WHO Surgical Site Infection Prevention Guidelines

Web Appendix 21

Summary of a systematic review on the use of surgical gloves

1. Introduction

The invasive nature of surgery introduces a high risk for the transfer of pathogens that may cause bloodborne infections in patients and/or the surgical team, including postoperative surgical site infection (SSI). This risk may be reduced by implementing protective barriers, such as wearing surgical gloves.

The latest WHO guidelines for safe surgery published in 2009 *(1)* recommend that the operating team should cover their hair and wear sterile gowns and sterile gloves during the operation, but without any indication on single- or double-gloving. The gudielines of the Society for Healthcare Epidemiology of America (SHEA)/ Infectious Diseases Society of America (IDSA) *(2)* recommend that all members of the operative team should double-glove and change gloves when perforation is noted. The modalities and frequency of the changing of gloves have not been included in any guidelines or recommendations *(1-3).*

A Cochrane Review *(4)* published in 2009 investigated whether additional glove protection reduces the number of SSI or bloodborne infections in patients or the surgical team and the number of perforations to the innermost pair of surgical gloves. There was no direct evidence that additional glove protection worn by the surgical team reduces SSI in patients. However, the review had insufficient power for this outcome as only 2 trials were found with the primary outcome of SSI, both of which reported no infections. No trials were found with transmitted bloodborne infections as the outcome in surgical patients or the surgical team in relation to the gloving method. Thirty-one randomized controlled trials (RCTs) were identified with the outcome of glove perforation, leading to the result that the use of a second pair of surgical gloves, triple-gloving, knitted outer gloves and glove liners significantly reduces perforations to the innermost gloves.

The objective of this review was to assess the evidence on the effectiveness of double-gloving, the criteria for changing gloves during the operation and the optimal type of gloves to be used to prevent SSI.

2. **PICO questions**

1. When is double-gloving recommended?
2. What are the criteria for changing gloves during an operation?
3. What type of gloves should be used?

- **P**opulation: inpatients and outpatients of any age undergoing surgical operations (any type of procedure)
- **I**ntervention: (1) use of double gloves
  (2) change of gloves
  (3) other types of gloves: glove liners, coloured perforation indicator systems, cloth outer gloves, steel outer gloves, triple gloves
- **C**omparator: (1) use of a single pair of gloves
  (2) retaining gloves
  (3) latex gloves
- **O**utcomes: SSI, SSI-attributable mortality

