Development and validation of the unifying elective orthopaedic score (UnEOS). A pilot study

ABSTRACT

Keywords:

PROM
Patient reported outcomes
Outcome score
Elective surgery

Background: Patient reported outcome measures (PROMs) are increasingly valued in orthopaedics. There are already many site specific or pathology specific scores. These scores are usually validated for specific pathologies and can be complicated and time consuming to use. The aim of the present pilot study is to develop a new orthopaedic score for elective operations, which measures patient satisfaction simply and quickly, and is not limited to a single site or pathology.

Materials & methods: The UnEOS questionnaire has 16 questions. Eleven questions relate to the three main dimensions (Symptoms, Function, Mental Status) and can be used both preoperatively and post-operatively. Five questions are added to the questionnaire at the postoperative mode, which form the satisfaction dimension. For this pilot study we enrolled all patients listed for surgery from our foot and ankle clinics. Each patient was asked to complete the UnEOS and FADI questionnaires.

Results: A total of 181 questionnaires were collected from patients (aged 56.4 ± 14.8 , range 20–85) with a variety of foot and ankle pathologies. Scores were obtained both pre- and post-operatively. The scale reliability was checked with the Cronbach's Alpha score, which was 0.87 for the UnEOS scale. Each subscale had good reliability with 0.73, 0.77 and 0.76 respectively (Symptoms, Function, Mental Status). The validity of the scale was checked using the Spearman's Rho correlation, which was strong between the UnEOS and the FADI score (0.79) and each subscale (0.7, 0.75 and 0.69 respectively).

Conclusion: The UnEOS score is a valid and easy to use PROM which is not limited by site or pathology. Further validation with other orthopaedic pathologies will lead to a Unified Elective Orthopaedic score.

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1. Background

In the last few years there has been an increased demand for the use of patients reported outcome measures (PROMs) in all surgical specialties, and particularly in orthopaedics. PROMs have been formally used by NHS England as primary outcome measures for hip and knee replacement surgery since 2009.¹

PROMs have been used widely by orthopaedic surgeons to measure their outcomes, and many scores have been developed to fulfil this need. All the orthopaedic scores which have been developed so far are site or pathology specific and are focusing on the impact that this may have on patients' symptoms and function.² Even though the validation of some scores has been performed for specific conditions, they are being used at times for different conditions of the same anatomic body part.

The scores are supposed to be more representative of the patients' overall condition and not the clinical outcome which some scoring systems include.^{3,4} EQ5D and SF-12/SF-36 are PROMs which are focusing on the patient's activity levels and overall quality of life.^{5–7} These questionnaires are often being used to demonstrate the impact some orthopaedic conditions have on the patients' lives or when the patient has more than one condition which may affect their function.

The aim of the present pilot study was to develop and validate a new orthopaedic score, designed for all orthopaedic pathologies, to monitor the evolution of their recovery and measure their satisfaction for their treatment. The questionnaire needs to be easy to use and easy to understand by the patients.

2. Materials and methods

The authors used a previous developed score by the same research group as guide. This score had been previously validated for trauma conditions (The Chertsey Outcome Score for Trauma – COST).⁸ The wording and the aim of the questions have been amended accordingly in order to represent elective orthopaedic conditions and not trauma conditions. After the initial development of the questionnaire by a study group consisting of orthopaedic surgeons/orthopaedic nurses and physiotherapists, the questionnaire was given to ten patients and feedback was collected. The content of the questionnaire was revised, finalised and distributed to all foot and ankle consultants for patient recruitment.

