ORIGINAL ARTICLE

Patient-reported Outcome and Quality of Life after Treatment with External Fixation: A Questionnaire-based Survey

Shuhei Ugaji[1], Hidenori Matsubara[2], Satoshi Kato[3], Yasuhisa Yoshida[4], Tomo Hamada[5], Hiroyuki Tsuchiya[6]

Abstract

Background: This survey aims to assess the satisfaction of patients who have had treatment using external fixation (EF).

Materials and methods: An original questionnaire and a Short Form 36 (SF-36) were distributed to 121 patients who underwent treatment using EF for deformity correction and lengthening between 2006 and 2016. A multivariate analysis was performed on the factors associated with satisfaction.

Results: Sixty patients returned a response. The average satisfaction score was 83.6 points. In the 5-point satisfaction survey, 43 of 60 patients (71.7%) responded "very satisfied" or "satisfied" and 27 patients (45.0%) responded "yes" to the question as to whether they would request EF treatment again if presenting with the original preoperative condition. In addition, the subjectively expressed tolerance for having an external fixator device on the limb was 92.1 days on average. A correlation was established with the ISOLS score.

Conclusion: The top three factors that determined subjective inconvenience with EF are pain, walking, and heaviness. Although EF treatment was stressful, the satisfaction scores were high. Furthermore, the satisfaction with EF treatment was improved by (1) pain control, (2) shortening the EF period, and (3) psychological support.

Keywords: External fixators, Pain, Patient satisfaction, Surveys and questionnaires, Taylor Spatial Frame, Walking.

Strategies in Trauma and Limb Reconstruction (2021): 10.5005/jp-journals-10080-1519

Introduction

This study reveals that the site of wearing EF and EFP did not affect the satisfaction level. Overall, this study reveals that the satisfaction with EF treatment could be elevated by pain control, shortening the EFP, and mental care.

Despite being a highly effective tool for correction and lengthening, the use of an external fixator (EF) is cumbersome for patients.[1-3] Recently, where lengthening without deformity correction is required, an upsurge in the use of intramedullary lengthening nails (PRECICE Nail®) has been seen[4,5] in other countries; however, such devices are not approved for use in Japan by the insurance systems. This results in a dependence on EF for lengthening and deformity correction.

Patients treated with EF are concerned about the potential discomfort, limited mobility, and need for care over the several months[6] in external fixation. In the assessment of outcomes of external fixation-based treatment, Harris et al. reported that surgeons' satisfaction was driven by objective data which did not correlate with patients' satisfaction.[7] This prompts for the investigation of outcomes pertinent to patients' satisfaction.[8] This study aims primarily to investigate the health-related quality of life (QOL) and patient-reported satisfaction after lengthening and deformity correction using EF. In addition, this study assesses the types of burden during treatment with EF and factors affecting treatment efficacy.

Materials and Methods

Study Design and Participants

This was a questionnaire-based survey in which 121 patients (68 males, 53 females, age; mean 60, 7–73) who underwent correction or lengthening of lower-limb deformities using the Taylor Spatial Frame® between 2006 and 2016 were enrolled. Patients who were treated during the inclusion period but records did not hold correspondence addresses were excluded. This research was approved by the IRB of the authors' affiliated institutions.

Questionnaire

In September 2016, questionnaires were mailed to patients from demographic data obtained from the hospital records. The questionnaire included items from the Japanese version of the Short Form 36 (SF-36)[9,10] to assess the health-related QOL. The measures were summarized under the following three headings of the SF-36: physical component score (PCS), mental component score (MCS), and role component score (RCS); each summary was scored to have a mean of 50 and a standard deviation of 10, based on the mean established in 2007 from healthy Japanese individuals.[11] The higher the component score relative to the Japanese mean of 50, the better the QOL for that section.

For a separate subjective assessment of the overall EF treatment, all patients were asked to select one of the following options:

[1-6]Department of Orthopaedic Surgery, Graduate School of Medical Sciences, Kanazawa University, Kanazawa, Ishikawa, Japan

Corresponding Author: Hidenori Matsubara, Department of Orthopaedic Surgery, Graduate School of Medical Sciences, Kanazawa University, Kanazawa, Ishikawa, Japan, Phone: +81-76-265-2374, e-mail: ortho331@yahoo.co.jp

How to cite this article: Ugaji S, Matsubara H, Kato S, *et al.* Patient-reported Outcome and Quality of Life after Treatment with External Fixation: A Questionnaire-based Survey. Strategies Trauma Limb Reconstr 2021;16(1):27–31.

