Review

Infection prevention in breast implant surgery − A review of the surgical evidence, guidelines and a checklist

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Abstract

Introduction: As a result of increasing use of implant-based breast reconstruction, complications such as infection are being encountered more frequently. Surgical Site Infections (SSIs) cause morbidity for the patient, can lead to capsular contracture or implant loss and are costly to healthcare systems. National Guidelines suggesting methods to reduce SSI related complications have been produced, but are limited in the scope of interventions covered and underlying evidence presented.

Methods: We performed a literature review encompassing a wide variety of possible SSI prevention strategies. We aimed to present summaries of the available evidence and give pragmatic recommendations as to their validity to use as guidelines for infection prevention strategies for implant-based breast reconstruction.

Results: A lack of high quality data relating to the benefit of SSI prevention strategies in implant-based breast reconstruction exists. Many papers relate to orthopaedic implant surgery, or clean surgery in general. Following review of the evidence, sufficient data exists to support use of perioperative antibiotics at implant-based breast reconstruction, with continuation for an extended period in "high risk" patients. Alcohol containing skin preparations should be used over aqueous solutions. Laminar air flow use is suggested. Theatre traffic should be kept to a minimum, as should duration of operative procedure. The implant pocket should be washed prior to implantation. Double gloving and conductive warming are also endorsed.

Conclusions: We have produced a perioperative "Theatre Implant Checklist" for SSI prevention in implant-based breast surgery, with a set of pragmatic up to date guidelines, which allows the reader to evaluate the evidence upon which our recommendations are based.
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Introduction

The rising incidence of breast cancer and the psychosocial benefit of breast reconstruction have seen increasing numbers of breast-reconstructive procedures over recent years.[1,2] In the United States (U.S.), the number of breast reconstructions increased from 78,832 in the year 2000 to 95,589 in 2013.[3] In the United Kingdom (U.K.), implant-based reconstructions now account for approximately 85% of immediate breast reconstructions.[4] Implant-based breast reconstructions are popular due to the benefits of reduced operating/recovery time, lack of donor site morbidity, an increase in breast surgeons being trained in the their use and the availability of a variety of acellular dermal matrices (or similar types of internal meshes) which can be used to provide an internal hammock and improve aesthetic outcome compared to complete sub-muscular placement of the implant.[5]

The surgical site is the most common focus for infection after an operation and this can be attributed to multiple confounding preoperative, intra-operative and post-operative factors. The most frequent source for infection is the patient's own skin at the time of surgery.[6] Surgical Site Infection (SSI) is a significant problem in implant-based breast reconstruction, with infection rates of approximately 5%.[7] Risk factors for SSI include smoking, radiotherapy, chemotherapy and skin necrosis.[7] SSI can lead to prolonged hospital admission, re-operation, multiple outpatient visits and implant loss (which has been reported as high as 19% in implant-based reconstruction).[8] The cost of SSI is significant; one U.S. study published in 2008 showed that the average cost of a SSI in breast surgery was $4091.[9]

Infections in implant-based reconstruction pose the additional complication of increasing the incidence of capsular contracture (CC) — a leading cause of implant revision.[10] The aetiology of capsular contracture is multifactorial, but subclinical infection in particular with a *Staphylococcus epidermidis* (*S. epidermidis*) biofilm has been implicated in its pathogenesis.[11]

U.K. guidelines for breast reconstruction were published in 2012 and include recommendations for reducing reconstruction related infections, however, the evidence for these guidelines is not clearly referenced and no mention is made of the quality of the data on which they are based. Suggested measures include preoperative *Staphylococcus aureus* (*S. aureus*) screening, antibiotic use, the use of ultra clean ventilation (UCV) and chlorhexidine skin preparation.[12] Specific guidance for breast implant use includes a suggested wash of the implant cavity and the use of a "minimal touch" implant insertion technique, with a glove change prior to handling the implant. The American Society of Plastic Surgeons has produced guidance for implant-based reconstruction, but in terms of infection prevention only covers the use of a perioperative antibiotics, with a recommendation that antibiotics be given on induction and discontinued within 24 hr of surgery (unless a drain is present).[13]

SSI rates post implant-based reconstruction of between 3 and 6.1% compare unfavourably to both cosmetic augmentation, with infection rates of between 0.9 and 1.7%[14,15] and orthopaedic joint replacement surgery, where SSI is as low as 0.7% for knee and 1% for hip replacements.[16] Orthopaedic SSI rates can be seen as the "gold standard" to which breast implant-based reconstruction should aspire. Due to unpreventable risk factors for infection such as poor skin flap perfusion following mastectomy (compared to cosmetic augmentation), patient co-morbidities and the need for adjuvant chemotherapy and/or radiotherapy, this may be hard to achieve. These factors need to be considered preoperatively when assessing individual patient suitability for an implant-based reconstruction. There are many modifiable risk factors for SSIs. This review presents the evidence (and lack thereof) behind commonly used and recommended infection prevention measures.

Methods

We searched Embase, Medline, PubMed, Scopus and The Cochrane Library in May 2015 for articles printed in English and based on human populations. Articles that could inform practice in infection prevention were analysed. Our search terms included infection and augmentation or breast implants or prosthesis with: Antibiotics, laminar air flow, operative team size, scrub type, chlorhexidine, iodine, pocket irrigation, surgical approach, implant type, nipple shields, perioperative warming, drains, surgeon grade, double glove, Methicillin-resistant *Staphylococcus aureus*, *S. aureus*, showering and operative time.

