Pain and Satisfaction Levels upon Removal of External Fixator at an Outpatient Facility*

Nível de satisfação e dor na retirada de fixador externo em um ambulatório

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Abstract

Objective To quantify the levels of satisfaction and pain of patients submitted to external fixation removal without anesthesia at an outpatient facility.

Methods The present was a prospective study involving 28 patients using external fixators who answered 3 questionnaires associated with the Visual Analogue and Numerical Pain Scale during different moments of the removal.

Results The average pain prior to fixator removal was of 3.61. Shortly after the procedure, the patients reported that, on average, the most intense pain scored 6.68, and the least intense pain, 2.25 points. The average pain variation was of 4.43 points, and pain after 1 week scored, on average, 2.03 points. The recollection of the pain after fixator removal scored lower than the pain reported immediately after the procedure (mean value: 5.29). Most patients were middle-aged men, and 89.3% used circular external fixators. The main limb segment involved was the leg, and most patients (71.4%) had never used an external fixator before; they preferred the removal at an outpatient facility because it was faster (75%), and to avoid hospitalization (25%). The most intense pain was felt during the removal of Schanz pins (60.7%), being worse in the extremities of the limbs for 75% of the patients. An absolute majority of 85.7% was satisfied with the removal, and 82.1% stated that they would undergo the procedure again.

Conclusion External fixator removal at an outpatient facility without anesthesia is a well-tolerated option for patients, with good levels of approval and satisfaction.

Keywords

- external fixators
- Ilizarov technique
- pain
- outpatient clinics, hospital
- patient satisfaction

Resumo

Objetivo Quantificar os níveis de satisfação e dor dos pacientes submetidos a retirada ambulatorial de fixadores externos sem anestesia.

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Métodos Estudo prospectivo envolvendo 28 pacientes usando de fixadores externos submetidos a três questionários associados à Escala Visual Analógica e Numérica da dor durante diferentes etapas da retirada.

Resultados A média de dor prévia à retirada foi de 3,61. Logo após o término do procedimento, encontramos média de 6,68 para a dor mais intensa, e de 2,25 para a dor menos intensa. A variação da dor média foi de 4,43, e a dor após uma semana teve média de 2,03. A lembrança dolorosa da retirada foi menor do que a dor referida imediatamente após a retirada (média de 5,29). A predominância no estudo foi de pacientes do sexo masculino de meia-idade, e 89,3% usavam fixador externo do tipo circular. O principal segmento dos membros envolvido foi a perna, e a maior parte dos pacientes não havia feito uso do fixador externo previamente (71,4%); eles optaram pela retirada ambulatorial por se tratar de opção mais rápida (75%), e para evitar internação hospitalar (25%). O momento de dor mais intensa ocorreu durante a retirada dos pinos de Schanz (60,7%), sendo pior nas extremidades dos membros para 75% dos entrevistados. Uma maioria absoluta de 85,7% mostrou-se satisfeita após a retirada, e 82,1% afirmaram que se submeteriam novamente ao procedimento.

Conclusão A retirada ambulatorial de fixadores externos sem anestesia é uma opção bem tolerada pelos pacientes, tratando-se de um procedimento com bons níveis de aceitabilidade e satisfação.

Palavras-chave
- fixadores externos
- técnica de Ilizarov
- dor
- ambulatório hospitalar
- satisfação do paciente

Introduction

External fixators are a group of devices that provide rigidity or stability to bone structures through the percutaneous implantation of wires and pins.[1] Ilizarov[2] introduced a circular fixator in which multiple pieces form a final assembly that strictly respects limb anatomy. It is a complex and laborious therapeutic method, and it should consider the patient's opinion, choice, socioeconomic conditions and psychological characteristics.

