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Chairmen:

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قسمت دهم: محیط جراحی

(Tenth Section: Operative Environment)

Question 22: After skin incision, should the knife blade be changed for deeper dissections?

Consensus: We recognize high contamination rates in studies of scalpel blades that have been used for the skin incision and recommend changes after skin incision.

Delegate Vote: Agree: 88%, Disagree: 8%, Abstain: 4% (Strong Consensus)

Justification: In the majority of institutions, separate blades are used for incision of the skin and the deeper tissues during TJA. However, several studies have questioned the necessity of such practice. 113-115 When comparing contamination of skin and deep knives, Ritter et al. were unable to identify any difference in contamination rates in both conventional and laminar air flow conditions¹¹⁵ Furthermore, organisms retrieved from deep wound cultures did not correlate with those that were on the knife blades, thus refuting deep wound contamination by the blades. Other authors subsequently corroborated these findings. 113, 114 However, Davis et al. identified a 9.4% contamination rate of superficial blades and supported the routine practice of changing blades after incision.23 Schindler et al. reported a 15.3% contamination rate for skin blades, 74% of which grew coagulase-negative Staphylococcus (CNS), one of the most frequent causes of PJI. 116 In this study, 10.8% of deep blades were contaminated, 50% of which with CNS, Based on their findings, the authors supported changing the skin blade after incision.

Question 23: Should electrocautery tips be changed during TJA? If so, how often?

Consensus: In the absence of evidence we recommend further study and no specific behavior.

Delegate Vote: Agree: 95%, Disagree: 0%, Abstain: 5% (Strong Consensus)

Justification: After review of the literature, there were no studies relevant to the necessity and frequency of change of electrocautery disposable tips during elective TJA.

Ouestion 24: Should suction tips be regularly changed during surgery? If so, how frequently? Should suction tips enter the femoral canal?

Consensus: We recommend changing suction tips every 60 minutes based on studies showing higher rates of contamination. Suction tips can be introduced into the femoral canal for the time necessary to evacuate fluid but should not be left in the canal, where they circulate large amounts of ambient air and particles that may contaminate the surgery.

Delegate Vote: Agree: 85%, Disagree: 8%, Abstain: 7% (Strong Consensus)

Justification: Several studies have demonstrated high rates of contamination of suction tips during the intraoperative period²³, ¹¹⁷⁻¹²³ In 1988, Strange-Vognsen et al. identified a 54% contamination rate in orthopaedic procedures 123 Twenty years later, Givissis et al. found the same rate of contamination, with 78% of cases growing Staphylococcus species.117 The authors reported one case of deep SSI where the organism was the same as the one isolated from the suction tip. When looking at procedure duration, they showed a 9% contamination rate in procedures lasting less than an hour compared to a 66.7% in procedures lasting over an hour, which led them to advise changing of the catheter tip every hour. Similarly to Strange-Vognsen et al., they recommended turning the suction off when not in use. However, there are concerns that turning off the suction might impose risk of contamination of the surgical field due to backflow of the material along the suction tube and tip.

Greenough et al. found a 37% rate of contamination of operative suctions used in THA. However, when evaluating the suction tips used only for cleaning the femoral shaft, only one of those (out of 31) was contaminated. The authors advised changing the suction tip before preparing the femur in THA. The same conclusion was drawn by Robinson et al. who conducted a similar study among patients undergoing THA in laminar flow rooms and identified a 41% contamination rate of suction tips. ¹²²

Question 25: Should splash basins be used, as they are known to be a source of contamination?

Consensus: We recommend against the use of fluid filled basins that sit open during the surgery.

Delegate Vote: Agree: 88%, Disagree: 3%, Abstain: 9% (Strong Consensus)

Justification: Andersson et al. showed that 13 out of 21 irrigation solutions stored in basins were contaminated at the end of the procedure in conventional ventilation rooms. Baird et al. revealed a contamination rate of 74% in their series among specimens taken from splash basin fluids. In their series, *Staphylococcus epidermidis* was the most prevalent organism. Anto et al. demonstrated a 24% rate of contamination of liquid samples removed from the basins. Conversely, Glait et al. recently showed much lower rates of contamination of samples taken from basins that were used to wash and store instruments with only one contaminated case out of 46 (2.17%). However, they used culture swabs as opposed to culturing fluid in other studies.

