

Comparative Study of Function and Quality of Life in Patients with Fracture of the Tibial Plateau Operated with Locked or Conventional Plates*

Função e qualidade de vida de pacientes com fratura do planalto tibial operados com placa bloqueada ou convencional: estudo comparativo

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Abstract

Objective To compare clinical, functional, and quality of life outcomes between patients with tibial plateau fractures operated with locked or conventional plates, and to compare the costs of these implants.


Methods This was a comparative cross-sectional study of a consecutive series of patients with tibial plateau fractures treated surgically from August 2015 to June 2016. Patients < 18 years old, those unable to answer the questionnaires or to attend the outpatient reassessment, polytrauma patients, those with associated injuries on the ipsilateral limb, and patients who had not undergone treatment with bone plates were excluded. The present study compared the costs of the implants for the hospital, quality of life (with the 12-Item Short Form Health Survey [SF-12]), Lysholm score, pain scale, and clinical and radiological parameters.

Results A total of 45 patients with tibial plateau fractures were admitted, and 11 cases were excluded. Two cases were lost to follow-up; therefore, 32 remained for the analysis (94%). The mean follow-up time was of 15.1 months (standard deviation [SD] = 4.8 months). In group A (locked plates), there were 22 patients (69%), at an average hospital cost of BRL 4,125.39/patient (SD = 1,634.79/patient) for the implants. In group B (conventional plates) there were 10 patients (31%), at an average cost of BRL 438.53 (SD = 161.8/patient) ($p < 0.00001$). For the other parameters, no differences were observed, except for a greater articular depression in group A ($2.7 \text{ mm} \pm 3.3 \text{ mm}$ versus $0.5 \text{ mm} \pm 1.6 \text{ mm}$; $p = 0.02$; TE = 0.90).

Keywords

- ▶ tibial fractures
- ▶ bone plates
- ▶ quality of life
- ▶ Lysholm knee score
- ▶ sick leave
- ▶ cost and cost analysis
- ▶ unified health system

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Resumo

Conclusion The costs of locked implants for the treatment of tibial plateau fractures are significantly higher than those of conventional implants, without any clinical, quality of life, radiological, or functional advantages of the locked implants demonstrated in the present series.

Objetivos Comparar resultados clínicos, funcionais e de qualidade de vida de pacientes com fratura do planalto tibial operados com placa bloqueada ou convencional e comparar os custos hospitalares dos implantes.

Métodos Estudo comparativo de coortes transversal, retrospectivo, em uma série consecutiva de pacientes com fratura do planalto tibial tratados cirurgicamente entre agosto de 2015 e junho de 2016. Foram excluídos: menores de 18 anos; indivíduos incapazes de responder os questionários ou de comparecer para reavaliação; politraumatizados ou com lesões associadas no mesmo membro; pacientes não tratados com placa ou conservadoramente. Os autores compararam os custos dos implantes, a qualidade de vida (SF-12), o escore de Lysholm, a escala visual de dor e os parâmetros clínicos e radiográficos.

Resultados Foram observadas 45 fraturas no período, das quais 11 foram excluídas. Dos 34 pacientes, dois não compareceram à entrevista (seguimento de 94%). O tempo de seguimento foi $15,1 \pm 4,8$ meses. O grupo A (placa bloqueada) incluiu 22 pacientes (69%), com custo hospitalar médio dos implantes de R\$ 4.125,39 (dp = R\$ 1.634,79/paciente). O grupo B (placa convencional) incluiu dez pacientes (31%), a um custo médio de R\$ 438,53 (dp = R\$ 161,8/paciente; $p < 0,00001$). Para os demais parâmetros avaliados, não foram observadas diferenças significativas entre os grupos, exceto por um maior grau articular no grupo A ($2,7 \text{ mm} \pm 3,3 \text{ mm}$ versus $0,5 \text{ mm} \pm 1,6 \text{ mm}$; $p = 0,02$; TE = 0,90).

Conclusão O custo dos implantes bloqueados para o tratamento das fraturas do planalto tibial é significativamente superior aos implantes convencionais, embora não tenham apresentado vantagem clínica, radiográfica, funcional ou de qualidade de vida, nos pacientes dessa amostra.

