

# A Novel Strategy to Substantially Reduce the Incidence of Periprosthetic Joint Infection Following Total Hip Arthroplasty with Antimicrobial Agents

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## ABSTRACT

**P**eriprosthetic joint infections (PJI) are devastating complications following total hip arthroplasty (THA) and are the most common reason for revision following primary arthroplasty. Although several devices, techniques, and procedures have been developed to combat this serious complication, there is little consensus as to how to prevent the development of PJI at the time of index arthroplasty. This article reviews the concept and implementation of a novel antimicrobial agent to substantially reduce the incidence of PJI. The regular implementation of this infection prophylaxis should be successful in drastically reducing the rate of PJI following primary THA.

## INTRODUCTION

Periprosthetic joint infections (PJI) are a common and serious complication following primary total hip arthroplasty (THA), which if left inadequately treated, can lead to substantial morbidity and death. One study estimated the incidence of PJI after routine THA for osteoarthritis between 0.3 and 1.9% with projections estimating that the burden will increase over three-fold by 2035.<sup>1,2</sup> There is also a major burden to healthcare systems when treating hip PJIs—a recent

study of the National Inpatient Sample (NIS) reported that total charges for revision hip PJIs increased from \$320 to \$566 million and was estimated to reach \$1.6 billion by 2020.<sup>3</sup> Moreover, a recent study suggests that at 10-year follow up, patients who had a hip PJI and underwent surgical intervention had higher mortalities, lower patient-reported outcome scores, lower independent living abilities, and higher assistive device usages<sup>4</sup> when compared to patients with a non-infected THA. It is clear from these studies that PJIs lead to a substantial impact on

patients, providers, and healthcare systems, making it critical that we diminish their incidences and concomitant effects.

The development of hip PJI after primary THA is associated with substantial morbidity and mortality. Indeed, a population-cohort study performed in Denmark found that 8% of patients who underwent intervention for hip PJI within one year died, and the mortality adjusted relative risk was 2.18 compared to primary THA for those who did not undergo revision ( $p < 0.001$ ).<sup>5</sup> A meta-analysis of 23 relevant studies found the one-year

mortality rate of hip PJI was 4.22%, and mortality after five years was 21.12%.<sup>6</sup> It is clear from these studies that PJIs lead to a substantial impact on patients, providers, and healthcare systems, making it critical that we diminish their incidences and concomitant effects.

As a result of the deleterious impact of hip PJIs, there have been many strategies aimed to reduce the development and mitigate the risk of mortality in PJI cases. In a large review of prevention strategies to reduce rates of PJI following joint arthroplasty, these techniques included using multidisciplinary teams for co-management of these patients, optimizing modifiable risk factors, applying specific antiseptic solutions for skin preparation prior to surgery, reducing traffic within the operating room, decreasing procedure time when possible, and extending use of oral antibiotics for high-risk patients, among others.<sup>7</sup> Despite all of the research on the prevention of PJI, this complication is the most common reason for revision for primary THA.<sup>8,9</sup> Therefore, there is a clear need for continued innovation to develop efficacious and available strategies to minimize the risk of PJI.<sup>10</sup>

As noted previously, the preparation of the intended incision is of paramount performance in the preoperative period to reduce the risk of PJI. Human skin hosts many pathogens, making it an important area to target to reduce the risk of PJI. There are many options to prepare the operative skin site including, but not limited to, iodine, isopropyl alcohol, chlorhexidine, and chloroxylenol, among others. Similarly, there are different ways in which to administer the aforementioned preparation product topically to the skin. The Center for Disease Control (CDC) and World Health Organization (WHO) published common practice guidelines for skin preparation products and recommended the use of alcohol-based preparations rather than aqueous ones.<sup>11</sup> In a large network meta-analysis, patients who received 2 to 2.5% chlorhexidine in 70% alcohol had a lower incidence of surgical site infection (SSI) than similar patients who received povidone-iodine.<sup>12</sup>