3. **Methods**

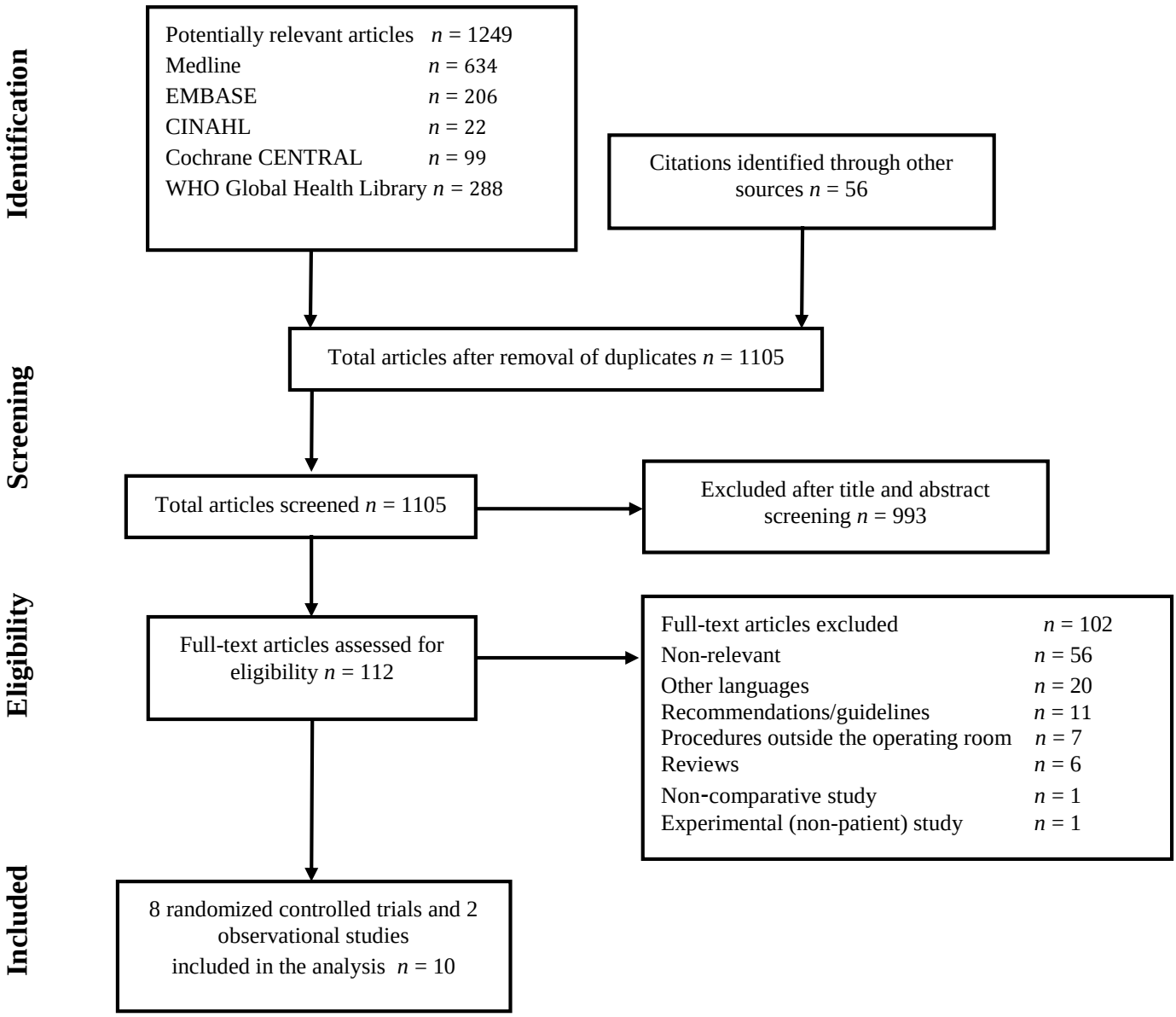
The following databases were searched: Medline (PubMed); Excerpta Medica Database (EMBASE); Cumulative Index to Nursing and Allied Health Literature (CINAHL); Cochrane Central Register of Controlled Trials (CENTRAL); and WHO regional medical databases. The time limit for the review was between 1 January 1990 and 24 April 2014. Language was restricted to English, French and Spanish. A comprehensive list of search terms was used, including Medical Subject Headings (MeSH) (Appendix 1).

Two independent reviewers screened the titles and abstracts of retrieved references for potentially relevant studies. The full text of all potentially eligible articles was obtained and two authors then independently reviewed these for eligibility based on inclusion criteria. Duplicate studies were excluded.

The two authors extracted data in a predefined evidence table (Appendix 2) and critically appraised the retrieved studies. Quality was assessed using the Cochrane Collaboration tool to assess the risk of bias of randomized controlled studies *(5)* (Appendix 3a) and the Newcastle-Ottawa Quality Assessment Scale for cohort studies *(6)* (Appendix 3b). Any disagreements were resolved through discussion or after consultation with the senior author, when necessary.

4. **Study selection**

Flow chart of the study selection proces



5. Summary of the findings and quality of the evidence

A total of 10 studies (8 randomized controlled trials [RCTs] *(7-14)* and 2 observational studies *(15, 16)*) were identified. Only 6 studies were identified with a SSI outcome *(8-12, 15)*, one with cerebrospinal fluid (CSF) shunt infection *(16)*. Thus, it was decided to include also studies with bacterial contamination as a surrogate outcome. Bacterial contamination was evaluated by making an impression of gloves on sterile culture media immediately before removal of each set of gloves. The culture plates were sent to a microbiology laboratory for incubation and the degree of contamination was evaluated by counting the number of bacterial colonies.

Due to heterogeneity among the selected studies regarding comparison, design and outcome, quantitative meta-analyses were not performed.

Findings related to PICO question 1: double-gloving vs. use of a single pair of gloves

Two observational studies *(15, 16)* comparing double-gloving vs. the use of a single pair of gloves were identified with an infectious outcome. Included patients were adults undergoing neurosurgery and hernia repair. One retrospective "before/after" study *(16)* investigated the effect of double-gloving on CSF shunt infection rates and showed that the overall infection rate was significantly higher in the single-gloved group compared to the double-gloved group (odds ratio [OR]: 2.48; 95% confidence interval [CI]: 1.50–4.22). Another non-randomized "before/after" study *(15)* found no difference in the risk of SSI between double- vs. single-gloving in patients undergoing hernia repair.