Palavras-chave

- ▶ fraturas da tibia
- ▶ placas ósseas
- ▶ qualidade de vida
- ▶ escore de Lysholm para joelho
- ▶ licença médica
- ▶ custos e análise de custo
- ▶ sistema único de saúde

Introduction

Tibial plateau fractures represent between 1 and 2% of all fractures, and ~ 8% of the fractures in the elderly.^{1,2} A study from 2015 revealed that the incidence of tibial plateau fractures is ~ 10.3 cases per 100,000 people. These fractures affect both genders, with a higher incidence in women > 50 years old and in men < 50 years old.² In Brazil, in 2015, 11,071 surgeries were performed to treat tibial plateau fractures by the Brazilian Unified Health System (SUS, in the Portuguese acronym), with a total cost of BRL 9,317,006.85.³

Deviated tibial plateau fractures require surgical treatment.² Several factors appear to influence the outcome of the treatment, including the quality of the reduction, the type of fracture, age, associated lesions, and the type of implant.² Although results may vary according to the type of implant and due to the current trend of choosing locked implants by orthopedic surgeons, it is not clear if the use of a specific type of implant influences the clinical and functional results.⁴

In addition, there is a growing concern about the costs of the implants and their impact on both the public and on the private health care systems.⁵ In order to enable cost-efficiency studies to answer if the adoption of a given implant type is adequate,

researches comparing the efficacy of different implants and taking in account several factors, such as pain, function, quality of life, and time off work, are required.^{5,6}

In our field, we did not find comparative studies that help to clarify possible differences between tibial plateau fractures surgically treated with locked (► Fig. 1) or conventional plates (► Fig. 2). The present study aims to compare clinical, functional and quality of life results among patients with tibial plateau fractures submitted to locked or conventional plate osteosynthesis. In addition, we aim to compare the hospital costs of the different types of implants in the sample.

Material and Methods

This is a retrospective, comparative cohort study in a consecutive series of patients with tibial plateau fractures, surgically treated with locked plates (Group A) or conventional plates (Group B) from August 2015 to June 2016, in a tertiary teaching hospital that cares exclusively for SUS patients.

All of the patients admitted for tibial plateau fracture, at the same hospital, from August 2015 to June 2016, were enrolled. Exclusion criteria were the following: underage

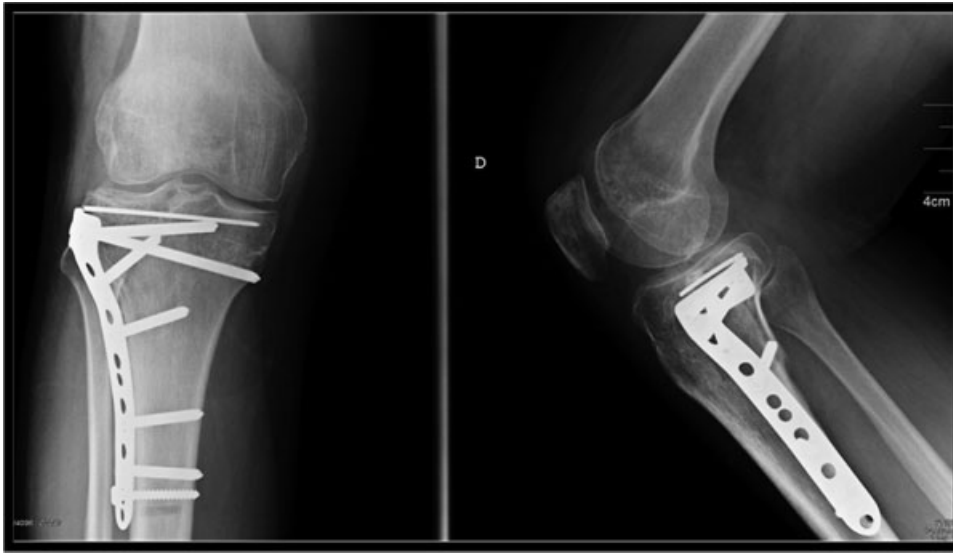


Fig. 1 Locked plate osteosynthesis viewed in anteroposterior and profile radiographs.