Question 26: Do disposable instruments and cutting guides reduce contamination and subsequent PJI?

Consensus: We recognize possible theoretical advantages of disposable instrumentation but in the absence of data we can make no recommendations.

Delegate Vote: Agree: 95%, Disagree: 2%, Abstain: 3% (Strong Consensus)

Justification: Mont et al. have recently demonstrated a decreased contamination rate of 57% in non-navigated and 32% in navigated cases of total knee arthroplasty (TKA) when using singleuse instruments, cutting blocks, and trials. ¹²⁷

Patient specific instrumentation can shorten the duration of surgery in TKA. However, there are no studies that have specifically evaluated the incidence of subsequent PJI in patients that received custom cutting guides or disposable instruments versus those undergoing TJA using conventional instruments and cutting guides. Thus, this issue remains unresolved.

Question 27: Is there a role for incise draping? What type of incise draping should be used (impregnated or clear)?

Consensus: We recognize the presence of studies that show iodine impregnated skin incise drapes decreased skin bacterial counts but that no correlation has been established with SSI. We do not make any recommendations regarding the use of skin barriers but do recommend further study.

Delegate Vote: Agree: 89%, Disagree: 7%, Abstain: 4% (Strong Consensus)

Justification: There is concern about the recolonization of skin and surgical site with the host flora during surgery. 129-132 Incise drapes are intended to provide a sterile barrier at the beginning of the surgical procedure. They are used on prepped surgical sites to provide additional protection and minimize the risk of recolonization. While it has been shown that impregnated incise drapes decrease the recolonization rate of skin flora, there have been inconsistent conclusions about the existing evidence regarding the value of drapes in preventing SSI. Highquality evidence with PJI as an endpoint is lacking. Use of adhesive incise drapes impregnated with iodine should be avoided in patients with systemic or topical allergy to iodine. The bactericidal action of iodine-containing incise drapes is inferior to conventional skin preparation solutions such as betadine. The sole use of incise drapes as a substitute for conventional skin preparation is not recommended. 133 In an experimental study on the skin of normal individuals, use of an iodophor-incorporated drape was significantly associated with a lower rate of recolonization of skin bacteria compared with skin-site preparation methods, with or without non-impregnated drape. 131 However, another experimental study on an animal model found that after contamination of skin samples with Staphylococcus aureus suspension, iodine-containing adhesive drapes were as inefficient as the control group in reducing the number of colony-forming units.¹³⁴ Another experimental study found that non-impregnated drapes can facilitate the rate of recolonization of skin after antiseptic preparation. 135 In contrast, in an earlier investigation, bacteria did not multiply underneath a plastic adhesive drape and lateral migration of bacteria did not occur. 136

In a prospective RCT, Chiu et al., with the numbers available could not demonstrate a difference between the wound contamination rates after surgery of acute hip fractures with and without the use of plastic incise drapes (4/65 versus 1/55 for with and without drapes, respectively). 137

In another prospective RCT in abdominal surgery, within the group of clean and cleancontaminated procedures, iodophor-impregnated incise drapes significantly reduced the contamination of the surgical wound by normal skin flora organisms, but the study was unable to detect any significant difference in the rate of SSI compared with the control group in whom no drape was utilized (5.9 vs 5.6% for procedures performed with and without drapes, respectively). 138

In a prospective study comparing¹²² patients undergoing hip surgery in which Ioban (3M Company, USA) was applied to the operative site 24 hours before surgery, bacterial sampling of the wound at the end of the procedure showed that the wound contamination rate was reduced from 15 to 1.6% by this method.¹³⁹

One review combined the results of clinical trials of a wide range of clean and cleancontaminated surgical procedures (caesarean sections, abdominal, and hip fracture procedures), most of which did not meet criteria for high quality evidence. In these studies plastic (defined as polyethylene, polyurethane, or polyvinyl) adhesive drapes (eg Op-Site (Smith and Nephew), Ioban (3M), Steridrape (3M, United Kingdom) were utilized. The authors concluded that adhesive drapes are not associated with a reduced infection rate compared with

no adhesive drapes and appear to be associated with an increased risk of infection. However, the quality of the few studies included in this systematic review was not high. The authors concluded that if adequately disinfected prior to surgery, the patient's skin is unlikely to be a primary cause of SSI; therefore, attempts to isolate the skin from the wound using an adhesive drape may be pointless and potentially harmful, as excessive moisture under plastic drapes may encourage bacteria residing in hair follicles to migrate to the surface and multiply. 137,140

