

1.9. PREVENTION: SURGICAL SITE PREPARATION

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QUESTION 1: Does preoperative skin cleansing at home prior to orthopaedic surgery have a role in the reduction of subsequent surgical site infection/periprosthetic joint infection (SSI/PJI)?

RECOMMENDATION: Yes. Preoperative skin cleansing at home prior to orthopaedic surgery does have a role in the reduction of subsequent SSIs/PJIs. Specifically, chlorhexidine gluconate (CHG) has been shown to have excellent results in preventing PJIs/SSIs.

LEVEL OF EVIDENCE: Moderate

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

RATIONALE

As noted by the Centers for Disease Control and Prevention, preoperative skin cleansing with an antiseptic agent can substantially decrease skin microbial counts [1,2]. Studies examining this practice and its role in the reduction of SSI and PJI rates have produced conflicting findings. To determine the utility of preoperative skin cleansing in preventing SSIs/PJIs, the effectiveness and logistics of the practice must be taken into account.

Preoperative skin cleansing can be executed using a variety of agents. Garibaldi et al. performed a prospective trial on over 700 patients and found rates of positive intraoperative wound cultures to be 4% for patients who showered and scrubbed with CHG, 9% for those who used povidone-iodine, and 14% for those who used medicated soap and water [3]. Several other published studies supported a connection between preoperative skin shower and CHG with decreasing overall culture rates [4–8].

Chlorhexidine bathing at home prior to surgery involves the use of either a 4% solution or a 2% cloth for a varying number of days based on the literature. Low-level evidence recommends the use of CHG cloths over bathing in its soap form [9]. Regardless of application methodology, CHG can either be bacteriostatic or bactericidal based on the concentration used for cleansing and its efficacy has been known to improve with frequency and duration of use [5,10,11]. The applicability of the aforementioned findings to SSI/PJI prevention in patients undergoing orthopaedic surgery remains unclear due to contradictory findings in the literature.

Kapadia et al. studied 3,717 patients who underwent primary or revision total knee arthroplasties. The group found that the use of a pre-admission chlorhexidine protocol was associated with a reduced relative risks of PJIs after total knee arthroplasty (TKA), when compared to patients who did not receive a CHG protocol (0.3% vs. 1.9%; rate ratio (RR): 6.3, 95% confidence interval (CI) 1.9 to 20.1, $p = 0.002$) [12]. Similar results were seen even when the two patient cohorts were risk-stratified. A review of modern papers from 2009 to 2015 also showed a reduction in infection rates with preoperative chlorhexidine preparation [13].

A systematic review by Webster et al. of over 10,000 patients in the Cochrane Database also concluded chlorhexidine washes were better than not bathing at all. However, the use of chlorhexidine washes did not seem to change infection rates [11]. Nevertheless, the review reported a lower relative risk for SSIs in patients who used CHG compared to those who used placebo (RR: 0.91, 95% CI 0.8 to 1.40). Farber et al. reported on over 3,700 total joint cases with 1,891 using 2% cloth wipes at the surgical site one hour prior to their procedure [12]. They also found no differences in infection rates at the one-year follow-up for either group.

As described above, the literature cannot affirm emphatically that skin cleansing at home prior to orthopaedic surgery has a role in reduction of subsequent SSIs or PJIs. There has yet to be any reports on the negative effects of preoperative skin cleansing at home prior to arthroplasty surgery and concerns for skin hypersensitivity associated with use of CHG are minor [4]. With really no downside and some potential upside (Table 1), it seems reasonable to consider some form of preoperative skin cleansing at home. Moreover, well-controlled trials are required to truly assess the efficacy of the preoperative skin baths. Initial cost data seems promising but may be institutionally-related with a potential net savings of \$0.78 to \$3.1 billion [14]. A true cost-assessment is necessary to understand if this low-risk means of infection prevention is cost-effective and whether it should be the standard of care prior to any orthopaedic/arthroplasty surgical procedure.

