1.13. PREVENTION: OPERATING ROOM, SURGICAL ATTIRE

QUESTION 1: Does changing surgical gowns during prolonged operations reduce the risk of surgical site infections/periprosthetic joint infections (SSIs/PJIs)? If so, how frequently should gowns be changed during the procedure?

RECOMMENDATION: We cannot recommend for or against gown changes at specific time intervals, as there are no studies evaluating the temporal associations with gown contamination. We do, however, recommend that surgical gowns be changed if saturation or perforation of the gown occurs during surgery.

LEVEL OF EVIDENCE: Consensus

DELEGATE VOTE: Agree: 97%, Disagree: 2%, Abstain: 1% (Unanimous, Strongest Consensus)

RATIONALE

The sterilized surgical gown was first donned by Gustav Neuber in 1883, and soon after their introduction to the operating room (OR), a decrease in surgical infections was reported. Prior to this paradigm shift in surgical attire, surgeons wore a favorite coat, perhaps, which was often soiled from previous operations [1]. Due to the wide variation of surgical gowns available, there is no consensus for which gown design is most efficacious for the prevention of SSIs. Presently, data supports the use of impermeable gowns and further research into disposable versus reusable gowns with regard to the prevention of deep SSIs is required [2–7]. There is no available literature to suggest that changing an otherwise well-functioning gown intraoperatively is of any benefit with regard to the prevention of SSIs or PJIs.

Based on several studies that suggest an increase in contaminants on the OR back table as well as on operative gloves, it stands to reason that prolonged time in the OR also increases contaminants on surgical gowns. According to Dalstrom et al., there was a time-dependent contamination of open sterile trays on the back table with 4% of trays contaminated at 30 minutes, 15% contaminated at one hour, 22% at 2 hours, and 30% at 4 hours [8]. Al-Maiyah et al. performed a randomized control trial (RCT) comparing the frequency of glove changes in two groups of orthopaedic surgeons performing total hip arthroplasties (THAs). One group of surgeons changed gloves every 20 minutes during THA, the other group of surgeons only changed gloves at the time of component implantation. The study demonstrated significant reductions in glove perforations and contaminations in the 20-minute group [9]. Kaya et al. performed a study with a similar scope and determined that glove perforation occurred approximately every 90 minutes during surgery. The group advocated glove changes after this time interval [10]. There is no published data, however, to suggest specifically that changing gowns during prolonged surgical cases ultimately reduces the rate of contamination or, furthermore, deep surgical infections in arthroplasty.

In a study assessing the sterility of various areas of the surgical gown during spine procedures, Bible et al. found that after an average duration of 134 minutes the contamination rate of impermeable disposable gowns ranged from 6 to 48% depending on location. The highest levels of contamination were at the shoulders (48%) and the bottom of the gown (26%) and the least contamination at the level of the chest (6%) [11]. Based on the results of this study, there is, at a minimum, some documented evidence that gown contamination occurs at 134 minutes to varying degrees on the surface of surgical gowns. Flaherty et al. also demonstrated that the permeability of gowns increases after contact with blood after one hour, potentially increasing contamination [12]. Further investigation is required, however, to specifically answer how often surgical gowns should be changed during prolonged procedures, if at all.

In the absence of definitive evidence to support changing gowns intraoperatively, this practice should be left to the discretion of the surgeon. However, it is worth keeping in mind that several studies have linked increased surgical time directly with an increase in PJIs and thus, all efforts toward efficient completion of the operation should be made [13,14]. In a study of 69,663 primary TKA patients, 1,400 of which went on to develop a deep postoperative infection, Kurtz et al. reported a hazard ratio of 1.59 for surgical times greater than 210 minutes, as compared to cases performed in less than 120 minutes [15]. Several European registry-based studies and the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) corroborate these findings and identify surgical times as an independent risk factor for infections [16–18]. In a recent American registry-based study of 56,216 TKAs, a subgroup analysis found a 9% increase in the risk of deep surgical site infections per every additional 15 minutes of operative time (95% confidence interval (CI), 4 to 13%) [19]. In light of this evidence, reasonable efforts should be made to perform surgery in an efficient manner, mitigating time consuming steps and procedures that do not have an evidence-based effect on outcomes.

