

Implementing an orthoplastic treatment protocol for open tibia fractures reduces complication rates in tertiary trauma unit

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ABSTRACT

Introduction: Open tibia fracture (OTF) causes a considerable increase in morbidity and risk for complications compared to closed fractures. The most significant OTF complication leading to morbidity is commonly considered to be fracture-related infection (FRI). In September 2016, Tampere University Hospital (TAUH) introduced a treatment protocol for OTFs based on the BOAST 4 guideline. The aim of this study is to investigate the outcomes before and after implementation of the OTF treatment protocol.

Materials and methods: A retrospective cohort study was conducted using handpicked data from the patient record databases of TAUH from May 1, 2007, to May 10, 2021. For patients with OTF, we collected descriptive information, known risk factors for FRI and nonunion, bony fixation method, possible soft tissue reconstruction method, information about the timing of internal fixation and soft tissue coverage, and timing of primary operation. As outcome measures, we collected information on FRI, reoperation due to non-union, flap failure, and secondary amputation. We then compared the incidence of complications before and after the implementation of the OTF treatment protocol at TAUH.

Results: After predefined exclusions, a total of 203 patients with OTF were included. Of these, 141 were treated before and 62 after the implementation of the OTF treatment protocol. The FRI rate in the pre-protocol group was significantly higher compared to the protocol group (20.6% vs 1.6%, $p = 0.0015$). The incidence of reoperation due to nonunion was also significantly higher in the pre-protocol group (27.7% vs 9.7%, $p = 0.0054$). According to multivariable analysis, definitive fixation and soft tissue coverage performed in separate operations was an independent risk factor for both FRI and reoperation due to nonunion.

Conclusions: After implementation, the BOAST 4 based OTF treatment protocol reduced the rate of FRI and reoperation due to nonunion in patients with OTF treated at TAUH during the study period. We, therefore, recommend the implementation of such a treatment protocol in all major trauma centers treating patients with OTF. Furthermore, we also recommend the immediate referral of patients with complex OTF from hospitals lacking the preconditions to provide BOAST 4 based treatment to specialized centers.

Introduction

Tibia fractures are a common type of long bone fracture. The incidence of proximal, diaphyseal, and distal tibia fractures is reported to be 7.2 to 12 per 100 000 person-years, 8.1 to 21.5 per 100 000 person-years, and 6.9 to 15 per 100 000 person-years, respectively [1–5].

Moreover, it is estimated that at least 12 % of tibia fractures are open

fractures [6], making them the most common long bone open fracture with an incidence of 3.4 per 100 000 person-years [7]. The leading mechanism for open tibia fractures (OTF) is a high energy trauma due to road traffic accidents or falls from heights [4,8–10].

Compared to closed fractures, OTF cause a considerable increase in morbidity and risk for complications [11]. The most significant OTF complication leading to morbidity is commonly considered to be deep

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infection. Indeed, previous studies have revealed the incidence rates of deep infection in patients with OTF to be as high as 36% [12].

The management of OTF has been debated for many years, and clinical practices have varied in regards to the timing of the operation, antibiotic treatment, method of bony fixation, and wound management strategies [13–15]. In the United Kingdom, collaboration between orthopaedic and plastic surgeons generated the BOA/BAPRAS (British Orthopaedic Association/British Association of Plastic, Reconstructive, Aesthetic Surgeons) treatment protocol, Standards for the Management of Open Fractures of the Lower Limb, Standards for Trauma Number 4 (BOAST 4) guideline [16]. Based on the findings of previous studies conducted in the United Kingdom, the implementation of the BOAST 4 guideline has led to a markedly decreased rate of deep infections and an increased rate of union [17,18].