Findings related to PICO question 2: change of gloves vs. no change of gloves in the course of the operation

Three RCTs *(8, 9, 12)* comparing change of gloves vs. retaining gloves were identified with an SSI outcome. Included patients were adults undergoing caesarean section. Changing the entire surgical team's gloves intraoperatively after delivery of the placenta or removing the external second glove by a circulating nurse after delivery of the fetus showed no difference in the rate of post-caesarean SSI and/or endometritis. All 3 studies addressed a specific question in a particular setting. Two studies had an additional intervention comparing different placental delivery techniques. None of the studies had superficial SSI as the primary outcome, but rather investigated endometritis.

One RCT *(14)* investigating a change of gloves vs. no change of gloves before the first contact with the vascular prosthesis in synthetic vascular graft surgery was identified with an SSI outcome. The authors reported 2 superficial SSIs in the glove change group and 5 superficial SSIs in the no change group ($P<0.02$). There were no acute graft infections in either group.

Two RCTs *(13, 14)* comparing a change of gloves vs. no change of gloves were identified with bacterial contamination as the outcome. One RCT *(13)* showed that in

clean orthopaedic procedures, surgeons retaining the outer gloves one hour after the start of surgery had a subsequent positive glove contamination rate of 23% compared with 13% among surgeons who had exchanged their outer gloves (OR: 1.97; 95% CI: 1.02–3.80). The second RCT *(14)* investigated a change of gloves vs. no change of gloves before the first contact with the vascular prosthesis in synthetic vascular graft surgery and found the number of contaminated grafts to be similar in both groups. In a third RCT *(7),* a change of outer gloves after draping and prior to cementation during hip arthroplasty was implemented as standard of care in both groups. The authors investigated whether a systematic change of outer gloves at 20-minute intervals during surgery had an additional effect and found a significantly lower incidence of glove contamination in this group.

Findings related to PICO question 3: specific types of gloves vs. latex gloves

Two RCTs *(10, 11)* comparing 3 different types of gloves (double-gloving) in orthopaedic surgery were identified with an SSI outcome.

- An inner pair of standard latex gloves with cotton cloth outer gloves vs. 2 pairs of latex gloves *(10).*
- An inner pair of standard latex gloves with outer "orthopaedic" gloves vs. 2 pairs of latex gloves *(11).*
- Repel cloth gloves between 2 pairs of regular latex gloves vs. 2 pairs of latex gloves *(11).*

Neither of the trials reported any SSI in any of the groups.

The body of retrieved evidence focused on adult patients and no study was available in a paediatric population. The literature search did not identify any studies that reported on SSI-attributable mortality.

After discussion, 9 studies *(17-25)* were excluded. These concerned a comparison of sterile vs. non-sterile gloves in procedures performed outside the operating room, that is, dental extractions, dermatological procedures and emergency repair of uncomplicated traumatic lacerations, studies related to the impact of gloves on contamination by bloodborne infections (for example, human immunodeficiency virus, hepatitis, etc.), and studies investigating the impact of double-gloving on glove perforation. One non-comparative observational study *(26)* found a reduced risk of contamination and perforation of the outer gloves associated with systematic changes of the outer gloves at key situations during total hip arthroplasty operations. However, this study was excluded from further assessment due to a lack of comparison.

In conclusion, there is no relevant evidence to determine the effectiveness of wearing an additional pair of gloves, the criteria for changing gloves during an operation or of a specific type of gloving on the reduction of the SSI rate.

Of note, the identified studies have several limitations. The methodological quality of most studies was poor as the majority of the trials did not provide sufficient details of their process of randomization, allocation, sample size calculation and blinding. SSI definitions varied across the studies and there were few studies with SSI as the primary outcome. The selected studies with bacterial contamination as a surrogate

outcome showed a great heterogeneity in the setting, design and outcome measures. There is no direct evidence demonstrating the link between bacterial contamination and SSI rates.