Source of support: Nil

Conflict of interest: None

(1) very satisfied, (2) satisfied, (3) neutral, (4) dissatisfied, or (5) very dissatisfied. In addition, the following questions were included in the questionnaire: (1) Would you have treatment with EF again if you returned to your presurgical status? (2) For how long can you tolerate external fixation? Further selective questioning included "What was inconvenient when the EF was in place?" with options to be chosen from nine items: "pain", "walking", "toileting", "sitting", "weight-bearing", "bathing", "unable to roll over", "waking up", and "difficulty with strut adjustment".

The ISOLS (International Society of Limb Salvage) scores were also used to assess outcome.[12]

Statistical Analysis

A statistical evaluation on responses to questions and patient factors (age, part of the limb in EF, external fixation period (EFP), numbers of operations, amounts of lengthening, ISOLS score, and SF-36). In addition, a multivariate logistic regression analysis was performed to analyse factors affecting satisfaction. Power analysis was performed *a priori* using the G* Power program (Heinrich Hein University, Dusseldorf, Germany)[13] and post hoc analysis used. The methodology was validated for small sample-size studies. In order to attain a power of 0.95, a minimum group size of 97 was required. One hundred patients were therefore recruited. The data for satisfaction were tested for normality using the Shapiro–Wilk W-test. We inspected the correlation matrix but as there were no variables for which $|r| > 0.9$, all variables were included. In addition to descriptive statistics, potentially influencing variables on the ISOLS score were tested and these included age, part of the limb in EF, external fixation period, operation times, and length gained. These variables were analysed using chi-square test for nonparametric groups. Using the Mann–Whitney *U*-test, the following three patterns were assessed: (1) satisfaction between children (23 cases) and adults (37 cases); (2) satisfaction between the femur (13 cases) and the tibia (35 cases); and (3) factors exhibiting a significant difference between the satisfied or would have EF again (or both) group and the dissatisfied or would not wish to have EF again (or both) group. We focused on factors that led to dissatisfaction or would not wish to have EF again. Statistical Package for the Social Studies version 23.0 software (SPSS Inc., Chicago, Illinois) was used to perform all statistical analyses. Significance was set at $p < 0.05$. CI level was set to 95% with $\alpha = 0.05$.

Results

There were responses from 60 patients (30 males, 30 females, age 34.8 ± 21.9) with an average postoperative duration of 73.4 ± 30.9 months. Nineteen patients were excluded because of missing addresses and another two were excluded as they were still under treatment. The overall questionnaire collection rate was 60%. The diagnoses for which treatment was sought included congenital disease (n = 15, 25%), infected nonunion (n = 11, 18.3%), osteoarthritis (n = 7, 11.7%), bone tumours (n = 6, 10%), malunion (n = 6, 10%), equinus deformities (n = 6, 10%), and other miscellaneous conditions (n = 9, 14.9%) (Table 1). The site of external fixation was the tibia (n = 35), femur (n = 13), ankle (n = 10), and both femur and tibia (n = 2). The average EFP was 213.2 ± 116.9 (range, 21–376) days with the average lengthening 2.6 ± 2.3 (range, 0–9) cm. The average number of operations was 2.6 ± 2.0 (range, 1–13), and the average postoperative ISOLS score was 25.3 ± 11.7 (range, 7–30) points.

Table 1: The disease groups

Disease	*Numbers (%)*
Congenital disease	15 (25.0)
Infected nonunion	11 (18.3)
Osteoarthritis	7 (11.7)
Malunion	6 (10.0)
Bone tumour	6 (10.0)
Equinus foot	6 (10.0)
Bone dysplasia	3 (5.0)
Polio	2 (3.3)
Growth plate injury	2 (3.3)
Metabolic disease	2 (3.3)