In conclusion, Table 1 summarizes studies that have been completed regarding chlorhexidine preoperative bathing and its effects on SSIs/PJIs. The heterogeneity of skin cleansing regimens and varying compliance rates make it difficult to isolate preoperative preparation as the main determinant for infection prevention in patients undergoing orthopaedic surgery. Despite the data listed, it is important to understand that compliance is always a concern with this protocol as one study found 78% noncompliance despite focused pre-surgery education efforts [15].

TABLE 1. Studies related to preoperative skin cleansing protocols in TJA

Author	Number of Patients	Treatment	Outcomes	Level of Evidence
Webster [11]	10,157 all surgeries	Chlorhexidine, bar soap and no wash	No evidence that chlorhexidine was better	I

Farber [16]	3,715 TJAs THA—845 CHG; 815 no CHG TKA—1,046 CHG; 1,009 no CHG	2% chlorhexidine wipes	No reduction in infection at 1 year follow-up; 1.0% v. 1.3% infection overall; THA 1.2% v. 1.5%; TKA 0.8% v. 1.2%	III
Chlebicki [17]	17,932 all surgeries	Chlorhexidine, bar soap and no wash	No evidence that chlorhexidine was better	III
Eiselt [18]	1,463 TJAs	2% chlorhexidine wipes	50.2 % reduction in SSIs (3.19% down to 1.59%)	III
Johnson [19]	954 TJAs	2% chlorhexidine wipes	1.6% infection among noncompliant and 0% in the compliant cohort	III
Kapadia [12]	3,844 THAs; 998 with CHG and 2,846 without	2% chlorhexidine wipes	Decreased infection rate with CHG wipes; 0.6% v. 1.62%	III
Zywiol [20]	136/912 TKAs	2% chlorhexidine wipes	0% infection in CHG wipe group v. 3.0% in 711 other TKAs	III
Wang [21]	8,787 TKAs (2,615 CHG; 6,172 controls)	Variable	1.69% reduction in infection overall as well as in moderate and high risk patients	III
Cai [22]			6 studies reviewed and found a reduction in the risk of infection, revision surgery and length of stay	III
Kapadia [23]	564 TJAs (275 CHG and 279 Controls)	2% chlorhexidine wipes	CHG with 0.4% v. Controls with 2.9%; no adverse events—RCT	I
Kapadia [12]	3,717 primary or rev TKA (991 with CHG and 2,726 without)	2% chlorhexidine wipes	Risk reduction of infection from 0.3% compared to 1.9%, better reduction in medium risk compared to low risk	III

CHG, chlorhexidine gluconate; RCT, randomized control trial; THA, total hip arthroplasty; TJA, total joint arthroplasty; TKA, total knee arthroplasty

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QUESTION 2: Should skin and hair around a planned surgical incision be removed? If so, what is the best method and timing of removal?

RECOMMENDATION: Hair at the surgical incision site should be removed immediately prior to surgery using clippers or depilatory creams.

LEVEL OF EVIDENCE: Consensus

DELEGATE VOTE: Agree: 84%, Disagree: 13%, Abstain: 3% (Super Majority, Strong Consensus)

RATIONALE

Skin preparation prior to surgical incision has traditionally involved localized preoperative hair removal [1]. Despite a lack of statistical significances between the incidence of surgical site infections (SSIs) with and without hair removal, it is still utilized during total joint arthroplasty (TJA) [1–3]. A recent meta-analysis conducted by Lefebvre et al. included findings from 19 randomized controlled trials (RCTs). Six trials included in the analysis compared shaving with no hair removal and results showed that no hair removal was associated with a lower risks of SSIs [3]. Another study compared chemical depilation with no depilation, and one study compared clipping with no depilation. In both cases, no significant differences were observed in paired analyses [3].

A 2006 Cochrane Systematic review of preoperative hair removal (updated in 2011) analyzed a total of nine RCTs, and found no significant differences in SSI rates among patients with or without hair removal at the incision site prior to surgery. It is worth noting, however, that investigators acknowledged that the comparison was underpowered [2,4]. Despite conflicting evidence on whether or not hair should be removed preoperatively, there is rationale behind the practice which should not be discounted. Depilation is thought to serve as a precautionary measure to reduce the risk of hair entering the open wound during the procedure. Potentially adverse outcomes due to hair contamination at the site of incision include foreign body tissue reactions subsequent to mechanical irritation during the wound healing process and infections [5].