Another issue that should be considered is that the type of skin preparation affects drape adhesion. 141 A few studies demonstrated that addition of Duraprep (3M) enhanced the adhesive capacity of drapes. 129, 130 Choosing a skin preparation that enhances drape adhesion may minimize drape lifting and the potential for wound contamination. It has been concluded that the separation of incise drapes from the skin was associated with a 6fold increase in the infection rate compared with surgical procedures in which the incise drape was not lifted. 142 A prospective RCT on patients with TJA confirmed that Duraprep solution was associated with significantly better drape adhesion than povidone-iodine scrub and paint. However, the study was not able to demonstrate a significant difference in skin contamination between the groups, although Duraprep was associated with slightly lower rate of contamination. 130

Allergic reactions to povidone-iodine can occur and there is at least one case report of allergic contact dermatitis associated with the use of iodophor-impregnated incise draping. 143, 144

Question 28: Does the application of towels or other sterile materials to wound edges and subcutaneous fat during an operation, clipped securely to the edges of the wound, diminish the chances of wound contamination and wound infection? **Consensus**: We recognize the traditional practice of covering skin edges with sterile draping but there is wide variation in clinical practice and we make no recommendations.

Delegate Vote: Agree: 94%, Disagree: 2%, Abstain: 4% (Strong Consensus)

Justification: Evidence regarding the application of sterile material to wound edges is mainly available for abdominal open surgery. There is no evidence regarding its use in orthopaedic surgery and we found no recommendation regarding their use for PJI. Towels can serve to support the drapes against instrument strikethrough. They may also protect the wound edges from trauma by instruments such as retractors or broaches.

Literature: Wound edge protection devices (wound protectors or wound guards) have been used in abdominal surgery to avoid contamination and trauma of the wound edges during laparotomy. 145, 146 There are two main types of protectors: (1) wound protectors with an external and internal ring connected by an impermeable plastic that covers the wound edges and (2) those with an internal ring connected to a drape that extends outward and over the abdomen and is fixed by adhesive material or clips. 146 They provide a physical barrier to protect the incision site from contamination. In contrast, adhesive drapes do not cover the edges of the wound. Wound protectors have only been used in abdominal surgery. 145 Two meta-analyses of RCTs compared the use of wound protectors with no protection in abdominal laparotomy. The authors concluded that their use seems to be protective against SSI. 145, 146 However; the quality of those RCTs has been poor. Two multicenter trials on abdominal laparotomy procedures have been registered and are being conducted at the time of writing. 147, 148

Question 29: What type of draping should be used (reusable or disposable)?

Consensus: We recognize that penetration of drapes by liquids is believed to be equivalent to contamination and recommend impervious drapes. In the absence of data on disposable versus cloth drapes, we make no recommendation except for further study.

Delegate Vote: Agree: 90%, Disagree: 6%, Abstain: 4% (Strong Consensus)

Justification: The available evidence is solely experimental. Most of the studies have been performed in models with rigorous conditions that are unusual in real-life situations. Clinical trials with PJI as an endpoint are lacking.

Literature: In addition to the physical properties of material applied for fabricating drapes, factors such as pressure, friction, contact time with contaminated material, state of

moisture/dryness, and the moisturizing agent (blood, normal saline, or antiseptic solutions) can affect bacterial permeability of drapes. 149, 150 While passage of bacteria through dry drapes does happen, the strike-through rate of bacteria is enhanced when wetted by normal saline or blood and diminished when wetted by antiseptic solutions (iodine or chlorhexidine). 149 Moreover, drape material may demonstrate different levels of imper-meability depending on the penetrating particle (aqueous fluids, albumin, or bacteria). 151-153 Woven and non-woven materials vary in their ability to resist bacterial strikethrough. Disposable nonwoven drapes are superior to reusable woven cotton/linen drapes in resisting bac-terial penetration. When wetted by normal saline, reusable woven drapes were penetrated by bacteria within 30 minutes, while the majority of disposable nonwoven drapes were not. 151 Being impervious does not necessarily mean being absolutely impenetrable to bacteria and impermeability can vary between different disposable drape brands. However, disposable drapes considerably decrease bacterial load passing through them. 154

