

# PROSPECTIVE AND RANDOMIZED STUDY OF PATIENTS WITH OPEN FRACTURES OF THE FEMORAL SHAFT, TREATED WITH PLATE OR OPEN INTRAMEDULLARY LOCKED NAIL

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## SUMMARY

We assessed the complications and treatment outcomes in a prospective and randomized study of two osteosynthesis techniques in open femoral shaft fractures. Between January 2002 and April 2004, 40 patients with open fractures of the femoral shaft were assessed, with 20 being treated with open reamed intramedullary locked nail and 20 with plate. Twenty-six (65%) fractures were classified as Gustilo type -I open fractures; ten (25%) as type II and four (10%), as type IIIA. There were 21 blunt injuries and 19 gunshot injuries. Three patients were excluded from the final assessment. Complications were observed in 12 (32.4%) patients, 4 in the plate group and 8 in

the nail group. Reamed intramedullary locked nail resulted in two deep infections (10%), two superficial infections (10%), and one nonunion (5%). With plate techniques, we had one deep infection associated to nonunion (5,8%) and one superficial infection (5.8%). Good and excellent outcomes were found in 28 fractures (75.7%), fair (7.5%) in three cases, and poor (15%) in six, according to Thorensen's criteria. In this study, the stabilization with plate results in lower complications rate when compared to the open intramedullary nail, although with no statistical significance.

**Keywords:** *Fracture fixation intramedullary; Femoral fractures; Bone plates; Diaphyses; Fractures open.*

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## INTRODUCTION

The advantages and disadvantages of locked nails employed on the stabilization of femoral shaft open fractures are rarely compared to the stabilization with plates, despite being the most common technique reported in literature. The approach to this kind of injury is usually agreed upon the need to perform an emergencial surgical debridement and early stabilization, whenever possible<sup>(1)</sup>. However, the selection of an application technique in our environment raises some discussions and not seldom, stabilizations are distinguished and performed with plates. The use of plates to fixate femoral shaft open fractures is selected with some caution due to concerns about the potentially high complication rates seen when this technique was employed targeting anatomical reduction and interfragmentar compression. The review of synthesis concepts with the application of principles for protecting soft parts, gave a new perspective

about its use<sup>(2)</sup>. Although there is some controversy regarding the use of intramedullary nails in terms of application technique, milled or not, and also due to potential local and systemic complications, this is a much frequently employed stabilization technique, and the results reported on literature for open fractures of the femoral shaft are quite favorable<sup>(3,4)</sup>. Targeting to identify the treatment results, the complications, and their frequency on patients with open fractures of the femoral shaft in our service, we conducted a randomized, prospective and comparative study of both techniques, with a group treated with plates and screws, and the other with intramedullary locked milled nail in open insertion techniques.

## MATERIAL AND METHODS

A randomized clinical study was conducted on 40 patients with femoral shaft open fractures, submitted to emergencial debridement and to therapy with antibiotics, according to the

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protocol recommended by Gustilo et al.<sup>(5)</sup>. After the initial debridement, the patients were kept with skeletal traction as a second step. As inclusion criteria, we studied only open femoral shaft fractures in skeletally mature patients and with surgical debridement performed within six hours from the trauma, and presenting no systemic complications. The patients were invited to take part of the study after a thorough explanation about the research design and upon signing an informed consent term. Following the randomization made with sealed envelopes, 20 patients were submitted to osteosynthesis with plates and screws, and the remaining 20 with intramedullary locked milled nails by open insertion technique. The surgical procedures were made in a public hospital between January 2002 and April 2004. The patients were followed up for nine months when regarded as cured or when presenting union failure, requiring re-surgery. Concerning the mechanism of injury, the fractures were classified as blunt or penetrating trauma. The type of exposure was classified according to the criteria by Gustilo, and for fracture configuration, we used the AO classification<sup>(6)</sup>. Union delay was regarded for fractures not united until the 26th week, and union failure after nine months with no progression at X-ray images<sup>(7)</sup>. The method by Thoresen et al.<sup>(8)</sup> was employed for providing a clinical evaluation of the results.

