# Primary Closure or Secondary Wound Healing of Pin Sites After External Fixator Removal

## A Single-Center Blinded Randomized Controlled Trial

Franz Tillmann, MD*, Ruben J. Hoepelman, MD*, Flavio Cagienard, MD, Björn-Christian Link, MD, PhD, Reto Babst, MD, PhD, Bryan J.M. van de Wall, MD, PhD, and Frank J.P. Beeres, MD, PhD*

*Investigation performed at Luzerner Kantonsspital, Lucerne, Switzerland*

**Background:** The aim of this single-center randomized controlled trial was to compare primary wound closure using a suture with secondary wound healing of pin sites after removal of temporary external fixation.

**Methods:** This noninferiority trial included all patients who were treated with a temporary external fixator on an upper or lower extremity at 1 institution. The primary outcome was pin-site infection. Secondary outcomes were measured at 2, 6, 12, 24, and 52 weeks and included all other complications, time to pin-site wound healing (in weeks), the most satisfactory pin site as rated by the patient, the visual analog scale (VAS) score for pain, and the Vancouver Scar Scale (VSS). The most proximal pin site was randomly allocated (1:1) to either primary closure or secondary wound healing, and the other pin sites were treated alternately.

**Results:** Seventy patients, providing 241 pin sites, were included between January 1, 2019, and March 1, 2020. A total of 123 pin sites were treated with primary closure and 118, with secondary wound healing. The median age was 55 years (interquartile range, 46 to 67 years), 44% were male, and the median duration of the external fixation was 6 days (interquartile range, 4 to 8 days). There were no pin-site infections in either group. Wound healing was significantly faster in the primary closure group (median of 2 versus 6 weeks, p = 0.013). The VSS and patient satisfaction showed no differences between groups. There was 1 case of fracture-related infection not related to any pin site.

**Conclusions:** Primary closure of temporary external fixator pin sites did not result in higher infection rates compared with secondary wound healing, and pin sites healed significantly faster after primary closure. Primary closure should therefore be considered in patients treated with a temporary external fixator.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

An external fixator is commonly used in orthopaedic and trauma surgery as a bridge to definitive osteosynthesis and, in some cases, it is used as the definitive treatment[1,2]. A major disadvantage is the occurrence of pin-site infections, which have been reported as occurring in 1% to 100% of patients[1-3].

Bacterial contamination of pin sites is almost inevitable. Efforts to prevent infection are aimed at keeping these wounds as clean as possible, thus reducing the bacterial load after removal of the external fixator[2,4-6]. However, it remains unclear whether primary closure at the time of fixator removal or secondary wound healing is preferable[7]. It is generally thought that suturing of pin-site wounds increases the risk of infection, which is reflected in a survey in which 84% of surgeons stated that they leave the pin sites open[8]. Notably, there are no comparative studies on this topic, to our knowledge.

The aim of this randomized clinical trial was to compare primary closure and secondary healing of pin-site wounds after removal of the temporary external fixator. The primary outcome was the pin-site infection rate. Secondary outcomes included the time to wound healing, Vancouver Scar Scale (VSS) score,

*Franz Tillmann, MD, and Ruben J. Hoepelman, MD, contributed equally to this work.

**Disclosure:** The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H350).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H352).

patient satisfaction, visual analog scale (VAS) score for pain, and all other complications, measured at each follow-up time point. We hypothesized that primary wound closure would not result in a higher pin-site infection rate compared with secondary open wound healing.

## Materials and Methods

A detailed description of the methods used in this study is available in the published protocol[9]. The article was written in adherence to CONSORT (Consolidated Standards of Reporting Trials) statement guidelines[10,11].

### *Study Design*

We performed a prospective randomized controlled noninferiority trial at a level-1 trauma center in Switzerland. The study was approved by the Ethical Commission of Northwest- and Central Switzerland (EKNZ) (ID: 2018-01316) and was conducted in accordance with the Declaration of Helsinki. This trial was registered at ClinicalTrials.gov (NCT03842956).