In conclusion, there is no direct evidence in the literature to support changing gowns during prolonged operations in order to prevent SSIs or PJIs. There is data, however, to suggest that longer operative times increase contamination on surfaces, including the surgeon, as well as evidence that demonstrates an increase in SSIs with increased operative times. With the current literature, as presented, we cannot recommend for or against the proposed intervention, but do highlight that operations should be performed in as efficient a manner as safety and technique allow.

REFERENCES

QUESTION 2: Does the type of surgical gown (disposable or reusable) used by the operating room (OR) personnel affect the rate of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing orthopaedic procedures?

RECOMMENDATIONS: Unknown. The available low-level evidence suggests that disposable gowns may have a higher ability to prevent bacterial dispersion in the OR. Evidence to demonstrate that gown type influences SSI/PJI outcomes is lacking.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 94%, Disagree: 3%, Abstain: 3% (Super Majority, Strong Consensus)

RATIONALE

A systematic review of the literature was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [1] aimed to identify whether the type of surgical gown, disposable or reusable, could affect the rate of postoperative wound infections in orthopaedic surgeries (Fig. 1). A search of the Embase, Scopus, Cochrane, PubMed and Google Scholar search engines was conducted using various combinations of the keywords: “Disposable gown,” “Reusable gown,” “Surgical attire,” “surgical gown,” “orthopaedic,” “arthroplasty” and “infection.” No limit was set regarding the year of publication.

The initial search provided a total of 1,264 records after adjustment for duplicates. Of these, 1,224 studies were excluded by title/abstract for clearly not meeting inclusion criteria. The full text of the remaining 40 citations was examined in detail and a further 23 were excluded as outlined in (Fig. 1). A total of 17 full text studies written in English were included in the quantitative synthesis of the review (Fig. 1).

We divided the 17 reports into 2 groups, the first including studies reporting the amount of bacterial penetration and OR contamination in relation to the surgical gown material and the second including the studies reporting about the type of gown and incidence of postoperative SSI.

Of the 17 studies included, 10 reported on gown contamination [2–12], which was expressed as gown bacterial count or penetration, air contamination and wound contamination, 6 reported on deep infection rates [13–18] and 1 reported on both outcomes [19]. Data were based on orthopaedic procedures in seven studies, and on non-orthopaedic procedures in seven studies, non specified procedures in two studies, and one study was in vitro (Tables 1 and 2). Quality assessments of the 16 studies are based on the American Academy of Orthopaedic Surgeons’ (AAOS) criteria for observational and randomized trials and all of the Level of Evidences ranged between moderate to low/conflicting evidence [20].

Despite decades of research, there remains a lack of consensus regarding certain aspects of optimal aseptic technique, including selection of surgical gown type [21]. The presence of bacteria on surgical gloves or gowns, along with airborne bacteria or persistence of bacteria on the skin after skin preparation and subsequent contamination of surgical incision, are considered the principal causes of infection in the operative setting [22].

Surgical gowns, as defined by the Food and Drug Administration (FDA) in 1993, are “surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.” These gowns can be further sub-divided into standard performance or high performance, based upon their ability to allow simulated bacterial/contaminated talc strikethrough in laboratory studies [2]. The testing conditions are done on dry and wet samples and a ratio known as the barrier index is determined for each material. A barrier index of 2.8 is required for standard surgical gowns and a barrier index of 6 is deemed impenetrable, which is required for high-performance surgical gowns [2].

Although there is some conflicting evidence, there seems to be a consensus in the research that impervious surgical gowns are an essential part of reducing SSIs/PJIs in patients undergoing any surgical procedure [21,23–26]. Disposable paper gowns demonstrated less bacterial transmission in the laboratory and lower rates of contamination in the OR [21]. The research indicates that reusable gowns have a high strike through rate when compared with disposable gowns especially at the cuffs, forearms and thighs [21,25]. Similarly, in relation to drapes, it has been shown that reusable woven drapes showed a higher permeability to bacteria when compared to their non-woven disposable counterpart [27].