One of the main questions of the patients regarding the treatment with an external fixator is its duration. The patient is often concerned not only with the end of illness, but also with the prolonged treatment time. The desire to remove the external fixator is frequent, not only due to the inconvenience and limitations regarding daily activities, but also due to the visual impact on social life. These fixators are strongly associated with depression, social isolation and negativity, especially in the adolescent population.[3,4]

Since patients are eager to remove the external fixator and due to the difficulty in scheduling surgery at the Brazilian Unified Health System (Sistema Único de Saúde, SUS, in Portuguese), we proposed fixator removal at an outpatient facility, with great acceptance. This is an interesting alternative considering the growing pressure to reduce costs and improve efficiency without compromising patient care.[5] In addition, this method is also employed in several developed countries.[5,6]

Thus, we intend to quantify the satisfaction and pain levels of patients submitted to external fixator removal at an outpatient facility, without anesthesia. We hope to show that this method is based on concretely positive results, and it is safe, effective and a preferred choice on the part of the patients.

Materials and Methods

The research project was approved by the Ethics in Research Committee of Universidade Federal de São Paulo under number 66861517.0.0000.5505. The present is a prospective study involving 28 patients using linear, biplanar and circular external fixators with pins of all sizes and shapes, in addition to 1.5 and 1.8 Kirschner wires, applied to the lower limbs. Patients with hydroxyapatite-coated pins (due to the increased extraction torque when compared to the insertion torque,[7] causing uncontrollable pain) or olive wires, as well as children under 12 years of age, were excluded from the sample.

Neither the surgeon nor the technique were considered, but asepsis and antisepsis were strictly observed, and no prior anesthetic agent was used. The patients were instructed about the possibility of fixator removal at the operating room under sedation, and only those individuals who voluntarily opted for fixator removal at the outpatient facility were included in the study. The right to withdraw from the study or to interrupt the procedure at any time was duly emphasized. After signing the informed consent form, two questionnaires for acute pain evaluation were presented by the physician; the first one was applied before, and the second one was applied immediately after fixator removal. A third questionnaire was applied one week later, at the patient's return visit to the outpatient facility. The questionnaires consisted of general information from the participants and the external fixation used, associated with the Visual Analog Scale (VAS) pain score for easier understanding and the Numerical Visual Scale pain score, which range from 0 to 10, as objective methods of pain assessment.

For the data analysis, the following software was used: Statistical Package for the Social Sciences (SPSS, IBM Corp., Armonk, NY, US), version 20.0, Minitab 16 (Minitab, LLC,

Table 1 Distribution, analysis and comparison of the answers to questions 1, 2 and 3

Descriptive	Mean	Median	Standard deviation	CV	Q1	Q3	Min	Max	N	IC
Age	40.75	40	19.10	47%	25.3	48.5	15	80	28	7.08
Preremoval	3.61	3	3.19	88%	0.75	6	0	10	28	1.18
Postremoval: worst pain	6.68	7	2.54	38%	5	8.25	0	10	28	0.94
Postremoval: mildest pain	2.25	2	1.82	81%	0.75	3	0	7	28	0.67
Pain variation	4.43	4.5	2.10	47%	3	6	0	10	28	0.78
After 1 week	2.07	1	2.83	136%	0	3	0	10	28	1.05
Removal recollection	5.29	5	2.48	47%	4	6.25	0	10	28	0.92

Abbreviations: CI, confidence interval, CV, coefficient of variation; Max, maximum; Min, minimum; N, number of individuals; Q1, first quartile (up to 25%); Q3, third quartile (up to 75%).

State College, PA, US) and Microsoft Excel 2010 (Microsoft Corp., Redmond, WA, US). A complete descriptive analysis was performed for the quantitative variables. The qualitative variables were analyzed through absolute and relative frequencies, proportional equality tests, and statistical confidence interval (CI) analysis (assumed at 95%); the *p*-value (assumed statistical error) was defined as ≤ 0.05. The data were compared to those reported in the world literature. All results other than the established parameters were detailed.

Results

All patients satisfactorily answered the three questionnaires, which are shown in Attachments 1–3. ►**Table 1** describes the information obtained from the first three questions, and ►**Figure 1** shows the distribution of the CIs for each pain level described in the table.