### *Participants*

All adult patients (≥18 years old) who were treated with a temporary external fixator on an upper or lower extremity were considered for inclusion. Exclusion criteria were immunodeficiency (HIV [human immunodeficiency virus] infection, hepatitis, leukemia, steroid therapy, an autoimmune disease, or immunosuppressive therapy), inability to complete follow-up, substance abuse, a treatment method requiring primary closure of wounds (e.g., osteosynthesis under the pin site), insufficient German language fluency, or inability to fill out questionnaires. Patients were informed about the study by the local treating surgeon. Informed consent was obtained from all patients who were willing to participate.

### *Randomization of Closure Methods*

Patients were randomized after having received an external fixator, using simple 1:1 computerized randomization. In the first group, primary closure of the most proximal wound (index wound) was performed using a vertical mattress suture at the time of removal of the external fixator. In the second group, the index wound was left open and allowed to heal. The pin-site wounds, from proximal to distal, in each patient were alternately left open for secondary healing or closed using a suture, depending on the treatment of the index wound. For example, the randomized wound treatment from proximal to distal in a patient with 4 pin sites would be either closed-open-closed-open (in the first group above) or open-closed-open-closed (in the second group). Randomization of pin sites rather than individual patients was performed to ensure that factors related to wound healing or complications would be equally distributed between the 2 groups; each patient contributed at least 2 wounds to each treatment group.

For the back of the hand or foot, the most medially located pin site (i.e., metatarsal 1 or metacarpal 1) was considered to be the index pin site. Pin-site wounds at the calcaneus were not included in the study, as these wounds are frequently not suitable for closure due to tension.

### *Procedures*

The preoperative, intraoperative, and postoperative protocol was standardized for all pin sites in both treatment groups. Patients received a single preoperative 2-g dose of cefazolin prior to surgery. The management of the external fixator was according to the local protocol, which has been described in detail previously[7]. After removal of the external fixator, pin-site wounds were thoroughly cleaned with a sharp spoon and rinsed with an isotonic electrolyte solution (Ringerfundin; B. Braun). Only patients with open fractures routinely received postoperative antibiotics. If the open fracture was classified as Gustilo type 1 or 2, patients received 2 g of cefazolin 3 times per day for 24 hours. If the fracture was Gustilo type 3, patients received 2.2 g of amoxicillin/clavulanic acid intravenously 3 times per day.

Postoperative pin-site care by the attending nurse during hospitalization consisted of daily inspection, disinfection with Betadine (povidone-iodine), and a dry gauze dressing. After discharge, the same care was given at the outpatient wound care clinic, by the family physician, or by the patient in case of good compliance.

Photographic documentation of all sites was made at 2 and 52 weeks postoperatively. All patients had standardized follow-up visits at 2, 6, 12, 26, and 52 weeks after removal of the temporary external fixator.

Figure 1 shows a flow diagram of the study procedures.

### *Variables and Outcomes*

The primary outcome was the pin-site infection rate. Pin-site infections were defined as local redness, swelling, and/or purulent discharge from the wound requiring intervention with oral antibiotics or wound incision. Secondary outcomes, assessed at each follow-up, included the fracture-related infection (FRI) rate and all other complications, time to wound healing (in weeks), the most satisfactory pin site as rated by the patient, the VAS score for pain, and the VSS[12]. A wound was considered healed if it had complete epithelialization or closure without discharge, drainage, or a dressing. The VSS is a widely used tool with reliable interobserver variability that provides a structured expert opinion of scars[13]. The physician rates pigmentation, vascularity, pliability, and height, which results in a score between 0 (best) and 14 (worst)[14]. A certified orthopaedic trauma surgeon provided a VSS rating at each follow-up visit. Baseline characteristics included, age, gender, smoking status, presence of diabetes, and duration of external fixation (in days).