Tampere University Hospital (TAUH), Finland is a tertiary trauma unit with a catchment population of 900 000 inhabitants. At the beginning of September 2016, TAUH introduced a structured treatment protocol for OTFs based on the BOAST 4 guideline. The aim of the present study is to investigate patient outcomes before and after implementation of the OTF treatment protocol. We hypothesized that the protocol would reduce both the incidence of deep fracture-related infection (FRI) and the incidence of infection-induced nonunion. According to Finnish research legislation, review by a formal ethics committee is not required because the study was registry-based, and the integrity of the patients was maintained.

Materials and methods

The OTF treatment protocol implemented at TAUH is a modification of the BOAST 4 guideline (Fig. 1). On arrival at the emergency room, intravenous antibiotics are administered as soon as possible. The soft tissue injury is then documented with photographs. Neurovascular status is assessed, and signs of compartment syndrome or other limb-threatening conditions are monitored. Wounds are covered with saline-soaked gauze. After primary assessment, the limb is re-aligned and splinted. Primary debridement is performed within 12 h by senior plastic and orthopaedic surgery consultants. If secondary assessment is needed before definitive reconstruction, assessment is conducted in the

operation theatre every 2–3 days. No dressing changes are performed on the ward. A comprehensive treatment plan is then made by a multidisciplinary team of senior plastic and orthopaedic surgeons specialized in lower limb trauma. The definitive bony fixation and soft tissue coverage are performed within 7 days of initial trauma by an experienced orthoplastic team. Simultaneous soft tissue coverage and bony fixation is performed if internal fixation is used. Those patients with peri- and intra-articular open distal tibia fracture are preferably treated with a modern ring fixator rather than plate fixation to avoid implant-related deep infections.

Our OTF treatment protocol study was conducted as a retrospective cohort study using handpicked data from the electronic patient record databases of TAUH. We retrieved all operatively treated tibia fractures retrospectively from the TAUH operative database between April 1, 2007, and May 10, 2021, using the tibia fracture procedural codes NGJ60, NGJ62, NGJ70, NGJ84, NGJ99, NGJ64. In order to report OTF patients with primary or secondary amputation, we also retrieved the lower limb amputation procedural codes NGQ10, NGQ20, and NGQ48 associated with the tibia fracture related ICD-10 codes S82.1, S82.2, S82.3, S82.9, S88.1 or S88.9. We excluded patients with closed tibia fractures, lower limb fracture other than tibia fracture, patients under 15 years of age, patients treated with titanium elastic nail (TEN nailing, open physes), patients referred to another hospital for definite treatment, patients referred to another university hospital district for follow-up, patients referred to TAUH after primary procedure, patients who deceased before definitive treatment, and patients who underwent primary amputation (Fig. 2). Patients with bilateral OTF or consecutive OTFs were considered as separate cases. The follow-up data were collected one year after the end of the study period.

For all the identified patients with OTF, we handpicked further information from the TAUH electronic patient database. We also collected descriptive information (patient sex and age) and known risk factors for FRI and nonunion (smoking, diabetes, substance abuse, Gustilo-Anderson grading). Additionally, we collected information about the bony fixation method, possible soft tissue reconstruction method, information about simultaneous internal fixation and soft tissue coverage, time from trauma to definitive fixation, and information on whether the first operation was conducted during the first 24 h after the trauma. For

