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Main Operating Room Versus Field Sterility in Hand Surgery: A Review of the Evidence

Stérilité de la salle d'opération principale versus terrain dans la chirurgie de la main : synthèse des données probantes

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Abstract

Introduction: Many of the guidelines that are generally accepted as main operating room best practices are not evidence based. They are based on the concept that if some sterility is good, more must be better. They are not derived from evidence-based sterility. Evidence-based sterility is the study of which of our various sterility practices increase or decrease our infection rates, as opposed to guidelines based on how many bacteria are in the operating room. **Methods:** This article adds the most important evidence we could find that is not included in the first paper on evidence-based sterility in hand surgery published in 2019. In this review, we also balance the evidence with common sense opinion. **Results:** The 21st century has seen a rapid rise in the number and reports of hand surgery procedures performed with field sterility outside the main operating room. There is now an abundance of good evidence to support that the rate of infection is not higher when many hand operations are performed with field sterility in minor procedure rooms. **Conclusion:** Moving hand surgery out of the main operating room to minor procedure rooms should be supported by healthcare providers. The higher cost, increased solid waste, and inconvenience of main operating room surgery are not justifiable for many procedures because it does not reduce the risk of postoperative infection.

Résumé

Introduction : Plusieurs lignes directrices qui sont généralement admises comme représentant les meilleures pratiques en salle d'opération ne reposent pas sur des données probantes. Elles reposent sur le concept que s'il est bon d'avoir un certain degré de stérilité, il doit être encore meilleur d'en avoir plus. Elles ne sont pas tirées de données de stérilité basées sur des données probantes. La stérilité basée sur des données probantes est l'étude cherchant à savoir laquelle de nos diverses pratiques en matière de stérilité augmentent ou diminuent les taux d'infection, par opposition aux lignes directrices basées sur le nombre de bactéries présentes en salle d'opération. **Méthodes :** Cet article ajoute les données probantes les plus importantes que nous avons pu trouver et qui ne sont pas incluses dans le premier article publié en 2019 sur la stérilité basée des données probantes dans la chirurgie de la main. Dans cette revue, nous mettons aussi dans la balance les données probantes et le bon sens. **Résultats :** Le 21^{e} siècle a vu un nombre rapidement croissant d'interventions et de rapports de procédures chirurgicales sur la main réalisées avec une stérilité de terrain, en dehors de la salle d'opération principale. Nous disposons aujourd'hui d'une abondance de données probantes de bon niveau indiquant que le taux d'infections n'est pas plus élevé quand de nombreuses opérations de la main sont effectuées avec une stérilité de terrain dans des salles de procédures secondaires. **Conclusion :** Faire passer la chirurgie de la main hors de la salle d'opération vers des salles de procédures devrait être adopté par les professionnels de santé. Le coût plus élevé, la quantité de déchets et les inconvénients d'un bloc opératoire ne sont pas justifiés pour de nombreuses procédures, car ils ne diminuent pas le risque d'infection postopératoire.

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Introduction

Field sterility, also known as "minor procedure room field sterility," has been used for decades by emergentologists, plastic surgeons, and dermatologists.[1] It is becoming increasingly popular in hand surgery.[2] One description of field sterility is a single 40cm-by-40 cm drape, sterile gloves, surgical mask, and no gown.[3] Wheelock et al[4] have described the widespread use of field sterility for elective and trauma hand surgery in Canada. They advocate its use, citing equivalent infection rates to those of the main operating room (OR), expedited patient care and reduced costs.[5–7] Other advantages of field sterility include reduced solid waste,[8] as well as increased efficiency,[9] satisfaction,[10] and convenience for patients and surgeons.

Many of the currently accepted main OR sterility practices are based on the logic that: "If some sterility is good, more must be better." While the goal of sterility is to keep our rates of surgical site infections (SSIs) as low as possible, many of the very expensive current sterility routines we follow in the main OR are based on common practice and perceived benefit of reducing the number of bacteria in the room,[11] but may not meaningfully decrease our infection rates in patients.[12–14] Despite many new expensive strategies introduced by new association of perioperative registered nurses (AORN) guidelines to decrease bacterial counts in the main OR, large joint periprosthetic infection rates remained constant from 2002 to 2017.[15] A better knowledge of scientific and clinical evidence of which sterility practices truly improve infection rates and outcomes will be a better guide of cost effective sterility protocol.