2.1. Questionnaire design

The questionnaire has two modes, the pre-treatment and the

post-treatment mode. The main questionnaire consists of 11 questions, forming three dimensions of the score. This design remained similar to the COST score, but the patients are asked to compare their current status with their perceived normal status.⁸ The three dimensions evaluated included patient symptoms, their function and their mental status. For the first ten questions the 5-point Likert scale was used and for the last question, the patients were asked to grade their current condition from a scale of 0–10 (with 10 being their normal state). This forms the 'pre-treatment mode' of the questionnaire. For the 'post-treatment mode' a fourth dimension consisting of five questions was added. This fourth dimension consists of questions which using the 5-point Likert scale and evaluates the patient's satisfaction about their treatment. The questions are specifically targeted to the most recent orthopaedic intervention (operation), in order to derive the appropriate information from the patients. The questionnaire is presented in the supplement 1 (Suppl. 1).

This design of the Unified Elective Orthopaedic Score (UnEOS) score provides the clinician with valuable information about the main aspects of the patients' perception of their condition. The fact that the same 11 questions are given to the patients before and after treatment leads to an easy way of monitoring the evolution of the patients' condition pre- and post-treatment. The extra satisfaction dimension of the questionnaire provides information about the patients' perception of the treatment received.

To make the questionnaires comparable, two different scores are generated post-treatment. Scores obtained from Questions 1 to 7 – range from 0 to 4 points (with 0 – strongly disagree and 4 strongly agree). Questions 8 to 10 have a negative scoring scale from 0 to 4 points (with 0 being strongly agree and 4 strongly disagree). Question 11 scores from 0 to 10 points (0 – worst state and 10 is the normal state). All the scores are summarised and doubled in order to form the final UnEOS score which ranges from 0 to 100 points (0 points equals the worst outcome and 100 the best outcome). The satisfaction dimension scores individually. All five questions are scored from 0 to 4 points (0 is strongly disagree and 4 is strongly agree). These are summarised and multiplied by 5 in order to derive a final satisfaction score which ranges from 0 to 100 (where 0 is totally dissatisfied and 100 is totally satisfied). Each subscale of the main UnEOS questionnaire (Symptoms, Function, Mental status) can be individually scored as well.

2.2. FADI score

The Foot and Ankle Disability Index (FADI) score⁹ was used as this has been validated for both foot and ankle trauma and elective pathologies. The score ranges from 0 to 100 (with 0 being the worst condition and 100 the best condition), and consists from total 26 questions using the 5-point Likert scale. There are two subscales of this score, the function and the pain (consisting from 22 to 4 questions respectively).

2.3. Patient's recruitment

The recruitment of the patients was performed between December 2017 and July 2018, either in the outpatients clinic (pre-operative or post-operative) or on the day of surgery. There were no restrictions on the recruitment of patients whatever their pathology.

Each patient was asked to complete both the UnEOS questionnaire and the Foot and Ankle Disability Index (FADI) score⁹ for the condition being treated. The patients were encouraged to answer the questions based on their condition over the past fortnight.

2.4. Internal consistency

The internal consistency of the new scale was evaluated by using the Cronbach's alpha test.¹⁰ The scores of Cronbach's alpha can vary from 0 to 1, with values between 0.7 and 0.9 represent high internal consistency.^{11,12} The internal consistency was evaluated for the total UnEOS score and each dimension individually.

2.5. Construct validity

The validity of the new score was evaluated by using non-parametric correlation (Spearman's Rho correlation test). The FADI score and its two dimensions were used for the validation. Strong/moderate correlation was expected between the UnEOS and the FADI score and between the similar dimensions of the scores.¹¹

2.6. Statistical analysis

Statistical analysis was performed by using the SPSS ver. 23.0 statistical program (SPSS Inc, Chicago, IL, USA) and statistical significance was set to 0.05.