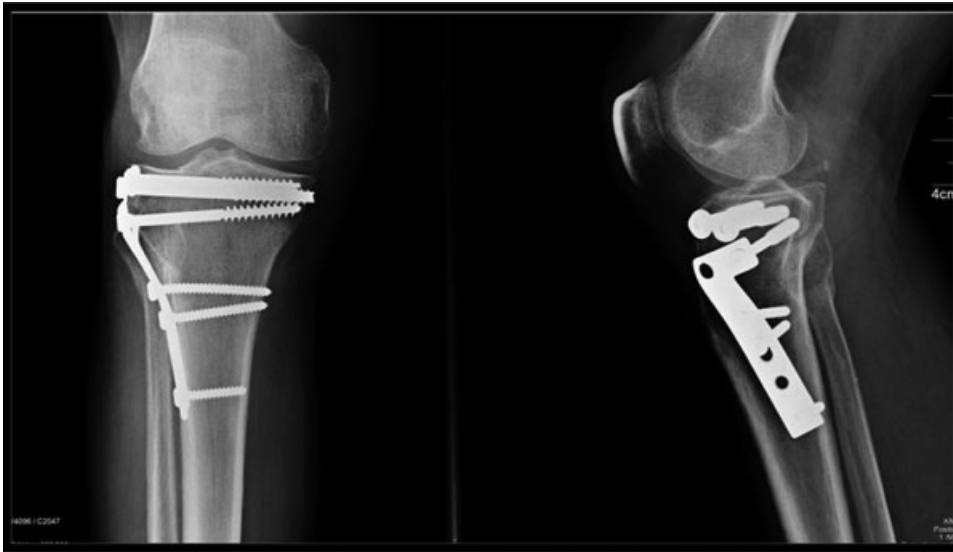


Fig. 2 Conventional plate osteosynthesis, viewed in anteroposterior and profile radiographs.

patients (< 18 years old), inability to answer functional evaluation questionnaires or to attend outpatient reassessments; individuals with polytrauma or associated lesions at the same limb or in another anatomical region decisively affecting the functional rehabilitation of the limb; patients treated with no plate; patients submitted to conservative treatment. The excluded cases and the reasons for their exclusion are presented in the results section.

The present study was approved by the Research Ethics Committee under the number 65959717.9.0000.5103, and all of the participants signed the informed consent form.

Participants were prospectively submitted, by the same examiner, to clinical and functional evaluations with standardized, validated questionnaires. Postoperative radiographies were also analyzed by the same examiner at the first follow-up visit. The quality of life of the patients at the follow-up visit was also recorded. Physical and electronic

records from the patients and all of the imaging results available were evaluated to collect data regarding demographics, events related to the trauma, type of fracture, materials used, and implant costs for the hospital. Neurological function was recorded pre- and postsurgery, as well as data concerning infection, but with a surgical wound, consolidation delay, and other complications.

The following parameters were recorded on a standard form: type of fracture according to the Schatzker classification, quality of the reduction (presence of joint deviations in millimeters, angle deviations on anteroposterior and profile x-rays), number of screws in each plate, number of screws outside the plate, and baseline, immediate postoperative and current radiographies. On the current x-rays, the consolidation status, implant loosening or failure, residual deviation, and arthrosis signs according to the Alback classification were also assessed.^{7,8} The following questionnaires were

applied at follow-up: analog visual scale for pain (AVS), Lysholm⁹ functional protocol, and 12-Item Short Form Health Survey (SF-12).¹⁰ Moreover, a standardized clinical examination evaluated the range of motion of the knee, the flexion deficit, and the extension and status of the surgical wound.