Table 2: Patients' demographic data

Response		*(+)60*	*(−)40*	*p value*
	Femur	13	9	
	Tibia	35	26	
	Ankle	10	5	
	Femur and tibia	2	0	
	Mean (SD)		Mean (SD)	
Age (years)	34.8 (23.5)		30.7 (20.2)	0.07
External fixation period (day)	213.2 (102.8)		242.3 (130.1)	0.41
Operation times (times)	2.6 (1.98)		2.8 (2.15)	0.35
Length gained (cm)	2.6 (2.43)		2.4 (2.17)	0.26
ISOLS score	25.3 (14.5)		23.1 (13.6)	0.08

In this study, both respondents and nonrespondents had similar demographic and clinical characteristics (Table 2). The average satisfaction score was 84.1 ± 16.5/100 (range, 30–100) points. Of the 60 patients, 43 (71.7%) responded "very satisfied" or "satisfied", 13 answered "neutral", and 4 answered "dissatisfied" (Table 3). In addition, 27 patients (45%) would undergo EF again if given the same treatment option for the presenting condition. The response to the question "How long can you tolerate external fixation?" averaged 92.1 ± 88.3 (range, 0–365) days. From the SF-36, the average PCS, MCS, and RCS were 42.8 ± 14.3, 54.1 ± 9.9, and 45.8 ± 15.8, respectively. Only the MCS reached the national standard value (Fig. 1). In response to selective questioning, over half of the patients chose "pain", "walking", and "heavy" as reasons of inconvenience from the EF (Table 4). Forty-one patients were "very satisfied" or "satisfied" with the EF treatment. In analysis of the nine patient factors associated with the "satisfied" category using multiple logistic regression analysis, we found the ISOLS score ($R^2 = 0.51$, odds ratio, 3.307, $p = 0.02$; Table 5) to be significant.

There were three additional findings from this study: (1) There was no significant difference in "satisfaction" numbers between children and adults ($p = 0.24$). However, we observed a significant difference in the ISOLS score between satisfied patients and unsatisfied patients in the adult group only ($p = 0.02$); (2) No significant difference was noted in the "satisfaction" ratings for those patients who had EF in the femur or the tibia ($p = 0.65$). The results from selective questioning showed that, for femoral cases,

Table 3: Satisfaction of patients

EF treatment	*Satisfied (n = 43)*	*Dissatisfied (n = 17)*
Very satisfied	14	
Satisfied	29	
Neutral		13
Dissatisfied		4
Very dissatisfied		0

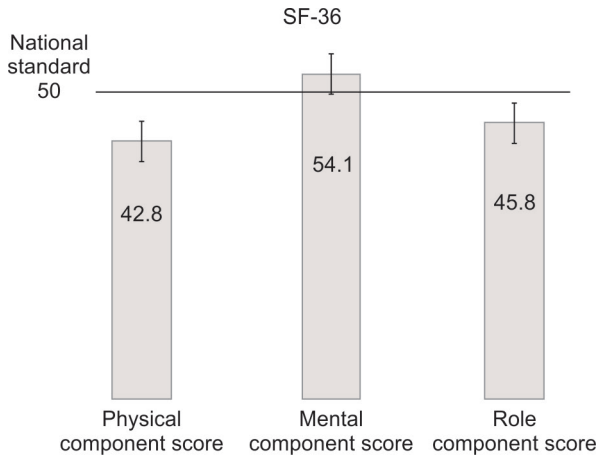

Fig. 1: Results of Short Form 36 (SF-36)

Table 4: Selective questioning on the burden on having an external fixator

Inconvenient while wearing EF	*Whole (n = 60)*	*(%)*	*Femur (n = 13)*	*Tibia (n = 35)*
Pain	36	60.0	7	7
Walking	31	57.4	6	6
Heavy (weight of device)	30	54.4	7	6
Bathing	28	46.4	4	8
Sitting	27	45.0	7	6
Toileting	25	42.6	8	6
Turning over in bed	18	36.8	2	7
Difficulty with strut adjustment	11	23.5	1	3
Interrupted sleep pattern	10	22.0	2	4

eight patients (66.7%) complained of difficulty in using the toilet, and seven described (58.3%) pain and difficulty sitting. The weight of EF (Table 4) was noted in seven complaints. In the tibia, eight patients (21.1%) complained of difficulty in bathing and seven (18.4%) about the pain and difficulty in rolling over in bed. We noted a significant difference in the number of complaints between both groups ($p = 0.01$, χ^2 test). (3) Those patients satisfied or those amenable to the same treatment with EF ($n = 24$) when compared to the dissatisfied group ($n = 13$) showed a significant difference in the ISOLS scores ($p = 0.01$). Furthermore, over half of the dissatisfied patients or those who would have declined treatment with EF again listed "pain" ($n = 8$, 61.5%), "walking" ($n = 9$, 69.2%), and "toilet" ($n = 8$, 61.5%) in response to the selective questions; however, no significant difference was found in these responses when the two groups were compared overall (Table 6).