Authors: Ibrahim El Ganzoury, Eoin Sheehan, Ahmed Nageeb Mahmoud, Ahmed Nageeb Mahmoud, Anthony Farrell

Despite a World Health Organization (WHO) report in 2016 which stated, “No recommendation is available on the use of disposable or reusable drapes and gowns,” [3] there is some laboratory research available which has shown disposable gowns have a lower strike through rate and hence a lower chance of bacterial contamination [21].

Surgical gowns may function to prevent SSIs, either by preventing skin organisms from direct contact from the surgery team’s skin and clothing to the surgical site, field or instruments and/or preventing bacteria from reaching the air, which may later settle into the OR areas and surgical wounds [28]. In this systematic review, we tried to present the available data about the relationship between the types of surgical gown, being disposable or reusable, and the risk of surgical wound infections.

All of these studies showed that disposable gowns that were made of different materials (Table 1) showed better resistance to gown material contamination, OR air bacterial load and surgical wound contamination. From these results, low evidence could be deduced that disposable gowns, made of polyester or polypropylene material, as well as the total body exhaust suits, worked much better as barriers for bacterial penetration that might lead to OR air and/or wound contamination. However, there are many other variables that could potentially affect dispersal of bacteria that were not controlled for in most of these studies. For instance the number of people in the OR seems to be one of the most important factors in bacterial air contamination and most studies did not account for this. Another study reported that the barrier provided by reusable gowns diminishes with laundering and is dependent on controlling all variables during reprocessing of the garment [29]. These unresolved issues can potentially reduce the evidence obtained from these studies.

Although the results of the first group of studies may possibly be interpreted by a reviewer as the non-disposable gowns can potentially reduce surgical wound infection by reducing bacterial load in the surgical gown, OR air or surgical wound, yet the studies from group 2 (Table 2) showed variable conflicting results. All the non-randomized studies concluded either a significant [13,14,16] or slight reduction [19] in the deep SSI rates with disposable gowns. Being non-randomized with many uncovered research aspects, the evidence they present ranges from low to very low. On the other hand, the three randomized studies (two randomized, one semi-randomized control trial (RCT) [15,17,18] have shown, with moderate to low evidence, that both types of gowns have comparable SSI rates. Again, there are many factors that were not controlled in these studies in Table 2 that could potentially affect the incidence of SSIs. The number of times garments were reused and their integrity were not part of any study outcome measures. Lengths of procedure, body mass index, antimicrobial prophylaxis, surgical scrubs and hair removal methods have all been shown to be important factors in SSIs. The type of procedure being performed is also likely to have dramatic effects on bacterial dispersal [28]. Lastly, as most of these studies are very old, many of the gown materials tested in earlier studies have undergone continuous improvements, thus the older studies may no longer be applicable. It should be mentioned that two other non-English studies [29,30], have shown that SSI rates are significantly higher with reusable cotton gowns. Yet, the evidence from these two studies remains questionable.
A review of the evidence conducted with WHO guidelines [3] based on many of the included studies in our systematic review showed with moderate and very low quality of evidence that the use of sterile disposable non-woven drapes and gowns has neither benefit nor harm compared to sterile reusable woven items. Similarly, the National Institute for Health and Clinical Excellence (NICE) in London, England, reported that there is no differences in incidences of SSIs between the use of single-use and reusable surgical drapes and gowns [31]. The NICE recommendation, therefore, was to consider the cost effectiveness of using one type of gown over the other. If the cost effectiveness is considered, one case study concluded that the use of disposable, non-woven gowns is more cost effective in prevention of SSIs, since for the single use items, direct purchase cost was the most important factor in the total cost. However, for reusable items, the most important factor was the combination of “number of reuses,” “laundering and reprocessing costs” and “number of drapes used per procedure” [32]. It must be mentioned that the current European standards recommend against the further use of reusable cotton and polyester/cotton-blended drapes and surgical gowns [33] based on the available studies that showed the superiority of disposable gowns and drapes materials in reducing the bacterial contamination or SSI, although their quality of evidence was low.

In conclusion, the available low-level evidence suggests that disposable gowns have a higher ability to prevent bacterial dispersions in the OR. Regarding the incidence of SSI, the available moderate to low evidence supports that both disposable and reusable gowns have equal ability for prevention of SSIs, as long as they are sterile and fluid resistant. However, because the Level of Evidence for these studies is not high, additional randomized controlled studies are needed to examine this issue further.