We examined the references of articles for additional papers of interest. The primary search focus was implant-based breast reconstructions. Where data was limited we widened this to include breast augmentation (acknowledging that aesthetic augmentations carry a lower infection rate and are a different patient population who lack some risk factors of the oncological cohort for infection such as a need for radiotherapy or lymph node dissection).[15,17] Where evidence was still lacking we expanded our search to orthopaedic implant surgery and finally surgery as a whole.

The infection prevention methods were categorised into preoperative, environmental/equipment and surgical technique related and each one was evaluated and a recommendation made with regard to its use. Where the evidence was weak, the measure was "suggested" rather than recommended. Tables were also produced for each category to summarise the evidence, including levels of evidence and relevant statistics.[18]

Pre-operative factors ([Table 1](#))

Pre-operative methicillin sensitive and resistant S. aureus screening and treatment

S. aureus is the commonest cause of SSI with most cases being caused by commensal bacteria brought to hospital by

Table 1
Pre-operative risk factors associated with infection.

Setting	Level of evidence	Sample size	Conclusion
Pre-operative mssa screening and treatment			
Patients screened and MSSA carriers treated either with placebo or mupirocin and chlorhexidine.[25]	1b	6771	Deep SSI 0.9% in treatment group vs. 4.4% in placebo (RR = 0.21; CI 0.07–0.62)
Oropharyngeal and nasal treatment with chlorhexidine vs. placebo for all patients undergoing cardiac surgery.[24]	1b	991	Deep SSI's less common in treatment group (ARR 3.2%, $P = 0.002$)
Nasal mupirocin vs. placebo administered preoperatively to S. aureus carriers undergoing cardiac surgery.[26]	1b	263	No significant reduction in number of SSI's.
Intranasal treatment with mupirocin vs. placebo in all patients across various surgical specialties.[23]	1b	4030	No significant difference in the rate of SSI's
Pre-operative mrsa screening and treatment			
Rapid screening on admission plus standard infection control measures vs. standard infection control alone.[29]	1b	21754	MRSA admission screening did not reduce MRSA SSI rate
Enhanced hand hygiene vs. MRSA screening and decolonization in surgical wards.[30]	2b	126750	In clean surgery wards MRSA screening and decolonisation did not decrease SSI rate ($P = 0.054$)
A review of MRSA screening, 14 surgical studies reported on MRSA SSI.[28]	3a	n/a	Majority of the low quality evidence supported screening to reduce MRSA SSI rates.
Prophylactic antibiotics			
Cochrane review - Prophylactic antibiotics and the incidence of SSI after breast cancer surgery without reconstruction.[43]	1a	2867	Preoperative antibiotics reduces the incidence of SSI (pooled RR 0.67, CI: 0.53–0.85)
Systematic review of current evidence for systemic (and topical) antibiotic prophylaxis in prosthesis based breast surgery.[33]	2a	2946 (studies on systemic antibiotics)	Extended (>24hr) antibiotic prophylaxis decreased SSI risk in reconstructive surgery (RR = 0.51; CI: 0.35–0.74)
Prophylactic antibiotics alone vs. multiple measures (inc. extended oral antibiotics) in implant-based reconstruction.[42]	2b	208	No difference in wound infection rates between cohorts
Antibacterial showering preoperatively			
Cochrane review of evidence for preoperative showering with antibacterials preventing nosocomial SSI.[44]	1a	10157	No evidence for preoperative showering with chlorhexidine rather than any other product
Solution for surgical field preparation (scrub type)			
Systematic review to determine efficacy of different preoperative skin antiseptics for clean surgery[47]	1a	2623	One study[48] suggesting chlorhexidine associated with lower rate of SSI compared to PVI (RR 0.47)

the patient.[19,20] General population carriage rates for *S. aureus* are as high as 37.2% and a carrier has a 7.1 relative risk (RR) of subsequently developing a related infection.[21] Methicillin Resistant *S. aureus* (MRSA) poses a further problem. Being resistant to beta-lactam antibiotics, treatment options are restricted. Infection with MRSA carries a higher relative risk of infection than Methicillin-sensitive *S. aureus* (MSSA).[21] Nasal carriage of *S. aureus* is the only independent risk factor for joint infections in orthopaedic surgery.[22]

With regards to MSSA, several large randomized controlled trials (RCT) have been carried out across surgical specialities examining colonisation, eradication and SSI rates. Significantly, two RCTs that did not screen for *S. aureus* and gave eradication treatment to all patients reported no decrease in SSI rates.[22,23] However, a single RCT that also did not screen patients prior to study enrolment reported a reduction in deep but not superficial

SSIs.[24] Interestingly, deep SSIs (defined as below the subcutaneous layer) were not separately reported by Perl et al., whilst Kalmeijer et al. found that deep SSI rates unexpectedly fell across all groups in the study period (thought due to surveillance effect) and therefore a comparison between treatment and placebo groups could not be made.

More recently, a Dutch RCT, randomised 917 *S. aureus* carriers (screened with polymerase chain reaction) to prophylaxis or no treatment, This study also concluded that deep surgical site infections (but not superficial) were less common in the mupirocin-chlorhexidine treated group than in the placebo group (4 infections vs. 16, $P < 0.05$).[25] A further RCT of *S. aureus* carriers found no reduction in SSI rates in the intranasal mupirocin treated group as compared to placebo, however, this trial did not decontaminate extra-nasal sites (included in other studies) that are recognised to cause *S. aureus* infection.[26,27]

A recent systematic review of MRSA screening in a variety of clinical settings reviewed 14 surgical studies (the majority being orthopaedic). It concluded that although the majority of evidence supported MRSA screening to reduce MRSA associated SSI rates, there was insufficient evidence to give firm guidance.[28] This was firstly because the studies used variable definitions of SSI. Secondly, the evidence was predominantly based on studies with a high-risk of bias and thirdly, a good quality Swiss study did not support screening.[29] A subsequent study by the same Swiss group showed that in clean surgical wards, MRSA screening coupled with contact precautions and decolonisation led to significant reductions in MRSA culture and infection rate. The reduction in SSI rate did not however reach significance.[30]

Summary: recommended

Despite minimal evidence specific to implant-based breast surgery, evidence from other specialities supports MSSA screening, and the majority of the (poor quality) evidence supports MRSA screening. MSSA and MRSA screening with appropriate treatment of carriers preoperatively in breast implant reconstructive surgery is recommended.

