



Original article

Open tibial shaft fractures. Treatment with intramedullary nailing after provisional stabilization with non penetrating external fixator[☆]

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ABSTRACT

Objective: To evaluate the incidence of union, nonunion, deep infection and factors influencing the time of bone healing in the treatment of open tibial shaft fractures Gustilo and Anderson types I and II initially treated with a non penetrating external fixator (Pinless®) followed by an unreamed intramedullary locked nail (UTN®).

Methods: It is a prospective study of 39 open tibial shaft fractures. According to the AO classification, 16 patients (41.0%) were type A, 17 (43.6%) were type B and six (15.4%) were type C. According to the Gustilo and Anderson classification, 14 patients (35.9%) were type I and 25 (64.1%) were type II. For the definitive stabilization of the fracture were used an unreamed intramedullary locked nail (UTN®).

Results: Bone healing was achieved in 97.4% of the cases, with a mean time of 21.2 weeks, ranging from 12 to 104 weeks. Deep infection was seen in 2.6% patients and malunion were seen in 5.1%. Only the presence of complications were statistically significant to the time of bone healing, with a risk of faster healing in patients without complications of 4.29 times (CI 95%: 1.25–14.71) comparing to patients with complications.

Conclusion: The treatment of open tibial shaft fractures with unreamed intramedullary locked nail allows high rates of bone healing, low rates of nonunion and deep infection, and only the presence of complications is statistically significant to the time of bone healing.

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Fratura exposta da diáfise da tibia – tratamento com osteossíntese intramedular após estabilização provisória com fixador externo não transfixante

RESUMO

Objetivo: Avaliar as taxas de consolidação, não consolidação e infecção profunda e quais fatores podem influenciar o tempo de consolidação nos pacientes com fraturas expostas da

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Fraturas expostas
Diáfises
Fixadores externos
Fixação intramedular de fraturas

diáfise da tibia graus I e II de Gustilo e Anderson, tratadas segundo um protocolo sequencial inicialmente com fixador externo não transfixante Pinless®, seguido por osteossíntese com haste intramedular maciça bloqueada não fresada (UTN®).

Métodos: Em estudo prospectivo, 39 fraturas expostas da diáfise da tibia foram acompanhadas. Segundo a classificação AO, 16 pacientes (41%) sofreram fraturas do tipo A, 17 (43,6%) do tipo B e seis (15,4%) do tipo C. Segundo a classificação de Gustilo e Anderson, 14 pacientes (35,9%) sofreram fraturas expostas grau I e 25 (64,1%) fraturas grau II. Para fixação interna foi usada haste intramedular maciça bloqueada não fresada (UTN®).

Resultados: Consolidação ocorreu em 97,4% dos casos com tempo médio de 21,2 semanas, variação de 12 até 104 semanas. Infecção profunda ocorreu em 2,6% dos casos e consolidação viciosa ocorreu em 5,1%. Da análise estatística observamos que apenas a presença de complicações é estatisticamente significativa para explicar o tempo de consolidação. O risco de consolidação mais rápida em pacientes sem complicações é de 4,29 vezes (IC 95%: 1,25-14,71) em relação a pacientes com complicações.

Conclusão: O tratamento das fraturas expostas da diáfise da tibia com osteossíntese intramedular maciça bloqueada não fresada apresenta taxa alta de consolidação, baixas taxas de não consolidação e de infecção profunda e apenas a presença de complicações apresenta relação estatisticamente significante com o tempo de consolidação.

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Introduction

Tibial shaft fractures are the commonest type among the long bones and mainly affect young male adults, i.e. individuals at their peak of physical and work capacity. Among the most frequent causes are high-energy trauma, such as car and motorcycle accidents and being run over. Because of the energy causing these tibial fractures, and the low degree of anteromedial cutaneous coverage, the tibia not only is the long bone that is most frequently fractured but also is the long bone that most frequently suffers exposed fractures.^{1,2}

Today, the indication in the worldwide literature for treating exposed tibial shaft fractures, of Gustilo and Anderson grades I and II,³ consists of immediate fixation using an intramedullary nail. In our service, like in the great majority of public services in Brazil,⁴ the technical resources or implants for immediate treatment of these exposed fractures are not always available. Thus, temporary external fixation is the option in such cases.

