Not all patient-reported outcome measures are equivalent at two years compared to one year after anterior cruciate ligament reconstruction based on a retrospective analysis

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ABSTRACT

Objective: This article aims to assess for clinically important differences in patient-reported outcome measures (PROMs) at one and two years post anterior cruciate ligament reconstruction (ACLR).

Methods: A retrospective comparison of prospectively collected PROMs for a single cohort who underwent a primary ACLR with or without associated meniscal surgery from 2016 to 2020 was assessed. Six externally validated PROMs were collected preoperatively and at standardized times postoperatively. Descriptive statistics and paired equivalence testing of PROMs at one and two years after surgery was completed using previously published or calculated minimal clinically important differences as upper and lower equivalence limits. A repeated measures analysis of PROMs that were not clinically equivalent at one and two years after surgery was completed to assess for a clinically significant difference. Subgroup analyses based on sex, age and associated meniscal injury were completed.

Results: One-hundred and forty-five participants with a mean age of 28.7 years (standard deviation: 9.9 years) were included in the final analysis. All PROMs were clinically equivalent at two years compared to one year after ACLR except the quality of life and sport and recreation domains of the Knee Injury and Osteoarthritis Outcome Score (KOOS). The quality of life (mean difference (MD):12.3, \( P < 0.01, \eta^2: 0.65 \)) and sport and recreation (MD: 8.78, \( P < 0.01, \eta^2: 0.50 \)) domains of the KOOS were clinically different at two years compared to one year postoperatively. No major differences were found in the subgroup analyses compared to the entire included sample.

Conclusion: While most PROMs were equivalent at two years compared to one year after ACLR, the quality of life and sport and recreation domains of the KOOS, which reflect knee performance during higher demand activities, exhibited a clinically significant difference.

Level of evidence: IV.

What are the new findings?

- Most, but not all, patient-reported outcome measures were equivalent at two years compared to one year after anterior cruciate ligament reconstruction.
- The quality of life and sport and recreation domains of the Knee Injury and Osteoarthritis Outcome Score exhibited clinically significant improvements at two years compared to one year after anterior cruciate ligament reconstruction.
- Sex and meniscal injury had minimal effect on the improvement in patient-reported outcome measures at two years compared to one year after anterior cruciate ligament reconstruction.
- A two-year, in-person follow-up visit may have minimal clinical benefit and increases the financial and opportunity costs for the patient, physician, and healthcare system.
INTRODUCTION

Anterior cruciate ligament (ACL) injury and reconstruction (ACLR) are common among the active population. Although there is no national registry in Canada or the United States, one Canadian province reported an ACLR rate of 48.5/100,000 in 2015 [1]. Multiple Scandinavian and Oceanic registries have reported similar rates of ACLR [2–6]. Additionally, the ACLR annual incidence increased by 43% from 2000 to 2015 and will likely continue to increase as our population stays active for longer [7]. Based on previous data and the current population, over 22,000 ACLRs will be completed in Canada during 2022 [1,8].

An important functional outcome after an ACLR is the return to sport, and there is ongoing debate about the appropriate time between surgery and the return to sport. There may be a decreased rate of ACL reinjury when the return to sport is delayed up to nine months after surgery [9]. However, the Knee Injury and Osteoarthritis Outcome Score (KOOS), a patient-reported outcome measure (PROM), was found to be equivalent in patients at one compared to two years after ACLR, across multiple patient-reported outcome measure (PROM), was found to be equivalent [10–12]. Other validated PROMs have not been directly compared at one year and two years after primary ACLR or likened to previously established minimal clinically important differences (MCIDs). In a 2019 scoping review of criteria used to return to sport after ACLR, only six of 178 studies used a checkpoint of 12 or more months after surgery as a milestone to return to sport [13]. Recovery of proprioceptive and kinesthetic senses, muscular strength, and balance also play important roles in the postoperative (PO) rehabilitation after ACLR and should be considered in addition to time since surgery [14]. While there is no current consensus, it is generally agreed that return to sport should occur at least six months following ACLR and in most cases is appropriate by one year after surgery [15].