Prophylactic antibiotics

Half of all antibiotics used in hospital are for surgical prophylaxis.[31] The use of prophylactic antibiotics in breast implant surgery, especially in the face of increasing antibiotic resistance, remains controversial. The National Institute for Health and Clinical Excellence (NICE) advocates the use of systemic antibiotics in "clean surgery involving a prosthesis".[32] Following discussions with microbiologists, The Association of Breast Surgery (ABS) guideline for implant-based reconstruction recommends a single intravenous dose of antibiotics on induction of anaesthesia.[12]

There are currently no RCT's comparing antibiotic prophylaxis versus no antibiotic prophylaxis for implant-based breast reconstruction. A recent systematic review appraised eight studies of systemic antibiotics from a heterogeneous group of breast-implant reconstruction and aesthetic surgery research articles.[33] Four studies included reconstructive breast patients with the remainder being aesthetic augmentations alone. Three of the eight studies[34–36] compared systemic prophylactic antibiotics (cephalosporins) versus no antibiotics. Five further studies (which included 2438 patients) were also reviewed to compare perioperative (single-dose or within 24 hrs of the operation) prophylactic antibiotics versus extended antibiotic prophylaxis (>24 hrs post-operatively).[37–41] Extended antibiotic use was associated with an average infection-rate of 4.6% versus 11.1% with a single perioperative dose (number needed to treat [NNT] 15.38). Subgroup analysis comparing aesthetic to reconstructive procedures showed extended prophylactic antibiotics significantly reduced the incidence of SSI in reconstructive but not aesthetic surgery. The authors also concluded that extended prophylaxis could particularly reduce the incidence of SSIs in reconstructive patients perceived to be at "higher risk" of SSI (e.g. patients who had diabetes or recent radiation therapy). However, a subsequently published retrospective cohort study of implant-based reconstruction found that extended antibiotic prophylaxis had no effect on infection rates when compared with a single preoperative intravenous dose.[42] Furthermore, perceived problems with antibiotic resistance, side effects of medication and current expert opinion explain our recommendation for only a single dose of antibiotics at induction.

A 2014 Cochrane review of prophylactic antibiotics to prevent SSIs after breast cancer surgery (without reconstruction) has also been published.[43] For routine breast cancer procedures without reconstruction, preoperative antibiotics reduced the incidence of surgical site infections.

Summary: recommended

A single dose of antibiotics at induction is recommended as a minimum, with selective use of extended prophylaxis to 24 h or longer in those patients deemed "high risk" for infection.

Antibacterial showering preoperatively

A 2015 Cochrane review looked at seven RCT's involving over 10,000 patients to evaluate whether preoperative showering with antiseptics prevented nosocomial SSIs.[44] This review included studies from orthopaedic, vascular, breast and general surgical disciplines. None of the studies were breast implant specific. The trials comparing chlorhexidine with placebo or chlorhexidine with normal soap showed no difference in the rate of SSI. Only one of the three trials (n = 978) comparing chlorhexidine with no washing found a significant difference in favour of bathing with chlorhexidine in general surgery patients.[45] The majority of these trials were performed in the 1980s and did not include breast implant procedures.

Summary: no recommendation

From the current evidence it is not possible to conclude that preoperative antibacterial washing prevents SSIs.

Solution type for surgical field preparation (scrub type)

The topical removal of bacteria from the skin prior to surgery is routine practice. Povidone iodine (PVI) works by penetrating the cell wall of bacteria and oxidising their contents with free iodine, whilst chlorhexidine works by disrupting the bacterial cell wall.[46] Chlorhexidine and PVI have broad ranges of action, however PVI may be inactivated by blood or serum proteins.[46]

A Cochrane review of antiseptics for surgical wound infection prophylaxis in clean surgery[47] reported one study where there was some evidence that preoperative skin preparation with 0.5% chlorhexidine in methylated spirits was associated with lower rates of SSIs compared to alcohol based iodine.[48] This study was poorly reported and the risk of bias (e.g. due to concentration of iodine not being stated) was unclear. No other statistically significant differences in SSI rates in the other comparisons of skin antisepsis were found. The authors concluded that alcohol-containing products had the highest probability of being effective, however the quality of available evidence was low. It was suggested that surgeons consider other factors such as cost and side effects when choosing between alternatives.

Summary: suggested

Evidence supports the use of an alcohol as opposed to aqueous containing preparation, with weak evidence that alcoholic chlorhexidine is superior to alcoholic iodine based preparations.