Methods for depilation around a planned surgical incision include shaving, clipping and chemical removal. In 2011, Tanner et al. performed an update to a Cochrane Review previously published in 2006. A total of 11 randomized controlled trials related to hair removal prior to surgery were identified. The meta-analysis found electric clippers and depilatory creams to be associated with lower rates of SSIs in comparison to shaving with a razor blade [2]. These outcomes are attributed to the microtrauma inflicted on the skin during the shaving process, which then creates a nidus for bacterial colonizations and subsequent SSIs [6,7]. Chemical hair removal is a suitable alternative to clipping, however, there has been conflicting evidence on its efficacy. Lefebvre et al. showed that chemical depilation was associated with fewer SSIs compared to shaving. In the same study, indirect comparison with clipping as the reference showed no significant differences with chemical depilation [3]. Increased lengths of time to complete chemical depilation and the potential risk for chemical irritation of the skin make its utilization less advantageous [1–3,8]. In light of these findings, it is highly recommended that hair depilation be completed with an electric clipper [5,9]. Support for clipping has been reinforced by RCT results from Cruse and Foord, Alexander et al., Balthazar et al., Ko et al. and Taylor and Tanner [9–13].

In accordance with findings from the previous International Consensus Meeting, current literature lacks evidence to support an optimal time for hair removal [14]. Alexander et al. examined hair removal the night before and the morning of operations across a variety of surgical disciplines using both shaving and clipping. Excluding stitch abscesses, rates were lowest in the morning clipper group (at discharge: $\chi^2 = 4.894$, $p < .027$, at 30 days: $\chi^2 = 7.439$, $p < .006$) [9]. In an RCT of 798 patients undergoing spinal surgery, Celik and Kara found that shaving (with a razor) of the incision site, immediately before spinal surgery, may increase the rate of postoperative infections over not shaving at all [15]. According to a network meta-analysis of 19 randomized control trials conducted by Lefebvre et al., differences in outcomes based on timing of depilation were not statistically significant enough to conclude when hair should be removed prior to surgery [3]. If hair removal is to be done prior to surgery, it should be completed as close to the time of surgery as possible by either the surgical team or the trained nursing staff [1,3,6–9,14]. Though there is an overall lack of research specific to the environment in which preoperative hair removal should take place, it is recommended that it take place outside of the operating room, if practical [5,14,16].

Given what has been published to date, definitive evidence to dictate hair depilation practices with greater statistical significance is desired. Based on what has been established in the literature, it is recommended that hair be removed at the site of incision with depilatory creams or clipping shortly before the operation or outside of the operating room. This practice should be followed out of necessity and not routinely. If hair around the site of surgical incision does not interfere with the operation, it should not be removed due to the potential risks of skin and wound contamination.

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QUESTION 3: Does additional skin cleansing after placement of surgical drapes have a role in reducing the rate of surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: Repeat skin cleansing following placement of surgical drapes may reduce bacterial colonization and the incidence of subsequent superficial SSIs.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 74%, Disagree: 15%, Abstain: 11% (Super Majority, Strong Consensus)

RATIONALE

The prevention of SSIs is a multifaceted effort. Among the many measures taken to reduce the incidences of SSIs, cleansing of the surgical site using a povidone-iodine or chlorhexidine solution prior to incision is considered a routine practice as this technique is thought to reduce the bacterial load at the surgical site [1–3]. Typically, the surgical site is draped after the cleansing solution has been applied. It has been hypothesized that bacteria may be

reintroduced to the surgical site during this draping process [4]. There are a number of mechanisms through which this has been thought to occur, including lift-off of the draping, contamination of the surgical glove-tips, contact of the skin with non-sterile material and/or dropping of airborne particles from the room air onto the surgical site [5–7]. Thus, repeat skin cleansing following draping has been proposed as a way to prevent contamination of the surgical site before the procedure is initiated.

