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Original Research

Evaluation of the Measurement Properties of Four Performance Outcome Measures in Patients with Elective Hip Replacements, Elective Knee Replacements, or Hip Fractures

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ABSTRACT

Objectives: To evaluate the measurement properties of four performance outcome (PerfO) measures (timed up and go, four-step stair climb, long stair climb, and repeated chair stand) in three patient populations (elective total hip replacement [eTHR], elective total knee replacement [eTKR], and hip fracture [HF]). **Methods:** A cross-sectional and longitudinal design was used to assess the PerfO measurement properties using the US Food and Drug Administration guidance for industry around patient-reported outcome measures to support labeling claims. Patient-reported outcome measures and patient- and clinician-reported global concept items were completed along with four PerfO measures at visit 1 and two follow-up visits. Measurement properties assessed included reliability, construct validity, ability to detect change, and estimates of meaningful change. **Results:** A total of 280 patients (100 eTHR, 105 eTKR, and 75 HF) were recruited, with most (n = 276) providing data at visit 1. Most of the patients were female (64%) and retired (64%), and had at least one comorbidity (91%). Inter-rater and test-retest reliability ranged from good to excellent

(0.73 ≤ intraclass correlation coefficient ≤ 0.95) for each PerfO measure. Known-groups validity was demonstrated for all PerfO measures, with those reporting less pain better physical functioning and those who did not use an assistive device having quicker mean completion times. Construct validity and ability to detect change were demonstrated and estimates of meaningful change derived. **Conclusions:** This study found the measurement properties of four PerfO measures in samples of patients with eTHR, eTKR, and HF to be supported for consideration of future use, and provided estimates for interpretation of change.

Keywords: hip fracture, joint replacement, performance outcomes, psychometric evaluation.

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Introduction

A rise in overall life expectancy has led to a corresponding increase in demand for joint arthroplasty and hip fracture (HF) surgery [1,2]. This is primarily a consequence of the increased risk of bone and joint conditions among older people. The most common underlying condition for knee and hip arthroplasty—osteoarthritis—is set to rise in prevalence as the population ages [3]. Joint replacements are also carried out in patients with inflammatory arthritis, fracture, dysplasia, or malignancy, typically when physical therapy, analgesics, and anti-inflammatory therapy have been unsuccessful [1]. These procedures reduce pain and improve both function and health-related quality of life in most patients [4]. Elderly populations also have greater incidence rates of HF, thus reflecting their increased susceptibility to falls and age-related decreases in bone density and strength

[2]. Serious fractures are associated with increased morbidity and mortality [5], necessitating surgical repair aimed at stabilizing the fracture and mobilizing the patient as soon as possible.

Given the increased prevalence and importance of joint arthroplasty and HF surgery, accurate assessment of patients' postsurgical functional ability is required. Methods to assess this remain under discussion, with current guidelines recommending the inclusion of patient-reported outcome (PRO) measures of functional status in all randomized controlled trials relating to knee, hip, and hand osteoporosis [6]. An increasing body of evidence, however, suggests that PROs fail to accurately capture changes in functional status, being more likely to represent the experience when performing activities rather than ability per se [7,8]. Furthermore, because pain and physical functioning represent different but related health concepts, and interventions to address these issues differ, separate assessments are

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recommended [6]. The assessment of physical functioning remains optional within the guidelines, however, and PRO-related methods continue to be the favored assessment method [6,9].

The use of performance outcome (PerfO) measures to assess patients after HF surgery or joint arthroplasty provides an opportunity to gather important information about functional status while eliminating errors in personal judgment, memory, and the influence of pain, thus overcoming the limitations and biases associated with commonly used PRO measures [10]. There is, however, a lack of data to support the validity of specific outcome measures to assess functional status in patients after joint arthroplasty or HF surgery, as well as guideline recommendations on their use in these populations. Therefore, further testing of the measurement properties of these measures is necessary.