It is the aim of this article to examine and compare some of the current evidence for field sterility versus main OR sterility in hand surgery. We will also look at the incidence of severe infections that we are trying to prevent by applying these sterility practices in common hand surgery operations. We will then try to analyse the balance of risks and benefits of our practices with common sense.

Putting the Hand Surgery Postoperative Infection Problem into Perspective

In the study of hip and knee joint replacement periprosthetic infections, one of the lowest infection rates reported is 0.6%.[16] With over a million Americans having these operations every year,[17] at least 6000 patients undergo this human infection tragedy which carries a mortality rate of between 2% and 7%.[18,19] The financial cost of these infections has been estimated to be between \$100 000 and \$500 000 per case.[20] A recent projected annual hospital cost estimate of treating these infections in the United States will be \$1.85 billion by the year 2030.[15]

Those are hips and knees. In contrast, patient morbidity and the cost of postoperative infections in hand surgery are minimal. What is the incidence of serious morbidity from major infection in the most common hand operations? The worst case infection scenario is necrotizing fasciitis after soft tissue surgery. When we search Pubmed for "carpal tunnel necrotising fasciitis,"[21] only 2 case reports appear in the entire world literature.[22,23] There was a third case report, but it was the result of a brachial plexus block for carpal tunnel release (CTR) in the main OR.[24] When we search for "trigger finger necrotising fasciitis,"[25] the only result is a case report of an infection that happened after a steroid injection in the hand to cure the disease.[26] A recent British study of 855 000 CTRs reported that 43 patients (0·0050%) had an infection serious enough that they required reoperation or readmission to hospital.[27] No one died. Most infections after CTR are easily managed as outpatients with oral antibiotics. Considering the millions of CTRs and trigger fingers performed throughout the world every year, the incidence of major morbidity infections in these operations is extremely rare.

An American study of 4500 CTRs performed in the main OR reported overall SSI rate of 0.32%.[28] A 2017 systematic review of SSI rates in hand procedure room surgeries outside of the main OR revealed 6 studies with infection rates between 0 and 0.4%.[29] The data from these 2 papers provide powerful evidence that expensive main OR sterility offers no significant infection advantage to field sterility in CTR, a problem which has a very low minor infection risk and an extremely rare serious infection morbidity risk. It therefore does not make sense to treat minor hand surgery like carpal tunnel release with the high level of main OR sterility that total knee surgery and the like require.

Field Sterility Versus Main OR Infection Rates

What are the infection rates when we take hand surgery outside of the main OR? One of the earliest papers on field sterility reported an SSI rate of 1% in 1035 patients having 9 categories of hand surgery.[30] Van Demark et al[8] described their experience of transitioning to field sterility as part of an environmentally focused service improvement. Their cohort of 1099 patients had the same SSI rate as patients operated on with main OR sterility prior to adopting field sterility. Halvorson likewise, found no increase in complications, including infection, in a retrospective study comparing SSIs of CTRs performed in the main OR (3.2%)

with those performed with field sterility (2.2%).[31] Oakes concluded the same in their retrospective series of elective and closed trauma hand surgery (main OR 2.78% vs field sterility 1.24%).[32]

The use of field sterility has not been limited to soft tissue operations. A 2022 Canadian multicenter prospective study of infection rates after hand Kirschner wire (K wire) insertion in 1047 patients showed no statistical difference when performed in the main OR (2.5%) versus minor procedure room field sterility (1.4%).[33] A 2021 study[34] of 265 hand soft tissue and bony procedures, including plate fixation performed in a procedure room with minor field sterility, reported a 0.37% SSI rate. A smaller 2022 study of K wire and plate fixation in closed fractures using the same operating conditions found a similar infection rate.[35] Looking back at earlier evidence, a 1995 study described hand fracture fixation in the emergency room with limited sterility with no infections among 68 patients, concluding that the taboo against such practice was not justified.[36] Recently Garon et al[37] examined hand fracture fixation in an emergency room procedure room and found it to be equally safe to fixation performed in the OR. A “Semi-sterile” technique of K wired pediatric supracondylar humerus fractures was reported in 2007 with a 0% infection rate.[38] Bashyal also used this technique and reported an infection rate of 1% in a retrospective analysis of 622 patients.[39] On the other hand, one study of semisterile technique used to K wire 700 supracondylar fractures reported a 7.3% superficial infection rate, with no deep infections.[40] In 2019 Dua[41] retrospectively compared semisterile K wire fixation to full OR sterility in 220 pediatric fracture fixations of proximal/distal humerus, olecranon, radius/distal radius, metacarpals, and phalanges. The semisterile group had no infections.