To our knowledge, there has been one prospective study assessing the efficacy of a second skin cleansing once surgical drapes have been applied. In a single-center randomized controlled trial, Morrison et al. compared two skin cleansing protocols in 600 patients undergoing total joint arthroplasty. The control arm consisted of a single cleansing, performed prior to the placement of surgical drapes, using a combination of 7.5% povidone iodine, 75% isopropyl alcohol and 10% iodine paint. The intervention arm consisted of a similar protocol, with a subsequent second skin cleansing with iodine and isopropyl alcohol, following the placement of surgical drapes. There were significantly lower rates of superficial SSIs in the intervention arm (6.5 vs. 1.8%). However, no significant differences were noted in the incidence of overall SSIs (both superficial and deep) between the two cohorts [8].

In conclusion, and based on a single prospective study, it appears that skin cleansing following the application of surgical drapes may reduce bioburden at the skin and result in lower rates of subsequent superficial SSIs. However, there is a need for additional evidence to determine if a second skin cleansing after draping truly leads to lower rates of SSIs/PJIs.

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QUESTION 4: What pre-surgical skin preparation is most effective in reducing the risk of surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing orthopaedic procedures?

RECOMMENDATION: There appear to be no differences between various skin preparation agents (chlorhexidine gluconate (CHG) versus povidone iodine (PI)) as long as isopropyl alcohol is part of the preparation.

LEVEL OF EVIDENCE: Limited

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

RATIONALE

Skin preparation agents play an important role in reducing the risk of SSIs for patients undergoing surgical procedures. Organisms found in skin flora targeted by antiseptic solutions include staphylococci, diphtheroid organisms, *Pseudomonas* and *Propionibacterium* species, all of which can lead to harmful infections if they are allowed to multiply [1]. As recommended by the Centers for Disease Control and Prevention (CDC), counts of the aforementioned resident organisms and transient bacteria should be reduced on the surface of the skin by a bactericidal antiseptic prior to surgery [1]. The ideal skin preparation solution needs to work rapidly and also prevent the growth of pathogens for at least six hours after application [2]. Available skin prepping solutions used preoperatively to prevent SSIs include: iodine povacrylex and isopropyl alcohol, PI and CHG and isopropyl alcohol [3,4].

In a study of clean-contaminated upper gastrointestinal or hepatobiliary-pancreatic open surgery between 2011 and 2014, patients were randomly assigned to chlorhexidine gluconate or povidone-iodine, neither with alcohol. No differences were detected between chlorhexidine gluconate and povidone-iodine antiseptics for the prevention of SSIs [5]. Furthermore, Savage et al. found CHG to be an equally effective skin-preparation solution for lumbar spine surgery in comparison to PI [6].

Contrary to these findings, studies have found CHG to be a more superior agent to iodine povacrylex and isopropyl alcohol and/or PI. Saltzman et al. found CHG and isopropyl alcohol to be more effective than iodophor, isopropyl alcohol and PI in shoulder surgery cases [7]. Support for the use of CHG is evident a study done by Darouiche et al., which compared 2% CHG mixed with 70% isopropyl with 10% PI in clean contaminated wounds and found superiority of the former solution in reduction of SSIs [8]. A potential explanation for these results is that CHG has a high antibacterial activities, strong affinities for binding to the skin and prolonged residual effects [9]. It is important to note, however, that the CHG in the latter study was combined with alcohol, whereas, the PI was an aqueous solution. So effectively, the investigators compared two agents (alcohol plus CHG) against one.

