The Use of GAITRite and PROMIS as Physical Function Outcome Measures for ACL Reconstruction

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Disclosures:

Introduction: Introduction: Many validated clinical research instruments have been used to assess functional outcome following anterior cruciate ligament (ACL) reconstruction surgery. Patient reported outcome measures may be too specific to a particular injury or treatment, or too broad to be clinically useful. Many physical ability assessments must be administered at a separate research facility by engineers or investigators, and are incompatible with large volume clinical practice. There is a need for validated, high-throughput measures of physical function to enable cost-effective research and quality measures of large numbers of patients (>1,000) in the setting of a single clinical practice. National Institutes of Health (NIH) developed the Patient-Reported Outcomes Measurement System (PROMIS) as a dynamic tool, which utilizes computerized adaptive testing (CAT) of a robust item bank to measure psychosocial outcomes from the patient’s perspective directly. GAITRite is a commercially available instrument that has been clinically validated for assessing fall risk in patients with neuropathy from stroke and neurodegenerative diseases (1). It also quantifies various spatiotemporal gait parameters, some of which may correlate with improvement in physical function following orthopaedic surgery. Towards the development of validated high-throughput outcomes for ACL surgery, we assessed the feasibility of simultaneously obtaining PROMIS and GAITRite measurements from patients undergoing patellar bone-tendon-bone autograft for ACL reconstruction and correlated the results of these independent outcomes of physical function with the gold standard PRO for ACL the International Knee Documentation Committee Subjective Knee Form (IKDC).

Methods: Methods: IRB approved protocols were used to assess 106 skeletally mature patients aged13 years and older who were scheduled to undergo patellar tendon autograft ACL reconstruction. Eligible patients from one clinical practice were asked to participate during a pre-surgical clinic visit. Informed consent was obtained from adults, or assent and consent for those under 18 years of age. Early ACL healing was evaluated by administering the PROMIS, GAITRite and IKDC within 2-weeks prior to ACL surgery, and 3, 10, 20, and 52 weeks after surgery. The PROMIS physical function score (PFS), consisted of 6 to 12 questions regarding the patient’s perceived ability to accomplish physical activities. GAITRite testing to quantify the Functional Ambulation Profile (FAP) was done barefoot, and consisted of walking at a self-selected pace down a 26ft long walkway six times. The IKDC consists of 19 static questions administered via tablet computer.

Results: Results: Administration time of the PROMIS questionnaire was 85 ± 70 sec (mean± SD), while administration time of the GAITRite testing was 87 ± 19 sec, by comparison the IKDC was 195 ± 53 sec. Both tests found significant decreases in physical function from baseline at 3 weeks after surgery (p<0.01), and a subsequent significant (p<.001) increase at 10 weeks. Statistically significant improvement from baseline was detected by the PROMIS PFS at 10, 20, and 52 weeks after surgery (p<0.01), demonstrating the significant effect of surgery. Additionally, PFS captured continued recovery at the 20 and 52 week time points. The GAITRite FAP demonstrated significant improvement from baseline at 10 weeks but failed to detect increases at 20 and 52 weeks due to ceiling effects. Strong correlations were found between the PROMIS PFS and the IKDC (gold standard) while FAP and gait velocity measures showed significant but less robust correlation with IKDC (Table 1). Comparison of a subset of patients with poor outcomes was compared to the rest of the cohort. Significantly lower scores were found consistently at each time point with the PROMIS assessment (Figure 1). Neither gait velocity nor FAP showed significant differences between these two groups at any one time point. ROC curve analysis (Table 2) showed significant accuracy in the discrimination of those with poor outcomes for PROMIS at each time point, while Neither FAP or gait velocity reached a significant level of discrimination at any one time point.

Discussion: Discussion: Employment of HTOM in clinical practice can assist clinicians to make improvements in patient care. ACL reconstruction rate has a reported failure rate of between 5 and 10 percent (2,3). The ROC analysis we have conducted has shown that PROMIS assessment at any one time point can be predictive of complications or re-injury (poor outcomes). The accuracy of such discrimination is vastly increased at 20 weeks. By this time most poor outcomes have been identified by the patient/physician and subsequent intervention has been considered or carried out. We believe that early identification of patients that may be at high risk for poor outcomes is also an attainable goal based on the findings of our initial investigation. Preliminary evidence presented here points to the use of pre-operative PROMIS assessment as a means by which to help identify those patients at high risk of poor outcomes. Those individuals with the lowest PROMIS scores at baseline were indeed more likely to have poor outcomes. This finding may prove useful in developing specific post-surgical interventions (bracing, physical therapy techniques, etc.) that may help to reduce or mitigate the increased risk of poor outcomes. We have shown the feasibility...
of HTOM integrated into a high volume clinical orthopaedic practice. If fully utilized, these outcome measures can help inform physicians in individual surgical cases, as well as demonstration of overall practice trends. Early identification of potential poor outcomes after ACL reconstruction may result in ability to intervene earlier to prevent prolonged disability. This investigation into the use of GAITRite and PROMIS physical function assessment tools has shown some utility in the ability to discriminate between those individuals who go on to have a successful timely recovery versus those who experience a slower recovery, complications and/or need additional intervention. A larger sized study will be needed to further validate our findings.

**Significance:** Currently there are no validated high-throughput outcome measures of physical function to enable cost-effective research and quality measures of large numbers of patients (>1,000) in the setting of a single clinical practice. Here we demonstrate the feasibility and utility of the PROMIS PFS and the GAITRite FAP for this purpose in an on-going prospective cohort study of 106 ACL reconstruction patients.

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Table 1: Linear Regression Analysis. Associations among PROMIS physical function scores, IKDC scores, and GAITrite spatiotemporal parameters were quantified using Pearson's correlation coefficient at each time-point. The number of observations at each time point is given in column (N). The combined correlation of all time points is also given. Significant correlations are identified as those with p-values below 0.05 and are indicated by an asterisk. This analysis shows that PROMIS is strongly correlated with the IKDC at all individual time points, while velocity is only correlated at baseline. Combined data across all time points shows significant correlation for the PROMIS, velocity, and FAP with IKDC.
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Table 2: Receiver Operating Characteristic Curve Analysis of Poor Outcomes. PROMIS, FAP and gait velocity were analyzed for discriminatory ability in predicting “poor outcomes” using receiver operating characteristic (ROC) curve analyses, with overall accuracy summarized using the area under the ROC curve (AUC). Nonparametric estimates and 95% confidence intervals for the AUC are presented for each measurement at each visit. Corresponding p-values for testing the hypothesis that the AUC is 0.5 ('no discriminatory ability') were also computed (*p<0.05). PROMIS assessment was shown to have significant discriminatory ability at all time points, while neither the FAP nor velocity were discriminatory at any time point.
**Figure 1: Longitudinal Assessment of Poor Outcomes.** A subset of patients with poor outcomes were identified and longitudinally compared to the rest of the cohort. Average PROMIS scores for each group are shown. Significantly lower scores (p=0.004, p=0.026, p=0.002, p<0.001) were found at baseline, 3, 10, 20, 52 weeks respectively. Error bars indicate standard error of the mean, Asterisk indicate a significant difference from baseline.