**TABLE 1. Studies reporting bacterial penetration in relation to the gown type**

<table>
<thead>
<tr>
<th>Study/Year</th>
<th>Type of Surgery</th>
<th>Primary Outcome</th>
<th>Type of Gown</th>
<th>Result/Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alford 1973 [4]</td>
<td>Not specified</td>
<td>Gown contamination (index for resistance to bacterial penetration through the gown)</td>
<td>Paper, Plastic</td>
<td>Plastic, hooded gown had less microbial contamination than either the cloth or paper gowns by 71.8 and 57.3% (p &lt; 0.0005)</td>
</tr>
<tr>
<td>Whyte 1976 [5]</td>
<td>Total hip arthroplasty</td>
<td>Air contamination</td>
<td>Disposable non-woven, total body exhaust system (TBES)</td>
<td>Disposable non-woven, total body exhaust system (TBES)</td>
</tr>
<tr>
<td>Blomgren 1983 [19]</td>
<td>Elective total hip arthroplasty</td>
<td>Air and wound contamination</td>
<td>Disposable with body exhaust system (TBES)</td>
<td>Conventional reusable cloth</td>
</tr>
<tr>
<td>Whyte 1990 [6]</td>
<td>Total hip arthroplasty (Mainly)</td>
<td>Air contamination</td>
<td>Disposable polyester, total body exhaust system (TBES)</td>
<td>Disposable polyester, total body exhaust system (TBES)</td>
</tr>
<tr>
<td>Sanzén 1990 [2]</td>
<td>Total hip arthroplasty</td>
<td>Air contamination</td>
<td>Disposable non-woven or total</td>
<td>With the disposable gowns and the exhaust suits, the median air</td>
</tr>
<tr>
<td>Study/Year</td>
<td>Type of Surgery</td>
<td>Primary Outcome</td>
<td>Type of Gown</td>
<td>Result/Conclusion</td>
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<tr>
<td>Scheibel 1991 [3]</td>
<td>Total hip arthroplasty</td>
<td>Air and wound contamination</td>
<td>Disposable polypropylene gowns</td>
<td>Polypropylene coveralls reduced the bacterial contamination of the air of a conventionally ventilated operating room by 62%. The contamination of surgical wounds during joint replacement was also reduced, but not to a significant degree.</td>
</tr>
<tr>
<td>Verkalla 1998 [9]</td>
<td>Elective coronary artery bypass surgery</td>
<td>Air contamination</td>
<td>Polypropylene disposable air suits (exhaust suits)</td>
<td>With the disposable polypropylene air suits (along with other protective measures), the bacterial air counts decreased from 25 CFU/m³ to 7 CFU/m³, and postoperative surgical wound contamination was significantly reduced.</td>
</tr>
<tr>
<td>Tammellin 2001 [10]</td>
<td>Cardiothoracic surgery</td>
<td>Air and wound contamination</td>
<td>Tightly woven disposable cotton/polyester suits</td>
<td>Use of tightly-woven special scrub suits reduces the dispersal of total counts of bacteria and of <em>S aureus</em> from staff in the operating room, thus possibly reducing the risk of airborne contamination of surgical wounds.</td>
</tr>
<tr>
<td>Lankester 2002 [11]</td>
<td>Total hip arthroplasty, total knee arthroplasty</td>
<td>Gown contamination</td>
<td>Fabric 450’ Theta Barrier fabric woven polyester</td>
<td>Disposable gowns showed statistically significant reduction in bacterial penetration through the surgeon’s axilla (p = .02), the groin (p = .02) and the perianal region (p &lt; 0.01), compared to the reusable gowns. Authors recommended against the use of these tested reusable gowns in orthopaedic implant surgery.</td>
</tr>
<tr>
<td>Study/Year</td>
<td>Type of Surgery</td>
<td>Primary Outcome</td>
<td>Type of Gown</td>
<td>Result/Conclusion</td>
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<tr>
<td>Ward 2014 [21]</td>
<td>Clean orthopaedic procedures</td>
<td>Gown contamination (index for resistance to bacterial penetration through the gown)</td>
<td>Disposable paper gown</td>
<td>Bacterial transmission through the paper gown material has not occurred (0 of 27 gowns). Bacterial transmission through the reusable cotton gowns occurred in 26 of 27 cloth gowns (p &lt; 0.001). Authors stated that disposable paper gowns demonstrated less bacterial transmission in the laboratory with lower rates of contamination in the operating room. Authors recommended this type of disposable paper gowns for all surgical cases, especially those involving implants, because of the heightened risk of infection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Disposable non-woven showed the best. Polyester and cotton showed the least resistance.</td>
</tr>
</tbody>
</table>