Environment and equipment related factors (Table 2)

Laminar air flow and ultra clean ventilation

There is no evidence for the use of laminar air flow (LAF) or Ultra Clean Ventilation (UCV) in breast implant surgery; its benefits have been extrapolated from its use in orthopaedic implant surgery. The use of LAF/UCV is standard practice in orthopaedic implant surgery despite conflicting evidence of infection reduction. The only multi-centre RCT showed a reduction in joint sepsis in patients randomised to initial surgery in a LAF/UCV theatre versus a conventional theatre setting.[49] This study has been criticised for not controlling use of perioperative prophylactic antibiotics. Large cohort studies (based on national joint registries) have shown no benefit for LAF/UCV and in some cases found an increase in risk of deep SSI with the use of LAF/UCV.[50,51] Low event rates for joint infection following hip and knee arthroplasty and a high number of variables that are difficult to control make study design challenging. A decrease in air-borne and surgical field contamination with the use of LAF/UCV has been demonstrated however.[52,53] It is acknowledged that factors such as team size and movement within the operating theatre influence the effectiveness of air-flow systems.[53] In summary, the absence of evidence for reduction of SSIs with LAF/UCV is a product of the difficulties of study design.

Summary: suggested

There is a lack of clear evidence that LAF/UCV reduces SSI rates. However, given the evidence for a reduction in field contamination, we suggest the use of LAF/UCV.

Patient warming

Inadvertent patient hypothermia has been shown to have detrimental effects on surgical outcome due to increased oxygen consumption, cardiac morbidity and coagulopathy.[54] Perioperative normothermia decreases SSI in colorectal cancer surgery.[55] No trials have specifically looked at normothermia or patient/local surgical site warming in implant-based breast reconstruction. However, a RCT of 421 patients (43% undergoing breast surgery with no implant - the remainder having hernia or varicose vein surgery) compared standard care, targeted preoperative warming of the surgical site with a warming pad, or whole patient warming with a forced air warming blanket for 30 min before surgery.[56] Patients who had warming had a 5% wound infection rate, compared to 14% with no warming. All procedures were short and no patients became clinically hypothermic. No differences in seroma or haematoma rates were seen.

Concerns have been raised about the use of intraoperative forced air warmers and the potential for disrupting ultra clean ventilation systems. Forced-air blowers have been demonstrated to culture positive for bacteria and generate convection currents, which increase particle concentrations compared to radiant warming.[57] In orthopaedic implant surgery, one study showed a three-fold increase in infection with forced air warming compared to conduction heating, but patient demographics were not well balanced between each treatment arm.[58] A recent review recommends that in cases of implant surgery alternative warming systems such as heated blankets/mattresses should be considered over forced air devices.[57]

Summary: recommended

Prevention of hypothermia during implant-based breast reconstruction and intraoperative warming with a conductive warming device rather than a forced-air flow device should be considered.

Theatre staffing levels

Studies of the impact of volume of staff traffic are confined to orthopaedic implant surgery. The number of people present in theatre and the rates of door opening significantly increase air contamination.[53,59] This is thought to be due to disturbances in the unidirectional laminar flow and the shedding of bacteria by staff.[60] Airborne contamination is correlated to bacterial wound contamination and has been shown to cause SSIs.[61,62] There is however no direct evidence that increased traffic in theatre causes an increase in SSIs.

Summary: recommended

Minimisation of staff movement through theatre doors should be encouraged. Signs on theatre doors to indicate

Table 2
Environmental and equipment factors associated with infection.

Setting	Level of evidence	Sample size	Conclusion
Laminar flow and ultra clean ventilation			
Multicentre trial of ultra clean air system vs standard clean air ventilation in hip and knee replacement surgery.[49]	1b	8136	Deep sepsis rate in control group 1.5% vs 0.6% in UCV group. ($<$0.001).
Effect of LAF and space suits on the rate of infection and revision for early deep infection after joint replacement.[50]	2b	88311	Increased infection rate in hip and knee surgery with LAF ($P < 0.003$ and $P < 0.019$ respectively)
Mobile LAF vs turbulent air flow on incidence of SSI in abdominal and orthopaedic procedures.[51]	2b	99230	Laminar flow showed no benefit. (Risk of severe SSI after hip prosthesis insertion actually higher)
Efficacy of a mobile LAF unit in reducing bacterial contamination in the surgical area during arthroplasty.[52]	4	34	The LAF unit reduced the mean bacterial count in the wound area ($P < 0.001$).
Effect of displacement ventilation vs. LAF on air contamination rates during orthopaedic implant surgery.[53]	5	63	LAF resulted in a reduction of 89% in colony forming units ($P < 0.001$).
Patient warming			
Hypothermia vs. normothermia in colorectal surgery.[55]	1b	200	Wound infection rate higher in the hypothermia group (19% vs. 6%, $P = 0.009$)
General surgery patients (clean procedures). Standard (non-warmed) vs. warming for at least 30 min before surgery.[56]	1b	421	Wound infection rate higher in the non-warmed patients (14% vs. 5%; $P = 0.001$)
Forced air warming vs. conductive fabric warming in a simulated operation.[58]	4	1437	Forced air warming increased deep joint infection (OR 3.8, $P = 0.024$)
Theatre staffing levels			
Evaluating the effect of door opening on contamination in the operating room during orthopaedic cases.[59]	5	81	Door opening increases the number of colony forming units (CFU) by 69.3% (p = 0.022)
Displacement ventilation vs. LAF during orthopaedic implant surgery. (Secondary aim examining effect of number of staff).[53]	5	63	Displacement: every door opening and person increases CFUs 3 & 13% respectively (both P $<$ 0.001)
Nipple shields			
Nipple shields applied after standard skin preparation for augmentation. Post op both nipple and shield swabbed.[63]	4	32	34.9% of post procedure swabs from nipple and inner surface of shield positive for bacterial contamination.
Swabs taken from under and outside nipple shield post breast implant (augmentation or reconstruction) surgery.[64]	4	25	33% vs. 0% (under vs. outside nipple shield) post procedure positive swabs for bacterial growth.
Glove use			
Cochrane review of double gloving to reduce SSI.[68]	1a	14 RCTs	More perforations in single glove than inner layer of double glove (OR 4.10, CI. 3.30 to 5.09). Insufficient power to assess SSI risk.
Measuring bacterial skin populations of surgeon's hands. Antimicrobial vs. non-antimicrobial gloves.[71]	1b	25 (pairs of gloves)	Chlorhexidine impregnated gloves had a lower bacterial glove fluid load post op (P $<$ 0.001)
Prospective study on effect of glove perforation on SSI occurrence in gastrointestinal, vascular and trauma surgery.[69]	2b	4147	Without microbial prophylaxis glove perforation was associated with higher odds of SSI (adjusted OR: 4.2; CI: 1.7–10.8; $P = 0.003$),
Surgeons randomized into keeping or changing outer layer of double gloves 1 h into orthopaedic operations.[67]	2b	102	Palm contamination 23% in surgeons who kept vs. 13% who changed outer gloves (OR: 1.97, CI: 1.02–3.80, $P = 0.042$)
Implant type			
Retrospective review of augmentation and reconstructive operations.[72]	4	1655	SSI's are unrelated to surface texture or filler material