6. Key uncertainties and future research priorities

Well-designed RCTs investigating the effectiveness of double-gloving compared to the use of a single pair of gloves would be welcome, especially in low- and middle-income countries. RCTs evaluating whether a change of gloves during the operation is more effective in reducing the risk of SSI than no change of gloves are needed, including an assessment of the criteria for a change of gloves during an operation. To address the question of the optimal type of gloves to be used, it would be interesting to compare different types of gloving. All studies should focus on SSI as primary outcome, defined according to the United States Centers of Disease Control and Prevention criteria and subspecified as superficial, deep and organ/space occupying. Authors should use the CONSORT (Consolidating Standards of Reporting Trials) statement as a guideline for reporting parallel group randomized trials *(27)*.

APPENDICES

Appendix 1: Search terms

MEDLINE (via PubMed)

1 "surgical wound infection"[Mesh] OR (surgical site infection* [TIAB] OR "SSI" OR "SSIs" OR surgical wound infection* [TIAB] OR surgical infection*[TIAB] OR post-operative wound infection* [TIAB] OR postoperative wound infection* [TIAB] OR wound infection*[TIAB])
2 glove [TIAB] OR gloves [TIAB] OR gloving [TIAB]
3 Step 1 AND Step 2
4 "cross infection"[MeSH] OR "nosocomial infection" OR "nosocomial infections" OR "hospital acquired infection" OR "hospital acquired infections" OR "hospital-acquired infection" OR "hospital-acquired infections" OR "health care associated infection" OR "health care associated infections" OR "health care-associated infection" OR "health-care-associated infections" OR "infection control"[MeSH] OR infection control [TIAB] OR "infection reduction" OR “reduction infection” OR colonization [TIAB] OR transmission [TIAB]
5 "gloves, surgical"[Mesh]
6 Step 4 AND Step 5
7 Step 3 OR Step 6

EMBASE

1 'surgical infection'/exp OR 'surgical site infection':ti,ab OR 'surgical site infections':ti,ab OR ssis OR 'surgical infection wound':ti,ab OR 'surgical infection wounds':ti,ab OR 'surgical infection':ti,ab OR 'postoperative wound infection':ti,ab OR ‘postoperative wound infections':ti,ab OR 'post-operative wound infection':ti,ab OR 'post-operative wound infections':ti,ab OR 'wound infection':ti,ab OR 'wound infections':ti,ab
2 'surgical glove'/exp OR glove:ab,ti OR gloves:ab,ti OR gloving:ab,ti
3 'cross infection'/exp OR 'infection control'/exp OR ‘nosocomial infection’ OR ‘nosocomial infections’ OR ‘hospital acquired infection’ OR ‘hospital acquired infections’ OR ‘hospital-acquired infection’ OR ‘hospital-acquired infections’ OR ‘health care associated infection’ OR ‘health care associated infections’ OR ‘health care-associated infection’ OR ‘health-care-associated infections’ OR ‘infection control ‘:ti,ab OR ‘infection reduction’ OR “reduction infection” OR colonization:ti,ab OR colonization:ti,ab OR transmission:ti,ab
4 'surgical glove'/exp
5 STEP 3 AND STEP4
6 STEP 1 AND STEP 2
7 STEP 5 OR STEP 6

CINAHL

1 (MH surgical wound infection) OR (AB surgical site infection* OR AB SSI OR AB SSIs OR AB surgical wound infection* OR AB surgical infection* OR AB

post-operative wound infection* OR AB postoperative wound infection* OR AB wound infection*)
2 AB glove OR AB gloves OR AB gloving
3 Step 1 AND Step 2
4 ((MH "cross infection+") OR (MH "infection control+") OR (MH "infection preventionists") OR (MH "infection control (Saba CCC)+") OR (MH "infection control (Iowa NIC)") OR AB nosocomial infection OR AB nosocomial infections OR AB hospital acquired infection OR AB hospital acquired infections OR AB hospital-acquired infection OR AB hospital-acquired infections OR AB health care associated infection OR AB health care associated infections OR AB health care-associated infection OR AB health-care-associated infections OR AB infection control OR AB infection reduction OR AB reduction infection OR AB colonization OR AB transmission)
5 (MH gloves)
6 Step 4 AND Step 5
7 Step 3 OR Step 6