Although the preoperative use of these agents is imperative to reduce the risk of PJI, there is also an important role for their implementation intraoperatively,

especially in regard to irrigation. Povidone-iodine and chlorhexidine have both received considerable attention in the orthopaedic and arthroplasty community for their use in intraoperative irrigation. A large institutional retrospective study evaluated the use of dilute (0.35%) povidone-iodine for three minutes and found that 18 cases of infection occurred prior to the use of dilute povidone iodine and only one case afterward ( $p=0.04$ ).<sup>13</sup> A large systematic review and meta-analysis concluded that povidone-iodine significantly reduces postoperative infection compared to normal saline, with an odds ratio of 0.44 ( $p<0.001$ ). It also found no statistically significant result when compared to chlorhexidine skin prep (2 to 2.5% in alcohol), with an odds ratio of 0.79 ( $p=0.25$ ).<sup>14</sup> Though povidone-iodine is available and effective, there still is no gold standard for intraoperative irrigation, nor is there better eradication of postoperative prosthetic joint infection.<sup>15</sup>

Though lavage solutions have been effective at reducing superficial and deep infection rates in surgical and orthopaedic procedures, they are not without their potential limitations and disadvantages. For example, povidone-iodine has been implicated in soft-tissue toxicity and cartilage damage, which has tempered its widespread use.<sup>15</sup> Indeed, Keudell et al. exposed bovine cartilage explants to various concentrations of povidone-iodine and found that all forms reduced the viability of superficial chondrocytes if left for longer than one minute.<sup>16</sup> It is clear that, while both povidone-iodine is effective, it is not without problems, leaving the arthroplasty community without a gold standard to reduce PJI rates.

This article describes two products for infection prevention, one of which is a novel antimicrobial irrigation solution (XPERIENCE™, Next Science LLC, Jacksonville, Florida) which has been cleared by the Food and Drug Administration. The XPERIENCE™ is a surgical lavage system that does not require any irrigation to disseminate the group of agents, including 32.5 grams/liter (g/L) citric acid, 31.3g/l sodium citrate, and 1.00g/l sodium lauryl sulfate in water, to preferentially target the development of a bacterial biofilm near prosthetic devices. The sodium citrate acts as a buffer to maintain pH, the citric acid sequesters metal ions from the extracellular matrix, and the sodium lauryl sulfate is the surfactant (Table I). These ingredients, together, help to induce a cytotoxic environment

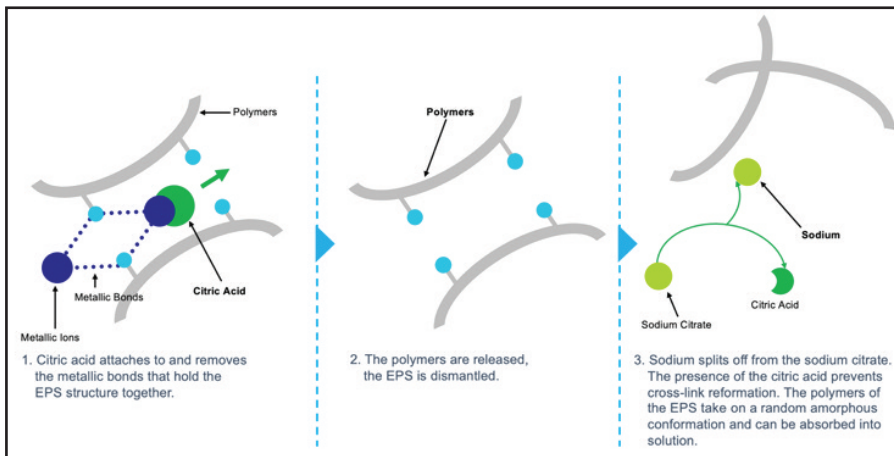


Figure 1. Mechanism of action of SURGX™ antimicrobial surgical gel against EPS.

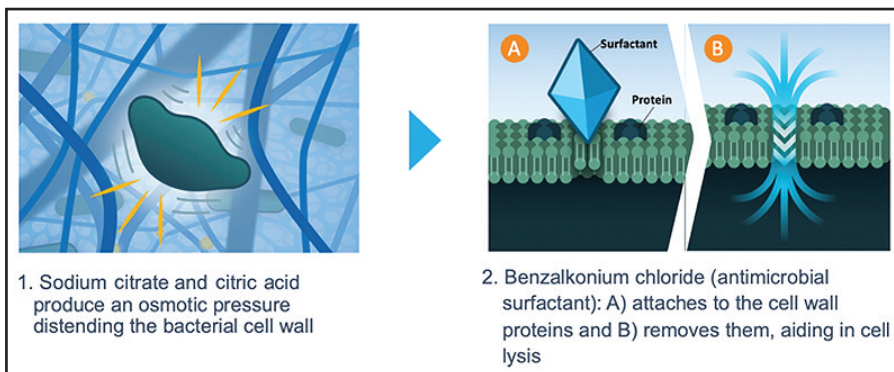


Figure 2. Bactericidal mechanism of action of SURGX™ antimicrobial surgical gel.

that preferentially targets these planktonic bacteria and those involved in the development of a biofilm.