that an implant-based case is in progress represent a simple common sense measure that could help reduce traffic.

Nipple shields

A nipple shield refers to an occlusive dressing applied over the nipple areola complex following skin preparation. This aims to prevent contamination of the surgical field by commensal bacteria residing in the nipple ducts and expressed from the ducts during surgery. When nipple shields have been used throughout a procedure and swabs are taken from the nipple and the under surface of the nipple shield following skin closure, 33–35% grow positive cultures.[63,64] No studies have reduced SSI with the use of

nipple shields. In addition, when considering skin sparing mastectomy, the ducts will be transected from the inside, so external shielding is of questionable benefit.

Summary: no recommendation

No evidence exists to suggest that nipple shields reduce infection rates.

Double glove use

Intact surgical gloves are a key defence mechanism for preventing bacterial transmission from surgeon to patient. Occult glove perforations are common, occurring in up to 61% of all operations.[65,66] Perforations are related to duration of the procedure and gloves worn for 90 min (or less) have a 15.4% microperforation rate, compared to 23.7% when worn for over 150 min.[65] A study of orthopaedic cases where the outer layer of double gloving was either kept in place or exchanged for a new outer glove after 1 h, showed that surgeons who retained the same gloves had 23% gloved palm contamination, compared to 13% who changed outer gloves.[67]

A Cochrane review of double gloving identified 14 trials (across a range of specialities but not including breast or plastic surgery) of double gloving compared to single glove use. This showed significantly more perforations to the single glove than the innermost (skin touching) double glove, but failed to translate this into an impact on infection rates.[68] A RCT in general surgery (not breast) that was published after the Cochrane review showed that SSI increased after glove perforation only if no microbial prophylaxis was given at surgery.[69] Of additional note, double gloving appears to have no demonstrable detriment to dexterity.[70] One small RCT has looked at chlorhexidine impregnated gloves.[71] This showed that bacterial load in the glove fluid post procedure was lower using the chlorhexidine impregnated gloves.

Summary: recommended

Double gloving is likely to decrease bacterial contamination compared to single gloves, largely by decreasing occult micro-perforations to the skin-side glove. Double gloving is recommended with outer glove change prior to handling the implant. In addition changing the outer gloves after a time frame of an hour to 90 min is suggested.

Implant type

Textured implant surfaces have been theorised to harbour bacteria within their shell. A retrospective review of 1655 breast implant insertions over a 15 year period (both augmentation and reconstruction) showed no difference in implant infection between textured, smooth or polyurethane implants or saline and silicone implants.[72]

Summary: no recommendation

There is no evidence that implant type or texture has a demonstrable effect on implant infection.

Surgical factors (Table 3)

Grade of operating surgeon

No convincing evidence exists suggesting that the more junior the operating surgeon, the higher the incidence of SSI. A single center retrospective study showed no influence of surgical experience on mastectomy complications including infection, however the most junior surgeons assessed were registrars who may already have extensive surgical experience.[73] Small studies of operations with a high baseline infection risk have shown higher SSI rates with inexperienced surgeons.[74,75] A study of 6103 visceral, vascular and trauma interventions, found no significant differences in post-operative infection rates across different operating surgeon grades with appropriate supervision.[76] A retrospective review of a large database of 10,356 plastic surgical cases in the U.S. showed no increase in infective complication when a resident was involved with the surgery.[77]

Summary: no recommendation

In the presence of appropriate supervision, surgical grade cannot be said to be a factor relating to SSI.

Operative duration

Prospective and retrospective studies across a range of surgical specialities, including both autologous and implant-based reconstructive breast surgery, have shown a direct relationship between infection rate and operating time.[78–81] A variety of explanations have been suggested: including desiccation of wounds edges, bacterial accumulation and a reduction in skin perfusion.[82]

Prolonged surgery is often deemed to be an operative time in excess of 3 h for breast surgery, as suggested by the US National Nosocomial Infection Surveillance Risk Index.[83] Operating times above this (which is the 75th centile of an average of breast cases) increase SSI risk.[83]

Summary: recommended

In bilateral procedures, we recommend concurrent bilateral operating with two teams of surgeons, to decrease overall surgical time, if local expertise and surgical staffing allows.

Drains

Suction drains can be used following breast reconstruction with the aim of reducing haematoma and seroma formation, however, bacteria can migrate along the drain tract from the skin into the wound. Indeed, closed suction

Table 3
Surgical Factors associated with infection.