### *Sample Size and Statistical Analysis*

The sample size was based on a noninferiority approach that aimed to show that the wound infection rate within 12 weeks after fixator removal was not significantly higher following primary wound closure compared with open secondary wound healing. The noninferiority limit was set at 10%, and noninferiority of the primary outcome would be confirmed when the 2-sided 95% confidence interval (CI) did not exceed the noninferiority limit. A sample size calculation was performed using an infection rate of 5% for both primary wound closure and secondary healing. This assumption was based on the infection rate found in a previous

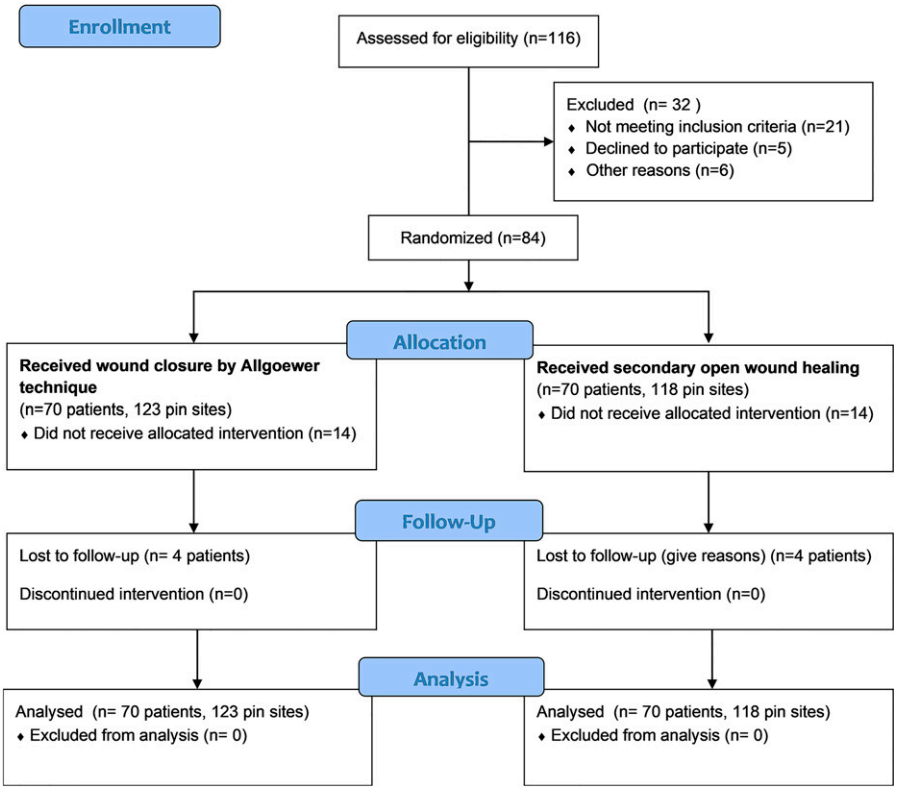


Fig. 1

CONSORT flowchart of patient inclusion, randomization, and follow-up.

study, performed in our hospital, of a study population similar to the one in the present randomized trial[7]. Assuming that the infection probabilities of the individual wounds (even within the same patient) were independent, at least 156 evaluable wounds were needed to assess noninferiority at the 10% level with a power of 80%. Accounting for a possible dropout rate of 25%, we aimed to include 70 patients, each contributing 2 to 4 sites, which would generate a total of approximately 234 pin sites.

Analyses were performed using IBM SPSS version 26. Odd ratios (ORs) were calculated using a 2 × 2 contingency table. Addition of 1 to every cell (a Haldane-Anscombe correction), rather than 0.5, was used because SPSS cannot handle addition of 0.5 to cells in a 2 × 2 contingency table. Normality of continuous variables was tested using the Shapiro-Wilk test and quantile-quantile (Q-Q) plots. Continuous variables that were not normally distributed are presented as the median with the interquartile range (IQR) and were compared using the Mann-Whitney U test. Discrete data are presented as frequencies with percentages. The chi-square test was used to compare nominal and categorical data. P values of <0.05 were considered significant. Patients with <3 outpatient clinic visits were considered lost to follow-up. All available follow-up data were used in the analysis; missing data were not imputed. A post-hoc subgroup analysis was performed for all study outcomes stratified by pin-site location (upper and lower extremity).

*Source of Funding*

No external funding was received for this study.