In practice, CHG is more commonly delivered within an alcohol-based solution, as opposed to PI which is usually aqueous. Subsequently, there is debate as to whether or not the presence of alcohol in CHG has led to a bias in study results establishing its superiority over PI [10]. A previous study by Hakkarainen et al. did not find any unique effects of isopropyl alcohol, possibly nullifying this argument [11]. An ongoing cluster randomization trial in

patients undergoing elective total hip arthroplasties (THAs) or total joint arthroplasties (TJAs) is being conducted to compare the efficacy of 0.5% CHG in 70% alcohol to that of 10% PI in 70% alcohol [12]. Results from this study may help clarify the role of alcohol in the efficacy of CHG and other skin prepping agents.

Further discrepancies in the selection of optimal skin-prepping solution can be found in a Cochrane review by Dumville et al. on skin antiseptics with a critical appraisal of the published articles on the issue of SSI [1]. This review demonstrated the following:

No statistically significant differences between skin preparation with PI and soap followed by methylated alcohol paint.

No differences between 7.5% aqueous povidone in 10% alcohol and CHG in 70% alcohol paint.

0.5% chlorhexidine in methylated spirit had reduced risk of SSIs compared with PI in alcohol (one study only, with poor reporting of details).

No significant differences in number of SSIs when comparing aqueous and alcoholic solutions for skin preparations.

Given the conflicting findings from previously-mentioned studies as well as those conducted by Segal and Anderson, Pinheiro et al. and Swenson et al., an ideal solution of choice has yet to be identified for surgical site skin preparations [8,13]. Current literature lacks evidence to support the use of one solution over another in the prevention of SSIs, but there is an overall consensus that skin preparation solution should contain alcohol, originating from recommendations made by the CDC, International Consensus Meeting Group (ICG) and previously-published studies [2,3,5].

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QUESTION 5: Does surgical preparation of the skin on the whole limb instead of a partial limb reduce the rates of surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: Surgical skin preparation of the whole limb may potentially reduce the risk of SSIs and/or PJIs by decreasing the risk of contamination associated with partial limb preparation. Despite the limited evidence, we recommend surgical skin preparation of the whole limb as there is a potential for contamination with partial limb skin preparation, and little downside to whole limb skin preparation.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 84%, Disagree: 12%, Abstain: 4% (Super Majority, Strong Consensus)

RATIONALE

SSIs and PJIs can be devastating and costly complications associated with joint arthroplasty [1–3]. As multiple variables are associated with SSIs and PJIs, considerable research has focused on reducing the rates of infections with the use of prophylactic antibiotics, utilization of laminar flow, various skin preparation solutions, medical optimization of patient risk factors, appropriate sterile techniques, etc.[4–9]. However there is a paucity of literature on partial versus whole limb skin preparation.

At the time of surgery, much effort is spent on sterile technique while prepping and draping the operative extremity to create a sterile surgical environment in an attempt to reduce the risks of SSIs and PJIs [10]. Often, surgical draping techniques are based on surgeon training and preferences rather than scientific evidences. Improper draping techniques may provide an opportunity for surgical field contamination [11]. One common extremity draping practice is to apply an impervious stockinette over a non-prepared foot rather than preparing the whole limb.

There are two potential sources of contamination associated with partial limb skin preparations: (1) potential bacterial contamination through the stockinette from strikethrough and (2) proximal bacterial migration from application of a sterile stockinette over a non-prepped foot.

Although the literature is limited, several small studies have evaluated partial versus whole limb skin preparation with conflicting conclusions. Bloome et al. assessed potential bacterial strikethrough utilizing an impervious stockinette over a non-prepped foot [12]. Of the twenty samples taken, only two grew one colony forming units of coagulase-negative *Staphylococcus*. Based on these findings, the authors concluded that strikethrough from a non-prepped foot is unlikely to be a significant source of contamination and therefore disinfecting the ipsilateral foot with a skin preparation solution is unnecessary.

Two other studies used either a fluorescent powder, or a non-pathogenic fluorescent *Escherichia coli* strain as a surrogate for contamination in order to evaluate proximal bacterial migration from application of a sterile stockinette over a non-prepped foot [13,14]. In both studies, the majority of extremities with a non-prepped foot had significant proximal migration of either fluorescent substance. The authors from both of these studies concluded that the application of a sterile stockinette over a non-prepped foot may be a source of proximal bacterial migration and, therefore, potential risk for surgical field contamination.