Most patients were male (78.6%). In total, 89.3% used circular external fixators, 7.1% used biplanar external fixators, and 3.6% used linear external fixators. The left side was affected in 64.3% of the patients, whereas the right side was affected in 32.1%; both sides were affected in 3.6% of the patients. The main segment involved was the leg (in 71.4% of the patients). ►**Figure 2** describes the distribution of limb involvement.

Most patients (71.4%) had never used an external fixator before, and 17.9% had already used such device and had had it removed under anesthesia in the operating room, whereas 10.7% had had it removed at an outpatient facility. Only 3.6% of the participants tried to schedule the removal in the operating room and the procedure was canceled.

In total, 75% of the patients chose to remove the external fixator at the outpatient facility because it was the faster option, whereas 25% reported doing so to avoid hospitalization. Only one individual mentioned other (family) reasons.

The most painful moment during fixator removal was during the removal of the Schanz pins for 60.7% of the patients, during the removal of the wires for 28.6% of the sample, and during the disconnection of the fixator for 10.7% of the patients. Pain was most intense in the extremities of the limbs (metaphyses) for 75% of the patients, and mid-limb (diaphyses) for the remaining 25%. The least painful moment occurred during fixator disconnection for 44.8% of the patients, pin removal for 27.6% of the sample, and wire

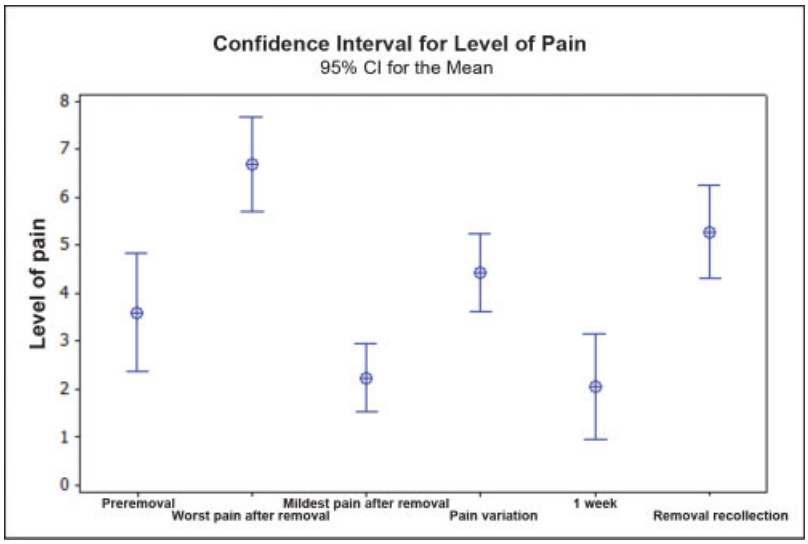

Fig. 1 Distribution of the mean values and their confidence intervals corresponding to each moment of pain assessment during the research.

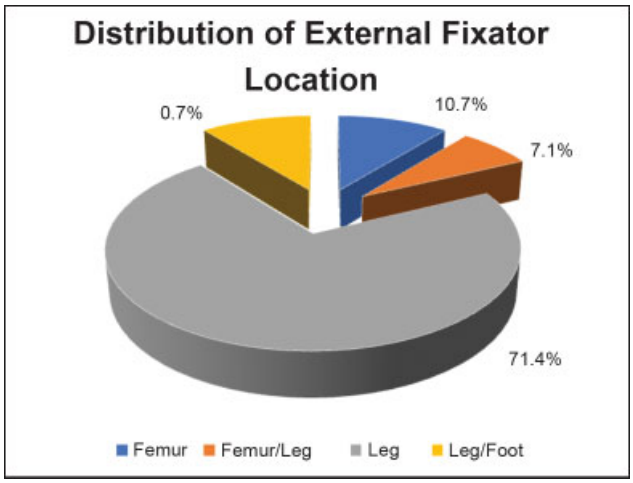

Fig. 2 Distribution of external fixator location among the population of patients included in the study.

