

## QUESTION 4: Does the use of topical incisional sealants (i.e., Integuseal, Dermabond, etc.) reduce the incidence of subsequent surgical site infection/periprosthetic joint infection (SSI/PJI) in patients undergoing orthopaedic procedures?

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RECOMMENDATION: While we recognize that the use of topical incisional sealants has the potential to reduce wound drainage, there is no evidence that the use of such products has any impact on the incidence of SSI/PJI.

**Strength of the Recommendation:** Limited

DELEGATE VOTE: Agree: 93%, Disagree: 2%, Abstain: 5% (Super Majority, Strong Consensus)

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### RATIONALE

Commercially-available topical incisional sealants (Integuseal, Dermabond, Liquiband and others) aim to add strength and integrity to wound closure and, by sealing the wound, may reduce the incidence of wound drainage. With the creation of an impervious mechanical barrier at the incision, these products are believed to reduce the entry of infecting organisms into the deeper tissues and the potential for subsequent SSI/PJI. These products can be convenient to use, as they may reduce the need for placement and removal of sutures and staples. These products remain popular in a variety of surgical specialties.

Some of the products have also demonstrated bactericidal activities against gram-positive bacteria *in vitro* [1]. However, effectiveness in preventing surgical site infection remains in question. To date, randomized studies across surgical subspecialties have not shown significant reductions in infection rate with the use of these products. Two recent systematic reviews were conducted evaluating the effectiveness of adhesive sealants across multiple surgical specialties, primarily outside of orthopaedics.

In 2010, 14 randomized clinical trials (1,152 patients) were published to determine the relative effects of various tissue adhesives and conventional skin closure techniques on the healing of surgical wounds. Only one of these studies was in the field of orthopaedics. This study demonstrated that sutures were significantly better than tissue adhesives for minimizing dehiscence (10 trials). There was no difference between low viscosity and high viscosity adhesives in respect to dehiscence. Surgical procedures that were described by the studies were diverse and included hand surgeries, blepharoplasty, circumcision and excision of benign skin lesions. None of these trials evaluated incisions around areas of high tension such as the knee.

There was no significant difference in the rate of infection comparing sutures and tissue adhesives. However, no study reported an a priori calculation for the sample size and this may be relevant [2].

In 2014, another update of the previous study identified 19 additional eligible randomized clinical trials resulting in a total of 33 studies (2,793 patients). There was low-quality evidence that sutures were significantly better than tissue adhesives for reducing the risk of wound breakdown (dehiscence, rate ratio (RR): 3.35, 95% confidence interval (CI) 1.53 to 7.33, 10 trials, 736 participants that contributed data to the meta-analysis). For other outcomes such as infection rate, patient and operator satisfaction and cost, there was no evidence of a significant difference for either sutures or tissue adhesives. Eighteen trials that compared the use of tissue adhesives with sutures reported wound infection data, however, as eight of these had no cases of infection, only data from the remaining ten studies contributed to the meta-analysis. The studies included for this review did not demonstrate any significant difference in the proportion of infections in incisions closed with tissue adhesives compared with other conventional techniques. No study reported an a priori calculation for the sample size, and this may be relevant. Even the largest of the studies would have been unlikely to have been adequately powered to show any significant difference given the relatively low incidence of wound infections following many types of surgery [3].

Recent SSI prevention guidelines from the World Health Organization (WHO) state that, “antimicrobial sealants should not be used after surgical site skin preparation for the purpose of reducing SSI” [4]. A Cochrane review also found that “sutures were significantly better than tissue adhesives for minimizing wound dehiscence” and there was no difference in the SSI when skin adhesives were used [2,3].

The effect of 2-octyl cyanoacrylate (Integuseal) on SSI was evaluated in randomized trials in sternotomy [5,6], colorectal [7] and trauma surgery wounds [8]. A prospective study found that 2-octyl cyanoacrylate reduced the rate of SSI versus the use of staples for skin closure in spinal surgery [9]. The use of Integuseal was also shown to decrease the incidence of SSI in cardiac surgery in another prospective study [10]. Non-randomized data in orthopaedics has evaluated its use in arthroplasty [11] and scoliosis [12] surgery. The arthroplasty study was a single-arm, single-surgeon series of 360 patients with a 0.8% rate of superficial SSI, no PJI and a single case of contact dermatitis.

Data on patients undergoing orthopaedic procedures on the use of Dermabond have not revealed differences in SSI/PJI rates. One randomized trial found no difference in scar cosmesis or infection rate [13], and another two studies found decreased wound drainage with the use of Dermabond, but no difference in SSI/PJI rate [14,15]. No trial was adequately powered to detect a difference. In a large historical control study of hip and knee arthroplasty patients, no differences in infection rate were noted at six-week follow-up [16]. A randomized controlled trial for skin closure after scheduled cesarean delivery demonstrated similar results using Dermabond or a monofilament synthetic suture [17].

Hypersensitivity reactions to these organic sealants are rare, but can be serious [18–22]. A recent report of three patients with blistering periincisional contact dermatitis was found [21,22].

Given the presence of extensive data in other surgical subspecialties suggesting that topical adhesives do not lower surgical infection rates, the lack of data suggesting efficacy in orthopaedics and the rare but serious hypersensitivity reactions to these agents, we cannot recommend the routine use of incisional sealants for the purpose of prevention of SSI/PJI in patients undergoing orthopaedic procedures.

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