## Results

### *Patient Characteristics*

Patients treated from January 1, 2019, to March 1, 2020, were screened for eligibility, and 84 of 116 were included. The remaining 32 were deemed not eligible because of inability to complete follow-up for compliance or logistical reasons (e.g., substance abusers, tourists) (n = 17), the treatment method (e.g., osteosynthesis material under the pin site that necessitated primary closure or definitive treatment with an external fixator) (n = 6), inability to fill out questionnaires due to mental capabilities (n = 4), and failure to acquire informed consent (n = 5). In addition, 14 patients had to be excluded because of surgeon nonadherence to the treatment allocation (mostly at the beginning of the study because they had forgotten that their patients were participants in the trial). The follow-up rate was 89% (with 8 lost to follow-up) (Fig. 1).

Baseline characteristics are shown in Table I. Seventy patients were analyzed; they provided 241 pin sites, of which 123 were treated with primary closure and 118 were treated with secondary wound healing. The median age was 55 years (IQR, 46 to 67 years); 44% were male, 4% had diabetes, and 11% were smokers. The median duration of external fixation was 6 days (IQR, 4 to 8 days). Almost all fixator pins (93%) were inserted into diaphyseal bone. A total of 83 (34%) of the pin sites were located in an upper extremity and 158 (66%), in a lower extremity. There were no significant differences between the groups. The pin-site distribution by bone is shown in Appendix Supplementary Table 1.

**TABLE I Baseline Characteristics of the Cohort***

| | Total Cohort (N = 241 Sites) | Primary Closure (N = 123 Sites) | Secondary Wound Healing (N = 118 Sites) | P Value† |
|---|---|---|---|---|
| Age *(yr)* | 55 (46-67) | 55 (46-68) | 54 (45-66) | 0.888 |
| Male gender | 106 (44%) | 54 (44%) | 52 (44%) | 0.979 |
| Diabetes | 10 (4%) | 4 (3%) | 6 (5%) | 0.476 |
| Smoking | 26 (11%) | 13 (11%) | 13 (11%) | 0.911 |
| Fixator duration *(d)* | 6 (4-8) | 6 (4-8) | 5 (4-8) | 0.953 |
| Pin-site location | | | | |
| Upper extremity | 83 (34%) | 42 (34%) | 41 (35%) | 0.922 |
| Diaphyseal bone | 225 (93%) | 112 (91%) | 113 (96%) | 0.142 |

*Values are given as the number of corresponding pin sites with the percentage in parentheses or as the median with the interquartile range in parentheses. †Analyses were performed with the Mann-Whitney U test or chi-square test, as appropriate. No p values were significant.

### *Outcomes*

Outcomes are summarized in Table II. Outcomes by follow-up visit are available in Appendix Supplementary Table 2.

#### Pin-Site Infection

There were no pin-site infections in either treatment group (OR = 0.96, 95% CI = 0.06 to 15.52).

#### Other Complications

There was 1 FRI, at the osteosynthesis site in the fibula in a patient in whom the external fixator pins were inserted in the tibia. This patient underwent surgery for removal of the osteosynthesis material, after which the fracture and wounds healed completely. One patient (1%) in each randomization group developed complex regional pain syndrome (CRPS), and 1 in each group (1%) developed pseudarthrosis (OR = 0.96, 95% CI = 0.06 to 15.5). No other complications were recorded.

#### Physician-Reported Outcomes

Wound healing was faster for primary closure compared with secondary wound healing (median, 2 versus 6 weeks; p = 0.013); 82% of the primarily closed wounds were healed at the first follow-up

**TABLE II Outcomes of Primary Wound Closure and Secondary Open Wound Healing***

| Outcomes | Total Cohort (N = 241 Sites) | Primary Closure (N = 123 Sites) | Secondary Wound Healing (N = 118 Sites) | P Value† |
|---|---|---|---|---|
| Total complications | 3 | | | 0.438 |
| Pin-site infection | 0 (0%) | 0 (0%) | 0 (0%) | — |
| FRI | 1 | | | |
| CRPS | 1 | | | |
| Pseudarthrosis | 1 | | | |
| Time to healing *(wk)* | 2 (2-6) | 2 (2-6) | 6 (2-6) | **0.013** |
| Wounds healed at first visit at 2 wk | 71% | 82% | 61% | **0.001** |
| Overall patient satisfaction | — | 55% | 45% | 0.157 |
| Vancouver Scar Scale | | | | |
| 2 wk | 1 (1-4) | 1 (0-4) | 2 (1-4) | 0.258 |
| 52 wk | 0 (1-1) | 0 (0-2) | 0 (0-2) | 0.722 |
| VAS pain | | | | |
| 2 wk | 1 (1-2) | 1 (1-2) | 1 (1-2) | 0.607 |
| 52 wk | 1 (1-1) | 1 (1-1) | 1 (1-1) | 0.940 |