In an attempt to avoid the complications from using external fixators, the AO group conceptualized an external fixator without transfixion pins (Pinless®; Synthes AG®) for initial treatment of exposed tibial shaft fractures, which enables conversion to an unreamed intramedullary locked nail.

In 2008, we described our experience⁵ from treating exposed fractures of the tibial shaft, of Gustilo and Anderson grades I and II,³ fixed provisionally using a non-transfixing external fixator (Pinless®; Synthes AG®).

At the beginning of the 1990s, there was a recommendation to convert external fixation of exposed tibial shaft fractures using an unreamed massive intramedullary locked nail, because of the lower risk of damage to the endosteal circulation.⁶ Today, use of a reamed intramedullary nail is recommended in the worldwide literature, even for exposed fractures, because of the possibility of using implants of larger diameter. This provides greater stability, and the reaming enables faster consolidation. However, our impression, based

on experience gained through treating closed and open fractures of the tibial shaft, is that unreamed intramedullary locked nails present satisfactory results. To test this hypothesis, we developed the present study, with treatment of exposed tibial shaft fractures of Gustilo and Anderson grades I and II³ by means of a sequential protocol, initially with a Pinless® non-transfixing external fixator as a form of provisional osteosynthesis, followed by osteosynthesis using an unreamed massive intramedullary locked nail (UTN®) and evaluation of the consolidation and infection rates.

Sample

Between June 2000 and March 2007, 43 exposed tibial shaft fractures in 43 skeletally mature patients were treated in the Department of Orthopedics and Traumatology of Santa Casa de Misericórdia de São Paulo, Fernandinho Simonsen Wing. A sequential protocol was used, consisting of Pinless® non-transfixing external fixation and subsequent conversion to an unreamed massive intramedullary locked nail (unreamed tibial nail, UTN®, Synthes AG®). All the patients were seen initially at the central emergency service and, after assessment and release by the specialty teams, were referred to the Department of Orthopedics and Traumatology for the fractures to be treated. Only one patient required surgical treatment within another specialty (head and neck surgery; oral and maxillofacial surgery), with an elective operation.

The inclusion criteria were that the patients should be adults with exposed tibial shaft fractures of Gustilo and Anderson grades I and II³ who were first attended at our service; and that surgical treatment of the fracture using an intramedullary nail was feasible. The following patients were excluded: patients who were not skeletally mature; patients attended initially at other services; fractures that it would not be possible to treat surgically using an intramedullary nail (i.e. very proximal and very distal fractures); and patients with exposed fractures of Gustilo and Anderson grade III.³

Table 1 – Distribution of the 14 patients with exposed tibial shaft fractures of Gustilo grade I (Gustilo and Anderson)³ with regard to the type of fracture according to the AO classification (Johner and Wruhs).⁷

AO classification	N	(%)
A	9	64.3
B	5	35.7
C	0	0
TOTAL	14	100

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

At the emergency service, the 43 patients underwent surgical cleaning, debridement and stabilization using Pinless[®] external fixation (Synthes AG[®]).⁵ After external fixation, all the patients were kept hospitalized so that the wound could be cared for, and no weight-bearing on the affected limb was allowed until conversion to UTN[®]. There was no need for further debridement before conversion to UTN[®], but this was done during the conversion when necessary. The mean time interval from Pinless[®] fixation to the conversion was six days, with a range from 3 to 22 days. The patients who presented associated fractures underwent surgical treatment of the injuries on an emergency basis, together with the initial external fixation of the exposed tibial shaft fracture, with the exception of one case, with facial and mandibular fractures that were treated surgically on an elective basis before the conversion.

Out of the 43 patients, 39 (90.7%) returned for outpatient follow-up. Our evaluation was based on these 39 patients. The mean length of follow-up was 28.2 months, with a range from 4 to 110 months. Out of the 39 patients, 34 (87.1%) were male and 5 (12.9%) were female. The mean age was 29.2 years, with a range from 18 to 49 years.