Cochrane CENTRAL

1 MeSH descriptor: [surgical wound infection] explode all trees
2 surgical site infections or SSI or SSIs or surgical wound infection* or surgical infection* or post-operative wound infection* or postoperative wound infection* or wound infection*:ti,ab,kw (word variations have been searched)
3 #1 or #2
4 glove or gloves or gloving:ti,ab,kw (word variations have been searched)
5 #3 and #4
6 MeSH descriptor: [infection control] explode all trees
7 MeSH descriptor: [cross infection] explode all trees
8 "nosocomial infection" or "nosocomial infections" or "hospital acquired infection" or "hospital acquired infections" or "hospital-acquired infection" or "hospital-acquired infections" or "health care associated infection" or "health care associated infections" or "health care-associated infection" or "health-care-associated infections" or infection control or "infection reduction" or "reduction infection" or colonization or transmission:ti,ab,kw (word variations have been searched)
9 #6 or #7 or #8
10 MeSH descriptor: [gloves, surgical] explode all trees
11 #9 and #10
12 #5 or #11

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((ssi) OR (surgical site infection) OR (surgical site infections) OR (wound infection) OR (wound infections) OR (postoperative wound infection)) AND ((glove) OR (gloves)

ti: title; ab: abstract.

Appendix 2: Evidence table

Appendix 2a: Studies related to double- vs. single-gloving: SSI outcome

Author, year, reference	Country/ study period	Type of study/ setting	Intervention	Comparator	Primary outcome	Results	Limitations
Tulipan 2006 *(16)*	USA 1998-2003	Retrospective, non-randomized, "before/after". **Neurosurgery (n=863)**	Single-gloving (n=521)	Double-gloving (n=342)	**CSF shunt infections** 6-month follow-up.	6.7% in double-gloving 15.2% in single-gloving **OR: 2.48; (95% CI: 1.50–4.22)**	No clear inclusion and exclusion criteria. No validated SSI definition. No *a priori* sample size calculation. Number of patients lost to follow-up unknown.
Dodds 1990 *(15)*	United Kingdom unknown period	Non-randomized, "before/after". **Hernia repair (n=200)**	Single-gloving (n=100)	Double-gloving (n=100)	**Wounds** were inspected for signs of infection at 7-10 days. Unknown criteria.	8% in double-gloving 10% in single-gloving (*P* value not provided)	Study period unknown. No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition. No *a priori* sample size calculation. Number of patients lost to follow-up unknown.

SSI: surgical site infection; CSF: cerebrospinal fluid: OR: odds ratio; CI: confidence interval.

Appendix 2b: Studies related to changing of gloves *vs.* retaining gloves: SSI outcome

Author, year, reference	Country/ study period	Type of study/ setting	Intervention	Comparator	Primary outcome	Results	Limitations
Ventolini 2004 *(12)*	USA 1996-1999	RCT: randomized by opening sealed, consecutive envelopes. **Caesarean section (n=92)**	Change of gloves following the delivery of the placenta by the entire team (n=46)	Retaining gloves, that is, no change of surgical gloves during the procedure (n=46)	**Wound infection** was defined as the presence of cellulitis (hyperemia, induration and tenderness), purulent drainage from the incision and/or fluctuant, tender, erythematous incision margins). Unknown follow-up.	5.5% in the change group. 25% in the no change group. **Relative risk: 4.5 (95% CI: 0.982-29.8)**	Blinding unknown. Follow-up period unknown. No validated SSI definition.
Cernadas 1998 *(9)*	USA 1995-1996	RCT: randomized by opening a consecutively numbered and sealed envelope. **Caesarean section (n=108)** Group A (n=26): no glove change with manual placental delivery. Group B (n=27): no glove change with expressed placental delivery. Group C (n=27): glove change with manual placental delivery. Group D (n = 28): glove change with expressed placental delivery.	Change of gloves If a patient was assigned to a glove change group, the delivery hands of the primary surgeon were double-gloved prior to surgery. The external second glove was removed by a circulating nurse after delivery of the fetus. (Group C+D: n=55)	No change of surgical gloves during the procedure. (Group A+B: n=53)	**Postpartum febrile morbidity** The diagnosis of **endometritis** was assigned based on the attending physician's clinical impression in conjunction with the presence of a maternal temperature >=100.4º F (38°C) occurring 24 hours after caesarean section in combination with a greater than expected uterine tenderness in the absence of another source of infection. Unknown follow-up.	For febrile morbidity: 27.3% with glove change; 18.9% with no glove change. **Relative risk: 0.7 (95% CI: 0.3-1.4)** For endometritis: 14.5% in the glove change group; 17% in the no glove change group **Relative risk: 1.2 (95% CI: 0.5-2.8)**	Follow-up period unknown. No validated SSI definition.