**TABLE 2. Studies reporting postoperative surgical site infection in relation to the gown type**

<table>
<thead>
<tr>
<th>Study/Year</th>
<th>Design</th>
<th>Surgery</th>
<th>Infection Rate</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moylan and Kennedy 1980 [13]</td>
<td>Prospective/crossover (not randomized)</td>
<td>Primary wound closure, including clean contaminated wounds specially in the reusable group</td>
<td>Single Use: 25/1100 (2.27%) Reusable: 74/1153 (6.41%)</td>
<td>Significant increase in infection rate with use of reusable gowns over disposable</td>
</tr>
<tr>
<td>Study Year</td>
<td>Study Design</td>
<td>Study Details</td>
<td>Primary Outcome</td>
<td>Infection Rate</td>
</tr>
<tr>
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</tr>
<tr>
<td>Baldwin 1981 [14]</td>
<td>Prospective/ crossover (not randomized)</td>
<td>Not specified</td>
<td>15/3236 (1.1%)</td>
<td>Use of disposable draping and gowns reduced SSIs from 1.1% to 0.43% (no statistical analyses performed)</td>
</tr>
<tr>
<td>Blomgren 1983 [19]</td>
<td>Prospective crossover (not randomized, statistical analysis not performed)</td>
<td>Total hip replacement</td>
<td>9/27 (number of bacterial growth on the wound wash per number of procedure)</td>
<td>Rate of superficial SSIs was slightly higher when conventional clothing was used instead of total body exhaust suit</td>
</tr>
<tr>
<td>Garlbaldi 1984 [15]</td>
<td>Prospective/randomized/blinded observer</td>
<td>Different elective operations. No mention of the number of clean or clean contaminated wounds</td>
<td>5/226 (2.2%)</td>
<td>No significant differences in SSIs between reusable and disposable gowns and drapes</td>
</tr>
<tr>
<td>Moylan 1987 [16]</td>
<td>Prospective/crossover</td>
<td>Clean and clean contaminated general surgery</td>
<td>30/1060 (2.83%)</td>
<td>Significantly higher infection rate with reusable drapes and gowns than disposable ones</td>
</tr>
<tr>
<td>Bellchambers 1996 [17]</td>
<td>Prospective/randomized</td>
<td>Coronary artery surgery</td>
<td>13/250 (5.2%)</td>
<td>No differences in SSI rates in either leg or sternal wounds between reusable and disposable gown and drape systems</td>
</tr>
<tr>
<td>Belkin 1998 [18]</td>
<td>Prospective/crossover/blinded observer (quasi RCT)</td>
<td>Different procedures with primary closure</td>
<td>108/2139 (5.0%)</td>
<td>No significant differences in SSIs between reusable and disposable gowns and drapes</td>
</tr>
</tbody>
</table>

REFERENCES

QUESTION 3: Does the use of occlusive strips at the sleeves of the surgical gowns reduce the risk of surgical site infection/periprosthetic joint infection (SSI/PJI)?

RECOMMENDATION: There is no direct evidence that occlusive strips at the sleeves of surgical gowns reduce the risk of subsequent SSIs/PJIs. However, there is evidence that occlusive strips prevent the egress of particles from the gown-glove interface of certain gowns systems, and thereby can reduce contamination of the surgical field and potentially reduce the risks of SSIs/PJIs.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 91%, Disagree: 3%, Abstain: 6% (Super Majority, Strong Consensus)

RATIONAL

Despite the sleeves of modern disposable gowns being repellent to liquids, the gown cuff is permeable to fluids and was recognized as a potential source of contamination to the surgical field over 60 years ago [1,2]. The failure of the gown-glove interface allows for blood and body fluids to reach the skin of the gown wearer in some circumstances [3–6].

