Preventing Infection in Implant-based Breast Reconstruction: Evaluating the Evidence for Common Practices and Standardized Protocols

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INTRODUCTION

Implant-based breast reconstruction (IBBR) is the most common breast reconstruction technique. A devastating complication of this technique is periprosthetic implant infection, with a reported incidence of 1%–30%. Implant infections are associated with wound healing, capsular contracture, suboptimal aesthetic outcome, and reconstructive failure, all potentially resulting in poor patient satisfaction. In addition, it has been demonstrated that implant infections increase rates of hospital readmission, reoperation, patient and hospital expenses, and reconstructive failure. IBBR is a complex, multistep procedure, and there is a relative lack of high-quality plastic surgery evidence regarding “best practices” in the prevention of implant infections. In the absence of strong data, standardizing procedures based on available evidence can reduce error and improve efficacy and outcomes.

Methods: We performed a focused literature review of the available evidence supporting specific interventions for infection prevention in the preoperative, intraoperative, and postoperative phases of care that are applicable to IBBR. In addition, we examined previously published standardized perioperative protocols for implant reconstruction.

Results: Preoperative, intraoperative, and postoperative planning and organization is crucial in IBBR. Preoperative planning involves skin decolonization in advance of surgery with either chlorhexidine gluconate or mupirocin. Intraoperative methods that have shown potential benefit include double-gloving, breast pocket irrigation, separate closing instruments, and the utilization of “no-touch” techniques. In the postoperative period, the duration of drain removal and postoperative antibiotic administration play an important role in the prevention of surgical site infection.

Conclusions: There is a crucial need to establish an evidence-based set of “best practices” for IBBR, and there exists a paucity of evidence in the breast literature. These data can be utilized to develop a standardized protocol as part of a rigorous quality improvement methodology. (Plast Reconstr Surg Glob Open 2022;10:e4208; doi: 10.1097/GOX.0000000000004208; Published online 22 March 2022.)
of high-quality, plastic surgery-specific evidence regarding best practices in infection prevention specific to IBBR. The purpose of this report is to critically review the evidence for the most common implant infection prevention measures used by plastic surgeons. We do not wish to advocate that any specific technique is the optimal approach; rather, we seek to provide a synthesized and summarized reference for surgeons to help facilitate objective and evidence-based decisions regarding infection prevention practices.

METHODS

First, a literature review was performed to identify previously published protocols targeting implant infection, and the composition of these protocols was used to guide and narrow down the specific interventions discussed in this manuscript. The frequency with which specific interventions appeared in the three protocols is listed in Table 1.

Next, a comprehensive literature review using PubMed, Embase, Cochrane Library, and Web of Science databases in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines was performed for each specific intervention using the search terms highlighted in Table 2. Applicable literature from other specialties was included given the relative lack of plastic surgery-specific literature. Exclusion criteria included duplicate studies, non-English language studies, and studies that did not utilize patient data.

Once eligible results were identified, all publications were reviewed, and data were compiled for inclusion in the manuscript. These data were then reviewed by two independent reviewers within our Division of Plastic Surgery as well as the senior author. The final list of infection prevention measures discussed in this review were those used most often, with the highest amount of evidence basis, and the highest potential for efficacy and ease of implementation.

RESULTS

Preoperative Interventions

Skin Decolonization

Cutaneous bacteria are normal human microflora, with *Staphylococcal* and *Streptococcal* species being the most prevalent. Carriage rates for *S. aureus* are approximately 37.2%, and positive carrier status has been shown to be associated with a 7.1-fold increased relative risk of developing an infection following any type of surgery. Likewise, *Staphylococcal* organisms and other Gram-positive skin flora are found to be the causative pathogen in most breast implant infections.

Preoperative skin decolonization protocols could potentially decrease the incidence of postoperative implant infection by reducing or eliminating the asymptomatic carriage. Twelve studies evaluated the efficacy of a chlorhexidine gluconate (CHG) or mupirocin regimen. Each of the prospective, nonrandomized studies demonstrated a significant improvement in infection rates following implementation of the skin decolonization protocol. Of the randomized controlled trials (RCTs), two demonstrated a significant improvement in surgical site infections (SSIs) with use of the skin decolonization protocol, and one demonstrated no difference.

Takeaways

**Question:** What are the data for current practices employed by plastic surgeons regarding preoperative, intraoperative, and postoperative implant-based breast reconstruction?