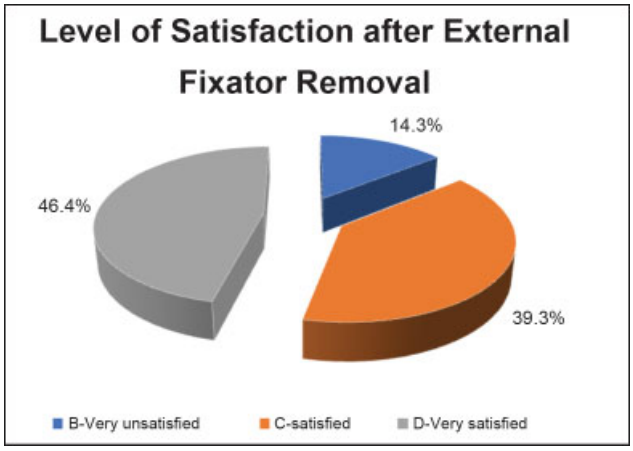

Fig. 3 Distribution of the answers to question 4. There was no statistical difference between the two most frequent answers ($p = 0.168$).

removal for 27.6% of the patients. There was no statistically significant difference between the three alternatives. Satisfaction level after fixator removal is displayed on ►**Figure 3**.

Most patients (82.1%) said they would undergo the procedure again, whereas 17.9% would not repeat it. No analgesia was used during the procedure in 96.4% of the patients (only 1 patient took oral tramadol before fixator removal). There was no apparent relationship between age, gender or fixator location and type.

Discussion

Despite the widespread use of external fixators in the orthopedic practice, very few studies in the literature address their removal. After an extensive review, we found only two studies assessing pain levels during this procedure.[5,6] In 1998, Di Cicco et al[6] reported their experience with the removal of external fixators using Schanz pins from tibias. In total, 29 fixators were removed in the operating room, and 30 were removed at an outpatient facility without anesthesia. A total of 24 patients (80%) submitted to the outpatient removal rated their pain as lower than 25% of the maximum score at the VAS. The total cost of the procedure in the operating room was of US$2,160, while the outpatient procedure cost was of US$248, and the authors concluded that because of cost savings and patient satisfaction, the outpatient clinic was their place of choice for the removal of external fixators.[5]

In 2007, Ryder and Gorczyca[5] evaluated a total of 106 patients who underwent outpatient external fixator removal without anesthesia (113 procedures). On average, pain was scored 3.6 on a scale from 0 to 10, and 95 patients (89.6%) would undergo the procedure again. Despite the association between local inflammation at the Schanz pin implantation site and higher pain levels found in 44 patients, 37 of them (84%) would repeat the procedure with no anesthesia. The authors concluded that the outpatient removal of external fixators without anesthesia is well-tolerated by most patients, even in the presence of pin-related inflammation.

The findings from both previously mentioned studies are compatible with those found in the present study. The visual numeric scale pain score, a discontinuous numerical range-based classification method,[8] and the most commonly used instrument to measure pain intensity, was employed. It is a valid and reproducible methodology, requiring little time, and it can be applied virtually anywhere.[9]

The pain reported ranged from 0 to 10 at all time points, except for the mildest pain immediately after the external fixator removal procedure (when it ranged from 0 to 7). No patient asked to stop the procedure at any moment.

The average pain before removal was of 3.61 points. Immediately after the procedure, the worst pain scored, on average, 6.68, and the mildest pain, 2.25 points. The difference between the patients' reported baseline and the worst pain was of only 3 points. The recollected pain was lower than the pain reported shortly after fixator removal (mean value: 5.29).