The trauma mechanism consisted of motorcycle accidents in the cases of 19 patients (48.7%), being run over in 13 (33.3%), car accidents in two (5.1%), sports trauma in two (5.1%), falling at ground level in two (5.1%) and falling from a height greater than two meters in one (2.6%). The right side was affected in 20 patients (51.3%) and the left side in 19 patients (48.7%). There were no patients with bilateral tibial shaft fractures.

Through using the Gustilo and Anderson classification³ for exposed fractures, 14 patients (35.9%) presented grade I exposed fractures and 25 (64.1%) grade II.

Out of the 39 patients, 33 (84.6%) had suffered associated fractures of the fibula, while six (15.4%) had not.

Regarding location, one patient (2.6%) suffered a tibial fracture in the proximal third, 25 (64.1%) in the middle third and 10 (25.6%) in the distal third; and 3 (7.7%) suffered segmental fractures of the tibia.

From the AO classification,⁷ 16 patients (41%) had type A fractures, 17 (43.6%) had type B and 6 (15.4%) had type C.

Among the 14 cases of Gustilo grade I exposed fractures, nine (64.3%) suffered type A fractures of the AO classification,⁷ five (35.7%) type B and none type C (Table 1). Out of the 25 cases of Gustilo grade II exposed fractures, seven (28%) suffered type A fractures, twelve (48%) type B and six (24%) type C (Table 2).

Table 2 – Distribution of the 25 patients with exposed tibial shaft fractures of Gustilo grade II (Gustilo and Anderson)³ with regard to the type of fracture according to the AO classification (Johner and Wruhs).⁷

AO classification	N	(%)
A	7	28
B	12	48
C	6	24
TOTAL	25	100

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

Table 3 – Distribution of the 16 patients with exposed tibial shaft fractures of type A of the AO classification (Johner and Wruhs)⁷ with regard to the degree of exposure according to the Gustilo and Anderson classification.³

Gustilo and Anderson	N	(%)
I	9	56.3
II	7	43.7
TOTAL	16	100

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

Among the 16 cases of type A exposed fractures in the AO classification,⁷ nine (56.3%) suffered grade I fractures in the Gustilo and Anderson classification³ and seven (43.7%) suffered grade II fractures (Table 3). Among the 17 cases of type B exposed fractures in the AO classification,⁷ five (29.4%) suffered grade I fractures in the Gustilo and Anderson classification³ and twelve (70.6%) suffered grade II fractures (Table 4). All the six cases (100%) of type C exposed fractures in the AO classification AO⁷ suffered grade II exposed fractures in the Gustilo and Anderson classification³ (Table 5).

Methods

To classify the fractures according to their degree of exposure, the Gustilo and Anderson classification was used.³ To locate the fractures, the tibia was divided into three equal parts: proximal, middle and distal thirds. Regarding morphology, the fractures were classified using the AO system.⁷ Thus, the fractures were divided into three types, according to the fracture

Table 4 – Distribution of the 17 patients with exposed tibial shaft fractures of type B of the AO classification (Johner and Wruhs)⁷ with regard to the degree of exposure according to the Gustilo and Anderson classification.³

Gustilo and Anderson	N	(%)
I	5	29.4
II	12	70
TOTAL	17	100

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

Table 5 – Distribution of the six patients with exposed tibial shaft fractures of type C of the AO classification (Johner and Wruhs)⁷ with regard to the degree of exposure according to the Gustilo and Anderson classification.³

Gustilo and Anderson	N	(%)
I	0	0
II	6	100
TOTAL	6	100

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

line: type A – fracture with a single line; type B – multifragmentary fracture with a wedge; type C – complex multifragmentary fracture.

The Pinless[®] external fixation was conceived to be used temporarily in treating exposed tibial shaft fractures.⁸ The technique for fracture reduction and installation of the Pinless[®] external fixation was described in another study⁵, as were the preliminary results from temporary fixation using this method, in treatments for exposed tibial shaft fractures. For definitive fixation, an unreamed intramedullary locked nail was used in all cases (UTN[®]) (Fig. 1).

Fractures that consolidated with angular deviations greater than 10° in the coronal plane and greater than 10° in the sagittal plane, rotational deviation greater than 10° and shortening greater than 10mm were considered to be cases of skewed consolidation.