**Findings:** We have compiled the data supporting several infection prevention interventions that are commonly employed in IBBR. Furthermore, we perform a comprehensive review of the available evidence supporting several specific interventions that have been included in these protocols.

**Meaning:** While data supporting specific interventions may not be particularly robust in study design or specificity to IBBR, it is possible that when bundled as components of a standard protocol, the benefit on infection reduction may be additive.
Intraoperative Interventions

**Double Gloving**

Gloves in the operating room serve two purposes: as personal protective equipment for surgeons and as a barrier to contamination of the surgical field. Four studies compared the rate of innermost glove perforation in double versus single glove; each demonstrated a significantly higher rate of skin barrier failure with single gloving vs. double gloving. 32–34,67 The largest of these was an RCT published by Laine and Aarnio 67 in which all surgeons across all specialties at a single institution were randomized to wear either single or double gloves and found that the innermost glove was found to be perforated in only 6.8% of cases when the surgeons double gloved compared to 36.8% of cases when only a single glove was worn. In 2009, Misteli et al 34 prospectively evaluated the rate of SSI following 4147 vascular and trauma procedures in cases with or without surgeon glove perforation. The authors found that there was a significantly higher rate of SSI in the setting of inner- or single glove perforation; however, multivariate logistic regression demonstrated that this effect was only statistically significant when preoperative surgical microbial prophylaxis was not administered. There were no studies specific to IBBR or plastic surgery which evaluated the practice of double gloving as it relates to infection.

**Summary:** Glove perforation with skin exposure, particularly when single gloving, may represent an occult source of surgical field contamination. There is evidence that double gloving reduces the rate of innermost glove perforation; however, there is no evidence definitively linking inner glove perforation to SSI.

| Table 1. Search Criteria for Literature Review |
|-----------------------------------------------|
| **Search Terms** | **Identified Studies** | **Included Studies†** | **Surgical Fields** |
| Skin Decolonization | 1.“Preoperative skin decolonization” OR “mupirocin” | 312 | 14 | Orthopedics, Cardiac, Dermatologic, General, ENT, Neurologic, Plastic |
| | 2.“Chlorhexidine” | | | |
| | 1.“Double gloving” | 40 | 4 | Obstetric, General, Plastic, Vascular/trauma |
| | 2.”Glove perforation” | | | |
| | 3.”Surgical site infection” OR “Breast implant infection” | | | |
| **Pocket irrigation** | 1.”Breast” | 239 | 13 | Plastic |
| | 2.”Irrigation” | | | |
| | 3.”Infection” | | | |
| **Minimal touch techniques** | 1.”No touch” OR “Keller” OR “Minimal touch” | 17 | 7 | Cardiothoracic, Hepatobiliary, Orthopedics, Plastic |
| | 2.”Breast reconstruction” | | | |
| **Closing instruments** | 1.”Closing instruments” | 5 | 3 | Colorectal |
| | 2.”Surgical site infections” | | | |
| | 3.”Sterile” | | | |
| **ADM** | 1.”Acellular dermal matrix” | 4 | 3 | Plastic |
| | 2.”Surgical site infection” | | | |
| | 3.”Sterile” | | | |
| **Postoperative antibiotics** | 1.”Postoperative” | 76 | 3 | Plastic |
| | 2.”Antibiotics” | | | |
| | 3.”Surgical site infection” | | | |
| **Drains** | 1.”Intravenous” | 3 | 3 | Plastic |
| | 2.”Breast reconstruction” | | | |
| **Implant infection prevention protocols** | 1.”Implant-based breast reconstruction” | 18 | 3 | Plastic |
| | 2.”Evidence based” | | | |
| | 3.”Protocol” | | | |

ADM, acellular dermal matrix. “OR” refers to the Boolean operator used to focus search results.

*Studies were identified in accordance with the PRISMA guidelines using PubMed, Embase, Cochrane Library, and Web of Science databases. Eligible studies included RCTs, retrospective and prospective cohort studies, case-control, and cross-sectional studies.