Statistical Analysis

The quantitative variables were described as mean and standard deviation (SD), and the qualitative variables were expressed as absolute frequency and percentages. To test differences between the groups regarding the quantitative variables, the Student t test was used for independent samples; alternatively, the Mann-Whitney U test was used when appropriate. The effect size was analyzed by the Cohen d test, and the following classification was adopted for interpretation: between 0.20 and 0.49, small; between 0.50 and 0.79, moderate; ≥ 0.80 , high.¹¹ To test differences between proportions, the Fisher exact test was used, while the Cramer V test measured the effect size, with the following interpretative classification: between 0.10 and 0.29, small; between 0.30 and 0.49, moderate; ≥ 0.50 , high.¹¹ Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. All of the analyses were performed with SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA). A p value < 0.05 was adopted for statistical significance.

Results

Between August 2015 and June 2016, 45 tibial plateau fractures were admitted and included in the study. A total of 11 patients were excluded: 7 had been submitted to the surgical treatment using only screws, 1 due to an associated femoral condylar fracture, 1 had been conservatively treated, and 2 for insufficient recorded data. From the initial sample of 34 patients, 2 did not attend the interview and, thus, the sample has 32 patients (94% follow-up) (►Fig. 3). The mean follow-up time was of 15.1 ± 4.8 months (ranging from 8 to 26 months).

Demographics data about the studied groups and their fractures are listed in ►Table 1. Groups A and B were similar regarding age, gender, affected side, mechanism and fracture type, time until surgery, and follow-up time ($p > 0.05$). However, from a practical standpoint, it seems to exist a relationship of moderate magnitude between fracture severity and implant type ($p = 0.12$; $V = 0.31$). Considering implant type as the outcome and fracture severity as the

exposure factor, 80% of the patients presenting with Schatzker types V and VI fractures had an implant with a locked plate versus 50% of the patients with Schatzker types I to IV fractures. This means that the chance of the surgeons choosing a locked plate implant is 4 times higher in patients with Schatzker types V and VI fractures than in patients with Schatzker types I to IV fractures (OR = 4.00; 95% CI: 0.83–19.32). Although not statistically significant, this result, from a practical point of view, has a high magnitude effect according to the Cramer V classification.

In group A, 22 patients (69%) received a locked plate, at a total hospital cost of BRL 90,758.60 (average value = BRL $4,125.39 \pm 1,634.79$ /patient) for the implants. In group B, 10 patients (31%) received a conventional plate, at a total hospital cost of BRL 4,385.36 (average = BRL 438.53 ± 161.80 /patient) for the implants, as shown in ►Fig. 4. The difference between the hospital costs for the two types of implants was statistically significant ($p < 0.00001$).

Data regarding hospitalization and surgical procedures are presented in ►Table 2. There were no statistically significant differences between the groups regarding the duration of the hospital stay, the number of used plates, and the number of access routes, as well as regarding complications and the requirement of a reoperation ($p > 0.05$).

►Table 3 presents data from the radiological evaluation. There were no statistically significant differences regarding consolidation time, tibial angles at the immediate postoperative period, and signs of gonarthrosis ($p > 0.05$). However, the locked group (group A) presented a higher joint depression compared with the conventional group (group B) ($2.7 \text{ mm} \pm 3.3 \text{ mm}$ versus $0.5 \text{ mm} \pm 1.6 \text{ mm}$, respectively; $p = 0.02$; TE = 0.90). From a practical standpoint, this difference has a high magnitude.

►Table 4 presents clinical, functional, and quality of life results. There were no statistically significant differences in the functional, pain, and quality of life evaluations ($p > 0.05$).

►Table 5 shows the social and economic impacts of the surgery. There were no statistically significant differences between the groups regarding the mean time off work and the frequency of return to work ($p > 0.05$).

Discussion

Our study confirmed the impression that surgeons tend to choose locked plates in more severe fracture patterns. Although it did not reach statistical significance, this data confirms the findings described in a recent meta-analysis.¹²

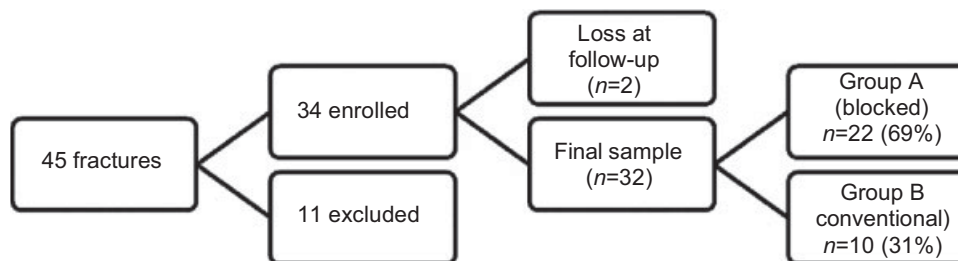


Fig. 3 Study follow-up sample.

