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.

**Background:** Infection following implant-based breast reconstruction (IBBR) results in increased 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.

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Likewise, breast implant infections.²⁰ Skin flora are found to be the causative pathogen in most men. Each of the prospective, nonrandomized studies of a chlorhexidine gluconate (CHG) or mupirocin regimen reported carriage. Twelve studies evaluated the efficacy of 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.¹⁵-²⁰,²¹-²⁵,²⁷ Of the randomized controlled trials (RCTs), two demonstrated a significant improvement in surgical site infections (SSIs) with use of the skin decolonization protocol.²⁶,²⁷ two demonstrated a trend towards fewer infections which was not statistically significant,²⁸,²⁹ and one demonstrated no difference.²⁸

A multicenter prospective study published in 2015 included over 14,000 screened 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.³⁰ Likewise, Staphylococcal organisms and other Gram-positive skin flora are found to be the causative pathogen in most breast implant infections.²⁹

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.¹⁵-²⁰,²¹-²⁵,²⁷ Of the randomized controlled trials (RCTs), two demonstrated a significant improvement in surgical site infections (SSIs) with use of the skin decolonization protocol.²⁶,²⁷ two demonstrated a trend towards fewer infections which was not statistically significant,²⁸,²⁹ and one demonstrated no difference.²⁸

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A multicenter prospective study published in 2015 included over 14,000 screened S. aureus carriers undergoing either orthopedic joint arthroplasty or cardiac surgery.¹⁷ The rate of SSI following implementation of the protocol was significantly lower in both groups (relative risk [RR] 0.48 and 0.86, respectively). In an RCT published in the New England Journal of Medicine, 917 S. aureus carriers were randomized to receive 5 days of showers with CHG and intranasal mupirocin twice daily, or placebo.²⁰ The rate of S. aureus infection in the treatment group was significantly lower (RR 0.42), and the effect was most profound to deep SSIs (RR 0.21). Smith et al.²⁰ evaluated preoperative skin decolonization versus placebo in 1350 S. aureus noncarriers undergoing Mohs surgery and demonstrated a 50% reduction in the rate of infection (2% vs 4%, P = 0.03). The effect of duration of decolonization duration was studied by Kline et al.²⁰ in an RCT, demonstrating that a 5-day regimen of showers with CHG and intranasal mupirocin was more effective than 2 days of showers alone. In most published studies, a 5-day CHG/mupirocin regimen is considered the standard for skin decolonization.

The only plastic surgery-specific study was an RCT published by Veiga et al.²⁰ One hundred and fifty patients undergoing plastic surgery (including 16 breast reconstructions and 9 breast augmentations) were randomized to receive either no treatment, a shower with CHG preoperatively, or shower with placebo. There was no significant difference between any group in this study; however, the overall infection rate was very low (two infections total).

Summary: Though evidence specific to IBBR is lacking, there is relevant high-level evidence from other specialties that a 5-day skin decolonization protocol with CHG and mupirocin can decrease rate of SSI.
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 Aarnio67 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.

Table 1. Search Criteria for Literature Review

<table>
<thead>
<tr>
<th>Search Terms</th>
<th>Identified Studies*</th>
<th>Included Studies†</th>
<th>Surgical Fields</th>
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<tbody>
<tr>
<td>Skin Decolonization</td>
<td>312</td>
<td>14</td>
<td>Orthopedics Cardiac Dermatologic General ENT Neurologic Plastic</td>
</tr>
<tr>
<td>Double gloving</td>
<td>40</td>
<td>4</td>
<td>Obstetric General Plastic Vascular/trauma</td>
</tr>
<tr>
<td>Pocket irrigation</td>
<td>259</td>
<td>13</td>
<td>Plastic</td>
</tr>
<tr>
<td>Minimal touch techniques</td>
<td>17</td>
<td>7</td>
<td>Cardiothoracic Hepatobiliary Orthopedics Plastic</td>
</tr>
<tr>
<td>Closing instruments</td>
<td>5</td>
<td>3</td>
<td>Colorectal General</td>
</tr>
<tr>
<td>ADM</td>
<td>4</td>
<td>3</td>
<td>Plastic</td>
</tr>
<tr>
<td>Postoperative antibiotics</td>
<td>76</td>
<td>3</td>
<td>Plastic</td>
</tr>
<tr>
<td>Drains</td>
<td>3</td>
<td>3</td>
<td>Plastic</td>
</tr>
<tr>
<td>Implant infection prevention protocols</td>
<td>18</td>
<td>3</td>
<td>Plastic</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Preoperative</th>
<th>Included in Protocol</th>
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</table>
| Skin decolonization | 3/3 (100%)
| Double gloving | 1/3 (33%)
| Pocket irrigation | 3/3 (100%)
| “No-touch” techniques | 3/3 (100%)
| Closing instruments | 1/3 (33%)
| Postoperative antibiotics | 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 Ancel, and 80mg Gentamicin) was most common and was used by 41% of surgeon respondents; 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 or retrospective studies performed to validate the in vitro efficacy of PhaseOne or other hypochlorous acid derived irrigation techniques.

Summary: Pocket irrigation with some form of antibiotic solution has been shown to reduce the rate of infection and capsular contracture in some studies involving breast augmentation. Although this data can be extrapolated to apply to breast reconstruction, the optimal type and method of irrigation has yet to be determined.