†Exclusion criteria included duplicate studies, non-English language studies, and those not utilizing patient data.

| Table 2. Incidence of Specific Measures Used in Previously Published Protocols |
|-----------------------------------------------|
| **Preoperative** | 3/3 (100%) |
| **Intraoperative** | 1/3 (33%) |
| **Pocket irrigation** | 3/3 (100%) |
| **“No-touch” techniques** | 3/3 (100%) |
| **Closing instruments** | 1/3 (33%) |
| **Postoperative** | 2/3 (67%) |
| **Drains and drain care** | 3/3 (100%) |
Pocket Irrigation

In a 2019 ASPS survey, 63% of reconstructive surgeons reported using some form of pocket irrigant. Triple-antibiotic solution (TAS) (50,000 IU Bacitracin, 1 g Ancef, and 80 mg Gentamicin) was most common and was used by 41% of surgeon responders; 12.7% utilized betadine at varying concentrations, whereas others used Hibiclens (CHG; 0.9% of respondents), Irrisept (0.05% CHG in sterile water, 0.6% of respondents), Clorapactin wcs-90 (oxychlorosene sodium, 0.6% of respondents), and PhaseOne wound irrigation (hypochlorous acid; 0.3% of respondents).

The optimal irrigant has been evaluated in several studies. Merceron et al performed a retrospective study that evaluated the effectiveness of CHG irrigation against TAS in IBBR. In this study, CHG proved to be superior to TAS in terms of infection reduction and rate of overall complications; however, there was no significant difference in rate of capsular contracture. Haynes et al compared CHG alone, TAS alone, and a combination of the two in IBBR. The authors found that TAS combined with CHG resulted in significant protection against surgical complications over either irrigant alone. These data suggest a role for the inclusion of CHG irrigation compared to TAS alone.

To our knowledge, there have not been any prospective studies that investigated closing instruments in colorectal surgery. However, the decision to prescribe postoperative antibiotics is highly variable. A 2011 ASPS survey of providers performing IBBR demonstrated a lack of uniformity, with postoperative antibiotics prescribed by 72% of respondents. Of those that prescribed antibiotics, 46% preferred to discontinue at time of drain removal, whereas 52% tended toward a specific postoperative day.

Five studies may help to inform decisions about antibiotic duration in IBBR. The largest retrospective report, published by McCullough et al found that there was a slight trend towards more infections in the less than 24 hours group (RR 1.12), though this was not statistically significant. A noninferiority RCT by Phillips et al involving patients undergoing IBBR with TEs compared oral antibiotic discontinuation at 24 hours postoperatively versus at the time of drain removal. A similar rate of infections was found between the two groups; however, patients in the extended group were more likely to require IV antibiotics and had a higher rate of TE loss (14.0% versus 4.8%). The authors concluded that 24 hours of antibiotics was equivalent to extended oral antibiotic therapy in regards to reducing SSI.

Wang et al corroborated the findings of Phillips et al via a systematic review of a total of 953 patients. The overall
risk of infection trended upward with less than 24 hour duration of antibiotic therapy compared to greater than 24 hours (19% and 14%, respectively, RR 1.3), though this result did not achieve statistical significance. Therefore, the authors concluded that prolonged antibiotic therapy was not effective in reducing SSI or implant loss.

Summary: There is significant heterogeneity regarding the decision to prescribe postoperative antibiotics. However, there is level II evidence suggesting there is no added benefit to continuing postoperative antibiotics longer than 24 hours postoperatively.

**Drains and Drain Care**

Closed suction drains play an important role in reducing dead space, thereby reducing the incidence of seroma in breast surgery. The practice of keeping drains in place for a prolonged period has been theorized to contribute to implant infections. We identified three studies relevant to drain duration and care. Hanna et al investigated the association between time to drain removal and the subsequent incidence of infection in 323 patients undergoing IBBR with TEs. In multivariate analysis, drain use for longer than 21 days was independently associated with a 3.3-fold increased risk of infection. However, the authors recognize that this does not necessary indicate causation: though patients with drains left in place longer appeared to have higher infection rates, prolonged high drain output may simply represent an early manifestation of infection rather than infection resulting from the drain itself.

Some surgeons believe that drains represent a potential communication between the sterile implant cavity and the outside world, which may allow for bacterial translocation into the implant cavity. In a retrospective, consecutive cohort study of 200 IBBRs using TEs, Murray et al investigated a protocol in which all reconstructions received mupirocin 2% cream to the drain sites compared to control. The authors found that this protocol led to a significant reduction in infections. It should be noted that there were significant limitations of this study: not only was there significant sample size discrepancy between the two groups, but drains were removed nearly two weeks earlier in the mupirocin group (7.5 versus 20 days postoperatively).