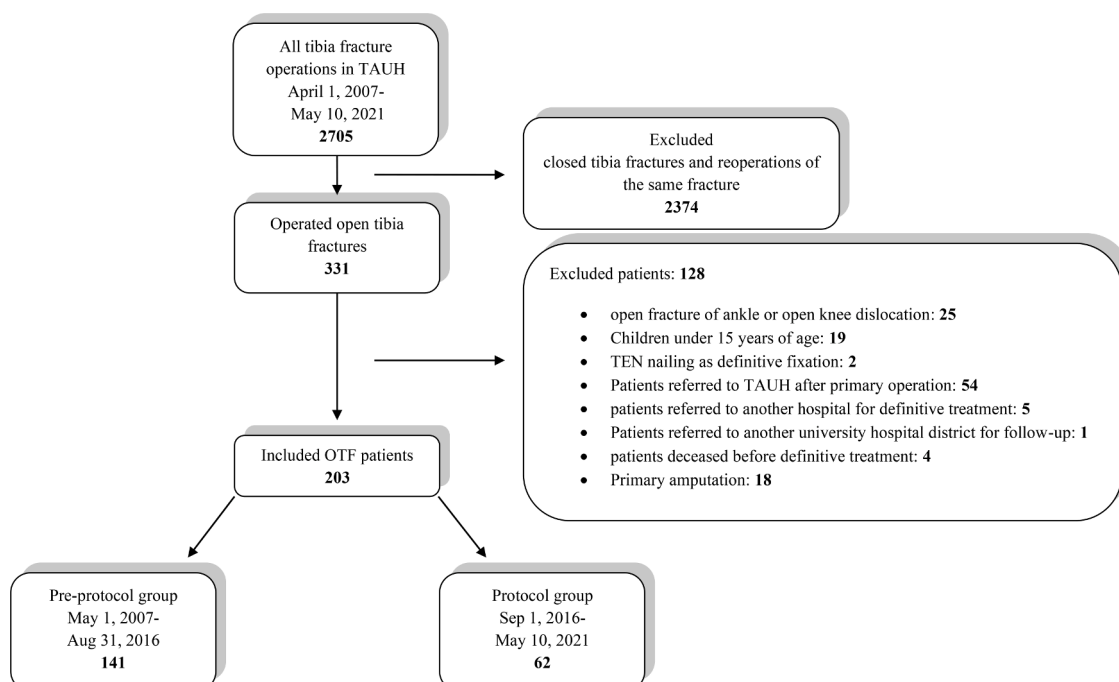


Fig. 1. Flowchart of patient selection.