Most patients (89.3%) used circular external fixators, and, in 17.8% of them, 2 body segments were involved. This implies large assembly processes with multiple components, resulting in longer and more complex removal procedures. A total of 5 patients (17.9%) would not undergo outpatient removal with no anesthesia again due to the high levels of pain. Among these patients, only two had previously been submitted to fixator removal in the operating room with anesthesia. Most of them opted for outpatient external fixator removal because it was a faster option (75%). An absolute majority of 85.7% of the patients were satisfied after the removal; in addition, most individuals (82.1%) said they would undergo the procedure again.

It is important to remember the psychosocial impact that external fixation has on patients. Long-term treatment can lead to psychological effects and increased risk of developing mental health issues, such as depression, anxiety and irritability; in addition, this stress can negatively contribute to diseases, including hypertension, chronic pain, strokes and cancer.[10]

In a literature review on the impact of external fixation in adolescents, Patterson[4] found that depression was universally evident on multiple levels, with some suicidal ideas and self-destructive behavior, although mostly transient. Social

isolation and eating and sleeping disorders have also been reported. All of these studies reported psychological and behavioral changes after the use of external fixators.[4]

The higher stress levels associated with external fixators, especially Ilizarov external fixators, were probably due to the fact that these devices strongly affected the patients' sleep and daily life.[11] Although the patients were informed about the inconvenience before surgery, the problems regarding daily activities and sleep exceeded their expectations.[10]

Treatment planning is challenging, since it must provide the safe and fast resolution of the bone condition with the smallest possible effect on the patient's mental health.[10] The long lines for surgical implant removal in many services and the patient's desire to have the device removed as soon as possible are important factors to consider in the decision-making process.

Other notable advantages of the procedure are the minimization of anesthesia-related risks and the reduction in financial costs. In 2000, the average cost for SUS hospitalization due to external causes was of R$503.70 for an average period of 4.98 days in Brazil; in the state of São Paulo, the average cost was of R$562.24 for an average period of 4.68 days. On average, the daily cost of hospitalization for external causes was of R $101.23 in Brazil, and of R$120.23 in the state of São Paulo.[12] Considering these data and the fact that outpatient implant removals use the same instruments and preparation as those performed during hospitalization, require fewer professionals, and do not need more expensive medications and anesthetic support, it is easy to infer that the outpatient procedure is much cheaper than its in-hospital counterpart.

Although the present is a study with level V of evidence, it addresses a topic that is scarcely explored in the international literature, with no previous Brazilian reports. However, it has many limitations, such as the approach to fixators only in the lower limbs, the absence of a comparative control group, and the small number of participants, resulting in high variability (coefficient of variation higher than 50%) of some evaluated variables and heterogeneous data. We should also remember the biases inherent to the use of questionnaires in scientific studies. Further research on the financial impact and validated quantification of patient satisfaction levels may help define the advantages of the outpatient removal of external fixators.

Conclusion

External fixator removal at an outpatient facility without anesthesia is a well-tolerated option for patients, with good levels of approval and satisfaction.

Conflict of Interests
The authors have no conflict of interests to declare.

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Attachment 1 – External fixator pre-removal questionnaire

Name: _____

Age: _____

Gender: ☐ M ☐ F **RR (registration number):** _____

External fixator: ☐ LINEAR ☐ BIPLANAR ☐ CIRCULAR

Location: ☐HUMERUS ☐FOREARM ☐FEMUR ☐LEG ☐FOOT

Side: ☐ RIGHT ☐ LEFT

1) Have you ever used an External Fixator? If **YES**, was it removed at an Outpatient Facility or in the Operation Room under anesthesia?

☐ NO ☐ YES

_____

2) Was there an attempt to schedule fixator removal in the Operation Room and the procedure was not performed for some reason?

If **YES**, how long ago?

☐ NO ☐ YES

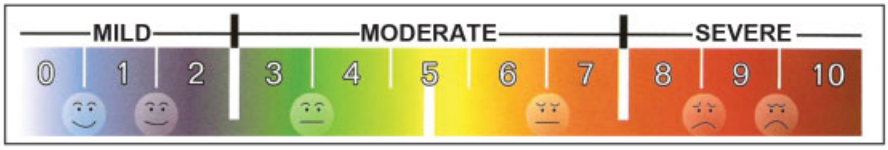
_____

3) Why did you choose to have the external fixator removed at an Outpatient Facility?