*Values are given as the number of pin sites with the percentage of sites in parentheses or as the median with the interquartile range in parentheses. FRI = fracture-related infection, CRPS = complex regional pain syndrome, VAS = visual analog scale. †Analyses were performed with the Mann-Whiney U test or chi-square test, as appropriate. Significant p values are bolded.

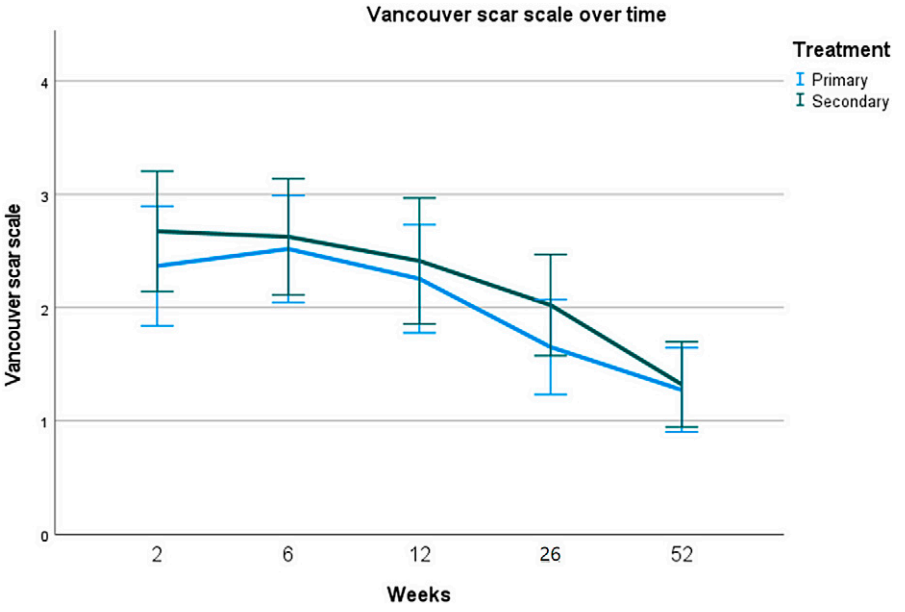


Fig. 2
VSS scores (mean and standard deviation) over the follow-up period.

compared with 61% of the secondarily healing wounds (p = 0.001). The VSS score showed a decrease over time in both groups; the differences between groups were not significant (Fig. 2).

**Patient-Reported Outcomes**

A primarily closed pin site was rated as the most satisfactory by 55% of the patients. This preference was more evident at the 2-week follow-up (61%; see Appendix Supplementary Table 2), but the difference was not significant at any time point. VAS pain scores did not differ significantly between groups and did not decrease over time (Fig. 3).

**Subgroup Analysis**

A faster time to healing in the primary closure group was also found for pin sites in the lower extremity (median, 2 weeks versus 6 weeks). In contrast, the time to healing did not differ between the 2 treatment groups for pin sites in the upper extremity (Table III).