We propose that surgical preparations of the skin should include the whole limb given that the aim of this procedure is to reduce the microbial load on the patient's skin as much as possible. The prepared areas of the skin should extend to an area large enough to accommodate potential shifting of the drape fenestration, extension of the incision, potential for additional incisions as well as all potential drain sites. Despite our current knowledge about the antimicrobial activity of many antiseptic agents and application techniques, the best approach for surgical site preparation still remains unclear and further high-quality studies are warranted.

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QUESTION 6: Does surgical skin preparation starting from the surgical site, proximal portion of the extremity or distal portion of the extremity affect the rate of surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: Despite the absence of supportive evidence, we recommend starting skin preparation from the site of surgical incision and moving towards the periphery. In general, skin preparation should be performed from a less-contaminated towards a more-contaminated area. In the case of a draining sinus, the area around the sinus should be prepped at the end of the preparation process.

LEVEL OF EVIDENCE: Consensus

DELEGATE VOTE: Agree: 95%, Disagree: 3%, Abstain: 2% (Unanimous, Strongest Consensus)

RATIONALE

Surgical skin preparation is one of the multiple steps implemented to minimize infections after surgical procedures [1]. Different techniques and antiseptic solutions are currently in use with proven efficacy for a number of agents. Skin preparation consists of application of an antiseptic solution to the surgical site and the surrounding areas. The most commonly-used antiseptics are alcohol-based solutions of chlorhexidine or povidone [2].

The process requires some mechanical effect (friction) for removing dead skin and bacteria from the surface of the surgical field, thereby reducing the number of viable bacteria.

Despite the lack of studies addressing the specific question cited above, reviews and guidelines are available recommending that skin preparation should start at the incision site and be directed towards the periphery [3–5]. In some guidelines/recommendations the use of concentric circles is recommended. It is commonly stated that the process should be directed from less to more contaminated areas, such as the foot, groin or the unsterile drape covering the tourniquet [4,6,7]. Including the entirety of the skin surface is important (for example, prepping the knee in full flexion and full extension can enhance the ability to obtain a thorough coverage of the intended sterile surgical surface areas) [8].

The amount of friction (force applied with the device soaked in antiseptic fluid against the skin), the number of applications over each area and direction are not specified in any guidelines or recommendations available to date. It is, however, known that sufficient time is required for an antiseptic solution to act on the surgical site allowing for maximum elimination of microorganisms [9]. Antiseptic agents have different action times and it is recommended that the manufacturer's instructions for each specific antiseptic be followed [10].

In the absence of specific studies addressing the above question, it is our recommendation that special attention be paid to preparation of the surgical site. The preparation should start from the surgical site, and then be directed to the periphery. It is also advisable to prevent the contact of the preparation sponge with more contaminated areas that could potentially transfer bacteria back to the surgical site.

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QUESTION 7: Does the type of surgical drape (disposable vs. non-disposable) used affect the risk of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing orthopaedic surgery?

RECOMMENDATION: Unknown. The data from non-orthopaedic procedures suggests that disposable drapes resist bacterial passage and reduce the risk of subsequent SSIs. Impermeable barriers should be used regardless of whether disposable or non-disposable drapes are used.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 90%, Disagree: 3%, Abstain: 7% (Super Majority, Strong Consensus)

RATIONALE

Surgical drapes act as a barrier to prevent the contamination of the surgical field during a procedure. They are used to isolate the prepared surgical field from the non-sterile, non-surgical area. Reusable drapes are made of a woven material and are laundered and sterilized between procedures. In contrast, disposable drapes are usually made of non-woven material and are disposed of after each operation. Various physical properties of drapes and surgical conditions can affect the bacterial permeability of drapes. For example, it is known that there is increased bacterial passage when drapes are made wet by normal saline or blood [1,2]. Disposable drapes have been shown to decrease rates of bacterial passage, even when made wet by normal saline. However, this decreased bacterial transmission does not clearly indicate decreased risks of SSIs/PJIs [3,4].