It is, however, less well-established that the gown-glove interface is also a potential source of contamination to the patient and thus a source of subsequent PJIs/SSls [7]. A study using 10 years of data from the New Zealand Joint Registry showed increased risk of reoperations due to infection at 6 months when surgery was performed using a surgical helmet exhaust system, although follow-up studies using multivariate analyses have refuted the latter findings [8–10]. It is postulated that one potential mechanism of contamination may be egress of particles at the gown-glove interface and that positive air pressure generated by the helmet fan may force air down the sleeve, resulting in escape of particles at gown-glove interface.

The type of gown sleeve material may also influence the ability and volume of particles that migrate out of the gown-glove junction. A study by Fraser et al. analyzing egress of fluorescent powder applied to the hands prior to gowning, compared various gowning systems (one standard gown and four surgical helmet systems), and found that all gowns had some contamination at the gown-glove interface [11]. However, one surgical helmet-gown system had significantly greater contamination (p < 0.001) compared to the other four, which did not differ significantly. The gowning system with the
most contamination was made of a stiffer, more plasticized material that allowed for deeper folds and a less air tight seal at the gown-glove interface. Additionally, the authors noted that the stiffer sleeve material allowed for further distal migration of the glove cuff, potentially exposing the woven gown cuff. There was no statistical differences in contamination between other surgical helmet systems and the conventional gown, thereby not supporting the hypothesis that positive pressures within the suit is the main driver of contamination at the gown-glove interface for the gowns tested, but rather the gown sleeve material.

This same gown material noted to have greater contamination in the study by Fraser et al., was also tested in a similar fashion in a study by Young et al. [12]. In this study, the authors noted greater egress of fluorescent powder at the gown-glove interface with the surgical helmet system gown compared to a standard gown. An additional arm of the study included the surgical helmet system with the gown-glove junction taped and sealed with a drape tap. The addition of the drape tape eliminated the egress of particles at the gown-glove interface.

There have been some recommendations for modifications that can be made to surgical gown cuffs, that increase the security of the gown-glove interface such as making a small cut in the cuff and introducing the thumb through this hole to potentially decrease surgical contamination [13]. While this modification has been suggested there is minimal research testing this theoretical approach to decreasing the risk of SSI or PJI.

In a randomized trial, Shirley et al. found no differences in wound surgical contamination in total knee arthroplasty with the use of normal surgical gowns versus surgical helmet systems. They also showed the addition of tape at the gown-glove interface did not alter the contamination rate [14].

Although there are no studies directly linking occlusions at the gown-glove interface to a reduction in SSIs/PJIs, there is evidence that occlusions of this interface eliminates the egress of particles that may act as source of contamination, thus potentially reducing the risk of SSIs/PJIs.

REFERENCES


Authors: Carlos M. Autorino, Fabio Catani, Andrew Battenberg, Andrea Giorgini

QUESTION 4: Should patients wear a mask and surgical cap in the operating room (OR) to reduce the risk of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: Unknown. The use of face masks and surgical caps by inhabitants in the OR has not been shown to impact SSI rates, but with the limited evidence available a recommendation for or against patient usage cannot be made. Surgical cap usage by patients in the OR may decrease the risk of SSIs/PJIs by decreasing microbial air contamination.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 93%, Disagree: 4%, Abstain: 3% (Super Majority, Strong Consensus)

RATIONALE

Surgical face masks were originally developed to contain and filter droplets containing microorganisms expelled from the mouth and nasopharynx of healthcare workers during surgery. Likewise, head coverings such as surgical caps have been utilized to limit potential contamination by the shedding of hair and scalp.

The effectiveness of such strategies have been questioned in the literature. Even with the use of face masks, it has been shown that conversations in the OR increase microbial contamination [1] and that the barrier properties of face masks decreases with accumulation of moisture and venting along mask edges [2]. Additionally, it has been shown that wearing face masks decreases bacterial dispersal in front of the mouth [3], but has no effect on overall bacterial counts in the OR [4], suggesting that face masks simply redirect bacterial dispersal. On the other hand, omission of head coverings has...
been demonstrated to increase microbial air contamination by 3 to 5 times and increase bacterial sedimentation in the wound area 60-fold [5,6]. However, two studies have found no differences in environmental contamination with the use of head coverings [7,8].

