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The Multi-Ligament Quality Of Life Questionniare - Development And Testing Of Measurement Properties In Patients With Multi-Ligament Knee Injuries.

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Summary:
This study describes the development and testing of a novel disease-specific quality of life instruments for patients with multi-ligament knee injuries - the Multi-Ligament Quality of Life (ML-QOL). The MLQOL has demonstrated excellent content validity, reliability and construct validity.

Abstract:
INTRODUCTION: There are no existing knee specific outcome instruments have shown to be reliable, valid, or responsive in patients with multi-ligament knee injuries. The objective of this study was to develop and test the measurement properties of a novel disease-specific quality of life instrument for this patient population.

METHODS: (1) Theoretical Framework: WHO's International Classification of Functioning, Disability and Health was used to guide instrument development. (2) Design: Multi-centre study using quantitative and qualitative methods.(3) Participants: Patients with chronic (>6 months) multi-ligament knee injuries (age 18-60) treated operatively or non-operatively. (4) Procedures: Development and testing was conducted in 3 distinct phases (see figure). PHASE I: 85 Eligible patients were mailed a questionnaire comprised of 124 items from 11 existing knee questionnaires. Items were rated in regard to importance and frequency on a 5 point Likert scale. Criteria for inclusion in the multiligament quality of life (MLQOL) questionnaire included
mean importance >3.5 AND frequency <30% for the response "never experienced". PHASE II: Patient focus groups and expert interviews were conducted until saturation was achieved to generate new content for the MLQOL. PHASE III: 150 eligible patients across 3 centers were mailed a preliminary MLQOL along with the Tegner activity scale , Short-Form (SF)36, and several global knee rating questions. Inter-item and item to total correlations were used for item reduction to generate a final MLQOL instrument.The internal consistency (Cronbach's alpha), test-retest reliability (intraclass correlation coefficient, ICC) and construct validity was determined for the final MLQOL.

RESULTS: The final MLQOL instrument was comprised of 52 items distributed over 4 domains [physical impairments (PI), emotional impairments (EI), activity limitations (AL), societal involvement (SI)]. The MLQOL domains did not demonstrate any floor or ceiling effects. Cronbach's alpha was 0.94 (PI), 0.93 (EI), 0.94 (AL), and 0.91 (SI) which suggests the domains have excellent internal consistency. ICC values were 0.89 (PI), 0.86 (EI), 0.91 (AL), and 0.88 (SI). 7 of 8 a priori hypotheses were satisfied indicating excellent construct validity.

DISCUSSION/CONCLUSION: The MLQOL instrument is a disease-specific quality of life tool with new items that are pertinent to patients with multiligament knee injuries. The MLQOL has demonstrated excellent content validity, reliability and construct validity. Future work will test responsiveness and implement use of the MLQOL in

randomized controlled trials.