The criterion for consolidation used was the presence of at least three consolidated cortical bone areas seen on both radiographic views (anteroposterior and lateral), along with absence of pain and mobility at the fracture focus, and the capacity to walk without aids and without pain. Cases were considered to be non-consolidated when consolidation did not take place within 24 weeks.

Cases of infection were considered to be superficial when there was local erythema in the region of the cutaneous lesion, at the nail insertion site and the site for introducing the locking screws. These cases were resolved using antibiotic therapy.⁹ Cases of infection were considered to be deep when there was continual drainage through the operative wound or positive culturing for bacteria.⁹

To meet the aims of the study, Kaplan–Meier survival function graphs were constructed,¹⁰ with estimates for the mean and median lengths of time to consolidation and the respective 95% confidence intervals according to the variables of interest, and log-rank tests were applied to compare the consolidation times between the categories of variables.¹⁰ A Cox multiple regression model¹⁰ was created for the consolidation time according to the variables that presented descriptive levels lower than 0.2 ($p < 0.2$) in the tests separately, and the statistically significant variables were kept in the model. The tests were done using the significance level of 5%.

For the statistical evaluation, we sought to ascertain the following relationships: between the length of time to consolidation and the sex of the patients with an exposed tibial shaft fracture; between the consolidation time and the age group; between the consolidation time and the fracture morphology

Table 6 – Time taken to consolidate among the 39 patients with exposed tibial shaft fractures.

Time taken to consolidate	N	(%)
Up to 12 weeks	9	23.1
Up to 16 weeks	6	15.4
Up to 20 weeks	16	41
Up to 24 weeks	5	12.8
More than 52 weeks	2	5.1
Non-consolidation	1	2.6
TOTAL	39	100

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

according to the AO classification⁷; between the consolidation time and the degree of exposure according to the Gustilo and Anderson classification³; and between the consolidation time and the presence of infection.

This study was approved by the Research Ethics Committee of Irmandade da Santa Casa de Misericórdia de São Paulo (CEP/ISCMSp, project 042/02).

Results

Consolidation was achieved in 38 patients (97.4%) out of the 39 who were followed up. However, in three patients (7.7%), it took more than 24 weeks: one patient presented consolidation 72 weeks after the operation, one patient at 104 weeks and one patient did not present consolidation. Nine patients (23.1%) achieved consolidation in up to 12 weeks, 6 (15.4%) in up to 16 weeks, 16 (41%) in up to 20 weeks, 5 (12.8%) in up to 24 weeks and 2 (5.1%) in more than 52 weeks, and one (2.6%) did not present consolidation. Considering the 39 patients, the mean time taken to consolidate was 21.2 weeks, but if the three patients who were considered to be non-consolidated are excluded, the mean time to consolidate was 17.5 weeks (Table 6).

The results relating to consolidation and the time taken for consolidation among the cases of exposed fractures classified as Gustilo and Anderson grades I and II³ are described in Tables 7 and 8.

The results relating to consolidation and the time taken for consolidation among the cases of exposed fractures according to the AO classification⁷ are described in Tables 9 and 10.

Among the 39 fractures, three patients (7.7%) presented superficial infection and one (2.6%) presented deep infection.

Table 7 – Distribution of the 39 patients with exposed tibial shaft fractures with regard to consolidation, according to the Gustilo and Anderson classification.³

	Gustilo I		Gustilo II	
	N	(%)	N	(%)
Consolidation	14	100	22	80
Non-consolidation	0	0	3	20

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).



Figure 1 – Male patient aged 32 years who was a motorcycle accident victim, with a right-side exposed tibial shaft fracture of Gustilo and Anderson grade II. (A) Initial clinical image; (B) initial radiograph on the right tibia, in anteroposterior view; (C) initial radiograph on the right tibia, in lateral view; (D) immediate postoperative radiograph on fixation with Pinless external fixator, in anteroposterior view; (E) immediate postoperative radiograph on fixation with Pinless external fixator, in lateral view; (F) clinical image after fixation with Pinless external fixator; (G) immediate postoperative radiograph on fixation with unreamed intramedullary nail (UTN), in anteroposterior view; (H) immediate postoperative radiograph on fixation with unreamed intramedullary nail (UTN), in lateral view; (I) postoperative radiograph after 20 months on fixation with unreamed intramedullary nail (UTN), in anteroposterior view; (J) postoperative radiograph after 20 months on fixation with unreamed intramedullary nail (UTN), in lateral view.