Setting	Level of evidence	Sample size	Conclusion
Surgeon grade			
Evaluation of supervised training during general surgery, vascular and trauma procedures.[76]	2b	6103	No effect of surgeon grade (when supervised) on SSI rate
Tanzanian study of Caesarean section.[75]	2b	345	Surgery by a junior doctor was an independent risk factor for SSI ($P = 0.001$)
Complications post mastectomy and axillary node clearance.[73]	3b	164	No difference in complications between surgical grades
Evaluation of complications with resident involvement in plastic surgical cases.[77]	3b	10,356	No increase in infection with resident involvement
Comparison of surgeon grade and departmental experience vs SSI rate[74]	4	N/A	Inverse correlation between cumulative cases performed and SSI rate (r = 0.42)
Operation duration			
Retrospective review of general and vascular surgery. Patients with an SSI were matched to a cohort without SSI.[81]	3b	10,253	Duration of operation was independent risk factor for SSI.(Odds Ratio (OR) 1.8; CI 1.2–2.8)
Retrospective analysis to assess risk factors for tissue expander loss following immediate breast reconstruction[79]	4	9305	Prolonged operative time associated with early TE loss (OR = 2.2, $P = 0.002$).
Retrospective analysis of mastectomy ± immediate reconstructions to identify risk factors for SSI's.[78]	4	48393 (9315 had IBR)	Prolonged operative time associated with 70% greater risk of an SSI
Prospective 28 day study of surgical wounds.[80]	4	23649	Increased rate of infection when the duration of the operation was longer
Drains			
Study of drain use in temporary expander to permanent breast implant exchange[85]	3b	2446	No increase in SSI rate with drain use ($P = 0.585$)
Introduction of drain care protocol (including tunnelling) to reduce infection rates in expander based reconstructions[88]	3b	200	Lower infection rate with drain care protocol ($P = 0.001$). Tunnelling one element of this protocol
Retrospective review of aesthetic breast augmentation.[86]	4	3002	Drain use increased the risk of infection 5 fold ($P < 0.05$)
Implant and pocket washing			
Systematic review of systemic (and topical) antibiotic prophylaxis in implant based breast surgery.[33]	2a	1724	Incidence of CC after topical antibiotic vs. control = 4.86% vs. 6.81% (RR 0.47, $P < 0.001$).
Pocket irrigation with saline/adrenaline vs. saline/adrenaline/cephalothin in breast augmentation.[90]	2b	436	Increase in infection in patients not treated with topical antibiotics (12.8% vs. 6.7%; $P = 0.044$)
Single centre retrospective review of aesthetic breast augmentation.[86]	4	3002	Local antibiotics vs. control was protective against the occurrence of infections ($P < 0.05$).
Incision site			
Retrospective review of complications for incision location in primary breast augmentation.[94]	4	619	No association between incision location and infection.
Report from 73 plastic surgeons of early and late implant infections (augmentation and reconstruction).[95]	4	54661	Insertion route had no influence on infection rates.

drains (as opposed to open) are used to establish a pressure gradient away from the wound towards the drainage reservoir with the aim of minimising this effect.[84]

A retrospective cohort study of 1863 breast reconstruction patients showed that the use of closed suction drains after exchange of a temporary expander for a permanent breast implant does not affect the incidence of infection.[85] The infection rate for this relatively simple procedure was low (1.3% with drain use and 1.1% without), raising the question of whether this is an appropriate group to investigate. A retrospective review of 3002 aesthetic augmentation patients, where one would expect more dissection than simple implant exchange, showed a significant increase in infection rate with the use of drains.[86] It should be noted that many surgeons would not routinely use a drain in either

of the above procedures so the relevance of these studies is limited.

A comprehensive review examined the evidence for closed suction drain use in several surgical disciplines, including discussion of the evidence specific to breast oncology, flap-based reconstruction and joint arthroplasty surgery. The authors concluded that drain use was not associated with an increase in SSI, however, there was no study reporting a reduction in SSI with drain usage. Limited evidence suggested prolonged drain use may be associated with increased risk of infection.[87]

Drains can be inserted directly through the skin or "tunnelled" into a subcutaneous plane for a distance (often of a few centimetres) before emerging through the skin. The theory behind the tunnelling of the drain is similar to

that for the placement of long-term indwelling venous catheters (such as Hickman lines) where increased distance from skin surface to wound is theorised to slow the ascending colonisation of the drain. One study of a drain care protocol in breast implant surgery, suggests tunnelling helps decrease infection rates.[88] The technique is also used in neurosurgery in an attempt to decrease infection, with evidence showing that longer tunnelling reduces infection rates in external ventricular drains.[89]

Summary: suggested (with regards to tunnelling)

Closed suction drains should be used judiciously, with use reserved for cases where the consequences of seroma or haematoma are significant. Tunnelling should be considered as a simple technique that may help to decrease bacterial transit from the skin to the surgical site, particularly where prolonged drainage is likely to be required.

Implant and pocket washing

Pocket washout using saline, PVI or topical antibiotics are commonly used, however no specific studies have addressed the impact of washout, or washout type on SSI rates in implant based breast reconstructions.