Even if most athletes return to sport by one year after surgery, and clinical outcomes have plateaued at that time, most orthopedic journals continue to define short-term follow-up as two years after surgery to capture outcomes associated with reinjury and revision surgery [10]. A replication study provides credibility and generalizability for previously established scientific claims through the assessment of new data [16]. The purpose of this replication study was to assess for a clinically important difference in multiple PROMs at two years compared to one year after ACLR. We hypothesized that there would be no clinically meaningful differences across PROMs at two years compared to one year after ACLR.

MATERIALS AND METHODS

Study design and setting

A retrospective comparison of prospectively collected data from a single cohort was completed utilizing a repeated measures design.

Participants

Prospective participants were identified at an initial orthopedic consultation by the principal investigator (PI). A research assistant described the PROM questionnaires and potential for future use in de-identified research and the participant role to prospective participants. Prospective participants were assured that acceptance or refusal of participation in completing PROM questionnaires would have no impact on the quality or timing of care they received. If prospective participants consented to participate, they were emailed a link to the PROM questionnaires at specific time points along their treatment course to be completed privately and anonymously.

The inclusion criteria comprised having a primary ACLR performed by the PI with or without concomitant meniscal surgery between October 15, 2016, and June 15, 2020, the ability to read and complete English PROM questionnaires independently, completion of both one- and two-year PROM questionnaires, and skeletal maturity determined by radiographic distal femoral and proximal tibial physeal closure at the time of surgery. Exclusion criteria comprised clinical failure defined by patient-reported recurrent knee instability, having a revision ACLR or ACLR reinjury, contralateral ACL injury during the study collection period, any concomitant surgery at the time of primary ACLR not listed in the inclusion criteria, skeletal immaturity determined radiographically by having open distal femoral or proximal tibial physeal closure, or failure to complete both one- and two-year outcome scores.

Intervention

The PI completed a primary ACLR for every participant using the graft and fixation techniques best suited for that participant in the opinion of the PI. Since a repeated measures design where each participant's scores were compared against their own previous scores was used, all graft and fixation types were included. The PI also addressed any concomitant meniscal injury at the time of the ACLR, if it was clinically indicated.

Meniscal surgery consisted of debridement or repair, depending on the tear chronicity, pattern, location, size, and patient characteristics. After surgery, participants were given a standardized physical therapy protocol (Appendix 1). However, to comply with ethical standards, participants were free to choose where to do their physical therapy.

Outcome scores

The included outcome scores were all externally validated for use to quantify subjective patient-reported outcomes (Appendix 2). The Visual Analog Scale (VAS) is a subjective pain scale rated on a continuous line from 1 to 100, with a positive relationship between pain and score, and high reported patient affinity [17]. Previously reported MCIDs of 19.9 in knee osteoarthritis patients and 20.0 in patients with patellofemoral knee pain have been established for the VAS [18,19]. The Marx Activity Rating Scale (MARS) consists of four questions regarding non-sport-specific components of physical function including running, cutting, deceleration, and pivoting, each rated on a 4-point Likert scale, with a maximum score of 16 [20]. The MARS has been validated with high correlation to other knee-specific PROMs such as the Tegner, Cincinnati, and Daniels knee scores [20].

The MARS MCID was calculated for each specific sample in question using the Spratt distribution-based method (Appendix 3) [21]. The Knee Injury and Osteoarthritis Outcome (KOOS)-global knee score is a 42-question knee-specific survey covering 5 facets of knee function including pain, symptoms, activities of daily living, sport and recreation (Sport/Rec) function, and knee-related quality of life (QOL) [22]. Each domain has dedicated questions, is separately scored, and is reported on a 0 to 100 scale, where higher scores indicate no knee problems. The KOOS-global is well established and widely used in the context of ACLR [23–25]. The previously reported MCID for each domain of the KOOS-global ranges from 8.0 to 10.0 [22,26,27]. The International Knee Documentation Committee (IKDC) subjective knee score consists of 19 function-specific questions about a symptomatic knee [23,28]. The IKDC has been validated in multiple different knee disorders including ligament injury [23–29]. The previously reported MCID of the IKDC knee score ranges from 9.0 to 16.7 [30,31]. The Single Assessment Numeric Evaluation (SANE) knee score consists of two ratings of knee function out of 100, that has been validated in several knee disorders [32,33]. The previously reported MCID of the SANE knee score ranges from 11.8 to 27.3 [32,34]. The Veteran's Rand 12-item (VR-12) Health Survey Physical (Px) and Mental (Mx) components are based on the Short-Form 12 survey, altered by using...
5-point response choices to improve the ceiling and floor effects \cite{35,36}. The previously reported MCID for the VR-12 Mx and Px are 4.9 and 6.0, respectively \cite{34}.