Operating Room Infection Prevention Practices

We have reviewed infection evidence with 5 sterility practices that are quite different between minor procedure room field sterility and main OR full sterility: (1) regular hospital room air, (2) no surgeon gowns, (3) surgeon managed head cover, (4) draping only the operated part, and (5) no “in between case floor washing” unless there is gross contamination. We have also reviewed infection evidence with 14 sterility practices that are not very different between minor procedure room field sterility and main OR full sterility. The most important parts of these sterility practices will be examined in the following 2 sections.

Five Sterility Practices That are Quite Different Between Minor Procedure Room Field Sterility and Main Operating Room Full Sterility

Regular Hospital Room Air

All of the studies quoted above with field sterility in minor procedure rooms with no special ventilation for soft tissue procedures and K wiring show minimal rates of infection with almost zero serious infections.

High numbers of bacteria carrying particles in the air may increase infection rates in hip and knee replacement surgery.[42] A 1982 prospective randomized trial of hip and knee implants in over 8000 patients in 19 hospitals[16] provided the best evidence that ultraclean OR air (fewer than 10 bacteria-carrying particles/m^3) had significantly fewer periprosthetic infections (0.6% vs 1.5%) than control forced air which contained a range of 50 to 500 bacteria-carrying particles/m^3. Although the cost and morbidity of infected joint implants in hand surgery is considerably less than that of large joint replacements, common sense would dictate that full OR sterility would be a wise choice for hand joint replacement with permanent implants. However, there is no evidence to support special ventilation as a successful tool in decreasing infection rates in any hand surgery operation. It does not make sense to limit non-implant hand surgery to rooms with special ventilation.

Although decreasing the number of bacteria in the air may be good, laminar air flow does not appear to be important for decreasing SSIs in joint replacements.[43] One study of 99 000 German patients showed no protective benefit of laminar flow ventilation and even demonstrated a higher risk of surgical site infections after hip replacements.[44] Modern surgical helmet exhaust systems do not appear to decrease the incidence of wound infection in major joint replacement surgery.[45] OR space suits that intend to keep all human air and body bacteria away from the patient wound may paradoxically increase wound infections.[46]

No Sterile Gowns

While many studies have focused on bacterial counts, a very careful 2020 review of propensity-matched, multivariate, and multi-institutional studies that specifically addressed SSI rates found no correlation between surgical attire practices and the incidence of SSIs.[47] Importantly, adoption of AORN guidelines of surgical attire did not decrease rates of surgical site infections in a 2018 study of 6517 patients.[48]

Many of our OR sterility practices are not evidence based. In the AORN evidence rating guide, no evidence is required to support a recommendation if the authors believe that benefits of an intervention outweigh the harm.[49] This means that opinion can become a guideline, as opposed to having a requirement of intervention data showing a reduction in SSI rates. For example, the AORN guidelines recommend that scrub attire should be laundered at a healthcare accredited laundry facility, that surgical attire should be stored in enclosed carts or dispensing machines, and that surgical attire should be removed before leaving the healthcare facility.[50] However, due to the paucity of adequate data, no recommendations can be made about any of these issues because there is no evidence to show that this has any influence on SSI rates,[47,51] Further work is required to determine the impact of theater clothing on SSI rates as its unnecessary use represents a significant cost and an environmental issue in terms of disposal.[52]

The Leblanc study of 1504 field sterility carpal tunnels (0.4% superficial SSI with none requiring reoperation or admission to hospital) were all performed in minor procedure rooms without special ventilation, without surgeon gowns, with surgeon chosen head cover, and without washing the floor between each case unless there was gross contamination.[3] The balance of evidence and common sense would support carpal tunnel surgery with non sterile surgical scrubs without sterile gowns.