Another proposed method to reduce risk of infection is the use of a Biopatch (Ethicon, Somerville, N.J.), a CHG-impregnated disk that is placed at drain exit sites. The idea is the use of a Biopatch in IBBR stems from data demonstrating its efficacy in decreasing central line-associated bloodstream infections. However, a retrospective review performed by Weichman et al failed to demonstrate a statistical reduction in overall infections when using Biopatch.

Summary: There is evidence that early drain removal may decrease risk of implant infections. While common practice to use local antimicrobials such as mupirocin or Biopatch to dress the drain insertion site, there is no strong evidence supporting their routine use.

**DISCUSSION**

In this review, we have systematically compiled the best available evidence regarding infection prevention interventions that are commonly employed in IBBR. We provide clear and concise summaries of the evidence for each intervention, which can serve as quick references for providers when considering intervention implementation or when seeking to augment an already established set of practices. Though some studies were limited by sample size, design, or were published in other specialty literature, we feel that the data presented represents the “best available evidence” for each individual measure. As with any proposed change, the risks of implementing these interventions must be weighed against the potential benefit toward reducing the risk of infection. Some interventions discussed in this review could have unintended negative consequences; for example, the use of topical antibiotics could result in an allergic hypersensitivity reaction, or the use and management of closing instruments operative room staff may prolong operative time.

Some of the evidence regarding any one intervention in isolation may be equivocal, yet there remains a potential for standardized protocols to have a significant positive impact on patient outcomes in IBBR. The concept of “care bundles,” as advocated by the Institute of Healthcare Innovation (IHI), may demonstrate the effectiveness of standardization of processes based on the “best available evidence.” IHI defines a care bundle as a “structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes.” Bundles have been proven to be effective in terms of reducing rates of central line-associated blood stream infection and ventilator-associated pneumonia. Within a particular bundle, each individual component may have a small and potentially even controversial benefit, and evidence for this benefit may come from a variety of sources other than specialty-specific level-one data. However, the effect of the whole bundle may be greater than the sum of its individual parts, resulting in a synergistic impact on patient outcomes.

As a complex, multistep process with high potential for variability amongst individual providers, IBBR is an appealing target for standardization. There are several published “proof-of-concept” protocols which suggests that implementation of standard protocols in IBBR can significantly improve postoperative infection rates (Table 3). In the largest of these studies to our knowledge, Khansa et al compared 198 patients undergoing IBBR with tissue expanders using a new infection prevention protocol with a historical cohort of 305 patients. The authors found that patients exposed to the protocol were 55% less likely to develop a SSI after controlling for potential confounders (OR 0.45, P = 0.022). Dassoulas et al then formulated a protocol again for IBBR with subpectoral tissue expanders which was also independently associated with a decrease in infection risk (OR 0.244, P = 0.021). Most recently, Knight et al published a more inclusive protocol used in patients undergoing IBBR using both implant types placed in either the subpectoral or prepectoral plane. Despite this promising data in support of protocols in IBBR, more study is needed. There remains a need to demonstrate that such protocols can be broadly effective.
## Table 3. Description of Previously Published Protocols, Including Patient Population, Protocol Components, and Outcomes