In separating the fractures according to the degree of exposure, among the 14 cases of exposed fracture classified as Gustilo and Anderson grade I,³ one patient (7.1%) presented superficial infection and none presented deep infection. Among the 25 cases of exposed fracture classified as Gustilo and Anderson grade II,³ two patients (8%) presented superficial infection and one (4%) presented deep infection. In separating the cases

according to the AO classification,⁷ among the 16 cases of type A, none of the patients presented superficial or deep infection. Among the 17 fractures of type B in the AO classification,⁷ three patients (17.6%) presented superficial infection and none had deep infection. Among the six fractures of type C in the AO classification,⁷ one patient (16.7%) presented deep infection and none had superficial infection.

Table 8 – Distribution of the 39 patients with exposed tibial shaft fractures with regard to mean time to consolidate, according to the Gustilo and Anderson classification.³

	Gustilo I (without)	Gustilo II (without)
Consolidation	16.4	23.9

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

Table 11 shows that the time taken to consolidate in patients who presented complications was statistically greater than in patients without complications ($p = 0.002$). The degree of exposure of the fracture according to the Gustilo and Anderson classification³ also suggests that the time taken to consolidate was longer for patients with a grade II exposed fracture, but the difference between the consolidation times was not statistically significant between the grades ($p = 0.051$).

The result from the Cox model that was tested with the variables of age, degree of the fracture and presence of complications showed that only the presence of complications was statistically significant for explaining the time taken to consolidate. The risk of faster consolidation in patients without complications was 4.29 times greater (95% CI: 1.25–14.71) in relation to patients without complications.

Discussion

Although exposed tibial shaft fractures are very common, controversy still exists regarding some stages of their treatment. Even among the better-known aspects, such as use of intramedullary nails for fixation of these fractures,^{4,11,12} there is still space for discussion about what the best technique to use would be^{1,11-13}: reamed or unreamed intramedullary nails.

However, despite several studies in this regard, there is still some controversy regarding the choice between reamed and unreamed nails.¹¹⁻¹³ Initially, unreamed nails were indicated for temporary fixation of severe exposed fractures while the bone's blood supply is maintained, which has priority in treating these fractures.¹⁴ In addition to this advantage, use of massive intramedullary nails avoids the presence of dead space relating to tubular intramedullary nails, in which bacteria can grow and the host's defenses are minimal.^{14,15} This is a fundamental factor in treating exposed tibial fractures.

However, some authors have advocated using reamed intramedullary nails for treating exposed tibial shaft fractures,

Table 10 – Distribution of the 39 patients with exposed tibial shaft fractures with regard to mean time to consolidate, according to the AO classification (Johner and Wruhs).⁷

	Type A (without)	Type B (without)	Type C (without)
Consolidation	15.8	21.9	32.7

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

since this technique has also produced good results, with low incidence of complications in exposed tibial shaft fractures of Gustilo types I, II and IIIA.^{11,16-21} This has generated great controversy regarding which technique would be ideal for inserting intramedullary nails for fixation of exposed tibial shaft fractures.

Keating et al.¹⁶ reported that they were unable to demonstrate that reaming of the medullary canal was associated with increased risk of deep infection or pseudarthrosis. Although reaming of the medullary canal damages the endosteal circulation, this process was not shown to have a prejudicial effect in the present study.

However, Templeman et al.²² reported that reaming the medullary canal might provide a stimulus for consolidating the fracture. The biological benefit is combined with the greater stability that is achieved through inserting an intramedullary nail of greater caliber. Court-Brown²³ reported that limited reaming of the medullary canal is not deleterious for bone consolidation and is probably beneficial. Although there is no definition of what constitutes limited reaming, fixation with an intramedullary nail currently rarely involves using nails greater than 11 mm in diameter. Unless the diameter of the medullary canal is particularly wide, there is no indication for use of larger-caliber intramedullary nails.