3. Results

A total of 200 UnEOS and FADI questionnaires were distributed to the patients. The response rate was 90.5% with total 181 fully completed questionnaires finally collected. Nineteen patients either refused to complete the questionnaires either completed only one of the questionnaires leaving the other blank, these patients were excluded from the study. The average age of the patients was 56.4 ± 14.8 years (range 20–85). Most of the patients were female (63.5%) and majority questionnaires were collected pre-operatively (55%). Table 1 summarises the descriptives of the cohort and the frequencies of the different pathologies. The total UnEOS score of the cohort was 50.6 ± 20.8 . Symptoms, function, mental status and satisfaction subscales had scores 45.3 ± 21.7 , 49.7 ± 23.1 , 56.7 ± 22.2 and 68.3 ± 20.5 respectively. FADI questionnaire scored 64.9 ± 20.5 with the function and pain subscales scoring 65 ± 21.2 and 63.8 ± 22.4 respectively. Table 2 summarises the UnEOS and FADI scores for each individual pathology at the pre-treatment questionnaires. The pre-treatment UnEOS total score of the cohort was 49.6 ± 20.5 and the total FADI score was 62.2 ± 21 .

3.1. Internal consistency

A strong internal consistency was found for the UnEOS questionnaire. The Cronbach's alpha score for the main questionnaire was 0.87. Its items-total correlation was varied from 0.85 to 0.87 (Table 3). Each subscale of the score was evaluated individually and the reliability of each scale was found to be strong. The Cronbach's alpha scores were 0.73, 0.77 and 0.76 for each individual subscale (symptoms, function and mental status respectively).

3.2. Construct validity

Spearman's Rho test was used to evaluate the validity of the new scale. The correlation between the total UnEOS and the total FADI score was strong (Correlation Coefficient = 0.788 with $p < 0.001$). Each subscale of the UnEOS had strong correlation with the total FADI score as well (correlations 0.7, 0.75 and 0.69 respectively for the symptoms, function and mental status subscales). There was a strong correlation between the function dimensions of both scores (0.74) and a moderate correlation between the UnEOS's symptoms subscale and the FADI's pain subscale (0.58).

Table 1
Descriptives of the cohort.

Gender	No	%
Male	66	36.5
Female	115	63.5
Pathology	Frequencies Pre-Operation	Frequencies Post-Operation
Ankle		
<u>Arthritis</u>		
Injection	3	1
Fusion	5	13
Total ankle replacement	7	6
<u>Soft tissue/bony impingement</u>		
Arthroscopic debridement	6	7
<u>Ankle instability</u>		
Lateral Ligament Reconstruction	1	4
Syndesmosis Fixation	1	0
Hindfoot		
<u>Subtalar arthritis</u>		
Injection	7	2
Fusion	2	0
<u>Achilles pathology</u>		
Medial Gastroc Release	1	0
Debridement	2	4
<u>Deformity</u>		
Calcaneus osteotomy	5	4
Coalition Excision	2	1
Midfoot		
<u>Arthritis</u>		
Injection	4	2
Fusion	1	3
Charcot Correction	1	0
Forefoot		
<u>Hallux Valgus</u>		
Correction	17	20
<u>Hallux Rigidus</u>		
Injection	7	0
Chilectomy	4	2
Fusion	4	7
<u>Toe deformity (Hammer/Claw)</u>		
Correction	8	3
<u>Lesser metatarsal pathologies</u>		
Bunionete	2	1
Metatarsalgia/DMMOs	1	1
Morton's neuroma	1	1
Foot metalwork removal	3	0
Misc foot operations not listed	4	0

4. Discussion

This pilot study focuses on the development and validation of the UnEOS questionnaire, by amending and transforming a pre-existing validated score for trauma⁸ to a new score for elective orthopaedic conditions. The development of the questions in this questionnaire focuses on the simplicity of the wording in order to try to derive as much relevant information from the patient as reliably as possible. By using the post-treatment mode of the questionnaire, it is possible to measure the satisfaction the patient has for his treatment. To the authors' knowledge this is the first orthopaedic score that includes such information, which can be really useful for the clinicians.

As there is no other similar to UnEOS questionnaire available in the orthopaedic literature, the decision was made to use the FADI score for the pilot validation. Other questionnaires such as EQ5D

Table 2
Summary of UnEOS and FADI scores for each individual pathology pre-operatively.