Two RCTs were conducted comparing reusable and disposable drapes and gowns in coronary artery bypass graft and elective abdominal surgery, with SSI as their main outcome. None of these studies found differences between the two types of gowns and drapes. 155, 156

Question 30: Is there evidence that the use of sticky U drapes, applied before and after prepping, effectively seals the non-prepped area from the operative field?

Consensus: We recognize that adhesive "U-drapes to isolate the perineum" has been

traditional practice but in the absence of data we make no recommendations.

Delegate Vote: Agree: 83%, Disagree: 11%, Abstain: 6% (Strong Consensus)

Justification: There are no published or unpublished reports that we could identify that were related to this issue.

Question 31: Is irrigation useful? How should the delivery method for irrigation fluid be (high pulse, low pulse or bulb)?

Consensus: We recognize the theoretical basis for irrigation to dilute contamination and nonviable tissue and that a greater volume of irrigation would be expected to achieve greater dilution. We recognize advantages and disadvantages of different methods of delivering fluid but make no recommendations of one method over another.

Delegate Vote: Agree: 91%, Disagree: 4%, Abstain: 5% (Strong Consensus)

Justification: There are indirect data regarding the optimal volume of irrigation in TJA. In both animal and human studies, increasing the volume of irrigation

solution removes more particulate matter and bacteria, but the effect plateaus depending on the system. There have been no reported human clinical studies related to the volume of irrigation. ^{157, 158} High-quality studies with PJI as endpoint are lacking. No evidence was found regarding differences in irrigation in primary and revision TJA. Use of high-pressure pulsatile lavage may have potential benefits of being time-saving and removing necrotic tissue and debris more effectively. 159-164 It also improves the mechanical stability of cemented arthroplasty by allowing better cement penetration in cancellous bone tissue. However, there are some concerns regarding damage to tissue structures and propagation of bacteria into the deeper layers of soft tissues with the use of high pressure lavage. High-pressure pulsatile lavage should perhaps be reserved for severely contaminated wounds or for open injuries for which treatment will be delayed. Low-pressure irrigation might be useful if contamination is minimal or treatment is immediate. High-quality evidence is lacking regarding optimum lavage pressure in primary or revision TJA.

Literature: Decreases in the amount of bacteria present in the surgical site have been observed with normal saline lavage, 165 indicating that a component of physical removal for every irrigating solution should be considered. For a clean contaminated surgery (appendectomy) irrigation with normal saline was found to decrease SSI in comparison with no irrigation. 166, 167 In one study that used pulsatile lavage with normal saline after cemented TKA, particles larger than 1 um were collected consecutively after each liter of lavage up to 8 liters. The weight of these particles peaked in the first 1L lavage fluid and gradually decreased until the eighth lavage fluid. Significant differences were found between the first and second, second and third, and third and fourth lavage. However, no significant differences were found beyond the fourth lavage. The results of this study indicated that 4L of pulse lavage is effective for removing the bone and cement particles during cemented TKA. The authors suggested that if bacteria are considered as particles of approximately more than 1 µm, 4L of pulse lavage may be effective for removal of bacterial particles. 158

The precise definition of high- and low-pressure lavage is not established in the literature.

Generally below 15 psi (103.4 kPa) and over 35 psi (241.3 kPa) are considered low or high pressure, respectively. High-pulsatile lavage has been shown to improve cement penetration in cancellous bone and increase mechanical strength at the cement-bone interface during in vitro studies. How in vivo studies have also demonstrated fewer radiolucency zones in follow up X-rays evaluation. In addition, a relationship between the pressure of irrigation and the quantity of cellular material removed from the bony trabeculae has been demonstrated.

