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Original article

Validation of a French patient-reported outcome measure for patello-femoral disorders: The Lille Patello-Femoral Score

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ABSTRACT

Background: The diagnosis of patello-femoral instability (PFI) relies chiefly on the patient's clinical findings. Nevertheless, few clinical scores specifically designed to evaluate the patello-femoral joint are available. The Lille scoring system is a 12-item self-questionnaire yielding a score from 0 to 100 that is used in France but has not been validated. We therefore conducted a validation study in a population of younger patients with PFI.
Hypothesis: The Lille scoring system meets validation criteria for patient-reported outcome measures (PROMs).
Material and method: A retrospective study done in two centres identified 136 patients with objective ($n = 109$) or potential ($n = 27$) PFI. Before and after surgery, the Lille score was determined by all patients and the Kujala score in 61 patients. The Lille score was also determined by 30 controls free of patello-femoral disorders to allow an evaluation of discrimination between PFI and other knee disorders in individuals of similar age.
Results: The response rate was 100%, indicating that the Lille questionnaire was easy to complete. Consistency was established: (a) the global score showed no floor or ceiling effect (in no questionnaires were over 85% of items given the highest or lowest possible score), and saturation occurred neither for the global score nor for the item sub-scores (fewer than 85% of patients had the lowest or highest possible score); (b) a single redundancy was found, between the items 'pain' and 'locking', for which the correlation coefficient was ≥ 0.7 ($P < 0.0001$). Discriminating performance was assessed by comparing the mean Lille score values in the controls (67.8 ± 9.2) and patients (38.1 ± 10.4); the difference was significant ($P < 0.05$) and the estimated effect size was > 0.8, indicating strong discrimination by the Lille scoring system. Item uniformity, with all items measuring the same phenomenon, was established by the Cronbach alpha coefficient value > 0.7. External consistency between the Lille and Kujala scoring systems was confirmed in the 61 patients for whom both scores were available (Pearson correlation coefficient, 0.5). Sensitivity to change was established by the > 0.8 effect size of surgical treatment.
Discussion: The Lille scoring system deserves to be used routinely in clinical practice as a patient-reported outcome measure. A prospective study will assess intra-observer reproducibility and sensitivity to change in patients treated non-operatively. Although confined to retrospective data, this study based on methods designed to assess PROMs establishes the validity of the Lille scoring system and supports its use in PFI.
Level of evidence: III, case-control design.

1. Introduction

The patello-femoral joint gives rise to a number of specific disorders, for which specially designed treatments are available [1]. The effects of these treatments must be assessed using appropriate tools [1–4]. Scoring systems that evaluate the entire knee do not provide

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detailed information on the patello-femoral joint [4–7]. The scoring system for the patello-femoral joint developed by Kujala et al. et al. [8] does not adequately assess patello-femoral instability (PFI). Furthermore, the Kujala score is determined by the physician, whereas patient-reported outcome measures (PROMs) are currently recommended for evaluating orthopaedic surgical procedures [9].

The outcomes of treatments for PFI are usually evaluated based on pain, residual sensations of instability, or return to sports [3,10]. These criteria fail to provide accurate quantification of treatment effects. In France, the Lille scoring system consisting in a 0–100 self-questionnaire was described in 1999 [11] (supplementary data, Appendix 1) as a tool for evaluating the patello-femoral joint and monitoring patients. This PROM is currently used in knee surgery [12,13], both during the initial workup to assess the patello-femoral disorder and subsequently to measure treatment effects.

Our objective was to validate the Lille scoring system using criteria recommended for assessing PROMs (content validity, construct validity, and sensitivity to change). Our hypothesis was that these criteria would establish the validity of the Lille scoring system.

2. Material and methods

2.1. Material

The Lille scoring system is a 12-item self-questionnaire that yields a score ranging from 0 to 100. The 12 items specifically evaluate the patello-femoral joint (supplementary data, Appendix 1). For each item, the patient chooses one among several response options.