Participants were emailed outcome questionnaires at the time of their preoperative, two-week PO, six-week PO, three-month PO, six-month PO, one-year PO, and two-year PO in-person or virtual appointments. Only relevant questionnaires were distributed at each time point. For example, only the VAS was sent two weeks after surgery because detailed questionnaires regarding advanced knee function were not applicable so early in the PO course.

**Minimal clinically important difference**

The MCID is the smallest change in a treatment outcome that a patient would identify as important and would indicate a change in the patient’s management \cite{37}. The MCID of a PROM may be calculated via anchor-based or distribution-based methods \cite{21}. The MCID has also been used as the “threshold for clinical irrelevance” and has previously been utilized in an equivalence trial comparing the KOOS score between one and two years after ACLR in the Swedish Registry \cite{10,38}. In contrast to Samuelsson et al., we used the previously established MCID for each respective PROM as the upper and lower equivalence thresholds rather than basing the equivalence interval on the concept of the MCID but not matching it to previously established MCIDs specifically.

**Statistical analysis**

Statistical analysis was performed with computation software (IBM SPSS Statistics version 23, Chicago, IL, USA, and Minitab version 20.1, State College, PA, USA). The mean and standard deviation of each PROM was reported at one and two years after ACLR. Paired equivalence testing of PROMs via the two one-sided test procedure at one and two years after ACLR was completed using previously published or calculated MCIDs as upper and lower equivalence limits \cite{39}. A paired-sample t-test was used to evaluate for a clinically significant difference larger than the previously reported MCID of PROMs that were not clinically equivalent at two years compared to one year postoperatively. Subgroup analyses based on sex, age, and presence and type of meniscal surgery were carried out to assess for equivalence and clinically significant differences between two- and one-year PROMs within each subgroup. Missing data or incomplete participant survey responses were excluded from the analysis.

A post hoc power analysis was completed using a sample size calculator (G*Power, version 3.1; Universität Düsseldorf). Given a two-tailed paired t-test design with a sample size of 145, effect size of 0.5, and \( \alpha \) error probability of 0.05, the achieved power to detect a difference between means was 99%.

**Ethical considerations**

Approval was obtained from the research ethics board at the institution this study was completed (H20-00981). Consent for study inclusion was obtained and maintained for all potential participants.

**RESULTS**

**Study population**

Three-hundred and fifty-four ACLR were completed during the study duration of which 59 met the exclusion criteria (Fig. 1). Two-hundred and ninety-five participants returned at least one survey, and 145 participants attended a two-year follow-up appointment and returned surveys at both one- and two-year follow-up. The maximum sample and included sample descriptive characteristics are documented in Table 1.

**One- and two-year outcomes**

The mean and standard deviation for every PROM is reported in Table 2 and improved over time (Fig. 2). However, every PROM was clinically equivalent at two years compared to one year after ACLR except the QOL and Sport/Rec domains of the KOOS (Table 2). When compared with a paired t-test, the KOOS-QOL (mean difference (MD):12.3, \( p < \) 0.05)
0.01, effect size ($\eta^2$: 0.65) and KOOS-Sport/Rec (MD: 8.78, $P < 0.01$, $\eta^2$: 0.50) domains were clinically significantly different at two years compared to one year postoperatively.