Table 5: Results of the multiple logistic regression analysis

Factors	*Satisfied (n = 43) (mean (SD))*	*Dissatisfied (n = 17) (mean (SD))*	*Odds ratio (95% CI)*	*p*
Patient factors				
Age (year)	38.3 (20.0)	33.8 (23.7)	0.684	0.236
Operation time	2.2 (1.3)	2.6 (2.2)	2.345	0.280
Extent of lengthening (cm)	2.4 (3.2)	1.4 (1.8)	5.198	0.430
External fixation period (days)	212.8 (115.8)	198.5 (164.8)	3.168	0.267
ISOLS score	26.5 (4.0)	24.0 (7.0)	3.307	0.02
SF-36				
PCS	42.8 (10.4)	49.4 (18.3)	2.274	0.083
MCS	54.1 (9.9)	51.9 (9.3)	4.130	0.195
RCS	45.8 (14.3)	49.3 (14.9)	0.861	0.561
Bone segment				
Femur	10	3		
Tibia	25	10		
Ankle	7	3		
Femur and tibia	1	1		

PCS, physical component score; MCS, mental component score; RCS, role component score; SF-36, Short Form 36

Table 6: Selective question of the burden wearing an external fixator

Inconvenient while wearing EF	*Satisfied and re-wished (n = 24)*	*Dissatisfied and undesired (n = 13)*
Pain	15	8
Walking	11	9
Heavy	12	6
Bath	8	7
Sitting	8	7
Toileting	8	8
Turning over in bed	5	5
Difficulty with strut adjustment	2	2
Interrupted sleep pattern	2	5

Discussion

External fixation-based treatment is used extensively for shortening, managing bone loss, and treating limb deformity.[14-16] Some studies have investigated the degree of satisfaction of EF treatment, but no previous work has explored patient-reported satisfaction or investigated the nature of the specific problems[17] associated with such treatment and whether patients would have EF treatment again. Complaints related to EF mostly stemmed from the "pain" and "size of EF"; the same was true for those who were satisfied and those dissatisfied patients who did not want EF treatment again. The findings of this study corroborate a prior study reporting that physical stress became a concern during EF.[18] These problems could be managed potentially by pain control and reducing the bulk of EF. Pain control is a factor that can be achieved through early medication, but the issue of reducing the bulk of EF is, presently, not possible to solve. Medication such as NSAIDs (celecoxib) is used as the first-line drug; however, based on the pain experienced, acetaminophen may be needed in children and weak opioids in adults. It is also imperative to consider robust

pain control, albeit temporary, in the immediate post-operative period including the use of nerve blocks.[19]

This study is notable for the absence of preoperative ISOLS scores. However, the postoperative scores which report on results and function correlate with satisfaction.[20,21] Age was not a factor in the satisfaction reports from either adults or children. Comparing the ISOLS scores and satisfaction levels in children and adults revealed a strong correlation between the satisfaction levels in adults to the ISOLS score. This may be because adult patients report being satisfied when the treatment outcome is good as there is greater understanding and involvement by the adult in the selection of treatment by EF.

A comparison between the femur and the tibia was made. Before this investigation, we hypothesized a marked difference in the degree of satisfaction between the femur and the tibia because EF application at the femur tends to induce knee contracture[22] and restricts activities of daily living more severely. However, there was no marked difference in the satisfaction score. While an EF on the femur was burdensome to the patient, it did not affect the satisfaction level. Nonetheless, we acknowledge the importance of reducing the time of EF in the femur.