Clinical studies have failed to demonstrate a difference in SSI rates with the use of surgical masks, while PJIs have not been specifically studied. A prospective randomized trial of 3,088 general surgery patients found no significant difference in the rates of SSIs when OR staff used a mask [9]. A prospective randomized trial of 811 patients that included orthopaedic procedures similarly found no differences in SSIs with the use of face masks by non-scrubbed staff [10]. Additionally, a meta-analysis of 3 trials and 2,113 patients found no significant difference in SSI with face mask use [11]. It is important to note that few of these trials included orthopaedic procedures and these trials had relatively high rates of SSI (3.5 to 11.5%), much higher than the current rates of SSI and PJI in total joint arthroplasty. Thus, interpretation of these findings must be made with caution.

Despite the lack of clinical evidence for the usage of face masks and surgical caps, a recommendation against patient use in the OR cannot be made for the following reasons:

While the evidence available shows no differences in SSIs with the use of surgical masks and caps by OR staff, no studies investigating the impact of patients wearing surgical masks or caps during surgery have been performed. As such, any recommendation would be extrapolation of the data from OR staff to patient usage.

The literature on SSI rates does not address the potential impact on non-enrolled patients having a subsequent surgical procedure in the OR that day. Particulates, such as shed hair and their impact on SSIs/PJIs on other patients have not been studied, but case order has been shown to impact risks of PJIs [12].

PJI has not been specifically studied as an end-point.

The literature does not address differential usage of masks in special populations, such as methicillin-resistant Staphylococcus aureus (MRSA) + nasal carriers. Eliminating mask or cap usage in these individuals may effect SSI/PJI rates.

Microbial contamination of air in the OR may be an underappreciated factor in the etiology of PJI [13]. Surgical cap usage in the OR may decrease the risks of SSIs/PJIs, by decreasing microbial air contamination.

REFERENCES


QUESTION 5: Does changing gloves during prolonged operations reduce the risk of surgical site infections/periprosthetic joint infections (SSIs/PJIs)? If so, how frequently should gloves be changed during the procedure?

RECOMMENDATION: Changing gloves intraoperatively may reduce the risks of SSIs/PJIs in arthroplasty surgery by reducing contamination. Based on prior studies, gloves should be changed after draping, before handling implants and when macroscopic perforation of the glove occurs. Gloves should also be changed at least once every 60 to 90 minutes, as contamination and glove perforation rates increase with duration of surgery.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 92%, Disagree: 5%, Abstain: 3% (Super Majority, Strong Consensus)

RATIONAL

Double-gloving is a widely-utilized technique by surgeons in many surgical subspecialties in the hopes to minimize contamination of the surgical site [1,2]. Microbiological contamination rates of gloves increases with duration of surgery, which warrants glove change during prolonged procedures [3]. However, no studies have been published that evaluate the direct relationships between changing gloves and the risks of SSIs/PJIs. Furthermore, there is conflicting evidence regarding the optimal frequency of glove changes.

Author: Simon W. Young
Multiple studies have demonstrated that the percentage of intraoperative glove contaminations by microorganisms during total joint arthroplasty (TJA) procedures ranges from 3.4 to 30% [2,4–8]. The high variability of contamination may be attributed to differing methods of quantifying contamination. Other factors, such as ventilation in the operating room, may also impact the rates of surgical glove contamination. Most studies are observational and only reported absolute intraoperative contamination rates. These studies have not compared the differences in contamination rates between cases where gloves were changed intraoperatively, during the middle of a clean orthopaedic procedure, versus cases when they were not changed. However, in one randomized trial of 102 surgical team members, Ward et al. demonstrated that changing gloves 1 hour into a clean orthopaedic procedure was associated with significantly decreased intraoperative glove contamination rates (13 vs. 23%) [2].

There are conflicting reports regarding the optimal frequency of changing gloves during a procedure. Most studies recommend changing gloves after draping because of the high contamination rates due to disturbed laminar flow [4,7,9]. Other studies advise changing gloves before handling implants in order to prevent transfer of pathogens onto the new prostheses [2]. Regardless of contamination rates, perforated gloves are ineffective as a protective barrier against contamination [10]. Therefore, changing gloves is also recommended whenever a macroscopic glove perforation is detected, which has been shown to occur after an average of 93 ± 50 minutes of intraoperative time [11]. The recommended timing of glove changes in studies using contamination and/or perforation is variable, ranging from every 20 minutes to 90 minutes [8,11–13], also after bone resection and before inserting implants [14].