Use of unreamed nails offers the advantage of less injury to the bone's intramedullary blood supply. This supply was already partially damaged through the initial trauma of the exposed tibial shaft fracture.^{1,2,11,16,19}

Reaming of the medullary canal obliterates the intramedullary vascularization and therefore overloads the blood supply of the tibia. On average, reaming of the medullary canal destroys 70% of the cortical bone's blood supply, while insertion of an unreamed nail only destroys the blood supply of the innermost third of the cortical bone. This is especially important in treating exposed fractures, in

Table 9 – Distribution of the 39 patients with exposed tibial shaft fractures with regard to consolidation, according to the AO classification (Johner and Wruhs).⁷

	Type A		Type B		Type C	
	N	(%)	N	(%)	N	(%)
Consolidation	15	93.7	16	94.1	5	83.3
Non-consolidation	1	6.3	1	5.9	1	16.7
Total	16	100	17	100	6	100

Source: SAME, Central Hospital of Santa Casa de Misericórdia de São Paulo (2011).

Table 11 – Estimate of mean and median times taken to consolidate according to variables of interest and results from comparative test on patients with exposed tibial shaft fracture.

Variable	Estimated mean time	95% CI of mean		Estimated median time	95% CI of mean		p
		Lower	Upper		Lower	Upper	
Sex							
Female	32	8.14	55.86	20	11.41	28.59	0.285
Male	19.09	16.35	21.83	20	19.33	20.67	
Age group							
<30 years	17.25	15.47	19.03	18	15.44	20.56	0.066
30 years or over	31.5;3	17.62	45.45	20	19.28	20.72	
AO							
A	20.19	11.57	28.80	16	6.85	25.15	0.283
B	20.41	16.87	23.95	20	19.02	20.98	
C	20	15.87	24.13	20	15.47	24.53	
Gustilo							
I	16.43	14.21	18.65	16	11.16	20.84	0.051
II	26.28	17.49	35.07	20	19.58	20.42	
Complications							
No	17.36	15.90	18.83	20	19.02	20.98	0.002
Yes	52.33	25.25	79.42	24	^a	^a	
Total	22.74	16.87	28.62	20	19.65	20.35	

^a Impossible to calculate.

which the blood supply of the external layer of the cortical bone may be damaged through deperiostization of the initial trauma.^{11,12,19}

Our study showed a total consolidation rate of 97.4% if the two cases of pseudarthrosis that consolidated after surgical procedures are taken into account. Over a 24-week period, we achieved consolidation of 92.3%, which is shown in some of the literature^{9,20} regarding treatment of exposed tibial shaft fractures using unreamed nails.

The mean time taken to achieve consolidation in our cases was 17.7 weeks, after exclusion of the cases of pseudarthrosis. This is concordant with some of the literature^{21,24} and can be explained by the large differences in interpretation of bone consolidation between different authors. Longer times taken to consolidate are reported in most of the literature.^{9,16,20,23,25}

Shah et al.²⁶ reported that there was no correlation between the degree of fracture exposure and the time taken to consolidate. In a meta-analysis, Giannoudis et al.² found a consolidation rate of 95%, i.e. similar to that of our study, taking into consideration the cases of delayed consolidation. Young and Topliss²⁷ reported that the mean time taken to consolidate was not affected by the degree of exposure of the fracture, the reaming of the canal or the patient's age.

Ziran et al.²⁸ reported that after 12 months, 73% of the fractures in the group treated with limited reaming of the medullary canal and 85% in the group without reaming of the medullary canal presented consolidation. After 18 months, these values were 82% in the group with limited reaming and 92% in the group without reaming. After 24 months, these values were 95% in the group with limited reaming and 96% in the group without reaming. There was no statistically significant difference in the consolidation rate. The unreamed group required a statistically significant greater number of

secondary procedures to reach consolidation, despite the greater incidence of consolidation.

In observing our cases, we could see that the cases of lesser severity (i.e. exposed fractures classified as Gustilo and Anderson grade I³ and types A and B of the AP classification⁷) presented better consolidation rates. Theoretically, this would be expected, but it is not very evident in the literature, perhaps because of lack of clarity regarding the subdivisions of the cases.