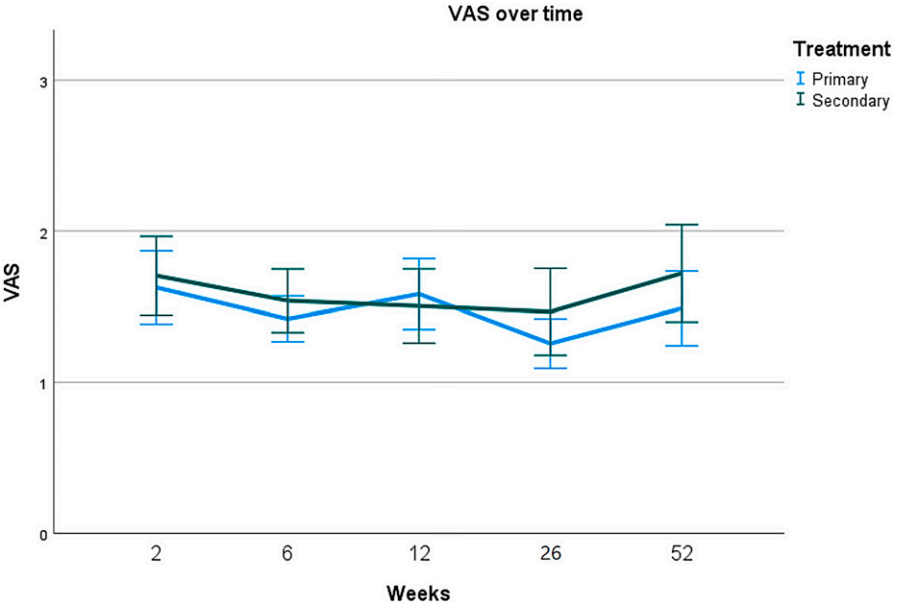


Fig. 3
VAS scores (mean and standard deviation) over the follow-up period.

**TABLE III Outcomes of Primary Wound Closure and Secondary Open Wound Healing Stratified by Extremity***

| Outcomes | Upper Extremity | | | | Lower Extremity | | | |
|---|---|---|---|---|---|---|---|---|
| | Total Cohort (N = 83 Sites) | Primary Closure (N = 42 Sites) | Secondary Wound Healing (N = 41 Sites) | P Value† | Total Cohort (N = 158 Sites) | Primary Closure (N = 81 Sites) | Secondary Wound Healing (N = 77 Sites) | P Value† |
| Total complications | 0 | 0 | 0 | — | 6 (4%) | 4 (5%) | 2 (3%) | 0.442 |
| FRI | 0 | 0 | 0 | — | 2 (1%) | 1 (1%) | 1 (1%) | 0.165 |
| CRPS | 0 | 0 | 0 | — | 2 (1%) | 1 (1%) | 1 (1%) | 0.971 |
| Pseudarthrosis | 0 | 0 | 0 | — | 2 (1%) | 1 (1%) | 1 (1%) | 0.971 |
| Time to healing *(wk)* | 2 (2-6) | 2 (2-2) | 2 (2-6) | 0.258 | 6 (2-6) | 2 (2-6) | 6 (2-6) | **0.023** |
| Wounds healed at first visit at 2 wk | 62 (83) | 34 (90) | 28 (76) | 0.115 | 72 (65) | 45 (78) | 27 (51) | **0.003** |
| Overall patient satisfaction | — | 57% | 43% | 0.107 | — | 55% | 45% | 0.135 |
| Vancouver Scar Scale | | | | | | | | |
| 2 wk | 1 (1-2) | 1 (1-3) | 1 (0-3) | 0.842 | 2 (1-5) | 2 (1-5) | 3 (1-5) | 0.197 |
| 52 wk | 0 (0-1) | 0 (0-1) | 0 (0-1) | 0.210 | 1 (0-3) | 0 (0-3) | 1 (1-1) | 0.475 |
| VAS pain | | | | | | | | |
| 2 wk | 1 (1-2) | 1 (1-2) | 1 (1-2) | 0.927 | 1 (1-2) | 1 (1-2) | 1 (1-2) | 0.454 |
| 52 wk | 1 (1-1) | 1 (1-1) | 1 (1-1) | 0.842 | 1 (1-1) | 1 (1-1) | 1 (1-1) | 0.918 |

*Values are given as the number of pin sites with or without the percentage of sites in parentheses or as the median with the interquartile range in parentheses. FRI = fracture-related infection, CRPS = complex regional pain syndrome, VAS = visual analog scale. †Analyses were performed with the Mann-Whiney U test or chi-square test, as appropriate. Significant p values are bolded.