However, there is no agreement on a cut-off point for high-pressure lavage. Some studies suggest that even lavage pressures that were considered to be too low to have macroscopic influence may still have an effect on bone marrow mesenchymal cells and direct them to differentiate into adipocyte tissues, thus declining the content of osteoblasts in marrow.¹⁵⁹

High-pressure lavage may result in tissue damage in cancellous bone, cortical bone, and muscle; and can negatively influence the healing process and early formation of new bone. 91, 176-178 Pulsatile lavage (either high or low pressure) results in greater deep bacterial seeding in bone than does brush and bulb-syringe lavage in *in vitro* models 162, 179 and can spread the contamination to nearby tissues. 179 High-pressure pulsatile lavage results in deeper bacterial penetration in muscle tissue in comparison with low-pressure pulsatile lavage. 168

There is a considerable body of evidence regarding open fractures and contaminated wounds.

A few early and recent studies, including *in vitro* and *in vivo* human and animal studies, demonstrated that high-pressure pulsatile lavage is more effective than low-pressure pulsatile lavage for removing particulate matter, bacteria, and necrotic tissue, particularly in contaminated wounds that had delayed treatment. Moreover, in an experimental model it was demonstrated that low-pressure pulsatile lavage was more effective and efficient than bulbsyringe irrigation in reducing bacterial removal. 180

One prospective RCT showed that pulsatile lavage in comparison with normal lavage by syringe or jug leads to a lower incidence of PJI after cemented hemiarthroplasty for hip fracture (3/164 versus 10/192 for pulsatile and syringe lavage groups, respectively). ¹⁸¹

In another study, the use of high-pressure pulsatile lavage during open debridement for the treatment of acute orthopaedic implant infections (mainly TKA, THA, and hip hemiarthroplasty) was associated with a similar success rate compared with the conventional manual lowpressure lavage (n=79). ¹⁸²

Question 32: What type of irrigation solution should be used? Should antibiotics be added to the irrigation solution?

Consensus: We recognize the mechanical advantage of irrigation as per section 31 but that conflicting evidence exists supporting the use of one agent over the other and make no recommendation regarding type of solution.

Delegate Vote: Agree: 90%, Disagree: 7%, Abstain: 3% (Strong Consensus)

Justification: Detergents such as castile soap or benzalkonium chloride are effective in decreasing the burden of bacteria in musculoskeletal wounds because of their surface-active properties. The detergents act by disrupting hydrophobic and electrostatic forces, thereby inhibiting the ability of bacteria to bind to soft tissue and bone. It is possible that some detergents act on some bacteria more efficiently than on others. ^{157, 183}

Weak evidence is available for the benefit of irrigation with diluted betadine solution before closure of surgical wound. However, no deleterious influence on wound healing or any other major adverse effects have been associated with their use. Concerns for its potential chondrocytotoxicity are supported by experimental evidence only. Lower concentrations (0.35 to 0.5%) with a short time of lavage might avoid potential chondrocytotoxic effects in partial knee arthroplasty. Further clinical evidence is required to define optimal concentration and length of exposure.

The pharmacodynamic profiles of antibiotics vary depending on the type, dose, and method of delivery.184 A variation of these factors, a difference in surgical settings in which studies have been performed, and a lack of specific efficacy criteria make it difficult to reach a conclusion regarding whether topical antibiotics are efficacious; and if so, what type should be used and which formulations are optimal for prophylaxis of SSI and PJI. Moreover, the safety of using topical antibiotics has been questioned. Evidence regarding wound irrigation with antibiotic solutions mainly comes from non-orthopaedic surgical specialties with cleancontaminated surgeries. Most of these RCTs found that adding antibiotics to irrigation solutions did not decrease the incidence of SSI significantly in comparison with irrigation with normal saline solution. 160, 185-189 This finding has also been supported by some experimental studies. 157, 190

Further high-level evidence with SSI or PJI as endpoints is required to evaluate the efficacy and potential adverse effects of local irrigation with antibiotic solutions on the surgical site.

Literature: *In vitro* studies show that Castile soap is more effective than antibiotic solutions at removing *Staphylococcus aureus, Staphylococcus epidermidis, and Pseudomonas aeruginosa* from metallic implants and bone^{191, 192}. In an RCT on open fractures, soap and bacitracin solution did not result in any difference in the incidence of SSI, although bacitracin was associated with more wound complications¹⁹³.