**Participant sex**

Equivalence testing based on participant sex for one- and two-year follow-up is presented in Table 3. In both sexes, the MARS, KOOS-QOL, and KOOS-Sport/Rec scores were not equivalent at two years compared to one year postoperatively. In females, the IKDC was also not equivalent at two years compared to one year postoperatively. When compared with a paired t-test, the KOOS-QOL was clinically significantly different at two years compared to one year postoperatively in both sexes (males: MD: 12.2, $P < 0.01$, $\eta^2$: 0.67; females: MD: 13.0, $P < 0.01$, $\eta^2$: 0.65). Additionally, the KOOS-Sport/Rec was clinically significantly different among females (MD: 11.9, $P < 0.01$, $\eta^2$: 0.57).

**Meniscal injury**

Equivalence testing based on associated meniscal injury for one- and two-year follow-up is presented in Supplementary Material 1. Among PROMs that were not equivalent at one and two years after ACLR, the KOOS-QOL was clinically significantly different in participants aged 20 years and younger (MD: 17.4, $P < 0.01$, $\eta^2$: 0.77). In participants 21–30 years old, the KOOS-Sport/Rec was clinically significantly different at two years compared to one year postoperatively (MD: 10.6, $P < 0.01$, $\eta^2$: 0.57). In participants 31–40 years of age, the KOOS-QOL (MD: 15.4, $P > 0.01$, $\eta^2$: 0.93), KOOS-Sport/Rec (MD: 11.8, $P < 0.01$, $\eta^2$: 0.81), and IKDC (MD: 10.5, $P > 0.01$, $\eta^2$: 0.77) were clinically significantly different at two years compared to one year postoperatively. In participants 41 years and older, the MARS (MD: 2.53, $P = 0.03$, $\eta^2$: 0.57) and KOOS-QOL (MD: 10.2, $P < 0.01$, $\eta^2$: 0.89) were clinically significantly different at two years compared to one year postoperatively.

**DISCUSSION**

**Key findings**

The primary finding of this single surgeon, retrospective cohort study was that while most PROMs were clinically equivalent at two years compared to one year after ACLR, the KOOS-QOL and KOOS-Sport/Rec scores exhibited a clinically important increase. Our results were not completely in keeping with a previous study that found equivalence across all KOOS domains at one year compared to two years after primary ACLR in the Swedish National Ligament Register [10]. Other studies also reported little change in other PROMs or population subgroups at one year and two years after ACLR [11,12,40,41]. A contributing factor to our study findings may be that the average age of our study population was older than that of the Swedish Ligament Register, which was the population used for previous studies that compared PROMs over time after ACLR [10–12]. Older age is associated with slower improvement in PROMs and a greater duration to return to sport after ACLR, which may have influenced our results [42–45]. Further, in contrast to our study, previous studies that compared PROMs over time after ACLR did not exclude ACLR reinjury, which potentially decreased the resulting two-year PROMs [10–12]. The QOL and Sport/Rec domains of the KOOS reflect higher levels of knee function through assessment of squatting, running, jumping, twisting, kneeling, lifestyle modifications, confidence, awareness, and subjective difficulty with respect to the affected knee [22, 46]. These subscores increase more than the other KOOS domains from 6 to 12 months postoperatively [25], and based on our findings may continue to increase from one to two years after ACLR.

The subgroup analyses in our study found greater improvement in two-year follow-up outcome scores in the older age groups compared to the younger age groups, and the meniscal repair group. Desai et al. found that individuals over 40 years old who undergo an ACLR have a longer rehabilitation period with greater improvements in the KOOS over a longer period compared to the younger population [45]. Our study
reinforced the association between increased age and longer rehabilitation. Interestingly, our study also found that almost all PROMs were not equivalent at two- compared to one year postoperatively in the meniscal repair group. However, none of these PROMs showed a clinically significant difference. Unfortunately, it is difficult to make strong conclusions from this subgroup due to the small size. Chalatsis et al. found that individuals who undergo meniscal repair at the time of ACLR have superior long-term PROMs compared to those who undergo concomitant meniscectomy [47]. The short-term comparison of PROMs after concomitant meniscal repair vs. meniscectomy at the time of primary ACLR deserves further investigation. The results of this study have the potential to impact patients, physicians, and our healthcare system at a personal and population level both in a social and financial manner.