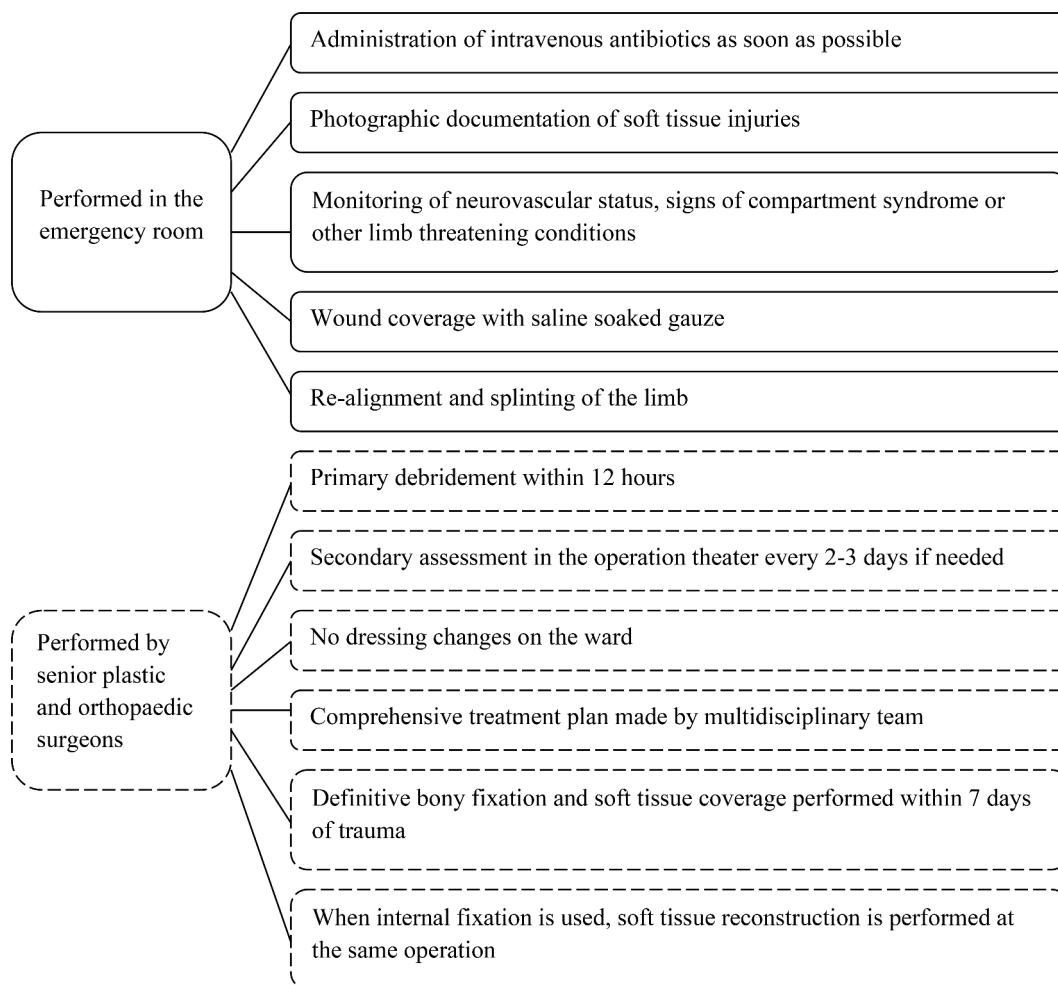


Fig. 2. BOAST 4 based OTF treatment protocol at TAUH.

outcome measures, we collected information on FRI, reoperations due to non-union, flap loss complications, and secondary amputations. The definition of secondary amputation was amputation after primary salvage attempt and fixation. The criteria for FRI was determined according to confirmatory criteria defined by the FRI consensus group [19]. Findings of purulent drainage, fistula, presence of pus or presence of microorganisms in deep tissue specimens was an indication for FRI.

We compared the incidence of complications before and after implementation of the TAUH OTF treatment protocol in September 2016. The primary outcome measure of this study was the incidence of FRI. Secondary outcome measures were incidences of reoperation due to nonunion, partial or total flap loss, and secondary amputation.

Statistical analyses between groups were made using R, version 3.6.2 (R Core Team (2019). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>). Fisher’s exact test and Mann-Whitney U test were used for assessing statistical differences between protocol groups. In addition, multivariable analyses were performed using binary logistic regression models separately for FRI and reoperation due to nonunion, with definitive fixation and soft tissue reconstruction in separate operations, GA grade, time from trauma to definitive fixation, and primary operation within 24 h as independent variables.

Results

A total of 331 OTFs were treated during the study period. The

medical reports of all the retrieved patients from the TAUH electronic patient record database were reviewed. We identified 203 OTF cases that met the inclusion criteria. Detailed information on the excluded patients is presented in Fig. 2.

Of the 203 included OTF patients, 141 were treated before the implementation of the TAUH OTF treatment protocol and 62 thereafter. There was no statistically significant difference between the characteristics of the study groups (Table 1). However, there was a statistically significant difference in the distribution of Gustilo-Anderson grades between the study groups (p-value 0.0012) (Table 2). Indeed, Gustilo-Anderson III OTFs were graded more often as IIIA in the pre-protocol

Table 1
Patient characteristics.

	Study population April 1, 2007 - May 10, 2021				
	203		2016		
	Pre-protocol group		Protocol group		
	April 1, 2007-Aug 31,	141	2016-May 10, 2021	62	p-value
Diabetes	9	6.4%	4	6.5%	1.0000*
Smoking	30	21.3%	11	17.7%	0.7047*
Substance abuse	25	17.7%	11	17.7%	1.0000*
Male	93	66.0%	43	69.4%	0.7462*
Female	48	34.0%	19	30.6%	0.7462*
Age (mean/median)	44.3	44.0	42.9	43.5	0.8254**

*Fisher’s test,.