We performed a systematic review using PubMed, Medline, Web of Science, Embase, Google Scholar and the Cochrane Library of studies in English. We included journal articles, communications and conference proceedings. Unfortunately, there is a paucity of studies relating specifically to orthopaedic surgery on this topic.

Randomized controlled trials in cardiac surgery and general surgery demonstrated no statistically significant differences in infection rates between the two types of drapes [5,6]. However, a different prospective randomized study of 102 reconstructive breast surgeries, demonstrated a statistically significant lower rate of infection 30 days after surgery in the disposable drape cohort (0 vs. 12%) [7]. The current literature on this topic is inconclusive and there are no studies involving orthopaedic or spine surgery patients. Future research efforts should be focused on this topic.

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QUESTION 8: Does the use of incise draping reduce the incidence of surgical site infections/periprosthetic joint infections (SSIs/PJIs)? Is there a difference in efficacy between incise drapes?

RECOMMENDATION: There is evidence to indicate that antimicrobial-impregnated incise drapes result in a reduction in bacterial colonization of the surgical site. While bacterial colonization of the incision may predispose to subsequent SSIs/PJIs, there is no literature to demonstrate that the use of incise drapes results in clinical differences in the rates of subsequent PJIs. Many surgeons prefer to utilize incise draping for physical isolation of sterile from non-sterile regions and to prevent migration of drapes during the procedure.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 89%, Disagree: 5%, Abstain: 6% (Super Majority, Strong Consensus)

RATIONALE

Surgical incise draping, which is an adhesive material applied to the skin around the incision, is utilized by surgeons to potentially reduce the recolonization of the surgical site with host flora, which may predispose the patient to subsequent infections. It is important to distinguish between antibacterial-impregnated and non-impregnated drapes as the use of an antimicrobial agent in the drape may have a different influence on the rates of contamination of the incision and colonization. Unfortunately, the literature does not make such distinctions and the majority of the systematic reviews and even the guidelines by the World Health Organization (WHO) and the Association of Perioperative Registered Nurses (AORN) have not made such distinctions. The adhesive barrier, usually containing an antibacterial material such as iodine, is applied prior to the incision and removed at the time of or after skin closure [1–3]. The rationale behind this practice is that the use of incise draping, in addition to conventional skin preparation, can reduce bacterial proliferation at the skin and serve as a physical barrier to block the translocation of recolonizing bacteria from the skin adjacent to the surgical site into the surgical field. This may then result in a decrease in the rates of subsequent SSIs/PJIs. However, it is important to note that using incise drapes as a substitutes for skin disinfection and preparation is not recommended [4].

Although many surgeons routinely utilize incise drapes, there is limited evidence to support that these drapes lead to a reduction in the incidence of PJIs or SSIs. Several associations do not support their routine use. The recent SSI prevention guidelines by WHO did not find any evidence to support the use of incise drapes during surgery and recommended against its use, however, none of the studies that formed the basis of such a recommendation were in orthopaedic surgery [5,6].

Several studies have demonstrated that impregnated incise drapes result in a reduction in bacterial colonization. Rezapoor et al. found that 12% of incisions with iodine-impregnated adhesive drapes and 27.4% without adhesive drapes were positive for bacterial colonization in a prospective randomized controlled trial of 101 hips undergoing hip preservation surgery [7]. Furthermore, patients without adhesive drapes were significantly more likely to have bacteria present at the incision at the time of skin closure and at all time-points of surgery. In addition, Fairclough et al. found that 122 hips undergoing acute hip fracture surgery, with iodophor-impregnated drapes placed 24 hours prior to the procedure, showed lower wound contamination rates from 15 to 1.6% compared to those without drapes [8]. In contrast, some studies have also found no differences in the rates of bacterial contamination with the use of adhesive drapes. Chiu et al. demonstrated no differences in wound contamination rates of 120 hip fracture patients when comparing plastic incise drapes with no drapes [9], while an randomized control trial (RCT) in cardiac surgery comparing use of drapes to no drapes showed earlier and more bacterial contamination following use of drapes [10].