Pathology	UnEOS score $\pm$ SD	FADI score $\pm$ SD
Ankle		
<u>Arthritis</u>		
Injection	42.7 $\pm$ 21.4	41.67 $\pm$ 20.54
Fusion	34.4 $\pm$ 11.1	40.2 $\pm$ 17.4
Total ankle replacement	32.3 $\pm$ 6	42.44 $\pm$ 15.3
<u>Soft tissue/bony impingement</u>		
Arthroscopic debridement	43 $\pm$ 13.37	59.78 $\pm$ 20.15
<u>Ankle instability</u>		
Lateral Ligament Reconstruction	34	44.2
Syndesmosis Stabilisation	30	47.1
Hindfoot		
<u>Subtalar arthritis</u>		
Injection	42 $\pm$ 7.4	58.9 $\pm$ 13.5
Fusion	35 $\pm$ 1.4	44.2 $\pm$ 9.5
<u>Achilles pathology</u>		
Medial Gastroc Release	18	47.1
Debridement	46 $\pm$ 16.9	51
<u>Deformity</u>		
Calcaneus osteotomy	50.4 $\pm$ 15.8	56.73 $\pm$ 17.6
Coalition Excision	44 $\pm$ 5.7	58.2 $\pm$ 19.7
Midfoot		
<u>Arthritis</u>		
Injection	41.5 $\pm$ 13.9	55.78 $\pm$ 18.6
Fusion	54	29.8
Charcot Correction	16	—
Forefoot		
<u>Hallux Valgus</u>		
Correction	66.24 $\pm$ 20.94	81.56 $\pm$ 16
<u>Hallux Rigidus</u>		
Injection	48.3 $\pm$ 21.8	58.8 $\pm$ 18.2
Chilectomy	50.5 $\pm$ 29.6	67.9 $\pm$ 21.2
Fusion	59 $\pm$ 18.3	68.5 $\pm$ 19.5
<u>Toe deformity (Hammer/Claw)</u>		
Correction	57.5 $\pm$ 19.6	74.6 $\pm$ 18.1
<u>Lesser metatarsal pathologies</u>		
Bunionete	68 $\pm$ 16.9	79.8 $\pm$ 5.4
Metatarsalgia/DMMOs	24	44.2
Morton's neuroma	76	74
Foot Metalwork Removal	78 $\pm$ 19.2	85.3 $\pm$ 14
Misc foot operations not listed	41.3 $\pm$ 24.1	62.5 $\pm$ 26.6

Table 3
Descriptive statistics and Cronbach's Alpha for each item of the UnEOS scale.

Question No	Min	Max	Mean	SD	Alpha ^a
1	0	4	1.24	1.23	0.86
2	0	4	1.57	1.25	0.86
3	0	4	1.69	1.31	0.86
4	0	4	2.04	1.37	0.86
5	0	4	2.28	1.25	0.85
6	0	4	1.26	1.31	0.85
7	0	4	2.24	1.31	0.85
8	0	4	2.38	1.26	0.86
9	0	4	2.76	1.22	0.87
10	0	4	1.86	1.29	0.86
11	0	10	5.92	2.43	0.87

^a Cronbach's Alpha if this item is removed.

and SF-12/SF-36 were not used for this pilot study,^{5–7} because they are focusing in the quality of life of the patients and are not validated for such specific pathologies. Furthermore the focus of this study was to use a questionnaire as similar as possible to the UnEOS score. FADI has been widely used for both trauma and elective foot and ankle pathologies and as it has the pain and the

function subscales, it was very good for validation purposes. A strong correlation was found between the UnEOS and FADI score (Spearman's rho 0.79). The correlations between the subscales were good as well (rho = 0.74 between function subscales and 0.58 between FADI pain subscale and UnEOS symptoms subscale). As these correlations were strong it could be stated that UnEOS provides a valuable tool evaluating the condition of the patients with variable foot and ankle pathologies.