Atkinson 1996 *(8)*	USA 1993-1994	RCT: randomized by opening the next numbered, opaque sealed envelope. **Caesarean section (n=643)** Four study groups A: No glove change plus manual placental extraction. B: No glove change plus spontaneous placental delivery. C: Glove change plus manual extraction. D: Glove change plus spontaneous delivery.	Change of gloves. If a patient was assigned to either of the glove change groups, the contaminated gloves were removed by the circulating nurse after delivery of the fetus and a sterile pair of gloves was donned. (n= 317)	No change of surgical gloves during the procedure. (n=326)	**Endometritis** was diagnosed by the finding of a maternal temperature of at least 38ºC and either uterine tenderness or foul-smelling lochia in the absence of another clinically obvious source. Unknown follow-up.	27% in the glove change group. 26% in the no change group. **Relative risk: 1.0 (95% CI: 0.79-1.3; *P*=0.9)**	Blinding unknown. No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition. Number of patients lost to follow-up unknown. Crude results unknown.

SSI: surgical site infection; RCT: randomized controlled trial; CI: confidence interval.

Appendix 2c: Studies related to changing of gloves vs. retaining gloves - bacterial contamination as primary outcome*

Author, year, reference		Country/ study period	Type of study/ Setting	Intervention	Comparator	Primary Outcome-	Results	Limitations
Ward 2014 *(13)*		USA Not specified	RCT **Clean orthopaedic surgery (n=251)**	Exchange of outer pair of gloves one hour into surgery (n=143).	No change of gloves (n=108).	**Bacterial contamination** of gloves (presence of bacterial CFUs vs. absence).	Positive glove contamination rate of 23% for surgeons retaining outer gloves one hour into surgery. Positive glove contamination rate of 13% among surgeons exchanging their outer gloves. **OR: 1.97; (95% CI: 1.02–3.80); *P*=0,04**	Study period unknown. Randomization method unknown. Blinding unknown. Allocation concealment unknown. No clear inclusion and exclusion criteria. No *a priori* sample size calculation.
Al Maiyah 2005 *(7)*		United Kingdom Not specified	RCT: randomization by pre-prepared sealed envelopes. **Primary total hip arthroplasty (n=50)**	Change of outer gloves after draping, either at 20-minute intervals or immediately before cementation if this occurred before the end of a 20-minute interval. In addition, gloves were changed whenever a visible puncture was detected. (n=25).	Change of outer gloves after draping and before cementation of the components. In addition, gloves were changed whenever a visible puncture was detected. (n=25).	**Bacterial contamination** of gloves.	4.8% in the intervention group. 13.9% in the control group. Significant difference reported by authors only.	Study period unknown. Blinding unknown. No *a priori* sample size calculation.

Author, year, reference		Country/ study period	Type of study/ Setting	Intervention	Comparator	Primary Outcome-	Results	Limitations
Zdanowski 2000 *(14)*		Sweden Unknown period	RCT **Implantation of vascular graft (n=40)**	Change of gloves before contact with graft (n=20).	No change of gloves before contact with graft (n=20).	The growth of all bacterial species from graft segments and gloves was recorded. Secondary outcome reported: superficial SSI Group 1:2/20 Group 2:5/20 *P*<0.02	Group "change of gloves" before contact with graft: 10% no growth, 70% with one bacterial species, 20% with ≥2 bacterial species. Group "no change of gloves" before contact with graft: 5% no growth, 50% with one bacterial species, 45% with ≥2 bacterial species. (***P*=0.04)**	Study period unknown. Randomization unknown. Blinding unknown. Allocation concealment unknown. No clear inclusion and exclusion criteria. No *a priori* sample size calculation.

*One RCT also reported on SSI.
SSI: surgical site infection; RCT: randomized control trial; CFUs: colony-forming units; OR: odds ratio; CI: confidence interval.