### Surgical techniques

**Locked nail** – The patients were operated on a standard surgical table at lateral position and with the fracture core opened in order to enable the guide wire to pass easily. A locally manufactured rigid threaded cylindrical nail with a slightly curved anterior surface was used, being performed manual reduction and canal milling for the anterograde introduction of the nail. It had a template for inserting distal and proximal locked screws, both static. **Plate and screw** – The patients were operated on a standard surgical table. The procedure was performed as least aggressively as possible to the soft parts, sometimes also more formally using the bridge plate technique with two small lateral incisions. The key surgeon was responsible for selecting the

synthesis material and for reporting the degree of satisfaction with the result. The plate was fixated with at least eight cortical screws on each side of the fracture.

### Statistical analysis

For the description of the continuous variables, the mean and standard deviation values, as well as the median were used. For testing continuous variables, the Student's t-test or the Mann-Whitney test were employed. For comparing three or more groups, the variance analysis (ANOVA) was used. In the comparison of categorical variables, the chi-squared test or the Fisher's exact test were employed. The Kolmogorov-Smirnov's test was employed to assess if the continuous variables showed a similar normality distribution. The groups of patients were compared by adopting an alpha error of 5%, with significance for  $p < 0.05$ .

### RESULTS

The general characteristics of the studied groups are described on Table 1. In three patients with femoral fractures caused by gun shots (cases 8, 15, and 17), we had a randomization break, because the surgeon was not experienced with inserting locked intramedullary nails, and the patients received plates and screws. These cases were excluded from the series, thus there were 37 cases left. Associated injuries were found in 12 patients (32.4% -  $n=37$ ) of the study: two patients with TCE, two peripheral neurological injuries, one heart injury caused by gunshot, two tibial fractures, one contralateral femoral fracture, one ankle fracture, one pelvic ring fracture, one humeral shaft fracture and one fracture-dislocation of the knee. Regarding the mechanism of injury, there were 11 penetrating injuries and 6 blunt injuries in the plate group, and 5 penetrating and 15 blunt injuries in the nail group. Table 2 describes the fractures and their corresponding treatments according to Gustilo's classification. Regarding fractures configuration, according to the AO classification, 59.4% were found to be type B, 29.7% type A, and 10.8% type C.

Characteristics			Nail	P
Gender	M	15 (88.2%)	19 (95.0%)	0.452*
	F	2 (11.8%)	1 (5.0%)	
Age (years)	Average ± SD		27.65± 8.4	0.75†
Time for synthesis	Average ± DP		14.05 ±8.7	0.209†
Affected side	R	8 (47.1%)	12 (60.0%)	0.43*
	L	9 (52.9%)	8 (40.0%)	
Mechanism of Injury	Penetrating	11 (64.7%)	5 (25.0%)	0.015*
	Blunt	6 (35.3%)	15 (75.0%)	

M= male; F= female / R= right; L= left / - average  $\mu$  SD = Average  $\mu$  standard deviation / - \*  $\chi^2$  test/ - † Mann-Whitney test. - Source: Orthopaedics and Traumatology Service, HUPES.

**Table 1** – General characteristics (gender, age, time [days] for osteosynthesis, affected side, and mechanism of injury)

		Synthesis employed		Total
		Plate Nr. (%)	Nail Nr. (%)	Nr. (%)
Gustilo´s classification	I	13 (76.5)	10 (50)	<b>23 (62.2)</b>
	II	2 (11.8)	8 (40)	<b>10 (27)</b>
	IIIA	2 (11.8)	2 (10)	<b>4 (10.8)</b>
Total (Nr.)		17 (100)	20 (100)	<b>37 (100)</b>