An important component of the XPERIENCE™ system is the use of a surgical lavage system, as opposed to gravity or bulb irrigation, in order to administer the product into the surgical wound. In a retrospective study of 138 patients scheduled for posterior lumbar interbody fusion, there were more bacteria cultured in muscle layers in the bulb syringe group (8 of 79 cases, 10.1%) versus the pulsed lavage group (1 of 59, 1.6%).<sup>17</sup> Another study of patients undergoing hemiarthroplasty for fracture found that patients who underwent pulsed lavage had a lower infection rate compared to those who underwent saline washout with a jug or syringe.<sup>18</sup> Even though some detractors of pulsed lavage have purported that it is wasteful, a recent break-even analysis found that pulsed lavage is cost effective in the prevention of PJI after joint arthroplasty.<sup>19</sup>

In *in vitro* testing, the XPERIENCE™ solution performed well, demonstrating a six log reduction in planktonic bacteria in five minutes. It was also able to develop a barrier to biofilm for five hours following application.<sup>20</sup> XPERIENCE™ should not be used in patients who have an allergy to any of the aforementioned chemicals (i.e., citric acid, sodium citrate, or sodium lauryl sulfate). It can be used in primary or revision hip arthroplasty and is recommended to be used after trial components are removed prior to implantation of true component(s). It is the author's recommendation that it should be left in the wound for one to five minutes for the solution to take effect. Once implants are placed satisfactorily, the wound should be again irrigated with XPERIENCE™ and left to soak for five minutes to ensure its potency.

The second product we will describe is a novel surgical incisional gel (SURGX™, Next Science LLC, Jacksonville, Florida), which has been cleared by the Food and Drug Administration. The SURGX™ antimicrobial surgical gel is composed of four key ingredients, including citric acid, sodium citrate, benzalkonium chloride, and polyethylene glycol in order to develop a bacteriotoxic environment that will eliminate planktonic bacteria and prevent the development of any biofilm at the incision site. The sodium citrate acts as a buffer to maintain pH, the citric acid sequesters metal ions from the extracellular matrix,

benzalkonium chloride is bactericidal and preferentially targets bacterial cell walls, and the polyethylene glycol promotes a moist wound environment (Table II). These components create a buffer system which is effective at chelating calcium and destabilizing matrix proteins associated with biofilm formation (Figs. 1 and 2).

The SURGX™ antimicrobial surgical gel has many qualities that make it an appealing option for surgeons to regularly implement. For one, the surgical gel is effective at inhibiting the biofilm formation of many problematic pathogens. In a basic science investigation that analyzed the basis of biofilm inhibition with SURGX™, the surgical gel was able to inhibit *Escherichia Coli*, *Enterococcus faecium*, *Staphylococcus aureus*, *Staphylococcus epidermidis* (both methicillin-susceptible *Staphylococcus aureus* [MSSA] and methicillin-resistant *Staphylococcus aureus* [MRSA] strains), *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Enterobacter cloacae*, *Bacillus subtilis*, *Streptococcus pyogenes*, and *Propionibacterium acnes*, many of which are common skin flora implicated in postoperative



Figure 3. Application of SURGX™ surgical gel to closed surgical incision.

infection.<sup>21</sup>

The SURGX™ gel is intended to be applied once the skin of the hip incision is closed and can be used after primary or revision hip procedures (Fig. 3). There are cotton-tip applicators that can be used to evenly disperse the gel so that there is adequate and equivalent coverage of the incision with the gel. Sterile gauze or