Appendix 2d: Studies related to different types of gloving - SSI outcome

Author, year, reference	Country/ study period	Type of study/ setting	Intervention	Comparator	Primary outcome	Results	Limitations
Sanders 1990 *(10)*	USA 1988	RCT: randomized by opening a consecutively numbered and sealed envelope. **Orthopaedic surgery (n=50)**	Inner pair of standard latex gloves + cotton-cloth outer gloves (n=25).	Inner pair of standard latex gloves + latex outer gloves (n=25).	**Postoperative infection** Unknown criteria Follow-up period unknown.	**No reports of postoperative infection.**	Blinding unknown. No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition. No *a priori* sample size calculation. Number of patients lost to follow-up unknown.

Author, year, reference	Country/ study period	Type of study/ setting	Intervention	Comparator	Primary outcome	Results	Limitations
Sebold 1993 *(11)*	USA 1990	RCT: randomized by opening a consecutively numbered and sealed envelope. **Orthopaedic surgery (arthroplasties and revision) (n=71)**	Inner pair of standard latex gloves + outer "orthopaedic" gloves (n=25). Repel gloves between 2 regular latex gloves (n=24).	Inner pair of standard latex gloves + latex outer gloves (n=22).	**Postoperative infection** Unknown criteria Follow-up period unknown.	**No reports of postoperative infection**	Blinding unknown. No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition. No *a priori* sample size calculation. Number of patients lost to follow-up unknown.

SSI: surgical site infection; RCT: randomized control trial.

Appendix 3. Risk of bias assessment of the included studies

Appendix 3a: Risk of bias in the included randomized controlled studies (Cochrane Collaboration tool)

Author, year, reference	Sequence generation	Allocation concealment	Participants blinded	Care-providers blinded	Outcome assessors blinded	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Ventolini 2004 *(12)*	Low risk	Low risk	Unclear	High risk	Unclear	Low risk	Low risk	Follow-up period unknown. No validated SSI definition.
Cernadas 1998 *(9)*	Low risk	Low risk	Unclear	High risk	Low risk	Low risk	Low risk	Follow-up period unknown. No validated SSI definition.
Atkinson 1996 *(8)*	Low risk	Low risk	Unclear	High risk	Unclear	Unclear	High risk	No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition.
Ward 2014 *(13)*	Unclear	Unclear	Unclear	High risk	Unclear	Unclear	Low risk	Study period unknown. No clear inclusion and exclusion criteria. No *a priori* sample size calculation.
Al-Maiyah, 2005 *(7)*	Low risk	Low risk	Unclear	High risk	Unclear	Unclear	High risk	Study period unknown. No *a priori* sample size calculation.
Zdanowski 2000 *(14)*	Unclear	Unclear	Unclear	High risk	Unclear	Unclear	High risk	Study period unknown. No clear inclusion and exclusion criteria. No *a priori* sample size calculation.
Sanders 1990 *(10)*	Low risk	Low risk	Unclear	High risk	Unclear	Unclear	High risk	No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition.

								No *a priori* sample size calculation.
Sebold 1993 *(11)*	Low risk	Low risk	Unclear	High risk	Unclear	Unclear	High risk	No clear inclusion and exclusion criteria. Follow-up period unknown. No validated SSI definition. No *a priori* sample size calculation. Number of patients lost to follow-up unknown.

SSI: surgical site infection.

Appendix 3b: Risk of bias assessment of the included observational studies (Newcastle-Ottawa quality assessment scale)

Author, year, reference	**Representative-ness of cohort**	**Selection of non-exposed cohort**	**Ascertainment of exposure**	**Demonstration that outcome of interest was not present at start**	**Comparability of cohorts**	**Assessment of outcome**	**Follow- up long enough**	**Adequacy of follow-up of cohorts**
Tulipan 2006 *(16)*	C. Selected group of interventions (only one surgeon, the same for non-exposed and exposed patients).	A. (*) Drawn from the same community as the exposed cohort.	A. (*) Secure records (computerized database).	B. No	A. (*)	B. (*). Record linkage.	B. No (6-month follow-up, not 1 year)	D. No statement. Number of patients lost to follow-up unknown.
Dodds 1990 *(15)*	D. No description of the derivation cohort.	A. (*) Drawn from the same community as the exposed cohort.	D. No description.	B. No	A. (*)	D. No description: "the wounds were inspected for signs of infection at 7-10 days".	B. No	A. (*) Complete follow-up – all subjects accounted for.

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