**Strengths**

The use of multiple different PROMs in this study decreased the risk of response bias associated with the exclusive use of a single survey. Further, the use of validated, reproducible outcome scores in a similar population as previous studies allowed us to make inferences about the PO knee function of this sample by comparing our results to previous research. Muller et al. established IKDC and KOOS domain thresholds that correlated with the patient acceptable symptom state (PASS), an acceptable knee condition with respect to pain, activity, and function after ACLR [48]. In our study, the one-year outcome scores were greater than or within 0.5 points of the PASS thresholds for the IKDC and every KOOS domain except KOOS-ADL, which also did not meet the PASS threshold at two years, and KOOS-QOL, which showed a clinically significant difference in our study at two years compared to one year postoperatively.

Our study also highlighted an opportunity and financial cost to the patient, physician and healthcare system associated with an in-person two-year follow-up visit after ACLR that may have minimal clinical benefit. An opportunity cost is the loss of potential gain, when one action has been chosen over another. From the patient perspective, based on previous Canadian studies assessing the monetary cost of in-person visits, the costs of an in-person two-year follow-up visit after ACLR are expected to be minimal. The cost of an in-person visit is likely to be lower than the cost of the two-year follow-up visit, and the benefits of the two-year follow-up visit are expected to be minimal.

Further, the use of validated, reproducible outcome scores in a similar population as previous studies allowed us to make inferences about the PO knee function of this sample by comparing our results to previous research. Muller et al. established IKDC and KOOS domain thresholds that correlated with the patient acceptable symptom state (PASS), an acceptable knee condition with respect to pain, activity, and function after ACLR [48]. In our study, the one-year outcome scores were greater than or within 0.5 points of the PASS thresholds for the IKDC and every KOOS domain except KOOS-ADL, which also did not meet the PASS threshold at two years, and KOOS-QOL, which showed a clinically significant difference in our study at two years compared to one year postoperatively.

**Table 2**

<table>
<thead>
<tr>
<th>Outcome score</th>
<th>No. of patients</th>
<th>One-year (SD)</th>
<th>Two-year (SD)</th>
<th>Mean difference (SD)</th>
<th>95% CI for equivalence</th>
<th>P value</th>
<th>Equivalence interval</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>145</td>
<td>10.4 (14.6)</td>
<td>7.61 (12.1)</td>
<td>−2.80 (15.4)</td>
<td>−4.9, 0</td>
<td>&lt;0.001</td>
<td>−20, 20</td>
<td>Equivalence</td>
</tr>
<tr>
<td>MARS</td>
<td>145</td>
<td>7.39 (6.2)</td>
<td>8.22 (4.66)</td>
<td>0.83 (4.56)</td>
<td>0, 1.46</td>
<td>0.002</td>
<td>−1.94, 1.94</td>
<td>Equivalence</td>
</tr>
<tr>
<td>KOOS</td>
<td>143</td>
<td>88.4 (10.5)</td>
<td>92.0 (8.94)</td>
<td>3.55 (9.04)</td>
<td>0, 4.81</td>
<td>&lt;0.001</td>
<td>−8.0, 8.0</td>
<td>Equivalence</td>
</tr>
<tr>
<td>Pain</td>
<td>143</td>
<td>79.8 (13.8)</td>
<td>84.7 (11.2)</td>
<td>4.87 (12.0)</td>
<td>0, 6.53</td>
<td>0.001</td>
<td>Equivalence</td>
<td></td>
</tr>
<tr>
<td>- Symptoms</td>
<td>143</td>
<td>95.3 (7.66)</td>
<td>97.0 (5.74)</td>
<td>1.72 (6.71)</td>
<td>0, 2.65</td>
<td>&lt;0.001</td>
<td>Equivalence</td>
<td></td>
</tr>
<tr>
<td>- ADL</td>
<td>143</td>
<td>58.9 (20.3)</td>
<td>71.2 (22.2)</td>
<td>12.3 (18.8)</td>
<td>0, 14.9</td>
<td>0.997</td>
<td>Not Equivalent</td>
<td></td>
</tr>
<tr>
<td>- QOL</td>
<td>125</td>
<td>74.8 (22.9)</td>
<td>83.5 (18.9)</td>
<td>8.78 (17.6)</td>
<td>0, 11.4</td>
<td>0.69</td>
<td>Not Equivalent</td>
<td></td>
</tr>
<tr>
<td>- Sport/Rec</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IKDC</td>
<td>138</td>
<td>77.2 (13.8)</td>
<td>83.7 (12.5)</td>
<td>6.45 (12.2)</td>
<td>0, 8.17</td>
<td>0.008</td>
<td>−9.0, 9.0</td>
<td>Equivalence</td>
</tr>
<tr>
<td>SANE</td>
<td>143</td>
<td>79.4 (14.8)</td>
<td>86.1 (12.6)</td>
<td>6.71 (13.9)</td>
<td>0, 8.64</td>
<td>&lt;0.001</td>
<td>−11.8, 11.8</td>
<td>Equivalence</td>
</tr>
<tr>
<td>VR12 Px</td>
<td>143</td>
<td>52.5 (5.86)</td>
<td>53.9 (5.61)</td>
<td>1.39 (6.17)</td>
<td>0, 2.25</td>
<td>&lt;0.001</td>
<td>−4.9, 4.9</td>
<td>Equivalence</td>
</tr>
<tr>
<td>VR12 Mx</td>
<td>143</td>
<td>52.0 (9.010)</td>
<td>52.1 (9.12)</td>
<td>0.08 (10.5)</td>
<td>−1.38, 1.53</td>
<td>&lt;0.001</td>
<td>−6.0, 6.0</td>
<td>Equivalence</td>
</tr>
</tbody>
</table>