The aim of this study was to evaluate the measurement properties of four PerfO measures in three groups of patients, each representing a population of patients after elective total hip replacement (eTHR), elective total knee replacement (eTKR), or HF surgery. Four PerfO measures were administered: the timed up and go (TUG) and four-step stair climb (4SC) in all groups, the long stair climb (LSC) in the eTHR and eTKR groups, and repeated chair stand (RCS) in the HF group. These PerfO measures were

selected on the basis of potential inclusion in future clinical trials, but had not been ascertained for which specific end points. Broadly, these measures may enable assessment of end points related to improvements in lower extremity functional capacity.

Methods

The study protocols and related documents for each of the three studies in eTHR, eTKR, and HF with similar cross-sectional and longitudinal designs were reviewed and approved by an independent ethics review board (reference: OXO3559).

Study Design

Data were collected at baseline/visit 1 and at repeat visits 2 and 3 to evaluate the measurement properties of the PerfO measures (Table 1). The patients in the eTHR and eTKR groups attended a baseline/visit 1 clinic appointment before surgery, and those with HF at 3 to 12 weeks after HF surgery. At this first visit, full patient details, including medical history, were collected and patients completed PRO and PerfO measures. PRO measures were used to assess construct validity (known-groups and convergent/

Table 1 – Planned timing of assessments and visits and psychometric properties assessed.

	Visit 1	Visit 2	Visit 3
Assessment	eTHR, eTKR: 8 wk to 15 d presurgery HF: 3–12 wk postsurgery	eTHR, eTKR: 2 wk (± 2 d) post baseline, presurgery (test-retest) HF: 12 wk (± 3 d post baseline) (change)	eTHR, eTKR: 12 wk (± 3 d) postsurgery (change) HF: 2 wk (± 2 d after visit 2) (test-retest)
Sociodemographic PRO	eTHR, eTKR, HF	–	–
AM-PAC	HF	HF	HF
LEFS	eTHR, eTKR	–	–
OHS/OKS	eTHR/eTKR, HF	–	eTHR/eTKR, HF
SF-12	eTHR, eTKR, HF	–	eTHR, eTKR, HF
Pain NRS	eTHR, eTKR, HF	eTHR, eTKR, HF	eTHR, eTKR, HF
GCI	eTHR, eTKR, HF	eTHR, eTKR, HF	eTHR, eTKR, HF
PerfO			
TUG	eTHR, eTKR [†] , HF	eTHR, eTKR, HF [†]	eTHR, eTKR, HF
4SC	eTHR, eTKR [†] , HF	eTHR, eTKR, HF [†]	eTHR, eTKR, HF
LSC	eTHR, eTKR [†]	eTHR, eTKR	eTHR, eTKR
RCS-A	HF	HF	HF [†]
RCS-B	HF	HF	HF [†]
ClinRO			
GCI	eTHR, eTKR, HF	eTHR, eTKR, HF	eTHR, eTKR, HF
Medical history	eTHR, eTKR, HF	–	–
Current medical status	eTHR, eTKR, HF	eTHR, eTKR, HF	eTHR, eTKR, HF
Psychometric properties assessed	eTHR, eTKR: construct validity, inter-rater reliability (TUG, 4SC, and LSC) HF: construct validity	eTHR, eTKR: test-retest reliability HF: sensitivity to change, anchor-based measures of meaningful change, inter-rater reliability (TUG and 4SC)	eTHR, eTKR: sensitivity to change, anchor-based measures of meaningful change HF: test-retest reliability, inter-rater reliability (RCS-A and RCS-B)

AM-PAC, activity measure for post-acute care; ClinRO, clinician-reported outcome; eTHR, elective total hip replacement; eTKR, elective total knee replacement; GCI, global concept item; HF, hip fracture; LEFS, lower extremity functional scale; LSC, long stair climb; NRS, numeric rating scale; OHS, Oxford hip score; OKS, Oxford knee score; PerfO, performance outcome; PRO, patient-reported outcome; RCS-A/B, repeated chair stand A/B; SF-12, 12-item short form health survey; TUG, timed up and go; 4SC, four-step stair climb.

* Where test is repeated by two raters in patients with eTHR and eTKR for assessment of inter-rater reliability.

[†] Where test is repeated by two raters in patients with HF for assessment of inter-rater reliability.

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