Regarding deep infection, the rate that we obtained was only 2.6%, which is in line with some of the literature,^{9,20,27} although the majority of the literature presents greater incidence of deep infection.^{9,17,24} The only cases of deep infection in our study occurred in an exposed fracture classified as Gustilo and Anderson grade II and as AO type C, which would be expected, since these are higher-energy fractures and therefore more liable to complications.

Regarding non-consolidation, we observed that 7.7% of the cases in our study did not present consolidation. Of these, only one remained unconsolidated until the conclusion of our study. The literature evaluated presents variable results regarding consolidation: some studies with results worse than ours,^{17,20,24,26} but some with results better than ours.^{9,16} All of our cases of pseudarthrosis occurred in exposed fractures classified as Gustilo and Anderson grade II: one with a type A fracture, one with type B and one with type C of the AO classification. Only one case remained unconsolidated, thus giving a final incidence of pseudoarthrosis of 2.6%.

The results in the literature relating to the consolidation rate from treatment of exposed tibial fractures using an unreamed intramedullary nail, compared with treatment using a reamed intramedullary nail, are variable. Oh et al.⁹ stated that there was no statistically significant difference

regarding the mean time taken to consolidate and the infection and pseudarthrosis rates, between the degrees of exposed fractures, but that there were longer consolidation times and higher pseudarthrosis rates in the complex multifragmentary fractures. However, we were unable to differentiate these. We only observed that there was low incidence of complications in exposed fractures of Gustilo and Anderson grade I³ and type A of the AO classification.⁷

Bhandari et al.¹³ reported that studies comparing reamed and unreamed intramedullary nails have suggested that there is a large reduction in the risk of pseudarthrosis or failure to consolidate when reamed intramedullary nails are used. Nonetheless, methodological limitations have left doubts regarding the efficacy of reamed intramedullary nails. In a randomized multicenter study, Bhandari et al.¹³ conclude that there was no difference between treatments for exposed tibial shaft fractures using reamed and unreamed intramedullary nails, with regard to infection, pseudarthrosis and reoperation.

The protocol for staged treatment of exposed tibial shaft fractures, using an external fixator followed by conversion to intramedullary osteosynthesis, is an option when the technical conditions for immediate internal fixation of the exposed tibial shaft fracture do not exist. This protocol has the disadvantage of requiring several surgical procedures and a longer hospital stay. In this regard, the Pinless[®] external fixator has the potential advantage that the conversion to an intramedullary nail can be done with the Pinless[®] external fixator fixed to the bone. If the primary reduction is satisfactory, the conversion to an intramedullary nail will not present difficulties.⁵

With regard to using unreamed intramedullary nails, some authors^{2,9,13,24,27} have concluded that this is a safe option for treating exposed tibial shaft fractures.

From a systematic review of the literature, Bhandari et al.¹¹ concluded that the advantage of using reamed rather than unreamed intramedullary nails remained uncertain with regard to infection, pseudarthrosis and reoperation rates. They suggested that large new randomized studies using reamed and unreamed intramedullary nails to treat exposed tibial fractures should be conducted. Bhandari et al.¹³ concluded, from a randomized study, that there was no difference between reamed and unreamed intramedullary nails in treatments for exposed tibial shaft fractures.

In evaluating our cases, we observed that only the presence of complications had a statistically significant relationship with the time taken to consolidate, which was to be expected. However, just like Shah et al.,²⁶ we did not observe any statistically significant relationship between the degree of bone exposure according to the Gustilo and Anderson classification and the time taken to consolidate, although the statistical analysis showed a tendency toward a relationship. We probably were unable to find such a relationship because of the small size of our sample. If our sample had been bigger, perhaps we would have obtained a statistical relationship between the degree of bone exposure and the time taken to consolidate. We can say the same thing about the exposed fractures when divided according to morphology, despite the lack of statistical relationship between the time taken to consolidate and the morphology of the fracture.

Conclusion

From the analysis on our results, we can conclude that the sequential protocol for treating exposed tibial shaft fractures of Gustilo and Anderson grades I and II, comprising initial treatment with a Pinless[®] external fixator followed by osteosynthesis using UTN[®], presented high consolidation rates and low non-consolidation and infection rates. Only the presence of infection showed a statistically significant relationship with the time taken to consolidate.

Conflicts of interest

The authors declare no conflicts of interest.

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