## Discussion

This randomized controlled trial compared primary wound closure to secondary open wound healing after treatment with a temporary external fixator. There were no pin-site infections in either group, and pin-site wounds healed significantly faster after primary closure compared with secondary healing of open wounds (median, 2 versus 6 weeks; p = 0.013). There were no differences in other outcomes.

### *Comparison with Previous Literature*

To our knowledge, no previous studies have compared closure to secondary healing of pin sites after removal of the temporary external fixator, and guidelines also do not give recommendations regarding this topic. We found only 1 study that described the authors' expertise with thorough wound debridement and suturing; however, no outcomes were reported[15].

### *Interpretation of the Results*

Based on the results of this study, primary closure of pin sites should be considered after removal of a temporary external fixator. However, certain aspects of the study should be taken into consideration.

The overall infection rate was lower than the rates generally reported in the literature, which can be partially explained by the definition that we used—i.e., requiring intervention. Some previous studies have used a definition of infection that did not include a need for intervention, thus inherently yielding a higher infection rate[1,5]. Furthermore, the only infection that occurred was an FRI that was not located near any of the pin sites. It is unlikely that this FRI was related to the pin-site treatment, although that cannot be ruled out completely[1].

The remaining complications, CRPS and pseudarthrosis, were distributed equally between the treatment groups. These findings seem plausible since no evidence exists that either of these complications are related to wound treatment of pin sites after removal of an external fixator.

According to the post-hoc subgroup analysis, the faster time to healing of the primarily closed wounds was only found among pin sites located in the lower extremity and not among the upper-extremity wounds. It should be noted, however, that the current study was not powered for this type of subgroup analysis. Care should therefore be taken when drawing conclusions, as it remains to be seen whether this finding will be reproducible in future studies. Lastly, although the differences in satisfaction were not significant, patients were overall more satisfied with the primarily closed wounds. In our opinion, this is clinically relevant even though the study had not been powered for this outcome and the difference was statistically insignificant in our cohort. In an era of shared decision-making, it is important to take patient preference into consideration during clinical decision-making. This finding supports that primary closure after local debridement and irrigation of temporary external fixator pin sites should be considered as the treatment of choice.

### *Study Limitations*

Several limitations of this randomized controlled trial should be acknowledged. First, this was a single-center study. Although

this inherently diminishes the external validity compared with a multicenter trial, the choice was deliberate[16], as acquiring enough patients was not an issue for this single institution and it reduced study costs[17].

Second, the strict protocol for pin-site treatment further diminishes its generalizability; physicians who wish to attain equal results would need to adhere to the same protocol. In addition, this noninferiority trial was conducted in an idealized situation, which might further reduce its generalizability.

Third, although the results of this trial favor primary wound closure, to our knowledge it is the only randomized controlled trial on the subject to date. Additional trials that also report more favorable results for primary wound closure should be performed before we can ascertain that it is noninferior. Fourth, although all surgeons in the study hospital adhered to the same definition of a healed wound, the assessment was clinical and therefore subjective to some extent. Lastly, the findings of this study cannot be applied to calcaneal pin sites, as these were not included.

### *Conclusions*

In this first study comparing primary wound closure to secondary healing of open wounds after removal of a temporary external fixator, primary wound closure did not result in a higher pin-site infection rate. Wounds healed significantly faster after primary closure, although this effect was only detected among pin sites in the lower extremity. Although the difference did not reach significance, overall patient satisfaction was higher after primary closure. Primary closure of the pin-site wounds after local debridement and irrigation should therefore be considered for non-immunocompromised patients who have been treated temporarily (for approximately 1 week) with an external fixator.

## Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H351). ■

Franz Tillmann, MD[1]
Ruben J. Hoepelman, MD[1,2]
Flavio Cagienard, MD[1]
Björn-Christian Link, MD, PhD[1]
Reto Babst, MD, PhD[2,3]
Bryan J.M. van de Wall, MD, PhD[1,3]
Frank J.P. Beeres, MD, PhD[1]

[1]Department of Orthopaedics and Trauma Surgery, Luzerner Kantonsspital, Lucerne, Switzerland

[2]Department of Trauma Surgery, University Medical Center Utrecht, Utrecht, the Netherlands

[3]Department of Health Sciences and Medicine, University of Lucerne, Lucerne, Switzerland

Email for corresponding author: Frank.Beeres@luks.ch

## References

**1.** Kazmers NH, Fragomen AT, Rozbruch SR. Prevention of pin site infection in external fixation: a review of the literature. Strategies Trauma Limb Reconstr. 2016 Aug;11(2):75-85.