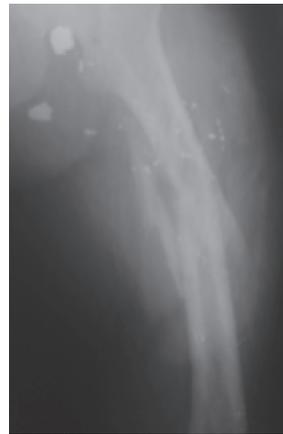
Fisher´s exact test = 0.159 - Source: Orthopaedics and Traumatology Service, HUPES

**Table 2** – Distribution of patients according to the kind of treatment and by Gustilo´s classification.

Complications were found in 12 patients (32.4%-n=37), 4 of these in the plate group (23.5%) and 8 in the nail group (40.0%),  $p=0.286$ . (Graph 1) Using the classification by Gustilo, for type-I, complications were seen in 26,1% (n=23), for type-II 40.0% (n=10), and for type-III 50% (n=4), with a  $p=0.51$ . Using the AO classification, for type A, complications were seen in 9.1% (n=11), for type B 40.9% (n=22), and, for type C 50% (n=4), with a  $p=0.90$ . Regarding infection, two patients in the nail group presented deep infections (10%) and two superficial infections (10%), and, in the plate group, one deep infection (5.8%) and one superficial infection (5.8%). Union failure occurred in one patient in the plate group associated with deep infection, while in one patient in the nail group the failure was associated to technical error. Two patients in the nail group and one patient of the plate group experienced significant shortenings, above two centimeters. An angle deviation above ten degrees was found in one patient in each group (Table 3). All infection cases were associated to some degree of joint stiffness, but none with less than 90 degrees of flexion. No systemic complications were found on studied patients. Union occurred within a mean time of  $20.71 \pm 2.72$  weeks,  $21.38 \pm 3.07$  (16 patients, excluding deep infection cases) weeks for fractures stabilized with plates and screws, and 20.07 weeks (17 patients, excluding deep infection and union failure cases) for fractures stabilized with locked nails. There was one patient in the plate group showing union within 26.7 weeks, thus being regarded as a union delay case, being also associated to superficial infection. When assessing the time for union according to Gustilo´s classification, we found, for type I, a mean value of  $20.29 \pm 2.9$ , for type II,  $21.7 \pm 2.2$ , and, for type III,  $21.62 \pm 2.2$  ( $p=0.425$ ). For time to union according to the AO classification, type A had a mean value of  $19.97 \pm 2.29$ , type B:  $21.42 \pm 2.91$ , and type-C  $19.55 \pm 2.65$  ( $p=0.259$ ). According to Thoresen´s classification, excellent and good results were achieved in 28 fractures (75.7%). Three cases (8.1%) were rated as fair and resulting from superficial infections accompanied by joint stiffness. Six poor cases (16.2%) representing the three deep infections, one case of union failure associated to material failure, as well as two significant shortenings. In the analysis of the groups, we found 82.4% (n=17) of excellent and good results for the plate group, and 70% (n=20) for the nail group ( $p= 0.84$ ).

## DISCUSSION

Open femoral shaft fractures are serious injuries presupposing a higher complications rate following treatment, which may range from 0 to 24%(3.9-11). Although our series is composed by kinds of bone exposure predicting good results (types I, II, and IIIA), we found general complications in 32.4%, which is a very high rate, but close to the rates found by other authors<sup>(1)</sup>. Penetrating injuries resulting from low-energy gun shots were included in this study due to the fact of being addressed in the emergency room with debridement and cleaning of the fracture core. For this group, a lower complications rate was found, as well as better results according to Thoresen´s classification, which is consistent with literature<sup>(12,13)</sup>. (Figures 1 and 2).