**Mann-Whitney test.

Table 2
Fracture and treatment characteristics.

	Study population April 1, 2007 - May 10, 2021 203				
	Pre-protocol group April 1, 2007-Aug 31, 2016 141		Protocol group Sep 1, 2016-May 10, 2021 62		p-value
Definitive fixation and soft tissue coverage in the same operation	117	83.0%	62	100%	0.0001*
Gustilo-Anderson grade					0.0012*
G-A I	54	38.3%	26	41.9%	
G-A II	28	19.9%	13	21.0%	
G-A IIIA	38	27.0%	4	6.5%	
>G-A IIIB	19	13.5%	14	22.6%	
G-A IIIC	2	1.4%	5	8.1%	
Primary operation <24 h	124	87.9%	54	87.1%	0.8214*
Time from trauma to definitive fixation (days)	Average Median	2.86 1	Average Median	3.21 2	0.0226**
Definitive fixation method					0.0355*
Plate fixation	46	32.6%	12	19.4%	
Intramedullary nailing	88	62.4%	42	67.7%	
External fixation	6	4.3%	8	12.9%	
Screw fixation	1	0.7%	0	0.0%	

*Fisher's test,
**Mann-Whitney test.

group (27.0% vs 6.5%) and as IIIB in the protocol group (13.5% vs 22.6%). The distributions of definitive fixation methods are presented in Table 2. A statistically significant difference was found between the study groups (p-value 0.0355). Intramedullary nailing was the most common bony fixation method in both groups (pre-protocol group 62.4% vs protocol group 67.7%). Plating was used in 32.6% of patients in the pre-protocol group and in 19.4% of patients in the protocol group. External fixation was used as definitive fixation more often in the protocol group (4.3% vs 12.9%). Before implementation of the OTF treatment protocol, 26 (18.4%) patients had soft tissue reconstruction with pedicled flap and 23 (16.3%) with free flap. After implementation of the OTF treatment protocol, 9 (14.5%) patients were treated with pedicled flap and 14 (22.6%) with free flap. However, no statistically significant difference was found (Table 3). There was no significant difference in the incidence of primary amputation between the study groups (11/220 5.0% vs 7/111 6.3% [p-value 0.6155]).

By the end of the follow-up period, FRI was diagnosed in only 1 OTF patient after the implementation of the OTF treatment protocol at TAUH, making the FRI rate significantly lower in the protocol group compared to the pre-protocol group (20.6% vs 1.6%, p-value 0.0015, Table 4, Fig. 3).

The incidence of reoperation due to nonunion was also significantly higher in the pre-protocol group (27.7% vs 9.7%, p-value 0.0054, Table 4, Fig. 3). Secondary amputation was performed on 4/141 (2.8%) patients before and on 1/62 (1.6%) patients after the implementation of the TAUH OTF treatment protocol, with no statistically significant

Table 3
Flap reconstruction.

	Study population April 1, 2007 - May 10, 2021 203				
	Pre-protocol group April 1, 2007-Aug 31, 2016 141		Protocol group Sep 1, 2016-May 10, 2021 62		p-value (Fisher's test)
Pedicled flap	26	18.4%	9	14.5%	0.5510
Free flap	23	16.3%	14	22.6%	0.3251

Table 4
Primary outcome measures.

	Study population April 1, 2007 - May 10, 2021 203				
	Pre-protocol group April 1, 2007-Aug 31, 2016 141		Protocol group Sep 1, 2016-May 10, 2021 62		p-value (Fisher's test)
Fracture-related infection (FRI)	29	20.6%	1	1.6%	0.0015
Reoperation due to non-union	39	27.7%	6	9.7%	0.0054
Secondary amputation	4	2.8%	1	1.6%	1.0000

difference (p = 1.000). Flap loss complications were reported in patients who had undergone soft tissue reconstruction with pedicled or free flap (Table 5). There was, however, no significant difference in flap loss complications between study groups.