| Publication | Study Design | Preoperative | Intraoperative | Postoperative | Outcomes |
|-------------|--------------|--------------|----------------|--------------|----------|
| Khansa et al\(^{13}\) | Submuscular TE reconstruction only: before protocol implementation (2005–2010) versus after (2010–2012) | -Chlorhexidine scrub day before and morning of surgery | -Preoperative IV antibiotics: cefazolin, or clindamycin if PCN allergy | -Perioperative antibiotics (cefazolin, or clindamycin if PCN allergy) for 24 hours | -305 patients (156 total reconstructions) before protocol; 198 patients (313 total reconstructions) after protocol |
| | | -Weight-based preoperative IV antibiotics 30 minutes prior to incision (cefazolin, or clindamycin if PCN allergy) | -Chlorhexidine skin prep, draping with plastic surgery team present | -Discharge on PO antibiotics until final drain removal | Fewer patients experienced infections in protocol group (11.6% vs 18.4%, \( P = 0.042\)); fewer total infected TE in protocol patients (9.3% vs 13.2%, \( P = 0.097\)) |
| | | -Soak TE in triple-antibiotic solution after opening (50,000 units of bacitracin, 1 g of cefazolin, and 80mg of gentamicin in 500 mL of normal saline) | -Pocket irrigation with antibiotic solution prior to implant placement | -Drain removal when output ≤ 30cc/day | -Protocol significantly reduced odds of infection on multivariate analysis (OR 0.45, \( P = 0.022\)) |
| | | -Pocket irrigation with antibiotic solution prior to incision (cefazolin, or clindamycin if PCN allergy) | -Preoperative IV antibiotics: teicoplanin and gentamicin | -Expansion started 2-4 weeks postoperatively (or rapid expansion prior to radiation therapy) | |
| Dassoulas et al\(^{5}\) | All immediate implant-based: before protocol implementation vs (2010–2014) after (implemented in 2015) | -Chlorhexidine scrub three days prior to surgery (specific instruction to pay attention to axilla, chest wall, IMF) | -Chlorhexidine skin prep | -Discharge on PO antibiotics until final drain removal (if previous XRT, prescribed TMP-SMX double-strength BID; if not, Keflex) | -235 patients (158 total reconstructions) before protocol; 85 patients (135 total reconstructions) after protocol |
| | | -Intranasal mupirocin BID for 3 days before surgery | -ADM soaked in Triple-antibiotic solution (cefazolin, gentamicin, bacitracin) | -Drain removal when output ≤ 30cc/day or by POD21 | -Reduced incidence of infection after protocol implementation (2.9% versus 9.5%, \( p = 0.013\)) |
| | | | -Pocket irrigation with antibiotic solution AND powdered-iodine | -All surgeons required to change outer gloves | -Protocol independently associated with decrease in infection risk (OR 0.24, \( p = 0.021\)) |
| Knight et al\(^{14}\) | All immediate implant-based before protocol (2012–2014) versus after (2015–2017) | -Patient selection: only included those with ≤1 risk factor (BMI > 30, smoker, DM, radiotherapy, neoadjuvant chemotherapy) | -Intraoperative personnel reduction and avoid door opening (use of locks and signs) | -Oral doxycycline 100 mg BD until final drain removal | -54 patients (77 total implant-based reconstructions) before protocol; 106 patients (129 total reconstructions) after protocol |
| | | -Preoperative IV antibiotics: teicoplanin and gentamicin | -Reduce operative time: two surgeons for bilateral procedures | -Drain removal when output <30 cc/day on 2 consecutive days or by day 10 | -Reduced rate of implant loss at three months after protocol implementation (14% vs 0%, \( P = 0.00001\)) |
| | | -Intraoperative personnel reduction and avoid door opening (use of locks and signs) | -Chlorhexidine skin prep | | |
| | | | | | |
| | | | | | | ADM, acellular dermal matrix; BID, bis in die; BMI, body mass index; DM, diabetes mellitus; IMF, inframammary fold; MRSA, Methicillin-resistant *Staphylococcus aureus*; MSSA, Methicillin-sensitive *Staphylococcus aureus*; PCN, penicillin; PO, per oral administration; TE, Tissue expander; TMP-SMX, trimethoprim/sulfamethoxazole; XRT, radiation therapy. |
in IBBR regardless of prosthetic type, plane of placement, and patient comorbidities.

This review has several important limitations. One must remember that outcomes are closely related to the “quality” of the mastectomy skin flaps: when thin and relatively de-vascularized, tissue healing can be compromised which plays a critical role in infection development. However, not only is this factor largely out of the control of the plastic surgeon but it is also out of the intended scope of this review. Second, the data analyzed are likely subject to publication bias, whereby results which demonstrate a positive treatment effect are more likely to be published, resulting in an over-estimation of the potential benefit of a given intervention. In addition, the design and objectives of the available studies supporting implant infection prevention protocols may be subject to the Hawthorne effect. In this form of observation research bias, investigators and study participants may alter their behavior due to awareness of participation in an experiment, potentially affecting outcomes of interest. Longer-term follow-up after implementation of an infection prevention bundle can help determine if outcome improvement is due to the direct effect of the interventions, or simply a self-limited observation bias.

CONCLUSIONS

Implant-based breast reconstruction is a ubiquitous practice in plastic surgery, and implant infections can have significant adverse effects on patient outcome and costs of care. In this review, we scrutinized the “best available evidence” in support of several infection prevention interventions that may aid in provider decision-making. Although data supporting specific interventions may not be particularly robust in study design or specificity to IBBR, it is possible that when bundled as components of a standard protocol, the benefit on infection reduction may be additive. Further investigation of this approach within the framework of a rigorous quality improvement methodology is necessary.

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