The strongest evidence for pocket washout relates to breast augmentation studies where capsular contracture, presumed secondary to infection and implant biofilm, is used as a surrogate outcome to reflect subclinical infection. A systematic review of implant washout techniques in breast augmentation showed that pocket washout decreases capsular contracture. Capsular contracture rates were reduced in the two studies where antibiotic washout was compared to no washout at all; but not in the two studies where washout types were compared to one another.[33]

Several poor quality studies have used SSI rate as the outcome in augmentation patients. In one study local antibiotic irrigation in the pocket reduced the incidence of infection by greater than four times from a baseline of 1.1%.[86] but it is not clear whether the comparison group had non-antibiotic pocket washout or no pocket washout at all. Another study of pocket washout with or without antibiotic, showed a reduction in infection from 12.8 to 6.7%.[90] However, the experimental cohorts were from two different study periods, all *suspected* (as opposed to verified) cases of infection were included, and with a large proportion of the infections reported occurred more than one year postoperatively.[91]

Summary: recommended

Breast augmentation research supports a pocket washout to reduce infection and capsular contracture. There is a paucity of data to support one form of washout to another. We recommend that the pocket should be washed out, but the exact solution for washout cannot be stipulated.

Incision site

The most common incisions for aesthetic implant procedures are inframammary, transaxillary or periareolar with the former favoured for cosmetic augmentation and the latter for skin sparing mastectomy and immediate reconstruction.

It is hypothesised that a periareolar incision disrupts lactiferous ducts, exposing the implant to commensal bacteria causing increased capsular contracture rates compared to inframammary incision.[92] The nipple areolar complex has the highest levels of bacteria, followed by the inframammary fold, with the axilla having the lowest bacterial count.[93] A single study in breast augmentation specifically compared site of incision with infection rate and found no association.[94]

Only one study considered incision site in breast reconstruction. A series of 54,661 cases (both reconstructive and augmentation) reported no association between incision location and infection.[95] However the use of a retrospective survey to collect data and the extremely low infection rates reported (<1% for reconstructions, including revisions) suggest under reporting of infection.

Summary: no recommendation

There is no convincing evidence that incision site affects infection rate. The applicability of these findings to reconstructive surgery where the surgery required often dictates the incision used is limited.

Conclusions

Patients undergoing breast implant surgery, whether for aesthetic or reconstructive purposes are exposed to a range of infection prevention measures which are not standardised across units or countries. Actions to reduce SSIs have varying degrees of evidence for their efficacy, ranging from expert opinion to randomised trials.

There is a lack of evidence based benefits of SSI prevention strategies in implant-based breast reconstruction. Low breast implant infection rates, especially in the aesthetic setting, make it difficult to sufficiently power studies to provide meaningful results. In addition, the rates of implant-based breast reconstruction infection rates are poorly documented, in part because the definition of infection is not standardised. The outcomes of implant-based breast reconstruction will hopefully become clearer following the publication of the iBRA study – a UK-based National Audit of Implant-Based Immediate Breast Reconstruction, with prospective data including infection rates being collated from over 1000 cases nationally.[96] As a breast surgical community we must make sure we continue to monitor our SSI rates at both local and national levels. Future proposals with this in mind could include the introduction of mandatory reporting of all breast implant procedures and related infections, in a similar fashion to orthopaedic joint
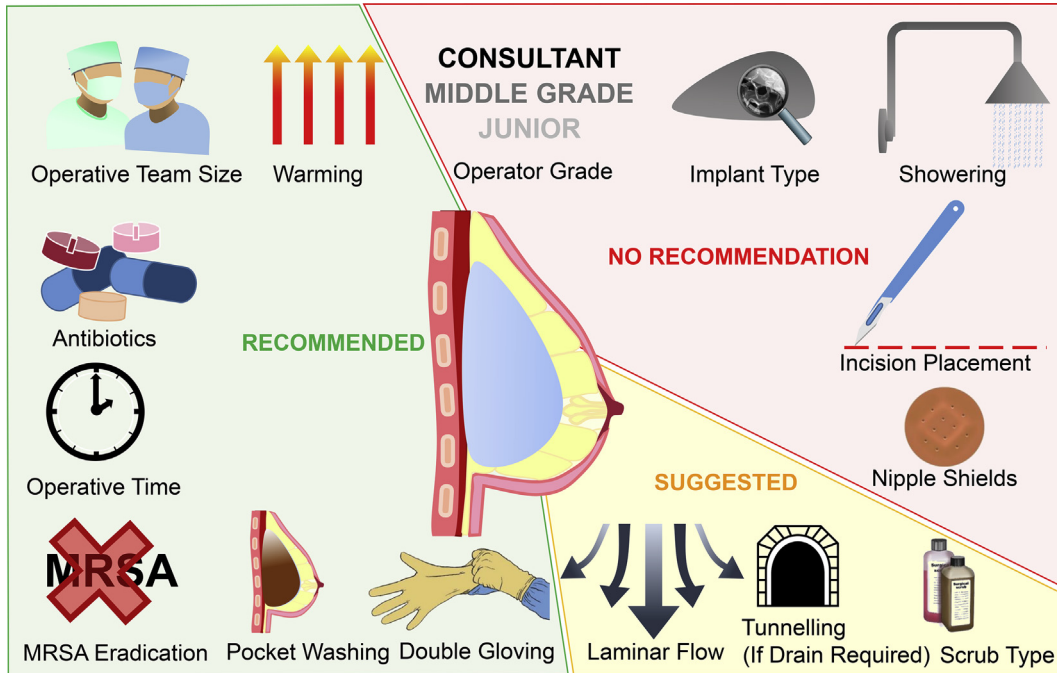
Figure 1. Guidelines for Implant-based Breast Surgery. Evidence based recommendations to reduce infection rates. (MRSA: Methicillin Resistant *Staphylococcus aureus*).
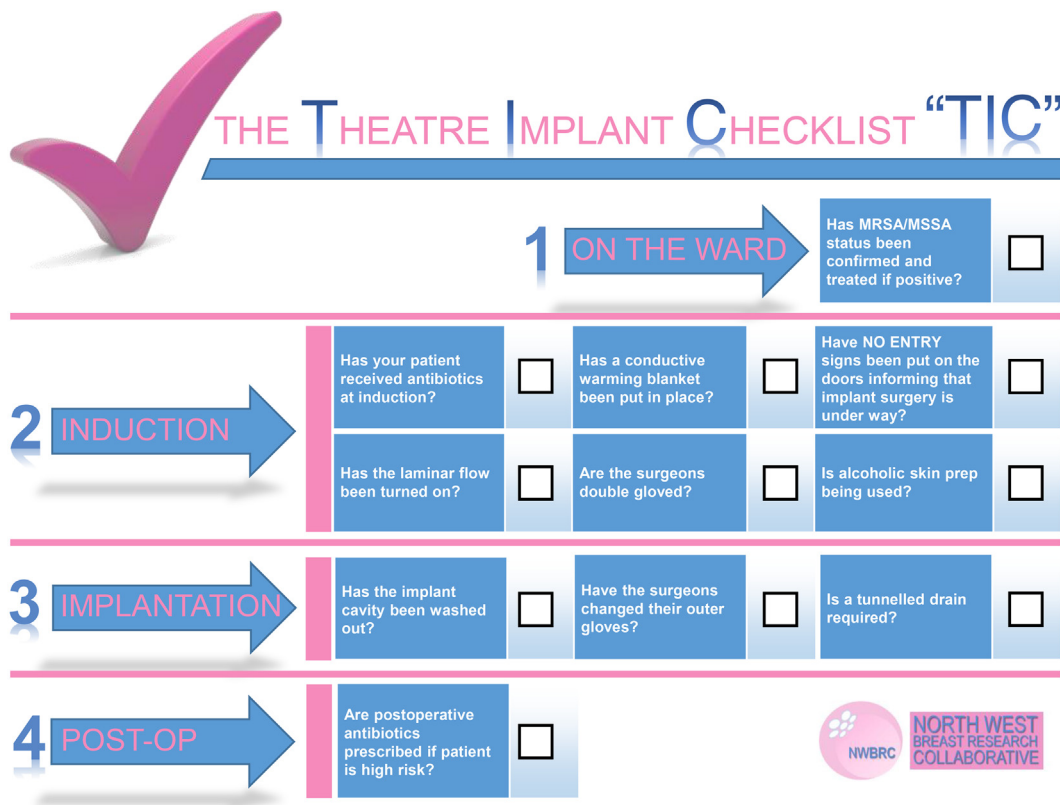