All patients in the OTF protocol group underwent direct wound closure or flap reconstruction in the same operation as definitive osteosynthesis. However, in the pre-protocol group, only 83% (117/141) of patients underwent definitive internal fixation and soft tissue coverage in the same operation (p-value 0.0001).

Multivariable analysis was conducted using the whole study population as one group. Definitive fixation and soft tissue coverage performed in separate operations was an independent risk factor for both FRI (OR 7.2517 [95% confidence interval (CI) 2.3875 to 22.0258], p-value 0.0005) and reoperation due to nonunion (OR 6.9648 [95% CI 2.4407 to 19.8751], p value 0.0003). Additionally, a delay between trauma and definitive fixation showed a progressive increased risk for FRI (OR 1.1038 [95% CI 1.0024 to 1.2156], p-value 0.0446).

Discussion

The present study found a significant reduction in incidence of FRI from 20.6% to 1.6% after the implementation of the OTF treatment protocol. Similar results have been published earlier showing a significant reduction in FRI rates after the implementation of OTF treatment protocols based on BOAST 4. Mathews et al. [13] compared the FRI rates of patients with Gustilo-Anderson grade III OTF treated with single-stage definitive fixation and soft tissue coverage (n = 48) to those patients who had separate operations (n = 26), resulting in FRI rates of 4.2% versus 34.6%, respectively. Wordsworth et al. [18] also reported a reduction in FRI incidence after the implementation of their BOAST 4 based OTF treatment protocol compared to historical data from the same unit. Their cohort of 65 consecutive Gustilo-Anderson IIIB tibia fractures had an FRI incidence of only 1.6% (1/65 patients), whereas a publication from the same institute in 2006 [20] reported an FRI incidence of 8.5% (6/71 patients). Ali et al. [17] reported a reduction in the incidence of FRI from 27% to 8% after implementation of a BOAST 4 based treatment protocol. However, the difference was not found to be significant (p = 0.247). In their treatment protocol, the objective was to complete soft tissue coverage within 72 h rather than a combined simultaneous approach to reconstruct soft tissue coverage and bony fixation; median time from bony fixation to soft tissue coverage was 2 days. Moreover, only limited conclusions can be drawn due to their small sample size (50 patients divided into three study periods).

At TAUH, the rate of reoperation due to nonunion was reduced from 27.7% to 9.7% in those patients treated after the implementation of the OTF treatment protocol. In previous studies, there has been a wide variation in incidences of nonunion reported in OTF patients. The most commonly reported incidences vary between 0% and 32.6% [12,21,22].

Based on the presented results, it would be reasonable to assume that the implementation of the BOAST 4 based OTF treatment protocol at

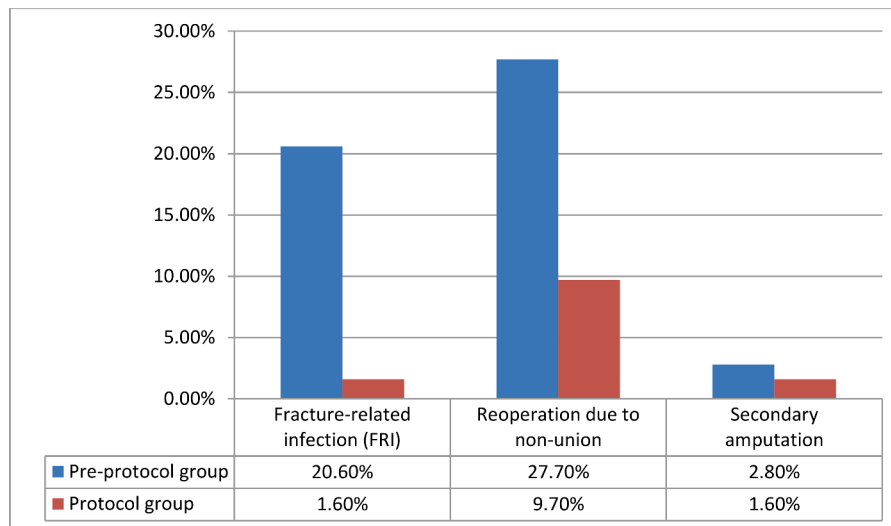


Fig. 3. Rate of FRI, reoperation due to non-union and secondary amputation in pre-protocol group and protocol group.