Surgeon Managed Head Cover

There is no association between the type of surgical cap worn and the incidence of postoperative wound events following ventral hernia repair.[53,54] Bouffant versus skull cap does not significantly impact SSI rates.[55,56] Although no study to date has clearly shown whether the use of head coverings influences SSIs,[57] common sense and current evidence would dictate that loose flying hair contaminating a surgical wound needs to be avoided with whichever head cover a surgeon deems appropriate.[47]

Draping Only the Operated Part

Alam et al reported an SSI rate of 0.37% in a prospective study 20 821 cases of Mohs micrographic surgery in the United States, where field sterility is the standard of care with no gowns, no special ventilation, draping only the operative area, and no routine washing of floor between cases.[58] Similar data is reported with skin cancer excision with minor procedure room field sterility by British dermatologists.[59] A field sterility study of 872 pediatric skin excisions reported a 0.3% SSI rate.[60] More than 88% of carpal tunnel surgery is performed this way[61] in Canada with an acceptable low infection rate no worse than main OR CTR.[3]

We were not able to find evidence that draping unoperated parts of the body reduces SSIs. The unnecessary cost and amount of solid waste from needless draping of unoperated parts is staggering. Common sense would validate only draping the operated part.

No "In Between Case Room and Floor Washing" Unless There is Gross Contamination

In Canadian minor procedure rooms, the floor is washed between cases only when gross contamination with pus or dead tissue occurs. Otherwise, the floors are washed once a day as in other parts of the hospital. In our main ORs, the floors are routinely washed between each case. In operations such as carpal tunnel syndrome without gross room contamination, it does not make sense to wash the floor between each case.

Evidenced-Based Recommendations for Sterility Practices That Do Not Differ Between Field Sterility and Main Operating Room

Steroid Injections

Several studies have explored the relationship between steroid injections in potential surgical sites and SSI rates of subsequent surgery. While the evidence is limited to underpowered, retrospective studies, higher rates of SSI have been correlated to surgery performed less than 3 months after injection for CTR,[62] trigger finger release (TFR),[63,64] and first carpometacarpal (CMC1) arthroplasty.[65]

Preoperative Bathing With Antiseptic Solution

While reduction of native flora following preoperative bathing has been demonstrated,[66,67] the clinical effects remain controversial. A 2015 Cochrane review analysed 7 randomized controlled trials (RCTs) involving over 10 000 patients and concluded that there is no clear evidence to support preoperative bathing with antiseptic solutions.[68]

Prophylactic Antibiotics

A recent review article highlighted just how procedure-dependent antibiotic prophylaxis is by collating evidence-based guidelines for 31 different categories of plastic surgery alone.[69] Studies of compliance with antibiotic prophylaxis policy have frequently reported over-use of antibiotics; when considering the use of antibiotics, their drawbacks must also be considered. These include cost, antibiotic resistance and adverse reactions.[70] A 2018 review article of antibiotic prophylaxis for hand surgery described conflicting evidence but concluded that antibiotics are unnecessary in soft tissue operations in patients who are at low risk of infection.[71]

Hair Removal

A 2021 Cochrane review considered all aspects of hair removal and concluded that there is low certainty evidence of a small reduction in SSI when depilatory cream or clippers are used, but increased SSI with razors.[72] Additionally, removal on the day of surgery is probably preferrable to the day before.

Skin Preparation

Several guidelines, including those of the world health organization (WHO)[73] advise alcohol-based chlorhexidine gluconate (CHG) as the antiseptic of choice and this is supported by basic-science[74] and clinical[75] evidence. A 2015 Cochrane review concluded that alcohol-based agents were likely superior to aqueous solutions, and that alcohol-based CHG is probably most effective.[76]

Table 1. Summary of Evidence for Practices Affecting SSI Rates.

