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

Shuhei Ugaji, Hidenori Matsubara, Satoshi Kato, Yasuhsa Yoshida, Tomo Hamada, Hiroyuki Tsuchiya

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.

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. Recently, where lengthening without deformity correction is required, an upsurge in the use of intramedullary lengthening nails (PRECICE Nail®) has been seen 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 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. This prompts for the investigation of outcomes pertinent to patients’ satisfaction. 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) 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. 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) 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 analysis 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.

Descriptive 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 α = 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 ± 146.9 (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.

| 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)     |

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 (R² = 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,
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, χ² test). (3) Those patients satisfied or those amenable to the same 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).

![Fig. 1: Results of Short Form 36 (SF-36)](image)

### 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                  |                       |

### 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                 | 7              | 7              |
| Walking                     | 31                 | 6              | 6              |
| Heavy (weight of device)    | 30                 | 7              | 6              |
| Bathing                     | 28                 | 4              | 8              |
| Sitting                     | 27                 | 7              | 6              |
| Toileting                   | 25                 | 8              | 6              |
| Turning over in bed         | 18                 | 2              | 7              |
| Difficulty with strut adj.  | 11                 | 3              | 2              |
| Interrupted sleep pattern   | 10                 | 2              | 4              |

### Table 5: Results of the multiple logistic regression analysis

| Factors                              | Satisfied (n = 43) (mean (SD)) | Dissatisfied (n = 17) (mean (SD)) | Odds ratio (95% Cl) 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 shortening (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                                |                       |

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

| Inconvenient while wearing EF | Satisfied 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 adj.   | 2                             | 2                                  |
| Interrupted sleep pattern    | 2                             | 5                                  |

### Discussion

External fixation-based treatment is used extensively for shortening, managing bone loss, and treating limb deformity. 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 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. 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...
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 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.

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. 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-36 in this study revealed only the MCS reached to be lower than normal before treatment. The post-treatment discrepancy of ≥2 cm exists.

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.

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