Table 1 Demographics and fracture type in patients with tibial plateau fractures submitted to locked or conventional plate osteosynthesis

Factor	Locked group (n = 22)	Conventional group (n = 10)	All (n = 32)	p-value
Age (years old)	45.9 ± 12.8	46.3 ± 16.4	46.1 ± 13.7	0.95 ^a
<i>Gender</i>				
Male	14 (64%)	09 (90%)	23 (72%)	0.21 ^b
Female	08 (36%)	01 (10%)	09 (28%)	
<i>Affected side</i>				
Left	12 (54%)	04 (40%)	16 (50%)	0.7 ^b
Right	10 (46%)	06 (60%)	16 (50%)	
<i>Mechanism</i>				
Motorcycle	10 (46%)	05 (50%)	15 (47%)	0.37 ^b
Running over	03 (14%)	04 (40%)	07 (22%)	
Fall from height	02 (09%)	00 (0%)	02 (6.3%)	
Car	01 (4%)	01 (10%)	02 (6.3%)	
Fall from own height	04 (18%)	00 (0%)	04 (12.5%)	
Other	02 (09%)	00 (0%)	02 (6.3%)	
<i>Type</i>				
Unicondylar (Schatzker I–IV)	06 (28%)	06 (60%)	12 (37.5%)	0.12 ^b
Bicondylar (Schatzker V–VI)	16 (72%)	04 (40%)	20 (62.5%)	
Time until surgery (days)	13.5 ± 7.8	12.5 ± 7.1	13.2 ± 7.5	0.73 ^a
Follow-up time (months)	15.2 ± 5.2	14.8 ± 3.8	15.1 ± 4.8	0.84 ^a

^aValues calculated with the Student t test.

^bValues calculated with the Fisher exact test.

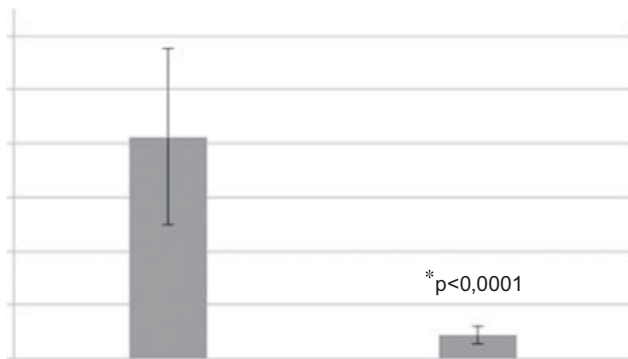


Fig. 4 Average implant cost in patients with tibial plateau fractures submitted to locked or conventional plate osteosynthesis. (*statistically significant difference, $p < 0.05$).

In that paper, no differences were observed between clinical, functional, and quality of life results between patients receiving both types of implants. Our study reached the same conclusion, except regarding the costs of the implants.

The direct costs of the locked plates for the hospital were significantly higher compared with the costs of the conventional plates (approximately 10-fold) ($p < 0.0001$). This finding was also reported in other types of fractures.^{13,14} A study comparing the surgical treatment of olecranon fractures showed an average increase of US\$ 1,263.50 in the costs

for patients receiving locked plates.¹³ In the knee, this financial difference was also found, reinforcing the need to discuss the actual indication of this type of implant.¹⁴

The SUS, with an exceedingly outdated procedural price list, currently allocates only BRL 252.08 to pay for the hospital care of these fractures; as such, we consider that the indiscriminate use of these implants is not feasible, since the deficit per patient (considering only the cost of the implant) would be BRL 3,873.81. In fact, our study proves that the value paid by the system does not even cover the costs of the conventional implants. Therefore, in the current scenario, special implants should only be used in cases in which they are really essential, even though the recent literature does not present absolute indications for locked implants,^{6,14} reinforcing the gap regarding their availability at the SUS.