Figure 2. The North West Breast Research Collaborative Theatre Implant Checklist A peri-operative checklist to reduce SSI prevention in implant based surgery.

replacement surgery.[97] Although, in the UK, Public Health England already has a web-based database for SSI reporting in breast surgery, use of this is not mandatory and only 52 breast (but not specifically implant) SSI's have been reported across 20 hospitals between 2008 and 2013.[98] Any mandatory SSI reporting system would need to be accurate and robust, particularly in an era of transparency, 'reporting by results' and the public's ability to freely access outcome data. This is highlighted by concerns expressed as to the accuracy of the current Public Health England reporting system in orthopaedic surgery.[99]

In an "ideal world" large multicentre prospective randomised trials looking at each of the factors described in this article would be proposed, but time, money and the large volume of patients necessary to power such trials will probably preclude these from ever becoming reality. And yet we must strive to try to find the best combination of infection prevention strategies for our patients with the evidence we have. The aim of this paper was therefore to extract pragmatic conclusions from studies that often report marginal gains with conflicting evidence to produce up to date guidelines to help reduce breast implant related SSIs. We therefore propose a practical set of recommendations (Fig. 1) with our Theatre Implant Checklist ("TIC") (Fig. 2) for perioperative and audit use, based on current best evidence.

Following review of the evidence we conclude that sufficient data exists to recommend the screening and treatment of MSSA and MRSA. The use of perioperative antibiotics for implant-based breast reconstruction, with an extension of prophylaxis in high-risk patients (e.g. with risk factors such as diabetes or radiotherapy) is recommended. Alcohol containing preparations are suggested as the skin preparation agent of choice over aqueous solutions, but care must be taken to avoid pooling of the solution, as their alcoholic nature makes them flammable. Laminar air flow theatre use is suggested. Theatre traffic should be kept to a minimum as should the duration of the operative procedure, which appears to have more of an impact on SSI than the grade of surgeon (if appropriately supervised). Simultaneous operating in two teams should be considered in bilateral cases, where practicalities allow, to minimise operating time. It also appears beneficial to washout the implant pocket prior to implantation, but the exact solution for use cannot be recommended. Double gloving (with outer glove changing before handling the implant or every 90 min) is also endorsed. Patient warming is recommended where possible, using conductive heating rather than a forced air warming device.

In summary, the above recommendations give a practical set of guidelines, based on current evidence, for use in implant-based breast reconstruction. These have been formatted into a checklist (Fig. 2) intended to be used in a similar way to the World Health Organisation checklist to help ensure that a comprehensive bundle of infection prevention measures are taken for each patient.[100] Infection prophylaxis measures are used inconsistently by surgeons, with large inter and intra-surgeon variability.[101] The proposed checklist could improve reliability of prophylaxis use and facilitate audit, with the ultimate aim of minimising breast reconstruction implant infection rates.

Conflict of interest statement

We have read and understood EJSO policy on declaration of interests. We declare that we have no competing interests.

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