No., number; SD, standard deviation; CI, confidence interval; VAS, Visual Analog Scale; MARS, Marx Activity Rating Scale; KOOS, Knee Injury and Osteoarthritis Outcome Score; ADL, activities of daily living; QOL, quality of life; Sport/Rec, sport and recreation function; IKDC, International Knee Documentation Committee; SANE, Single Assessment Numeric Evaluation; VR12, Veteran’s Rand 12-item Health Survey; Px, physical component; Mx, mental component; Equiv., equivalence.
follow-up after surgery, the combined loss of patient income, potential caregiver wage, patient travel and parking costs is 85.78 Canadian dollars (CAD) per visit [49, 50]. If an estimated 22,000 ACLRs were booked solid. The opportunity cost to the physician completing partial three-year period, a 10-minute follow-up visit for each participant who across Canada for two-year in-person follow-up visits. From a care perspective, the annual cost of an in-person follow-up (SD) for two-year in-person follow-up visit such as virtual or telehealth methods. These patients may consider alternative modes of communication for a two-year follow-up visit such as virtual or telehealth methods.

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A comparison of the age-group specific differences between one- and two-year follow-up scores and the MCID. No., number; SD, standard deviation; CI, confidence interval; MCID, minimal clinically important difference; VAS, Visual Analog Scale; MARS, Marx Activity Rating Scale; KOOS, Knee Injury and Osteoarthritis Outcome Score; ADL, activities of daily living; QOL, quality of life; Sport/Rec, sport and recreation function; IKDC, International Knee Documentation Committee; SANE, Single Assessment Numeric Evaluation; VR12, Veteran’s Rand 12-item Health Survey; Px, physical component; Mx, mental component; Equiv., equivalent.

and healthcare system savings [49,50]. The COVID-19 pandemic highlighted the importance of being able to provide care while minimizing face-to-face contact. Using alternate modes of communication for follow-up visits would minimize the spread of new variants as we continue to navigate this novel illness [55]. Future research to assess the change in other validated PROMs such as the Lysholm knee score, Tegner knee score and ACL Return to Sport after Injury between one and two years after ACLR could further strengthen the findings of this study [56-58].

CONCLUSION

While most PROMs were equivalent at two- compared to one year after ACLR, the QOL and Sport/Rec domains of the KOOS, which reflect knee performance during higher demand activities exhibited a clinically significant difference.

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Declaration of competing interest

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