**2.** Ceroni D, Grumetz C, Desvachez O, Pusateri S, Dunand P, Samara E. From prevention of pin-tract infection to treatment of osteomyelitis during paediatric external fixation. J Child Orthop. 2016 Dec;10(6):605-12.

**3.** Murgai RR, Compton E, Illingworth KD, Kay RM. The Incidence of Pin Tract Infections and Septic Arthritis in Percutaneous Distal Femur Pinning. J Pediatr Orthop. 2019 Jul;39(6):e462-6.

**4.** Mahan J, Seligson D, Henry SL, Hynes P, Dobbins J. Factors in pin tract infections. Orthopedics. 1991 Mar;14(3):305-8.

**5.** Lethaby A, Temple J, Santy-Tomlinson J. Pin site care for preventing infections associated with external bone fixators and pins. Cochrane Database Syst Rev. 2013 Dec 3;2013(12):CD004551.

**6.** Camathias C, Valderrabano V, Oberli H. Routine pin tract care in external fixation is unnecessary: a randomised, prospective, blinded controlled study. Injury. 2012 Nov;43(11):1969-73.

**7.** Hodel S, Koller T, Link BC, Rossi M, Babst R, Beeres FJP. Does temporary external fixation and staged protocol for closed fractures lead to bacterial contamination of the surgical site and associated complications? - A prospective trial. Injury. 2018 Aug;49(8):1532-7.

**8.** Hodel S, Link BC, Babst R, Mallee WH, Posso P, Beeres FJP; Collaborators (18). Perioperative management of external fixation in staged protocols: an international survey. Eur J Orthop Surg Traumatol. 2018 May;28(4):565-72.

**9.** Roth F, Cagienard F, Link BC, Hodel S, Lehnick D, Babst R, Beeres FJP. Primary or secondary wound healing of the pin sites after removal of the external fixator: study protocol for a prospective, randomized controlled, monocenter trial. Trials. 2020 Feb 19;21(1):205.

**10.** Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010 Mar 23;340:c869.

**11.** Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ; CONSORT Group. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. JAMA. 2006 Mar 8;295(10):1152-60.

**12.** Govaert GAM, Kuehl R, Atkins BL, Trampuz A, Morgenstern M, Obremskey WT, Verhofstad MHJ, McNally MA, Metsemakers WJ; Fracture-Related Infection (FRI) Consensus Group. Diagnosing Fracture-Related Infection: Current Concepts and Recommendations. J Orthop Trauma. 2020 Jan;34(1):8-17.

**13.** Truong PT, Lee JC, Soer B, Gaul CA, Olivotto IA. Reliability and validity testing of the Patient and Observer Scar Assessment Scale in evaluating linear scars after breast cancer surgery. Plast Reconstr Surg. 2007 Feb;119(2):487-94.

**14.** Finlay V, Burrows S, Kendell R, Berghuber A, Chong V, Tan J, Edgar DW, Wood F. Modified Vancouver Scar Scale score is linked with quality of life after burn. Burns. 2017 Jun;43(4):741-6.

**15.** Bibbo C, Brueggeman J. Prevention and management of complications arising from external fixation pin sites. J Foot Ankle Surg. 2010 Jan-Feb;49(1):87-92.

**16.** Bellomo R, Warrillow SJ, Reade MC. Why we should be wary of single-center trials. Crit Care Med. 2009 Dec;37(12):3114-9.

**17.** Dechartres A, Boutron I, Trinquart L, Charles P, Ravaud P. Single-center trials show larger treatment effects than multicenter trials: evidence from a meta-epidemiologic study. Ann Intern Med. 2011 Jul 5;155(1):39-51.