14] Nahabedian and Reish did not show a statistically significant association with ADM use.[4],[7] The use of dermal autograft also did not result in a significantly increased infection rate, which is in concordance with previous studies.[15],[16]

We found decreased odds of infection with skin preparation using 2% chlorhexidine gluconate in 70% isopropyl alcohol compared to iodine, although this difference was not statistically significant. A Cochrane review comparing the impact of surgical prep in clean surgery on surgical site infections (SSIs) found no difference in 12 studies. However, in this same review, one study was identified that showed a reduced risk of SSI with the use of a prep consisting of 0.5% chlorhexidine in alcohol.[17] It should be noted that none of these studies looked specifically at breast prosthesis cases. Breast surgeries are typically categorised as clean-contaminated due to bacterial colonisation of the nipple-areola complex.[18] A randomised controlled trial by Darouiche et al. of clean-contaminated operations found a chlorhexidine-alcohol prep to be superior to iodine prep in the prevention of infection.[19] Carefully designed randomised controlled trials are needed to definitively determine the ideal surgical prep for breast surgery.

Multiple studies have evaluated the impact of irrigation of the breast pocket with various antibiotic solutions. Most of these studies focused on the development of capsular contracture, as the broadly accepted etiology of capsular contracture is a subclinical infection and the formation of biofilms [20],[21],[22],[23]. Adams et al. found that triple antibiotic irrigation with iodine, cefazolin and gentamicin reduced rates of peri-prosthetic capsular contracture. In a similar study these authors found that a triple antibiotic irrigation mixture consisting of bacitracin, cefazolin and gentamicin was an equivalent alternative.[20],[21] In our study, we found no difference in infection rates with single antibiotic pocket irrigation versus saline alone. However, these prior studies indicate that incorporation of a triple antibiotic technique may be beneficial.

The association of implant infection and longer operative times may be related to the duration of implant or pocket exposure to potential contaminants. These contaminants could originate from accidental non-sterile contact with surgeons or circulating staff, surgical instruments or irrigation or circulating air through the ventilation system. We suspect that the longer the wound is open to the air, the more opportunities there are for contamination. More attention to timely closure of the incision is warranted. An area of interest is the effect of limiting the flow of personnel in and out of the operating room while the implant is exposed.

We found a significant correlation between the use of drains and infection. Prior studies have shown a decrease in breast implant infections with continued use of oral antibiotic prophylaxis until drain removal.[24] However, there is no consensus in the literature.[25] The Surgical Care Improvement Project guidelines recommend discontinuation of antibiotics after 24 h. However, breast reconstruction patients may benefit from an extended course of antibiotics due to the marginal blood flow to post-mastectomy skin flaps, presence of a breast prosthesis and the inherent bacterial flora of the nipple-areola complex.[24] The use of prophylactic antibiotics may be warranted in the post-operative period while drains are in place; however, this warrants further study. There is research to suggest that strict adherence to drain care protocols may decrease drain colonisation and subsequent infection. These measures include timely removal of drains, irrigation of the bulb with Dakin's solution, topical mupirocin use, use of chlorhexidine discs and subcutaneous tunnelling of the drain.[26],[27] Our current drain removal protocol (removal when the output is <30 ml/day for 2 consecutive days, not continuing prophylactic antibiotics until drain removal, and the lack of local wound care to drain sites) may contribute to the association with implant infection. The present study emphasises the importance of implementing a comprehensive drain care regimen.

In our study, the primary bacterial isolates were Staphylococcus species (57.5%) and Gram-negative rods (30%). Of the staphylococcal isolates, 20% were coagulase-negative Staphylococcus (CoNS), 15% were methicillin-resistant Staphylococcus aureus (MRSA) and 22.5% were methicillin-sensitive S. aureus (MSSA). These findings were consistent with Cohen et al.'s study that found a very similar distribution (27% CoNS, 7% MRSA, 25% MSSA and 20% Gram-negative species). In contrast, Feldman's study of 31 infections found a higher concentration of MRSA (45%) and fewer Gram-negative isolates (6%). These findings indicate the importance of understanding our local microbiomes to target antibiotic treatment appropriately.[9] The rising prevalence of MRSA and Gram-negative species in more recent studies justifies the initial use of broad antibiotic coverage when treating a breast implant infection until microbiological speciation and subsequent antibiotic de-escalation can occur.[9],[10]

Multiple studies have demonstrated general resistance of many bacterial species to the commonly used first generation cephalosporins in the perioperative period. Several authors suggest that oral antibiotic prophylaxis be with trimethoprim/sulfamethoxazole (or fluoroquinolones) and in the case of a breast implant infections broad empiric treatment with vancomycin, daptomycin or rifampin given the evolution of regional antibiograms.[10],[11] Further research is warranted to determine the most effective antibiotic regimen, but a transition to prophylactic trimethoprim/sulfamethoxazole in implant patients is being strongly considered.

Our implant salvage rate was found to be 61.5%. This is comparable to Spear and Seruya whose salvage rate was 64%. [7],[8] In the study by Reish et al. where the implant salvage rate was found to be 37.3%, higher white blood cell counts and MRSA isolates were associated with lower salvage success rates. [7] Lower rates of MRSA in our study may be responsible for the higher success rate of implant salvage. We did not specifically look at predictors for implant salvage in our population, but this is an area of focus moving forwards.

## Conclusions

The rate of breast implant infections at our institution and in the surgical literature is exceedingly high, emphasising the significance of this problem. Thus, it is important to explore risk factors, interventions and ideal treatment regimens to better address and reduce the incidence of infection. Our study is unique in that it includes a broader definition of infection, involves a complex patient population with more co-morbidities, and provides an updated analysis over the past 2 years. In our study, statistically significant factors for implant infection include elevated BMI, use of tissue expanders, increased operative times and the use of drains. More studies are warranted to further investigate antibiotic regimens and methods to improve implant salvage.

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Conflicts of interest

There are no conflicts of interest.

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