In our study, the evaluation of surgical patients from both groups revealed that clinical, functional and radiological results were similar, like other studies from the literature.^{14,15} In a comparison of Schatzker type II fractures,¹⁴ there were no differences between both plates, except for the cost. However, this study did not evaluate quality of life or time off work. Our study shows that, besides the lack of difference in the initially mentioned parameters, the use of locked plates did not evoke significant differences in the quality of life or time off work. The limited number of our sample did not allow, however, a stratification to identify

Table 2 Hospitalization and surgery characteristics in patients with tibial plateau fractures submitted to locked or conventional plate osteosynthesis

Factor	Locked group (n = 22)	Conventional group (n = 10)	All (n = 32)	p-value
Hospitalization time (days)	17.9 ± 10.5	13.7 ± 7.0	16.6 ± 9.6	0.25 ^a
<i>Number of plates</i>				
One	13 (59%)	07 (70%)	20 (62%)	0.7 ^a
Two or more	09 (41%)	03 (30%)	12 (38%)	
<i>Number of access routes</i>				
One	13 (59%)	07 (70%)	20 (62%)	0.42 ^a
Two	09 (41%)	03 (30%)	12 (38%)	
<i>Complications</i>				
Yes	01 (4.5%)	01 (10%)	02 (6.3%)	0.53 ^b
No	21 (95.5%)	09 (90%)	30 (93.7%)	
<i>Reoperations</i>				
Yes	03 (13.5%)	00 (0%)	03 (9.4%)	0.53 ^b
No	19 (86.5%)	10 (100%)	29 (90.6%)	0.25 ^a

^aValues calculated with the Student t test.^bValues calculated with the Fisher exact test.**Table 3** Radiographic evaluation of patients with tibial plateau fractures submitted to locked or conventional plate osteosynthesis

Factor	Locked group (n = 22)	Conventional group (n = 10)	All (n = 32)	p-value
Consolidation time (days)	71.9 ± 23.1	68.5 ± 16.1	70.8 ± 20.9	0.67 ^a
Articular depression	2.7 ± 3.3	0.5 ± 1.6	2.0 ± 3.1	0.02 ^{b,c}
Tibial articular angle (anteroposterior) (°)	3.5 ± 4.3	2.7 ± 4.0	3.2 ± 4.2	0.19 ^a
<i>Signs of gonarthrosis</i>				0.1 ^d
Yes	10 (45%)	01 (10%)	11 (35%)	0.67 ^a
No	12 (65%)	09 (90%)	21 (65%)	0.02 ^{b,c}

^aValues calculated with the Student t test.^bValues calculated with the Mann-Whitney test.^cStatistically significant difference, $p < 0.05$, according to the Mann-Whitney test.^dValues calculated with the Fisher exact test.

specific subgroups of patients who could potentially benefit from locked implants.

The demographics of our patients are similar to those presented by other studies. The main cause of fractures was traffic accidents (76%), and the mean age was 46 years old. In another Brazilian study,¹⁶ the main trauma mechanism was the same, and the mean age was 45.5 years old, supporting the external validation of our results. These findings implicate that these fractures have a relevant socioeconomic impact, since they often affect adults in working age and cause prolonged time off work. The mean work return rate was 72.7% until the end of our follow-up, supporting these findings. In fact, a prospective, randomized, multicentric trial demonstrated that, after 24 months, only 30% of the patients reported a complete return to their previous level of activity.¹⁷

Some studies demonstrate that the main effect related to the prognosis of these fractures is the quality of joint reduction,

and that joint deviations > 2.5 mm are associated with worse outcomes.¹⁵ In our study, an average deviation was deemed acceptable (1.9 mm), although the mean value in the locked plate group was marginally higher. In fact, there was a significant difference between the deviations observed in the locked and conventional groups, favoring conventional implants. This finding is similar to the one reported by Abghari et al,¹⁴ which attributed this worse reduction to the indirect technique used in cases treated by the minimally invasive route (common at locked implants). Moreover, in our casuistry, a higher prevalence of bicondylar fractures at the locked plate group (non-significant) could have some relation with this finding.