**Table I**  
**Mechanisms of action of XPERIENCE™ irrigation surgical ingredients**

Ingredient	Description	Mechanism of Action
Citric Acid	Chelator/Buffer	Chelates (bonds) with metal ions of the EPS and buffers gel to maintain an optimal pH
Sodium Citrate	Buffer	Buffers gel to maintain pH
Sodium Lauryl Sulfate	Surfactant	Reduces the surface tension of biofilm
Combined Ingredients	Osmolarity and Surfactant	Kills pathogens within the solution

**Table II**  
**Mechanisms of action of SURGX™ antimicrobial surgical gel ingredients**

Ingredient	Description	Mechanism of Action
Citric Acid	Chelator/Buffer	Binds with metal ions from the extracellular matrix and buffers gel to maintain optimal pH
Sodium Citrate	Buffer	Buffers gel to maintain pH
Benzalkonium Chloride	Surfactant and Antimicrobial	Reduces the surface tension of biofilm and kills pathogens within the gel
Polyethylene Glycol	Gel Base	Promotes a moist wound environment

dressings can be used to secure the gel to the incision, and patients can reapply the gel if necessary prior to their first postoperative visit. It should similarly not be used in patients who have an allergy to any of the aforementioned ingredients, citric acid, sodium citrate, benzalkonium chloride, or polyethylene glycol.

In the following discussion, we will describe a typical primary total hip arthroplasty and the ways in which the surgeon and surgical care team can reduce and/or eliminate the risk of PJI, especially with the use of these antimicrobial agents. Once the patient has been deemed an appropriate candidate for arthroplasty and provides informed consent, the surgeon and care team should 1) ensure that appropriate medical specialists are involved in the patient's care and 2) work seamlessly with other physicians to optimize the patient's modifiable infection risk factors. As previously described, the optimization of these risk factors is invaluable in reducing not only the risk of PJI, but many other postoperative complications. The night before surgery, it is the author's preference to instruct the patient to take a bath with chlorhexidine or use cloths over their body (sage 2% chlorhexidine gluconate [CHG], Stryker, Mahwah, New Jersey) at their leisure. Once the patient arrives in the preoperative holding area, nurses should also apply chlorhexidine cloths on and around the intended site of surgery.

A large meta-analysis of clinical randomized control trials on the benefits of chlorhexidine demonstrated a lower culture rate in the chlorhexidine group than the povidone iodine group in orthopaedic surgery.<sup>22</sup> All studies included in the meta-analysis reported a significant reduction in bacterial skin flora with either chlorhexidine or povidone-iodine, though four of eight studies found no difference in positive culture rate between the chlorhexidine and povidone-iodine groups. Some groups have also been utilizing a chlorhexidine-impregnated cloth as a tool to eradicate risk of infection prior to total joint arthroplasty. A retrospective review of 998 patients who used chlorhexidine cloths prior to joint arthroplasty sustained a 0.6% risk of infection versus a 1.62% in PJI patients without the use of the cloth.<sup>23</sup> A systematic review on the utility of a similar 2% chlorhexidine-impregnated cloth found a pooled reduction in infection rates across multiple studies.<sup>21</sup> In fact, a randomized control trial evaluating patients who had

2% chlorhexidine-impregnated cloths applied to their intended surgical area the night before and morning of surgery were found to have a lower (0.4%) PJI rate than the standard-of-care cohort (2.9%).<sup>24</sup>

In fact, several organizations of infection control and perioperative risk mitigation have based consensus statements, like the regular use of chlorhexidine baths and wipes, on these trials.<sup>11,25</sup> The Center for Disease Control (CDC) recommended that patients should shower or bathe with some sort of antiseptic the night prior to surgery, antibiotics should be administered when indicated and timed to optimize its bioavailability in the serum at the time of incision, an alcohol-based agent should be used for skin preparation, and glycemic control should be held at a maximum of 200mg/dL during surgery, among others.<sup>11</sup> Additionally, Edmiston et al. reported a standardized cleansing process, including 118ml of aqueous chlorhexidine gluconate, 4%, per shower; a minimum of two sequential showers; and a one-minute pause before rinsing, with chlorhexidine to minimize surgical wound pathogens in a large randomized trial.<sup>26</sup>