Practices that might affect SSI rates	Evidence summary
(1) Preoperative steroid injections	Higher rates of SSI have been reported with surgery performed less than 3 months after steroid injection for CTR,[62] TFR,[63,64] and CMC1 arthroplasty[65]
(2) Preoperative bathing with antiseptics	No clear evidence to support preoperative bathing[68]
(3) Prophylactic antibiotics	Antibiotics are unnecessary in soft tissue operations in patients who are at low risk of infection[69,71]
(4) Preoperative hair removal	Razors may increase SSI. Clippers and depilatory creams do not appear to affect SSI[72]
(5) Type of antiseptic used for skin preparation	Alcoholic chlorhexidine is likely the most effective agent[78]
(6) Nail polish use by OR staff	A Cochrane review found no relevant studies correlating nail polish with risk of SSI[77]
(7) Wearing of rings when scrubbed	There are no prospective clinical trials correlating ring wearing with SSI rates[82]
(8) Hand washing technique	No high-quality evidence available to justify one method over another[86]
(9) Skin barriers	Plain plastic adhesive drapes may increase infection.[86] Drapes impregnated with iodine, and cyanoacrylate sealant likely have no clinical effect[87]
(10) Routine wound irrigation	No high-quality evidence available to show this effectively reduces infection[88]
(11) Operating room traffic	Greater OR traffic increases microbial counts,[89] but this has not been proven to increase SSI[90]
(12) Wound closure method	No high-quality evidence available to show superiority of one type of suture over another.[91,96,97,104] There is insufficient evidence to determine if completely buried sutures decrease SSIs compared to transcutaneous sutures
(13) Type of wound dressing	A Cochrane review was unable to make conclusions regarding SSI risk between no dressing and different wound dressings[99]
(14) Time to dressing removal and wound showering	Early dressing removal (<48 h postoperative) does not increase SSI.[100,103] No conclusive evidence is available regarding wound showering

Abbreviations: CMC1, first carpometacarpal; CTR, carpal tunnel release; OR, operating room; RCT, randomized controlled trial; SSI, surgical site infections; TTR, trigger finger release.

Nail Polish Use by OR Staff

A Cochrane review found no relevant studies correlating nail polish with risk of SSI[77] and only a single study looking at microbial count in unpolished nails, freshly polished nails (<2 days) and old nail polish. This study found no significant differences between the groups before and after surgical scrubbing.[78]

Ring Use by OR Staff

Fagernes et al[79] showed that wearing a single plain ring did not increase the total bacterial load on the hands. Other studies have shown that rings do not increase microbial count even after surgical hand scrubbing[80] and wearing gloves for 3 h.[81] What these studies lack is clinical correlation. Recent systematic reviews have not identified any RCTs dealing with this topic.[77,82]

Hand Washing

Historically, surgeons were required to scrub their hands for 10 min with antimicrobial soap,[83] but in 2002 scrub-time was reduced by the CDC to 2 to 6 min and alcohol-based hand-rubs were recognized as an alternative,[84] however these guidelines are not based on high-quality eveidence. There are very few RCTs correlating antimicrobial type or hand preparation time to SSI. A 2016 review article was unable to draw any conclusions based on the current literature.[85]

Skin Barriers

A recent systematic review identified seven RCTs and found evidence that plastic adhesive drapes may increase infection rates, although drapes impregnated with iodine seem to have no clinical effect one way or another.[86] A separate systematic review of cyanoacrylate sealant use examined 7 RCTs with nearly 1000 patients and found insufficient evidence to determine effect on SSI.[87]

Routine Wound Irrigation

A 2017 Cochrane review examined 59 RCTs pertaining to multiple aspects of irrigation.[88] Despite identifying many RCTs, the certainty of all evidence was low or very low. They concluded that irrigating surgical wounds may make no difference to SSI.

Operating Room Traffic

Greater microbial counts have been associated with increased staff numbers and traffic in/out of OR.[89] While a detrimental clinical effect would seem logical, correlation with SSI has yet to be demonstrated. Some authors recommend a maximum of 6 OR staff.[90]

Wound Closure Method

Several studies have compared adhesive, sutures and staples, including multiple suture techniques, however very little good-quality evidence exists. Six separate Cochrane reviews were unable to make any clear conclusions due to poor evidence.[91–96] There is insufficient evidence to determine if completely buried sutures decrease SSI compared to transcutaneous sutures.[97]

Wound Dressing

A Cochrane review included 29 RCTs making 11 different comparisons but was unable to make conclusions regarding SSI risk between no dressing and different wound dressings.[98] This uncertainty was primarily due to small, low-quality trials.

