Author: David Lowenberg

QUESTION 2: What is the appropriate timing for flap coverage of open fractures and traumatic wound defects?

RECOMMENDATION: The optimal time for wound coverage ultimately reflects when the wound has been appropriately cleaned and converted to a "living wound." Early flap coverage is preferred, ideally within 3-7 days, when patient and wound are suitable.

LEVEL OF EVIDENCE: Strong

DELEGATE VOTE: Agree: 95%, Disagree: 5%, Abstain: 0% (Unanimous, Strongest Consensus)

RATIONALE

The timing of soft tissue coverage has long been recognized as one of the most critical determinants of the length of in-hospital stay, most of the early postoperative complications and ultimate outcomes [1]. Early coverage has been associated with higher union rates, and lower complication and infection rates compared to those reconstructed after 5-7 days [2–5]. Furthermore, early reconstruction improves flap survival, as microsurgical free flap integration becomes more challenging with a delay due to an increased prothrombotic environment, tissue edema and the increasingly friable vessels. Only those patients presenting to facilities with an actual dedicated ortho-plastic trauma service are likely to receive definitive treatment of a severe open tibia fracture with tissue loss within the established parameters of good practice [6]. "Fix and flap" has sometimes been recommended for specialist hospitals where the expertise is available. Antibiotic bead pouches to decrease infection rates have long been advocated when there is segmental tissue loss, gross contamination or established infection as pre-flap tissue infection seems to be an independent predictor of adverse flap and skeletal reconstruction outcomes [7,8].

Level IV series of free tissue transfer to address open traumatic wounds with accompanying fractures have been published since the first free tissue transfer for soft tissue coverage by Buncke in 1970 [9]. In 1986, Godina advocated early soft tissue coverage on a review of 532 patients based on an increased rate of flap failure in those wounds open > 72 hours [10]. However, during that time period, infection management and particularly the care and treatment of osteomyelitis were poorly understood, and dogma existed that simply the placement of a free tissue transfer over infection in the form of infected hardware or osteomyelitis was enough to treat and cure the infection. It took a great deal of time to break this dogma. Various series advocate the need for early soft tissue coverage in these cases, due to exposed soft tissue as well as the results of higher flap failure and often accompanying late infection rate [11-13]. These studies are found to be flawed in multiple respects, which include the lack of expertise and knowledge in the diagnosis and treatment of existing infection [12], low volume with resultant lack of expertise [11,13] and the inaccurate conclusion that time of flap placement could in any way affect the probability of successful bony union.

Many good studies have appeared confirming what the experienced non-union surgeon and microsurgeon know: that flap survival depends upon a decolonized and "living wound." Harrison et al. performed a thorough literature review of articles published from 1995–2011, and performed meta-analysis of 15 articles meeting inclusion criteria. They reported no difference in outcome between when free tissue transfer was performed and survival of the flap or eventual outcome [14]. Theodorakopoulou et al. reported a systematic review of 11 studies of war-related high energy extremity injuries treated with free tissue transfer in the subacute period (9 days to 3 years post-injury). There was no direct association to time of flap placement with a 95.5% free flap success rate in this particularly complex patient population [15].

Since 2000, numerous independent case series by experienced microsurgeons have also shown no difference in outcome in regard to timing of free flap placement [16-20]. These represent well-executed tissue transfers except for one series with a higher overall but uniform flap failure rate [19]. The consistent finding was that timing of free tissue transfer was not a direct cause of failure of flap survival.

The original work of Godina seems now to be outdated and not applicable to current surgical practice as it relates to timing of free tissue transfer of traumatic wounds.

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Authors: Nathan O'Hara, David Lowenberg, Robert O'Toole

QUESTION 3: Should open fracture wounds be closed primarily or closed secondarily? If closed primarily, which ones and under what criteria?

RECOMMENDATION: Yes. Primary wound closure of many open fracture wounds appears to be a safe and likely beneficial strategy in the modern setting of improved debridement techniques, better methods of fracture stabilization, and improved utilization of early systemic antibiotic administration. It appears safe for lower grade open fractures and a subset of higher-grade open fractures when the wound is deemed appropriate for primary closure on a clinical basis.

LEVEL OF EVIDENCE: Moderate

DELEGATE VOTE: Agree: 100%, Disagree: 0%, Abstain: 0% (Unanimous, Strongest Consensus)

METHODS

Randomized controlled trials, nonrandomized trials, prospective and retrospective observational studies were eligible for inclusion. We searched Medline, Embase, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL) up to March 2018 for published studies without language restriction. Our search strategy, including keywords and MeSH headings, are provided in the Appendix. Eligible studies met the following criteria: (1) all patients included in the study had an open fracture, (2) infection was an outcome variable and (3) there was a comparison between patients with wounds closed primarily and secondary wound closure. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria were followed. The initial search resulted in 303 papers. After removal of duplicates and screening of titles and abstracts, 12 articles were assessed and reviewed.

RATIONALE

The traditional practice of leaving all open fracture wounds open for repeat debridement at a later point in an effort to minimize risk of deep infection has changed over time. Many surgeons now routinely close most open fracture wounds at the time of initial debridement and fixation, particularly in lower grade open fractures and when wound severity and contamination are judged to be appropriate for primary closure.

A systematic review of the literature reveals no level I randomized trials in support of the practice of primary wound closure for open fractures, and the literature supporting this approach is consistently in favor of the practice, but it is also relatively weak. There is a group of more recent studies that has uniformly demonstrated lower surgical site infection rates with primary closure than with secondary closure for various open fractures in adults and children [1–7] and only one older study showing higher infection rates with primary closure [8]. However, all of these studies are methodologically limited as they do not account for selection bias between the less severe wounds that were closed primarily and the more severe wounds that were closed secondarily. As wound severity is very strongly associated with infection rates, this bias is important enough that results from these studies provide only limited insight on this issue except to point out that primary closure of some open fractures does not seem to be associated with high infection rates.

Other authors have provided similar data outlining low rates of infection utilizing a practice of primary wound closure in the vast majority of open fracture cases [9,10]. DeLong et al. used primary closure in 88% of type I, II and IIIA open fractures and had a 4% infection rate [9]. Similarly, Moola et al. used primary closure in 86% of 297 fractures and had a 4.7% deep infection rate [10]. However, while reassuring that primary closure of the majority of open fractures appears to result in an acceptable infection rate compared to historical controls, these studies are similarly methodologically limited as they lack a control group, so it is unknown if a practice of using more secondary wound closures in these patients would have resulted in a higher or lower infection rate.

One double-blind, randomized trial was published in 1993 using a factorial design to compare primary to delayed wound closure as well as the type of antibiotics used [11]. Although the random design is appealing, the sample size of only 82 patients with a low event rate presents a substantial risk of type II error and this study is very underpowered for the outcome of surgical site infection. The cohort only had two deep surgical site infections, so its conclusion that primary closure is safe is reassuring in that there was not a high infection rate in this group, but of limited value in comparing this practice to secondary closure.

The safety of primary closure was also demonstrated in a comparison between two South African trauma centers, one that used primary wound closure and one that did not [12]. This study also concluded that primary closure was safe, but again it was underpowered with a sample size of only 95 patients and an overall infection rate of only 3.3 % (3 patients). Therefore, there is significant risk of type II error with this study, and it therefore cannot provide