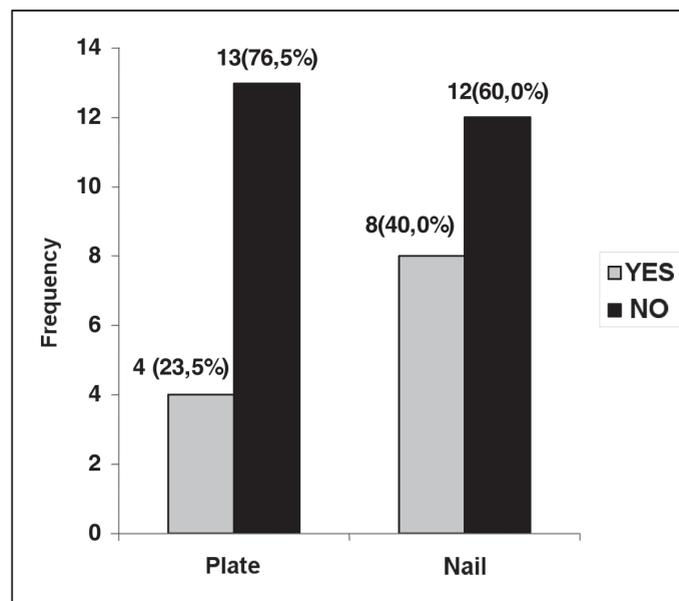
**Figure 1** – 20 year-old male patient. Open fracture of the left femur caused by gunshot classified as Gustilo´s type I, AO – B2.



**Figure 2** – Union within 17.9 weeks, uncomplicated. The rate according to Thoresen´s classification was excellent.

When to fixate open fractures has been extensively discussed, but the current approach is to stabilize during the debridement procedure, provided this is timely performed and the bone structure is covered<sup>(14)</sup>. The patients in this group waited in average  $11.4 \pm 8.44$  days until stabilization was definitively provided, and such amount of time is regarded as long when compared to other series<sup>(15,16)</sup>. This waiting time was not intentional, but it was the result of a high demand in public hospitals. In assessing complications, we found that the patients experiencing complications had a longer waiting time –  $16.75 \pm 9.93$  days – compared to those uncomplicated cases –  $9.68 \pm 6.86$  days – and this difference was statistically significant ( $p = 0.039$  – Student´s t-test). This can be explained, in part, by the challenges in appropriately reducing the fracture. Using the AO classification to evaluate if the kind of fracture influenced the average time for union and the complications rate, no statistically significant difference was found ( $p = 0.26$ , ANOVA). Table 3 shows a higher complications rate for Gustilo´s III-A type, but without statistical significance ( $p=0.38$ ). Infection – the most feared condition in open fractures – may present rates ranging from 0 to 16% (1,3,9,10,15). Riemer et al.<sup>(17)</sup> discussed the results of 141 femoral fractures treated with plates, including 63 open fractures, with an infection rate of 2%. O´Brien et

al.<sup>(1)</sup> studied 63 open femoral fractures primarily treated with intramedullary locked milled nail with an infection rate of 12%. The global infection rate was 16.2%, 20% for the nail group, and 11.6% for the plate group, being regarded as high when compared to literature reports (1,15,18). In the entire series, we found deep infection in three patients (8.1%) and superficial infection in three (8.1%). In the nail group, two deep infections (10%) and two superficial infections (10%) were found, while, in the plate group, we found one deep infection (5.8%) and one superficial (5.8%). The patient with deep infection in the plate group evolved with union failure, requiring the use of bone transport technique. The two patients in the nail group were submitted to new debridement procedures and antibiotics therapy, evolving to union, despite of a knee flexion restraint at 90°. After the infection was cured, the nails were removed. Superficial infections (3 cases) were definitively treated with antibiotic therapy. Union failure was found in two patients (5.4%): one patient treated with plate, and one patient treated with nail. One fracture with delayed union evolved to cure after treating the superficial infection. These rates are consistent to the ones described by literature<sup>(1,3,11,15)</sup>. At the end of the treatment, three patients showed shortening, one in the plate group, and two in the nail group. We found 2 cases of 10-degree angle deviations, one in valgus (nail group) and one in varus (plate group), a fact also found in other series<sup>(15)</sup>. By comparing both stabilization methods, we can see that the incidence of local complications was higher for fractures treated with nails (Graph 1); however, this difference was not



Graph 1 – Complications rate by type of synthesis ( $p = 0.319$ ).

statistically significant ( $p = 0.168$ ). There was no statistically significant difference for time to union between both groups. The complications discussed here are close to the results previously published in literature for closed fractures treated with plates<sup>(17)</sup>, but these numbers can be regarded as high for patients treated with nails<sup>(11,13)</sup>.