In the preoperative holding area, the patient is also likely to be evaluated by both the anesthesia and surgical teams at which point perioperative antibiotics are initiated. Though these antibiotics are not the focus of this article, cefazolin is generally the antibiotic of choice in normal risk patients who do not have any serious allergies.<sup>27</sup> Even in patients who have a penicillin allergy, most studies have determined that there is little cross reaction between cephalosporins and penicillin, and most patients can tolerate cefazolin. In fact, the use of vancomycin *in lieu* of cefazolin for penicillin allergy has been associated with an increase in PJIs, possibly due to the vancomycin being underdosed.<sup>28,29</sup> Once the patient arrives in the operating room, it is important to minimize traffic of personnel in and out of the operating room as excessive traffic has been linked with increased risk of infection.<sup>30</sup> After appropriate positioning, an electronic skin clipper is typically used to eliminate all hair from the intended surgical site. In a recent Cochrane review, there was moderate-quality evidence to suggest that hair removed with a razor may be associated with a higher risk of infection than clippers.<sup>31</sup>

Next, a member of the surgical team

will cleanse the intended surgical area with povidone-iodine or chlorhexidine. In general, studies tend to support the use of chlorhexidine over povidone-iodine.<sup>32,33</sup> A randomized control trial demonstrated a lower surgical site infection rate (9.5%) in patients who were cleansed with chlorhexidine as compared to povidone-iodine (16.1%).<sup>34</sup> During this time, the surgical team will thoroughly cleanse and sterilize their hands with povidone-iodine or chlorhexidine and practice aseptic techniques henceforth.<sup>35</sup> Sterile gowns and gloves are donned and sterile draping is performed with disposable, adhesive drapes, as these have been shown to be superior to non-adhesive drapes in reducing bacterial contamination.<sup>36</sup> In this study, there was about half the rate of positive wound culture results in adhesive drape cases as compared to non-adhesive drapes (odds ratio = 0.49,  $p < 0.001$ ).<sup>36</sup>

Once it is time for implantation of the acetabular cup and similarly for the femoral stem, the XPERIENCE™ solution is used in lieu of standard sterile irrigation. It is important to cleanse all the bony surfaces thoroughly as would be done with sterile irrigation. The authors prefer the use of a pulsed lavage system to administer XPERIENCE™ as it has been shown to be superior to gravity or bulb lavage.<sup>19</sup> It is the authors' recommendation that the antimicrobial should be used as an irrigant in the wound from one to five minutes immediately prior to implantation of components. Once components are inserted satisfactorily, XPERIENCE™ is used to irrigate the wound once again and kept in the wound sitting for five minutes prior to closure of the capsule and/or fascia.

A layered wound closure is performed as per the surgeon's standard protocol. Once subcutaneous stitches have been utilized, the SURGX™ antimicrobial surgical gel is applied directly over the incision. It is important that the gel is spread evenly over the incision. Following the application of the gel, sterile gauze or dressings can be used to protect the spread of the gel and then it can finally be secured with a sterile adhesive dressing. Patients will also be given their final dose of perioperative antibiotics following the conclusion of surgery and discharged home if criteria are met. Patients are normally provided additional aliquots of SURGX™ surgical gel for home use, though dressings are typically kept sealed until their first postoperative visit.

## CONCLUSION

Although several preventative measures have been implemented to reduce and eliminate the risk of periprosthetic joint infection, it still remains one of the most common causes for revision total hip arthroplasty. In this article, we have described the utilization of a novel antimicrobial product to reduce and help eliminate the risk of periprosthetic joint infection. The authors are confident that the regular implementation of these two products will substantially enhance infection prophylactic measures in total hip arthroplasty procedures. **STI**

## AUTHORS' DISCLOSURES

Dr. Mont is a board or committee member for the American Association of Hip and Knee Surgeons, Hip Society, and Knee Society. He holds stock in CERAS Health, MirrorAR, and PeerWell. Dr. Mont receives research support from CyMedica Orthopedics and the National Institutes of Health (NIAMS & NICHD), and he is on the editorial board for Surgical Technology International, the Journal of Arthroplasty, the Journal of Knee Surgery, and Orthopedics. He is a paid consultant for Kolon TissueGene, Pacira, Smith & Nephew, and Stryker. Dr. Mont receives royalties and research support from Stryker, UpToDate, and Wolters Kluwer Health - Lippincott Williams & Wilkins.

Dr. Myntti is a Next Science employee and has stock options. Dr. Sequeira has no conflicts of interest to disclose.

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