Long-Term Follow-up of a Randomized Clinical Trial Comparing Patellar Tendon, Hamstring Tendon and Double-Bundle ACL Reconstructions: Ten-Year Patient-Reported and Clinical Outcomes

Nick G Mohtadi[1], Denise S Chan[2], Dana Jaclyn Hunter[3]
[1]Sport Medicine Centre, Nicholas Mohtadi Professional Corp, [2]Sport Medicine Centre, University of Calgary, [3]Sport Medicine Centre

INTRODUCTION:
Only a few prospective randomized clinical trials comparing patellar and hamstring tendon autografts for primary Anterior Cruciate Ligament (ACL) reconstruction have been published with long-term outcomes at a minimum of 10-year follow-up. These studies are limited to small sample sizes, with insufficient patient follow-up and do not report disease-specific quality-of-life outcomes. This prospective, double-blind randomized clinical trial addresses this dearth in the literature as the largest study to compare patient-reported, disease-specific quality-of-life and clinical outcomes at 10 years following reconstruction for ACL deficiency, using a patellar tendon (PT), single-bundle quadruple-stranded hamstring tendon (HT), or double-bundle (DB) hamstring tendon construct.

METHODS:
Three-hundred-and-thirty patients (183 males; age 14-50 years), with confirmed Anterior Cruciate Ligament deficiency were randomized intra-operatively, using computer-generated, varied block sizes, to anatomic ACL reconstruction with either a patellar tendon graft (PT, n=110; mean age 28.7 years), a single-bundle quadruple-stranded semitendinosis-gracilis tendon construct (HT, n=110; mean age 28.5 years), or a 2-stranded semitendinosis and 2-stranded gracilis double-bundle construct (DB, n=110; mean age 28.3 years). All patients and an independent trained examiner were blinded to treatment allocation.

Patient-reported, clinical and functional outcomes were assessed at baseline, and at 2, 5 and 10 years post-operatively. Radiographs were also taken at each study visit and have been reported separately. The primary outcome was the patient-reported Anterior Cruciate Ligament Quality-of-Life (ACL-QOL) score, which has a visual analog response format ranging from 0 (poor quality of life) to 100 (high quality of life). The secondary outcome measures included: pivot shift measurements, kneeling pain, International Knee Documentation Committee (IKDC) Objective and Subjective scores, Tegner Activity Level, Cincinnati Occupational Scale, and Single Leg Hop test. The proportions of patients with complete re-ruptures, partial re-ruptures, combined total traumatic re-injuries, and contralateral ACL tears were also determined. An analysis of variance for repeated measures was used to compare continuous data, with 95% Confidence Intervals (95%CI). Chi-square analyses were used to compare categorical data. A 5% significance level was used for all analyses.

RESULTS:
Two-hundred-and-eighty-seven patients (87%) completed a minimum of 10-year follow-up (mean 10.2 ± 1.2 years). There were 6 patients who withdrew, 1 deceased, and 36 patients lost-to-follow-up. The demographic characteristics of the patients who completed 10-year follow-up were not different between groups. ACL-QOL scores increased from baseline to 10 years for all groups (Figure 1; $p < 0.001$). Mean 10-year ACL-QOL scores were not different between groups (Figure 1; $p = 0.912$): PT = 76.4 ± 21.0 (95% CI 72.1 – 80.7); HT = 77.7 ± 20.5 (95% CI 73.4 – 81.9); DB = 77.3 ± 21.5 (95% CI 73.0 – 81.7). The proportion of patients with a pivot shift grade ≥ 2 (PT = 18%; HT = 25%; DB = 24%) was not statistically significant between the groups ($p = 0.866$); however, it is clinically important. There were no differences in the proportion of patients reporting kneeling pain (PT = 6%; HT = 4%; DB = 7%; $p = 0.637$), or with Normal/Nearly Normal grades on the IKDC Objective score (PT = 73%; HT = 68%; DB = 72%; $p = 0.724$). None of the remaining secondary outcomes showed any statistically significant differences between the groups at 10-years.

More complete traumatic graft ruptures occurred with hamstring tendon and double-bundle reconstructions (HT = 16%; DB = 15%) compared to patellar tendon reconstructions (PT = 7%; $p = 0.142$). Revision ACL reconstruction was performed on 36 of these 37 patients. Twelve additional patients had partial ACL graft re-ruptures (PT = 1; HT = 5; DB = 6) with cumulatively less traumatic re-injuries in the PT group (PT = 8/95; HT = 21/93; DB = 21/99, $p = 0.023$). There was no difference in the proportion of contralateral ACL tears in each group (PT = 13%; HT = 13%; DB = 10%; $p = 0.801$).

DISCUSSION AND CONCLUSION:
At 10-year follow-up, there was no difference in disease-specific ACL quality-of-life outcome between patellar tendon, single-bundle hamstring tendon and double-bundle hamstring tendon ACL reconstructions. There were also no

differences between the three groups for any of the secondary patient-reported and clinical outcomes, including kneeling pain and IKDC Objective grades. However, there were significantly more traumatic graft re-injuries in the hamstring and double-bundle groups, and a clinically important difference between groups for the pivot shift test, favouring a patellar tendon reconstruction.

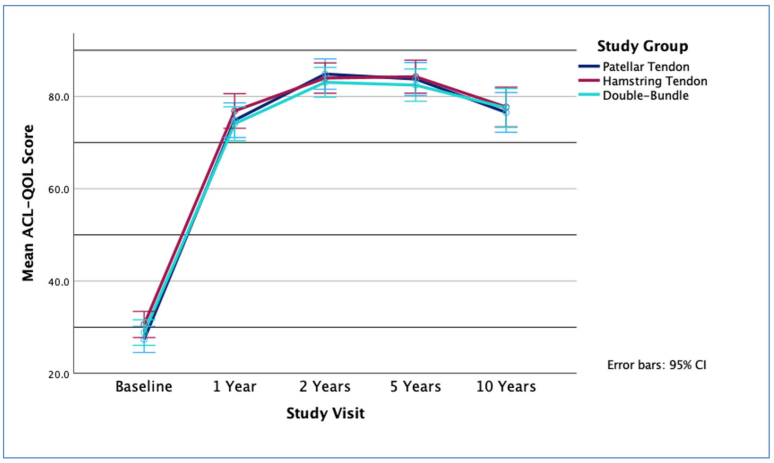

Figure 1: Change in mean ACL-QOL scores (with 95% confidence intervals) from Baseline to 10 years post-operatively