As employed by a number of surgeons, the nails used here were milled; however, the insertion of the nail was made with

Case	Mech. of Injury	Gustilo's class	AO class	Waiting time	Synth	Complications
9	B	TYPE III-A	B3	30	P	Sho. 4 cm
25	B	TYPE I	C1	30	N	Sho. 2 cm
37	B	TYPE III-A	C3	11	N	Sho. 4 cm
16	GSI	TYPE I	B3	10	P	10° varus
22	B	TYPE I	A3	7	N	10° valgus
18	GSI	TYPE I	B3	18	P	SI+ UD+ JS
33	B	TYPE I	B2	10	N	SI + JS
39	B	TYPE I	B2	7	N	SI+ JS
27	B	TYPE II	B2	10	N	UF+ FI
6	B	TYPE II	B3	1	P	UF+ DI
24	B	TYPE II	B2	27	N	DI
38	B	TYPE II	B2	20	N	DI

Mech. of injury = Mechanism of injury ;Gustilo class = Gustilo's classification /; AO class = AO classification; Waiting time = waiting time / Synth. = Synthesis /; B = blunt /; GSI = Gunshot injury /; P = plate /; N = nail /; Sho = shortening /; SI = Superficial infection /; DI = deep infection /; UD = union delay /; JS = Joint stiffness / UF = Union failure / . = Implant failure

Table 3 – Distribution of patients according to the mechanism of injury, classifications, waiting time, kind of synthesis and complications.

an open technique. The introduction of the nail by an open technique, the use of milling, and the use of a threaded nail, are factors influencing the results of open fractures in comparison to the closed technique, with solid non-milled nail<sup>(7,19)</sup>. Another cause that may be associated to the high complications rate is the fact that those patients are kept for a relatively long time under traction waiting for a definitive treatment. These factors associated to the heterogeneity in providing primary care and emergencial cleaning performed by different orthopaedic surgeons as well as the learning curve for nails insertion could explain our results. The results based on Thoresen's classification, in the overall analysis, showed 75.7% of excellent and good results, and in the analysis of groups, 85% of excellent and good results for the plate group, and 75% for the nail group, reflecting similar rates to literature reports addressing closed fractures series with some cases of open fractures included<sup>(6,16,20,21)</sup>. (Figures 3 and 4). The absence of a statistically significant result towards the use of plates in our study, the well known biomechanical superiority of the nail validated by literature, points out to the indication of reinforcing the approach with solid intramedullary locked nails inserted as an additional step of the debridement procedure, whenever possible<sup>(1,4,13)</sup>. In some cases of open type-III B femoral shaft fractures and in patients with compromised lung function, nails should be carefully employed<sup>(11)</sup>. The postoperative follow-up was short, and further studies must be conducted excluding penetrating injuries and with bigger and more uniform samples as well as including a long-term follow-up protocol.



**Figure 3** – 18 year-old male patient, victim of motorcycle accident, with open fracture on right femur, classified as Gustilo's type-I, AO- A3.



**Figure 4** – Union within 18.8 weeks, uncomplicated. The result according to Thoresen's classification was excellent.

## CONCLUSION

Injuries by blunt trauma and long time to osteosynthesis were associated to a higher complications rate. The stabilization technique using milled intramedullary locked nail with open insertion showed a higher incidence of complications when compared to the osteosynthesis provided by plates, although not statistically significant. In the results according to Thoresen's classification, the definition was not statistically significant, although the treatment with plates resulted in a higher rate of excellent and good results.

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