“No-touch” Techniques

Another important source of surgical site contamination is that from native skin flora that may persist despite standard preoperative skin preparation. A variety of “no-touch” techniques have been developed, and range from self-retaining sterile retractor systems to the Keller Funnel (Allergan, Madison, N.J.) that has traditionally been used in augmentation mammoplasty. There is data to support the underlying theory that these techniques minimize possible cutaneous contamination of the sterile breast implant. Moyer et al compared the Keller Funnel versus the typical digital insertion method. In this study, the authors demonstrated that using the Keller Funnel resulted in a 27-fold decrease in implant-to-skin contact. Separately, the authors also swabbed the cadaver breasts with methicillin-sensitive S. aureus before implant placement and found that implant contamination as measured by cultures from the implant surface was twice as common using the digital insertion technique.

We identified one study specific to IBBR with tissue expanders (TEs) that not only demonstrated the benefit of a “no-touch” technique, but also directly evaluated its effect on reconstructive failure due to infection. Wilson described a technique using a transparent drape and a series of hooks to create a self-retaining retractor system. This study found a statistically significant six-fold reduction in infection-related reconstruction failure from 11.5% to 1.9%.

Summary: There is evidence that the use of “no-touch” implant placement techniques can reduce implant-to-skin contamination during implant placement. There is also evidence that these techniques may translate to a reduction in rates of infection, including infection-related reconstructive failure in IBBR, though this data is relatively limited.

Closing Instruments

It is common during certain procedures to exchange surgical instruments for a new, sterile set of instruments before the wound is closed. This practice is particularly common in colorectal surgery, which has the highest rate of SSI in the literature (3%–30%). We identified two studies that investigated closing instruments in colorectal surgery before wound closure. However, neither study identified any benefit with regards to SSI. In contrast, a retrospective study in pancreatic surgery literature found a significant reduction in incisional SSI when using closing instruments and new drapes when compared to standard methods. The authors demonstrated a significant reduction in SSI from 12.4% in the control group versus to 2.2% in the clean group. There is a lack of evidence regarding similar practice in cosmetic breast surgery or breast reconstruction.

Summary: The available literature is equivocal regarding the clinical benefit of using new, sterile instruments during skin closure. However, this has not yet been studied with regards to IBBR.

Postoperative Interventions

Postoperative Antibiotics

Preoperative antibiotics are standard of care in breast reconstruction. 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 bloodstream infections 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

<table>
<thead>
<tr>
<th>Publication</th>
<th>Study Design</th>
<th>Protocol Specifics</th>
<th>Outcomes</th>
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-IV antibiotics 30 minutes prior to incision (cefazolin, or clindamycin if PCN allergy)
-Weight-based preoperative IV antibiotics 30 minutes before protocol implementation
-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
-Diabetes mellitus; 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. | Postoperative: Perioperative antibiotics (cefazolin, or clindamycin if PCN allergy) for 24 hours
-Discharge on PO antibiotics until final drain removal
-Drain removal when output ≤ 30cc/day
-Expansion started 2-4 weeks postoperatively (or rapid expansion prior to radiation therapy) | -305 patients (156 total reconstructions) before protocol; 198 patients (313 total reconstructions) after protocol
-Fewer patients experienced infections in protocol group (11.6% vs 18.4%, P = 0.014); fewer total infected TE in protocol patients (9.3% vs 13.2%, P = 0.097)
-Protocol significantly reduced odds of infection on multivariate analysis (OR 0.45, P = 0.022) |
| Dassoulas et al<sup>5</sup> | -All immediate implant-based: before protocol implementation vs (2010–2014) after (implemented in 2015) vs Excluded autologous reconstruction
-All surgeons required to change outer gloves | Preoperative: Chlorhexidine scrub three days prior to surgery (specific instruction to pay attention to axilla, chest wall, IMF)
-IV antibiotics 30 minutes prior to incision (cefazolin, or clindamycin if PCN allergy)
-Intranasal mupirocin BID for 5 days before surgery
-Preoperative IV antibiotics: teicoplanin and gentamicin
-Soak TE/implant in triple-antibiotic solution after opening
-Irrigate pocket again with antibiotic solution AND
-Redrape with sterile towels
-All surgeons required to change outer gloves | Postoperative: Discharge on PO antibiotics until final drain removal
-Drain removal when output ≤ 30cc/day
-Expansion started 2-4 weeks postoperatively (or rapid expansion prior to radiation therapy) | -235 patients (358 total reconstructions) before protocol; 85 patients (135 total reconstructions) after protocol
-Reduced incidence of infection after protocol implementation (2.9% versus 9.5%, P = 0.013)
-Protocol independently associated with decrease in infection risk (OR 0.244, P = 0.01) |
-Excluded patients with > 1 risk factor (BMI > 30, smoker, DM, radiotherapy, neoadjuvant chemotherapy)
-MSSA / MRSA screening
-Preoperative IV antibiotics: teicoplanin and gentamicin
-Intraoperative personnel reduction and avoid door opening (use of locks and signs)
-Reduce operative time: two surgeons for bilateral procedures
-Chlorhexidine skin prep
-Nipple shields for unilateral cases
-Surgeons require to double glove; must change outer glove prior to implant handling
-Implant handled only by single surgeon after glove change | Intraoperative: Oral doxycycline 100 mg BD until final drain removal
-Drain removal when output <30 cc/day on 2 consecutive days or by day 10 | -54 patients (77 total implant-based reconstructions) before protocol; 106 patients (129 total reconstructions) after protocol
-Reduced rate of implant loss at three months after protocol implementation (14% vs 0%, P = 0.00001) |
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.6,9,66 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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