Although no studies investigate the direct link between intraoperative glove changes and SSIs/PJIs following TJA, studies from other surgical specialties demonstrate a reduction in SSIs after outer glove changes [15,16]. Due to the low PJI rates in arthroplasty surgeries, conducting a randomized control trial (RCT) with PJI as the primary outcome would be uneconomical due to the high number of surgeries needed to be performed in order for one PJI to occur. Moreover, the relevance of the findings from other surgical specialties is unclear due to the unique nature and components used in arthroplasty surgery. More studies are required to draw a definitive conclusion regarding the effectiveness of changing gloves in reducing the risk of SSIs/PJIs.

REFERENCES


QUESTION 6: Does shoe wear (i.e., operating room (OR) dedicated shoes, uncovered outside shoes, covered outside shoes) of the surgeon and OR staff affect the rate of surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing orthopaedic procedures?

Authors: Setor Kunutsor, Ashley Blom, Victor Hernandez, Karen Goswami

RECOMMENDATION: There is little or no evidence to suggest that the use of dedicated OR shoes influence the rates of SSIs/PJIs. However, in view of the fact that shoes worn outside may be grossly contaminated, we recommend that outside shoes should not be worn in orthopaedic ORs, or shoe coverings should be worn to prevent the contact of outside shoes with the OR floors.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 94%, Disagree: 4%, Abstain: 2% (Super Majority, Strong Consensus)
RATIONALE

Though shoe soles are possible vectors for infectious disease, no studies currently exist directly linking shoe wear (OR only vs. outside shoes) with increased or decreased rates of SSIs/PJIs in patients undergoing orthopaedic procedures. However, published findings do suggest that OR shoes or OR over-shoes may be involved in the pathway of postoperative wound infection. In a study that assessed the level of bacterial contamination of OR shoes at the beginning and end of a working day and compared the results with outdoor footwear, findings showed the presence of pathogenic bacterial species responsible for postoperative wound infection on both shoe groups. However, outdoor shoes were the most heavily-contaminated. In addition, bacterial samples taken from OR shoes at the end of duty were less contaminated than those taken at the beginning of the day [1].

In a separate study that assessed bacterial floor colony counts in a general OR, use of OR over-shoes significantly increased colony counts, whilst non-use of over-shoes did not significantly increase colony counts [2]. However, there were no significant differences in mean bacterial floor colony counts when the two were compared. In another study that determined the effect of wearing shoe covers by medical staff and visitors on infection rates as well as the mortality and lengths-of-stay in an intensive care unit (ICU), use of shoe covers were not helpful in preventing infections of common ICU pathogens [3]. However, in the period when shoe covers were used, there were higher rates of infections compared to periods when shoe covers were not used. A study from the UK concluded that use of protective over-shoes was unnecessary for “day” surgery, which was classified as uncomplicated same-day surgical procedures, such as hernia repairs, varicose vein surgery and simple laparoscopy [4]. This poses an important question: should ambulatory versus inpatient ORs change our approach to shoe wear?

Conflicting findings have been reported. When OR floors were examined for contamination with and without the use of protective footwear, the results of the study performed by Copp et al. indicated that the use of over-shoes reduced the transfer of bacteria [5]. There is no evidence that outdoor shoes carry an increased risk of infection. However, it has been reported that the process of changing shoes or applying over-shoes can result in contamination of the hands of clinicians/surgeons [6]. In a study of 18 individuals whose hands were examined after contact with their over-shoes, findings showed that the organisms detected on their hands were likely to have been transferred from their outdoor shoes [7]. Ayliffe studied the role of the environment of the OR on postoperative wound infections. He noted that the use of surgical disinfectant mats, while proactive, may actually increase the number of organisms on the shoe soles of staff members entering the OR [8].

Based on the overall evidence, there is no evidence to support a direct link between shoe wear and the rates of SSIs and/or PJIs in patients undergoing orthopaedic surgery.

REFERENCES