In our study, 11 patients presented signs of gonarthrosis (34%) after an average follow-up period of 15 months. This incidence is similar to that reported in a study published in 2016,¹⁸ although the follow-up time was not sufficient to identify all of the cases with this evolution.¹⁹

Table 4 Clinical, functional, and quality of life outcomes in patients with tibial plateau fractures submitted to locked or conventional plate osteosynthesis

Factor	Locked group (n = 22)	Conventional group (n = 10)	All (n = 32)	p-value
<i>VAS</i>				
Mild	13 (57%)	07 (70%)	20 (62%)	0.87 ^a
Moderate	05 (24%)	02 (20%)	07 (22%)	
Intense	04 (19%)	01 (20%)	05 (16%)	
<i>SF-12</i>				
SF m	21.4 ± 6.2	24.2 ± 3.6	22.3 ± 5.6	0.13 ^a
SF f	16.3 ± 3.7	16.8 ± 4.2	16.5 ± 3.8	0.74 ^a
SF t	37.8 ± 8.3	41.0 ± 7.5	38.8 ± 8.1	0.3 ^a
<i>Lysholm</i>				
Excellent and good	12 (54%)	07 (70%)	19 (59%)	0.7 ^a
Regular and bad	10 (46%)	03 (30%)	13 (41%)	
Range of motion	121.4 ^o ± 21.9 ^o	129.0 ^o ± 19.1 ^o	123.8 ± 21.1	0.35 ^b
Flexion deficit	12.3 ^o ± 17.2 ^o	9.0 ^o ± 15.9	11.3 ± 16.6	0.61 ^b
Extension deficit	4.6 ^o ± 6.7 ^o	2.0 ^o ± 4.2 ^o	3.8 ± 6.1	0.28 ^b

Abbreviations: SF-12, 12-item short form health survey; VAS, visual analogue scale for pain.

^aValues calculated with the Fisher exact test.

^bValues calculated with the Student t test.

Table 5 Socioeconomic impact in patients with tibial plateau fractures submitted to locked or conventional plate osteosynthesis

Factor	Locked group (n = 22)	Conventional group (n = 10)	All (n = 32)	p-value
<i>On work leave</i>				
Yes	14 (63%)	8 (80%)	22 (68%)	0.78 ^a
No	2 (9%)	0 (0%)	2 (06%)	
Retired	6 (28%)	2 (20%)	8 (26%)	
Time of absence (days)	211.3 ± 126.5	174.3 ± 97.1	196.1 ± 113.5	0.53 ^b
Able to return to work (yes/%)	8 (50%)	7 (87.5%)	15 (62.5%)	0.39 ^a

^aValues calculated with the Fisher exact test.

^bValues calculated with the Student t test.

The present study has a series of limitations. First, its retrospective nature prevented the randomization of the patients, which would increase the homogeneity of the groups. However, since it evaluated procedures performed in an actual context, its findings have a higher probability of external validity and of representing measures of therapeutic efficacy. Another negative point was the limited number of patients, which prevented the exploration of subgroups in which the potential benefits of the locked implants could be identified. Nevertheless, the statistical analysis showed a low correlation between AVS and Lysholm scores and the type of implant, indicating that the lack of significance is not related to a beta error type (lack of power or insufficient sample). Notwithstanding, our findings demonstrate that, for the reality of our hospital, the costs of locked implants for tibial plateau fractures are prohibitive and that, initially, the use of conventional

implants did not have radiological, clinical, functional or quality of life results which were inferior to special locked implants. This does not mean, however, that this implant type is expendable, since it can be required in specific surgical indications and it seems to be well accepted among surgeons.

Conclusion

We have observed that the costs of locked implant for the treatment of tibial plateau fractures are significantly higher when compared with those of the conventional implants, but with no clinical, radiological, functional or quality of life advantage for the patients in our sample.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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