In one RCT in general surgery, there were more wound infections in the saline group (39/258) in comparison with the povidone-iodine solution group (7/242).194 Irrigation with dilute povidoneiodine solution (0.35%) before closure of the surgical wound in THA and TKA was associated with significant decrease in PJI. 195 The same solution was associated with a significant decrease in deep SSI in spine surgery (6/206 deep SSIs in the no betadine group versus 0/208 in the betadine group).196 Ten of 15 studies (11 RCTs and 4 prospective comparative studies) in a systematic review of different surgical specialties (2 studies of spine surgery) demonstrated that povidone-iodine irrigation was significantly more effective at preventing SSI than the comparative interventions of saline, water, or no irrigation. 197 The other 5 studies did not detect any significant difference. This study has considerable methodological limitations, such as considerable variety in the types of surgeries, quality of clean or contaminated interventions, inconsistent concentration of povidone-iodine, and variable use of prophylactic antibiotics. There

is no reported complication with the use of dilute betadine irrigation and no adverse effect on wound healing, bone union, or clinical outcome has been reported. 196 One study demonstrated an increased postoperative serum iodine which was not related to any adverse effects. 197 The cytotoxicity of povidone-iodine solution is controversial: Chondrocyte ability for DNA synthesis significantly decreased after 5 minutes of exposure to povidone-iodine 1%. Other studies similarly show toxic effects of povidone-iodine solution on fibroblasts, keratinocytes, synovial cells and chondrocytes. 198, 199 Cytotoxicity has been related in bovine chondrocytes with length of exposure, regardless of concentration, although higher concentrations were associated with less viability of chondrocytes. A concentration of 0.35% povidone-iodine was the least chondrotoxic but still reduced the cell viability when applied for longer than one minute.

Cytotoxicity has been observed in cultured embryonic chicken tibia osteoblasts at a betadine concentration of 5%. Less cytotoxic effect occurs at a povidone-iodine concentration of 0.5%. 200 Povidone-iodine preparations of 1, 5, or 10% do not have a deleterious effect on wound healing in animals and humans.²⁰¹ Povidone-iodine irrigation should not be used in patients with iodine sensitivity, burns, and thyroid or renal disease. 197 The sterility of povidone-iodine solution before its use should be meticulously monitored because its contamination has been associated with infectious complications. 202, 203 One experimental study showed that there was no difference in the quality of cement fixation when irrigation was done with povidone-iodine or normal saline, although both solutions were inferior to hydrogen peroxide solution.²⁰⁴

Topical antibiotics should have a broad spectrum and low systemic absorption and be relatively inexpensive and harmless to the tissue. The most commonly used topical antibiotics include cephalosporins, aminoglycosides (neomycin), glycopeptides, chloramphenicol, polymyxin, and bacitracin. 184, 205 The potential advantages of topical antibiotic use are their limited potential for systemic absorption and toxicity, low potential for development of antibiotic resistance, and the fact that their effect is essentially independent from the local physiological changes that may affect the efficacy of systemic antibiotics.²⁰⁶ However, topical antibiotics may produce contact dermatitis or hypersensitivity and their use has been reported to be associated with serious systemic effects such as anaphylaxis with bacitracin and deafness and renal failure with a neomycin-bacitracin-polymixin combination.²⁰⁷⁻²⁰⁹ Earlier studies demonstrated that prophylactic topical administration of antibiotics in the surgical incision during various orthopaedic and

nonorthopaedic procedures is more efficacious than normal saline. However, consistent results have not been reported regarding their efficacy. 165 In vitro and animal studies using bone or metal surfaces failed to show better performance for neomycin and bacitracin solutions in comparison with normal saline for removing bacteria from bone, titanium, and stainless steel. 190-192 Despite evidence that topical antibiotics decrease bacterial inoculum in clean surgical wounds, ²¹⁰ it has not been shown that they offer any advantage over intravenous antibiotic prophylaxis. nor that they have been proven to decrease the incidence of SSI. 184, 186 A study of acanine model for TJA reported a reduction in the SSI rate with neomycin containing irrigation solution.²¹¹ There is concern regarding the adverse effect of topical antibiotic solutions on wound and bone healing. An RCT on open fractures found that topical irrigation with bacitracin solution did not decrease the incidence of SSI in comparison with soap, yet it was associated with a higher rate of wound complications. 193

Question 33: Is there a role for intraoperative application of autologous blood-derived products to the wound in preventing infection?