☐ It is faster ☐ To avoid anesthesia ☐ To avoid hospitalization

☐ Other reason (please specify):

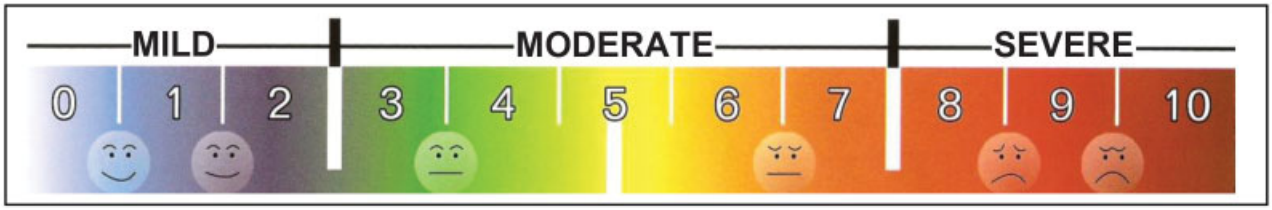
_____



4) What is your current pain level? (**According to the scale above**):

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

Attachment 2 - External fixator post-removal questionnaire



1) What was the variation in the pain level during removal? Please consider a score for the **Worst** pain and a score for the **Mildest** pain. (**According to the scale above**):

Worst pain:

☐0 ☐1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐6 ☐7 ☐ 8 ☐ 9 ☐10

Mildest pain:

☐0 ☐1 ☐ 2 ☐3 ☐4 ☐ 5 ☐ 6 ☐7 ☐8 ☐9 ☐10

Variation (worst pain score minus mildest pain score): _____

2) When was the pain at its **worst level**?

☐ Pin removal ☐ Wire removal

☐ When the equipment was disconnected

3) Where was the pain at its **worst level**? (Point out)

☐ Limb extremity (metaphysis) ☐ Mid-limb (diaphysis)

4) When was the pain at its **mildest level**?

☐ Pin removal ☐ Wire removal

☐ When the equipment was disconnected

5) Where was the pain at its **mildest level**? (Point out)

☐ Limb extremity (metaphysis) ☐ Mid-limb (diaphysis)

6) What is your satisfaction level after the removal?

☐ Unsatisfied ☐ Very unsatisfied ☐ Satisfied ☐ Very satisfied

7) If required, would you go through the procedure again? (Why?)

☐ YES

_____

☐ NO

_____

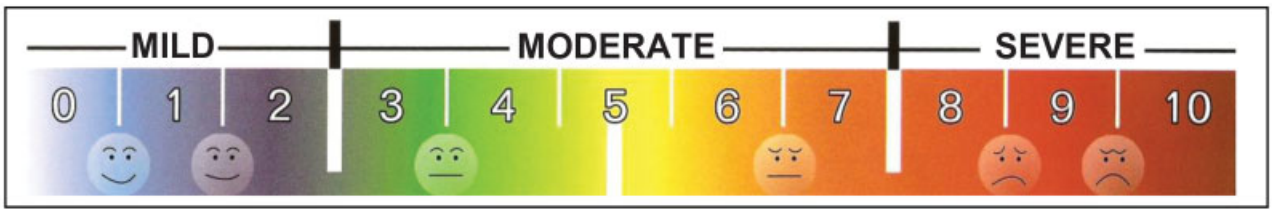
8) Was there any kind of analgesia during fixator removal?

☐ YES (please specify)

_____via_____

☐ NO

Attachment 3 – Outpatient return visit questionnaire:
1 week after external fixator removal



1) What is your current level of pain? (**According to the scale above**):

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

2) Evaluate today the level of pain you felt during fixator removal, one week ago

(pain recollection, **according to the scale above**):

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10