While there is some evidence to suggest that bacterial contamination is reduced with impregnated incise drapes in non-orthopaedic surgery, there is no evidence to demonstrate that impregnated incise drapes result in a significant decrease in infection rates. This is likely because the majority of studies are underpowered given the relative rarity of PJIs or SSIs. In a recent Cochrane review of 3,082 patients, Webster et al. found that a higher proportion of patients developed surgical site infections with plastic drapes than patients in whom no drapes were used ($p = 0.03$) [1]. However, no difference was found when iodophor-impregnated drapes were used (1.03, 95% confidence interval (CI) 0.06 to 1.55, $p = 0.89$).

There is a need for studies evaluating the effect of iodine-impregnated incise drapes on infection rates in total hip arthroplasties and total knee arthroplasties as no clinical studies on this subject have been performed.

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QUESTION 9: Does the use of cloth or impervious stockinettes around the ankle and extremity affect the rate of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing orthopaedic procedures?

RECOMMENDATION: In the absence of evidence, we propose that a stockinette always be used to cover the unprepared skin in order to prevent potential contamination of the surgical field. Impervious stockinettes may be more resistant to soaking through during the surgery.

LEVEL OF EVIDENCE: Consensus

DELEGATE VOTE: Agree: 89%, Disagree: 5%, Abstain: 6% (Super Majority, Strong Consensus)

RATIONALE

Bacteria are thought to inoculate surgical wounds via an airborne pathway or through direct contamination by the patient's natural flora. Skin flora is a common source of infections, which are why appropriate antimicrobial skin preparations are of great importance in the surgical theater. One common source of contamination is the foot. An impervious stockinette forms an impermeable barrier and is used to protect the surgical site from bacterial contamination. This is especially important because the feet are often held and handled by surgeons and assistants during hip and knee arthroplasty procedures.

Stockinettes are made of non-woven material and are designed for single usage. The efficacy of non-woven drapes in preventing contamination has been proven [1]. Stockinettes (cotton or impervious) are primarily designed to isolate foot microbes from the operative site, and additionally they provide circumferential coverage of the lower leg, including the popliteal fossa. There is no definite evidence in the form of a randomized controlled trial to suggest there are differences in deep or superficial infection rates with the use of a stockinette.

Another concern is whether the stockinette is used over a prepared or an unprepared foot. In 2012, Boekel et al. experimentally used fluorescent ultraviolet powder on volunteers and compared the contamination of the powder near the surgical site with below knee versus above knee application. The foot was not prepared and only the surgical site was disinfected. There was a significant proximal spread of the powder up to 71.8% proximally in the above knee application group. The most important conclusion from this study was that a stockinette should be used in conjunction with foot preparation [2].

This work was further tested by Marvil et al. in 2014, when non-pathogenic *E. coli* was applied to feet in cadavers and compared between the chlorhexidine prepared versus the unprepared foot with an impervious stockinette to mid-thigh level. Bacterial contamination at various sites including foot, ankle, 12 cm, 24 cm and 36 cm proximal to the ankle were assessed. In the non-prepared foot group, significant contaminations, as proximal as 24 cm to the ankle joint, were found, whereas no contaminations were found at any site in the prepared group. The merit of this study over the previous one was that the group used a non-pathogenic organism instead of a powder which may have had different adhesion characteristics [3].

In their recent review in 2016, Ratto et al. questioned the role of sterile stockinettes for the prevention of prosthetic joint infections [4]. The authors further highlighted the relevance of numerous preoperative, intraoperative and postoperative confounding factors that may have higher impact on causation of a deep infection. A 2014 study on glove contamination done by Makki et al. found that not a single incidence of glove contamination of the assistant who was holding the prepped foot with the stockinette occurred during prepping and draping [5]. Instead, the procedure of draping itself led to maximum incidences of contamination, especially with hip surgery. Thus, other aspects of draping could potentially be of more concern than the type of stockinette used with the antimicrobial prepared foot.

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