Consensus: In the absence of data we make no recommendation regarding autologous blood derived products to the wound to prevent infection.

Delegate Vote: Agree: 94%, Disagree: 2%, Abstain: 4% (Strong Consensus)

Justification: Although some benefits have been observed regarding intraoperative application of autologous blood-derived products in TJA, the majority of the studies were not sufficiently powered to be able to detect difference for PJI. Only one RCT demonstrated that use of these products directly decreased the incidence of postoperative wound infection. Larger-scale trials with PJI as an endpoint are required.

Literature: In TKA, application of autologous platelet gel and fibrin sealant together on the wound tissues at the end of surgery was associated with a higher postoperative hemoglobin level and decreased need for blood transfusion. The incidences of wound leakage, wound healing disturbance, and wound infection (0/85 versus 4/80) were significantly less in patients managed with platelet gel and fibrin sealant.²¹²

In a multi-center study (n=58) topical spraying of fibrin tissue adhesive (non-autologous cryoprecipitate-based fibrinogen) was added to standard hemostatic measures in TKA and resulted in a decrease in blood loss and reduced blood transfusion requirements. There were 3 cases of superficial wound infection (2/29 and 1/29 for the treatment and control groups, respectively) without any significant difference. Other similar RCTs on TKA (n=53)²¹⁴ and THA (n=81)215 reported similar findings regarding blood loss.

In one RCT, using autologous fibrin sealant in THA, there was an association with less wound drainage and blood loss (no significant difference), yet the transfusion rate and hospital stay remained similar to the control group. ²¹⁶

One review included 6 trials²¹³⁻²¹⁸ that studied the use of fibrin sealants in orthopaedic surgery.

In these trials 482 patients were included, of whom ²³⁵ were randomized to receive fibrin sealants. The review found use of fibrin sealant in the context of orthopaedic surgery that was associated with a reduced postoperative blood loss on average around ²²³ mL per patient, and reduced the risk of exposure to allogeneic red blood cell transfusion by 32%. Fibrin sealant treatment was not associated with an increased risk of wound infection, any infection, hematoma formation, or death. Hospital length of stay was not reduced in patients treated with fibrin sealant. ²¹⁹

Question 34: Do staples or the type of suture have an effect on infectious events? If so, what is the best closure method to prevent infectious events?

Consensus: In the absence of conclusive data and the wide variability in surgical practice, we make no recommendation regarding specific sutures or staples to prevent infection.

Delegate Vote: Agree: 92%, Disagree: 3%, Abstain: 5% (Strong Consensus)

Justification: We are unable to draw a clear conclusion about the best method for closure to prevent infectious complications, due to inadequate definitions for infection complications of surgical wounds. In addition, the majority of the studies reviewed were underpowered. Evidence is lacking regarding patients whose health may interfere with wound healing and in surgical sites of high tension. Tissue adhesives should be considered as a biological sealant rather than a closure method of mechanical strength.

Literature: In an RCT that included 90 patients who underwent TKA, no significant differences in infection, dehiscence, general health, and functional and clinical assessments were observed.

The study compared the following: (1) combined suture tissue adhesives defined by sutures for capsule and subcutaneous layers and tissue adhesive (2-octyl or nbutyl-2) for the final cutaneous layer, (2) staples, and (3) conventional subcuticular suture approach (sutures used for the capsule, subcutaneous, and cutaneous layers). It was observed that the length of hospital stay was higher with the staple group.²²⁷