The average EFP (external fixation period) in this study was 215 days. The patients reported that the maximum period they would tolerate an external fixator was 92 days on average, which was 42.8% of the actual EFP. In the context of achieving such wishes for the patient, conversion surgery to another form of fixation (internal) would be necessary to achieve the 92 days as EFP in order to support bone maturation. Reportedly, conversion surgery with a plate or intramedullary nail could be performed at the end of correction or lengthening for achieving the "92-day tolerance" while maintaining the desired quantity of lengthening. This could prove to be an option to shorten the EFP, and, despite concerns, it has a low infection rate.[22]

The patients who underwent treatment by EF understood the requirements upon referral to our hospital. Patients would usually select EF treatment as the last option, but many such referrals to the hospital are either severe or revision cases. Correspondingly, the physical abilities and social activities of these patients are often restricted before treatment. It has been reported that the physical and mental QOL is markedly declined if a limb length discrepancy of ≥2 cm exists.[23] Although this study did not include preoperative ISOLS and SF-36 scores, these were anticipated to be lower than normal before treatment. The post-treatment results of the SF-36in this study revealed only the MCS reached the national standard value. This suggests the treatment had enhanced this aspect of overall health, despite being based on EF. This is contrary to the reports of some studies where the EF treatment was successful at resolving problems of bone defects but exerted a negative impact on the patients' mental health.[24,25] Support for the mental health of the patient during treatment with EF has garnered considerable attention in recent years. Many units offer guidance and counselling to patients, as well as family members, who plan to undergo EF by providing actual photographs and care methods of EF treatment, as well as elucidating EF treatment details.[26] This may help to decrease the EF treatment-related problems.

Limitations

The major limitations of this study are the small sample size and a lack of preoperative ISOLS and SF-36 scores. Furthermore, being a retrospective study, patients' responses are subject to recall bias. Hence, further prospective studies are warranted to validate the findings of this study.

Conclusion

This study shows that both the site of EF and the period of EF did not affect the satisfaction level reported by patients. The top three factors contributing to inconvenience during EF were pain, difficulties walking, and the weight of the device. Satisfaction with EF treatment could be increased by (1) better pain control, (2) shortening the EFP, and (3) support for mental health.

References

1. Tsuchiya H, Tomita K, Minematsu K, et al. Limb salvage using distraction osteogenesis. A classification of the technique. J Bone Joint Surg Br 1997;79(4):403–411. DOI: 10.1302/0301-620x.79b3.7198.
2. Matsubara H, Tsuchiya H. Treatment of bone tumor using external fixation. J Orthop Sci 2019;24(1):1–8. DOI: 10.1016/j.jos.2018.06.022.
3. Watanabe K, Tsuchiya H, Sakurakichi K, et al. Treatment of lower limb deformities and limb-length discrepancies with the external fixator in Ollier's disease. J Orthop Sci 2007;12(5):471–475. DOI: 10.1007/s00776-007-1163-9.
4. Kirane YM, Fragomen AT, Rozbruch SR. Precision of the PRECICE® internal bone lengthening nail. Clin Orthop Relat Res 2014;472(12):3869–3878. DOI: 10.1007/s11999-014-3575-0.
5. Zhang YT, Jin D, Niu J, et al. A meta-analysis of external fixation and flexible intramedullary nails for femoral fractures in children. Acta Orthop Belg 2016;82(4):673–680. DOI: 10.1097/bpb.0000000000000336.
6. Schnidel F, Vogt B, Wacker S, et al. Walking ability of children with a hexapod external ring fixator (TSF®) and foot plate mounting at the lower leg. Gatit Posture 2012;36(3):500–505. DOI: 10.1016/j.gaitpost.2012.05.006.
7. Harris IA, Dao AT, Young JM, et al. Predictors of patient and surgeon satisfaction after orthopaedic trauma. Injury 2009;40(4):377–384. DOI: 10.1016/j.injury.2008.08.039.
8. Kato S, Murakami H, Demura S, et al. Patient-reported outcome and quality of life after total en bloc spondylectomy for a primary spinal tumor. Bone Joint J 2014;96-B(12):1693–1698. DOI: 10.1302/0301-620X.96B12.33832.
9. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30(6):473–483. DOI: 10.1097/00005650-199401000-00004.
10. Fukuhara S, Bito S, Green J, et al. Translation, adaptation, and validation of the SF-36 Health Survey for use in Japan. J Clin Epidemiol 1998;51(11):1037–1044. DOI: 10.1016/s0895-4356(98)00095-x.
11. Tetsworth K, Paley D, Sen C, et al. Bone transport versus acute shortening for the management of infected tibial non-unions with bone defects. Injury 2017;48(10):2276–2284. DOI: 10.1016/j.injury.2017.07.018.
12. Capanna R, Morris HG, Campanacci D, et al. Modular uncemented prosthetic reconstruction after resection of tumor of the distal femur. J Bone Joint Surg Br 1994;76(2):178–186. DOI: 10.1302/0301-620X.76B2.8113272
13. Erfelder E, Faul F, Bauchner A. G power: a general power analysis program. Behav Res Methods Insrtum Comput 1996;28(1):1–11. DOI: 10.3758/bf03193146.
14. Napora JK, Weinberg DS, Eagle BA, et al. Hexapod stacked transport for tibial infected nonunions with bone loss: long-term functional outcomes. J Orthop Trauma 2018;32(1):12–18. DOI: 10.1097/BOT.0000000000001005.
15. Meleppuram JJ, Ibrahim S. Experience in fixation of infected non-union tibia by Ilizarov technique – a retrospective study of 42 cases. Rev Bras Orthop 2016;52(6):670–675. DOI: 10.1016/j.rboe.2016.11.008.
16. Montpetit K, Hamdy RC, Dahan ON, et al. Measurement of health-related quality of life in children undergoing external fixator treatment for lower limb deformity. J Pediatr Orthop 2009;8:920–926. DOI: 10.1097/BPO.0b013e3181c1e2e2.