Table 5

Incidence of total and partial flap loss amongst patients who underwent soft tissue reconstruction with pedicled or free flap.

	Pre-protocol group April 1, 2007-Aug 31, 2016	Protocol group Sep 1, 2016-May 10, 2021	p-value (Fisher's test)
Free flap	23	14	0.77
Total flap loss	1 4.3%	0 0.0%	
Partial flap loss	4 17.4%	1 7.1%	
Pedicled flap	26	9	1.00
Total flap loss	0 0.0%	0 0.0%	
Partial flap loss	4 15.4%	1 11.1%	

TAUH has led to a reduction in FRI and reoperation due to nonunion rates. The lower complication rates cannot be explained by increased primary amputation rates, as no significant difference was found between the study groups. In the pre-protocol group, 11/220 (5.0%) patients and 7/111 (6.3%) patients in the protocol group underwent primary amputation ($p = 0.616$). Secondary amputation was performed on 2.8% of patients in the pre-protocol group and on 1.6% of patients in the protocol group with no statistically significant difference ($p = 1.000$). In previous studies, the amputation rate for Gustilo-Anderson IIIB OTFs has been reported to be 0% to 17.6% [11,12,23]. The lower amputation rates reported in the present study can be explained by the inclusion of all Gustilo-Anderson OTF types.

In the present study, Gustilo-Anderson grade III OTFs were graded more often IIIB in the protocol group (13.5% vs 22.6%) and IIIA in the pre-protocol group (27.0% vs 6.5%). This could be explained by the execution of the OTF treatment protocol. According to the protocol, plastic surgeons are involved in the treatment of OTF patients from the beginning, leading to a more accurate evaluation of the soft tissue injury and Gustilo-Anderson grade. During the study period, the use of plate fixation diminished in favour of intramedullary nailing and external fixation (Table 2).

The execution of all the independent parts of the TAUH OTF treatment protocol could not be reported in this study. Hence, comprehensive conclusions about which parts of the treatment protocol are the most efficient in preventing FRI and nonunion cannot be drawn. However, according to the multivariable analysis conducted on the collected data, wound closure and definitive fracture management in separate operations was the most important risk factor for both FRI and reoperation due to nonunion. Interestingly, the latest update of the BOAST open fracture guideline recommends soft tissue reconstruction within 72 h of

injury [16]. The results of the present study suggest that when a systematic treatment protocol is combined with meticulous orthoplastic execution, OTF can be treated with an acceptable risk for FRI or nonunion even if the 72-hour target time is sometimes surpassed.

Due to the retrospective nature of this study, only limited conclusions can be drawn. We were unable to present the patient-reported outcomes of our study population, which could have provided a better insight of the long-term outcomes of the two treatment groups. In addition, the follow-up period between the study groups varied between 5 and 14 years in the pre-protocol group and between 1 and 5 years in the protocol group. We considered the minimum follow-up period of one year to be satisfactory, since our primary outcomes (FRI and reoperation due to nonunion) generally occur within normal clinical follow-up periods.

Conclusions

The BOAST 4 based OTF treatment protocol reduced the rate of fracture related infection and reoperation due to nonunion in OTF patients treated at TAUH during the study period. We, therefore, recommend the implementation of such a treatment protocol in all major trauma centers treating patients with OTF. Furthermore, we also recommend the immediate referral of patients with complex OTF from hospitals lacking the preconditions to provide BOAST 4 based treatment to specialized centers.

Declaration of Competing Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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