The UnEOS questionnaire had a very good internal consistency. The high internal consistency of the UnEOS score alongside with the high correlation with the already validated foot and ankle disability index (FADI) demonstrates that UnEOS is a valid score that can be used by the orthopaedic surgeons. The Cronbach's alpha score reached the value of 0.87 for the entire construct. The internal consistency for each of the constructs subscales has been also calculated and it was found very good as well, with Cronbach's alpha scores varying from 0.73 to 0.77. Other foot and ankle scores had similar internal consistency scores (0.93 for the FADI score and 0.73 to 0.96 for the foot functional index¹³(9). IKDC score had internal consistency of 0.92¹⁴ and the KOOS subscales varied from 0.78 to 0.97.¹⁵ Oxford hip score internal consistency has been reported as high as 0.87.¹⁶ WOMAC osteoarthritis index's subscales have Cronbach's scores varying between 0.83 and 0.96.¹⁷ For the upper limb quick DASH score reliability is reported to be 0.9–0.94 and Penn shoulder score's up to 0.93.^{18,19} Health related quality of life questionnaires (SF-36, EQ-5D etc.) have been reported to have high internal consistency scores as well.²⁰

Traditionally each orthopaedic subspecialty is using separate PROMs, site or pathology specific, in order to monitor the patients' progress and outcomes. The most common scores used in foot and ankle surgery are the foot and ankle disability index (FADI)⁹ and the foot functional index.¹³ For the knee pathologies the most commonly used PROMs are the International Knee Documentation Committee (IKDC) Subjection knee form,¹⁴ the Knee Injury and Osteoarthritis Score (KOOS)²¹ and the Oxford knee score.²² Hip pathologies are being evaluated by the Harris Hip Score⁴ or the Oxford Hip Score.²³ Quick DASH²⁴(18) and constant score²⁵ are usually used for shoulder and upper limb pathologies. All of the above mentioned scores are site specific and focusing especially on the function of the specific joint that it is examined. General quality of life questionnaires have been used in orthopaedics as well, such as SF-36, SF-12v2 and EQ-5D scores.^{26,27} These questionnaires are not focused on a specific joint or part of the body and are measuring the general condition of the patient and the impairment they have in their life. These questionnaires have been designed for measuring the general quality of life of the population. Even though UnEOS is similar to these questionnaires in terms of that it is not site specific (despite only having assessed patients who attended Foot and ankle clinics), the focus of the UnEOS questionnaire is on the impact a condition may have on their life, in terms of symptoms, function and mental status. Its design, also allows the orthopaedic surgeons to measure patient satisfaction after treatment as well.

As mentioned above UnEOS is designed in order to be able to measure and monitor any elective orthopaedic pathology. This pilot study focuses mainly on the development of the score and the measurement of the internal consistency of the questionnaire. To date only foot and ankle pathology has been assessed. Further validation studies should be performed including other elective orthopaedic subgroups, such as shoulder, hand, hip and knee. These will enable the use of UnEOS to the entire spectrum of elective orthopaedic of pathologies. The possible floor and ceiling effect should also be examined for this questionnaire. Unfortunately the total number of the post-operative responders did not make it possible in this study.

5. Conclusion

UnEOS is a valid score this very good internal consistency. It is an easy to use PROM which gives important information to the orthopaedic physicians and it is not site or pathology specific. Further validation with other orthopaedic pathologies will lead to a Unified Elective Orthopaedic score.

Conflicts of interest

We have nothing to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jcot.2019.06.016>.

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Efthymios Iliopoulos*, Natasha Hossain, Richard Freeman,
Joel Vernois, Stephen Bendall
Brighton and Sussex University Hospitals, NHS Trust, Brighton, UK

* Corresponding author. Brighton and Sussex University Hospitals,
NHS Trust, Brighton, UK.
E-mail address: iliopoulouse@gmail.com (E. Iliopoulos).

21 April 2019
Available online 22 June 2019