17. Wang H, Wei X, Liu P, et al. Quality of life and complications at the different stages of bone transport for treatment infected nonunion of the tibia. Medicine (Baltimore) 2017;96(45):e8569. DOI: 10.1097/MD.0000000000008569.
18. Reitenbach E, Rödl R, Gosheger G, et al. Deformity correction and extremity lengthening in the lower leg: comparison of clinical outcomes with two external surgical procedures. Springerplus 2016;5(1):2003. DOI: 10.1186/s40064-016-3666-3.
19. Nishio S, Fukunishi S, Fukui T, et al. Comparison of continuous femoral nerve block with and without combined sciatic nerve block after total hip arthroplasty: a prospective randomized study. Orthop Rev (Pavia) 2017;9(2):7063. DOI: 10.4081/or.2017.7063.
20. Davies AR, Qare JE. Involving consumers in quality of care assessment. Health Aff (Millwood) 1988;7(1):33–48. DOI: 10.1377/hlthaff.7.1.33.
21. Persico F, Varges O, Fletscher G, et al. Treatment of extraarticular knee extension contracture secondary to prolonged external fixation by a modified Judet quadricepsplasty technique. Strat Trauma Limb Reconstr 2018;13(1):19–24. DOI: 10.1007/s11751-017-0302-x.
22. Monni T, Birkholtz FF, Lange DP, et al. Conversion of external fixation to internal fixation in a non-acute, reconstructive setting: a case series. Strat Trauma Limb Recon 2013;8(1):25–30. DOI: 10.1007/s11751-013-0157-8.
23. Vitale MA, Choe JC, Sesko AM, et al. The effect of limb length discrepancy on health-related quality of life: is the '2cm-rule' appropriate? J Pediatr Orthop 2006;15(1):1–5. DOI: 10.1097/01202412-200601000-00001.
24. Abulaiti A, Yilihamu Y, Yasheng T, et al. The psychological impact of external fixation using the Ilizarov or Orthofix LRS method to treat tibial osteomyelitis with a bone defect. Injury 2017;48(12):2842–2846. DOI: 10.1016/j.injury.2017.10.036.
25. Bullens PH, Loon VCJ, Waal MMC, et al. Patient satisfaction after total knee arthroplasty: a comparison between subjective and objective outcome assessments. J Arthroplasty 2001;16(6):740–747. DOI: 10.1054/arth.2001.23922.
26. Landge V, Shibata L, Gesheff M, et al. Patient satisfaction after limb lengthening with internal and external devices. J. Surg Orthop Adv 2015;24(3):174–179. DOI: 10.1007/s11420-017-9596-y