Dressing Removal and Wound Showering

Zhou et al compared thoracic surgical wounds exposed after 24 h (but kept dry) with those dressed until removal-of-sutures in their RCT and found no difference in wound complications.[99] A Cochrane review compared early dressing-removal (<48 h) with late dressing-removal and found no apparent detrimental effect, however evidence was low quality.[100] A small 1989 prospective study reported that wetting sutured surgical wounds did not lead to increased infections.[101] An RCT by Heal et al[102] showed equivalent SSI in wounds wet within 48 h and those kept dry, although the study had several limitations. A recent Cochrane review of postoperative wound showering determined that no conclusive evidence is available.[103]

Summary of Evidence for These 14 Sterility Practices

For the reader's convenience Table 1 below concisely summarizes the evidence for these 14 sterility practices.

Cost Savings

There is little doubt regarding the cost savings associated with field sterility.[105,106] Garon et al[37] retrospectively compared hand fracture fixation in an emergency department with those performed in OR, demonstrating a nearly 3-fold cost saving. A Canadian study of plate fixation of metacarpal fractures in a minor procedure room with field sterility showed a similar cost savings.[107] In an implementation study, Kamal et al[108] found CTR under field sterility in a procedure room to be 3.2-times cheaper than a traditional OR. Gillis et al performed a retrospective analysis, demonstrating nearly 5-times greater costs for hand fracture fixations performed in main OR compared to an ambulatory setting.[109] Rhee et al[110] performed a prospective cohort study and showed an 85% cost saving for CTR performed in clinic under WALANT instead of OR, making OR 6.6-times more expensive. Carr et al[111] reported equivalent cost savings in a small prospective study of patients undergoing CTR in different clinical settings. Halvorson et al[31] demonstrated a 10-fold increase in costs associated with OR over those of a procedure room using field sterility. Finally, Kazmers et al retrospectively compared various options for performing CTR and found that using WALANT in a procedure room with field sterility was by far the cheapest option. Simply moving from a procedure room to OR increased costs by 6.3-fold.[112] This amplified to a massive 29.3-fold increase over field sterility if the patient also underwent general anesthesia.

Environmental Impact

While most studies have focused on cost savings or complication rates, some authors have chosen to address the environmental impact. Van Demark advocated the use of field sterility and procedure rooms to dramatically reduce waste.[8] They described the North American "Lean and Green" initiative which aims to reduce costs and waste in hand surgery while improving patient safety/satisfaction. A recent article by Bravo et al[113] also examined the environmental impact of ORs and focused on hand surgery as a major contributor due to high volume of short cases. They too advocated the Lean and Green effort and one of their key recommendations was to promote the use of WALANT and procedure rooms. Thiel et al[114] described their use of a "Minimal Custom Pack" of surgical equipment for use in hand surgery with a limited sterile field. They prospectively compared these packs to regular packs and demonstrated reduced costs and waste. Dua et al[41] retrospectively studied time savings achieved by performing upper-limb fracture fixations in a procedure room with field sterility. Likewise, Chatterjee et al[106] included a time-efficiency analysis in their retrospective study of CTR in OR versus procedure room and showed that OR required twice as much time.

As the world's population increases and the environmental impact of human endeavors becomes more important, these advantages become more relevant. Field sterility is especially beneficial in countries with limited resources as it improves access to desperately needed surgery.[115,116]

Conclusion

There is ample evidence that field sterility does not increase the infection rate in many procedures compared to main operating room sterility. Moving hand surgery outside the main operating room to minor procedure rooms improves efficiency by reducing costs, solid waste, and time taken to operate. It also improves patient convenience and satisfaction rates. Current evidence and common sense clearly support moving minor hand surgery, such as carpal tunnel release and K wire insertion, out of the main OR into the minor procedure room field sterility environment.

Author Contributions

DL and NS conceived and designed the analysis; collected the data; contributed data or analysis tools; performed the analysis; and wrote the manuscript.

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