Another trial included 187 patients who underwent TKA (n=85) and THA (n=102) and compared wound closure with 2-octylcyanoacrylate (OCA), staples, and sutures.228 Early wound discharge (less than 24 hours

postoperatively) was reduced with OCA in both THA and TKA. In TKA, prolonged wound discharge was observed with OCA. No significant difference was observed in the incidence of superficial wound infections between groups. No deep infection was detected. Sealing of the wound as measured by blood strike-through onto the dressing was significantly improved with OCA in both joints. The authors concluded that for more mobile surgical wounds (such as with TKA). OCA might not be appropriate for skin closure because it does not provide adequate resistance for withstanding early rehabilitation. In another trial including 90 patients with THA, skin adhesive and surgical staples were both effective skin closure methods. Staples were quicker and easier to use than skin adhesive and less expensive. No significant difference was found regarding the occurrence of complications, although the study was not adequately powered to detect any case of deep infection. 229

A review of RCTs in a wide range of non-orthopaedic surgical specialty with pediatric and adult patients²³⁰ concluded that sutures were significantly better than tissue adhesives for minimizing dehiscence. Sutures were also found to be significantly faster to use. No differences were found between tissue adhesives and tapes for minimizing dehiscence or infection. Tapes and staples were significantly faster to use than tissue adhesives. For all outcomes of dehiscence and infection there were no statistically significant difference between high- and low-viscosity adhesives.

Smith et al. performed a meta-analysis to compare the clinical outcomes of the use of staples and sutures in orthopaedic surgery.²³¹ The authors included 6 small-sized studies and noted major methodological drawbacks including inadequate definitions for superficial and deep infections in most of them. Based on these studies, they found a significantly higher risk of developing wound infection when the wound was closed with staples rather than sutures (17/350 versus 3/333 superficial or deep infections for staples and sutures, respectively). Five of the 6 studies included data on patients who underwent hip surgery. A higher risk of infection with staples also existed in patients who underwent hip surgery. At this point there is need for future studies to evaluate this issue further.

Question 35: Does the use of a surgical safety checklist and time-out affect the rate of SSI in arthroplasty patients?

Consensus: We support the surgical checklist protocol as beneficial to patient safety, and specifically as it applies to correct administration of prophylactic antibiotics.

Delegate Vote: Agree: 97%, Disagree: 1%, Abstain: 2% (Strong Consensus)

Justification: Checklists seem to improve inter-professional communication in the OR. Highquality evidence exists supporting the beneficial effect of surgical safety

checklists and timeouts for reduction of SSI and other major postoperative complications by assuring timely administration of preoperative antibiotic prophylaxis. However, evidence shows that many elements of adapted checklists are not adequately performed. There is no evidence regarding the influence of implementing a mandatory surgical checklist on appropriate application of evidence-based measures for SSI in TJA. Existing evidence shows the beneficial effect of mandatory safety checklists on infectious complications for other simpler procedures.

Literature: One study showed that implementation of an inter-professional preoperative checklist in the OR was associated with a decline in communication failures (mean number of communication failures per procedure decreased from 3.95 to 1.31; the number of communication failures associated with visible negative consequences decreased by 64%).²³² A relationship appears to exist between the adoption of a routine preoperative checklist by the surgical team and improvement in the timing of antibiotic prophylaxis.²³³⁻²³⁵ In a prospective study of 8 diverse hospitals around the world (including high- and low-income locations), substantial decreases in major surgical complications and mortality during the early postoperative period was observed after implementation of a World Health Organization checklist in the OR. The

adherence rate to appropriate preoperative antibiotic administration increased from 5 to 83% and the incidence of SSI significantly decreased from 6.2 to 3.4% (p<0.001). The improvement in quality of care was observed even with incomplete compliance of the checklist.236 In another study performed in hospitals with a high standard of care in the Netherlands, performing the surgical patient safety system check list, which includes pre-, intra-, and postoperative elements. also reduced the incidence of SSI (from 3.8% to 2.7%, p=0.006) as well as other major postoperative complications. Compliance was associated with greater improvements in quality of care.²³³ In a prospective study, it was observed that many evidence-based measures for SSI reduction (prophylactic antibiotic timing, maintaining normothermia during surgery, appropriate urinary tract catheterization, and hand hygiene) were not applied adequately for arthroplasty procedures and the situation was even worse for fracture surgeries.²³⁷ There is no evidence regarding the influence of a mandatory checklist on appropriate application of its components. However, there are prospective studies demonstrating that implementing mandatory checklists resulted in decrease in the incidence of central line associated bloodstream infections in intensive care unit patients. 238, 239

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