2.2. Inclusion criteria

We studied a population with either objectively documented patellar dislocation (OPD) or potential PFI. They ranged in age from 18 to 35 years. Body mass index was < 40 kg/m^2 in all patients. No patient had patello-femoral osteoarthritis or other knee disorders.

To assess discriminating performance (ability to distinguish between two different disorders), we also studied a control group of patients in the same age range (18–35 years) who had other types of knee disorders that might yield positive item scores, namely, isolated anterior cruciate ligament (ACL) tear (without injury to any other knee ligaments) and/or meniscal injuries [14]. Among the Lille scoring system items, instability can be positive in ACL tears and locking, pain, and squatting in meniscal injuries.

2.3. Patients

The data were collected retrospectively at the Lille teaching hospital and Saint-Omer private hospital between 2007 and 2011. The main population comprised 136 patients with OPD ($n = 109$) or potential PFI ($n = 27$). There were 85 females and 51 males with a mean age of 24.2 ± 5.0 years. All 136 patients were treated surgically (trochleoplasty, $n = 59$; and anterior tibial tuberosity [ATT] osteotomy, $n = 77$).

The control group was composed of 30 patients, 15 males and 15 females, with a mean age of 24.3 ± 5.0 years. Among them, 15 had ACL tears and 15 meniscal injuries confirmed by magnetic resonance imaging.

2.4. Assessment methods

All patients with patello-femoral disorders determined their Lille score before and after surgery. In addition, 61 patients (50 with OPD and 11 with potential PFI) had the Kujala score [8] determined before and after treatment (supplementary data, Appendix 2). The controls determined their Lille score on a single occasion, before surgery.

2.5. Analysis methods

To achieve the primary study objective, we relied on the score validation method developed by Bouletreau et al. [15], which assesses validity and sensitivity to change. Validity includes face validity, criterion validity, content validity, and construct validity:

- face validity is the result of subjective judgments made by experts during the development of the questionnaire. The Lille questionnaire was developed by surgeons specialised in the management of patello-femoral abnormalities. Consequently, the Lille scoring system was considered to have face validity;
- criterion validity is assessed by comparison with a reference standard. However, no appropriate reference standard was available for our study. The Kujala score is not a self-questionnaire and, therefore, could not be taken as the reference standard;
- content validity reflects the relevance of the questionnaire to the phenomenon under study. Content validity is assessed based on quality of the questionnaire items, redundancies, and discriminating performance (supplementary data, Appendix 3);
- construct validity was measured by evaluating internal and external consistency:
  - for the evaluation of internal consistency, principal component analysis (PCA) was performed. When studying a subjective scale, the objective of PCA is to assess consistency among items and to determine whether the items belong to a single dimension or to several dimensions,
  - external consistency: the correlation coefficients between the Lille score and Kujala score [8] were computed in a subgroup of 61 patients with PFI [16];
- determining the Lille score before and after surgery in the patients with PFI provided information on sensitivity to change [16].

The Lille Patello-Femoral Score in French was translated to English for this article and the result validated by back-translation. However, the English version of the questionnaire was not tested.

2.6. Statistical methods

SAS version 9.3 software (SAS Institute, Cary, NC, USA) was used for the statistical analyses. All statistical tests were two-sided with the alpha risk set at 5%. Supplementary data, Appendix 3 describes the statistical tests in detail.

3. Results

3.1. Content validity

The response rate was 100%, providing clear evidence of the feasibility of completing the Lille questionnaire. There was no floor or ceiling effect: preoperative scores ranged from 8 to 87 and postoperative scores from 30 to 100. Saturation was noted for the 'yes' response option to the question about analgesic use (90% of patients). For each of the 11 other items, response rates for each item ranged from 4% to 77%, i.e., was never greater than 85%, indicating that saturation did not occur.

Redundancy occurred between the 'pain' and 'locking' items, for which the correlation coefficient was 0.8 ($P < 0.0001$). No other redundancies were identified. We removed the 'pain' item from the rest of the analysis, as the item on analgesic use also reflects the existence of pain.

The evaluation of discriminating performance showed that the mean score value was 67.8 ± 9.2 in the controls and 38.1 ± 10.4 in

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