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A Randomized Clinical Trial Comparing Patellar Tendon, Hamstring Tendon and Double-Bundle ACL Reconstructions: Patient-Reported and Clinical Outcomes at a Minimal Two-Year Follow-Up

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Summary:
This prospective, double-blind randomized clinical trial shows no difference in disease-specific quality-of-life outcome at two-years post-op, in patients receiving anatomic: patellar tendon, quadruple-stranded hamstring and double-bundle hamstring autograft ACL reconstruction. More traumatic graft injuries occurred in the HT and DB groups, but similar atraumatic graft "failures" between groups.

Abstract:
PURPOSE: To compare anterior cruciate ligament reconstruction using patellar tendon, quadruple hamstring tendons and the double-bundle hamstring tendons graft options, by measuring patient-reported disease-specific quality of life outcome in patients with isolated ACL deficiency of the knee at a minimum two-years post-operative follow-up.

METHODS: In this prospective double-blind randomized clinical trial, 330 patients (183 males, 147 females) aged 14-50 years were randomly allocated and equally distributed to one of three ACL autograft reconstruction techniques: 1) Anatomic Patellar Tendon (PT; mean age 28.7 years), 2) Anatomic Quadruple-stranded Hamstring Tendon (HT; mean age 28.5 years), or 3) Anatomic Double-Bundle using hamstring tendons (DB; mean age 28.3 years). Allocation was performed intra-operatively, using a computer-generated sequence with varied block randomization. The patients and the independent trained evaluator were blinded to the treatment allocation.

Outcomes were measured pre-operatively at baseline, and post-operatively at 3 and 6 months, 1 and 2 years. The primary outcome was the Anterior Cruciate Ligament Quality-of-Life (ACL-QOL) measure. Secondary outcomes included the International Knee Documentation Committee (IKDC) subjective score and objective grades, KT arthrometer measurements at 30lbs/134N, pivot shift, range of motion, Tegner activity level, and the Cincinnati Occupational Rating Scale. The proportion of traumatic re-ruptures and atraumatic graft failures were also compared for each treatment group. As a measure of the effectiveness of blinding from treatment allocation, the proportion of correct guesses of graft type by the patients and the evaluator were compared.

An analysis of variance for repeated measures, using a Bonferonni post-hoc method for multiple comparisons was used to compare mean outcome scores. Chi-square/contingency table proportional analyses were used to compare categorical data. A 5% significance level was used for all outcomes.

RESULTS: Three-hundred-and-twenty-two randomized patients completed a minimum two-year follow-up. There was no difference in baseline characteristics between the groups. The ACL-QOL score increased significantly over time for all groups (p=0.000). There was no difference in mean ACL-QOL score at two-years (p=0.591): PT = 84.6 (SD 16.6, 95% CI 81.4 – 87.8); HT = 82.5 (SD 17.7, 95% CI 79.2 – 85.9); DB = 82.4 (SD 17.5, 95% CI 79.1 – 85.7). At two-years, there were no differences in the proportion of patients with a Pivot Shift grade 2 or greater (p=0.573): PT = 14 out of 102 (14%); HT = 19 out of 104 (18%); DB = 20 out of 107 (19%). The proportion of patients with =5mm side-to-side-

difference (SSD) on the KT arthrometer (30lbs/134N) was not statistically different between groups at two-years (p=0.173): PT = 85 out of 102 (93%); HT = 91 out of 104 (88%); DB = 91 out of 107 (85%). Mean KT (30lbs/134N) SSD measurements (PT = 1.86mm; HT = 2.97mm; DB = 2.65mm) were statistically significant between the PT and HT groups (p=0.002) and between the PT and DB groups (p=0.044).

At two-years, there were no differences in mean IKDC subjective scores between groups (p=0.821): PT = 84.6 (SD = 13.8, 95% CI = 81.9 – 87.3); HT = 85.3 (SD = 11.6, 95% CI = 83.1 – 87.5); DB = 84.2 (SD = 11.8, 95% CI = 82.0 – 86.5). Based on the IKDC objective grades, the proportions of Normal/Nearly Normal knees at two-years, were not statistically different between groups: PT = 79/101 (78%); HT = 76/104 (73%); DB = 76/107 (71%), p=0.479. Mean passive flexion and extension measurements were not statistically different between the groups (p=0.412 and p=0.158, respectively). Tegner activity levels and Cincinnati Occupational Scores were not statistically different between the groups at two-years (p=0.874 and p=0.455, respectively).

The frequency of traumatic graft re-injuries was higher in the Hamstring and Double Bundle groups (PT = 3/110; HT = 12/110; DB =11/110; p=0.047), whereas atraumatic graft “failures” (PT = 16; HT = 17; DB = 20) were similar between groups (p=0.747).

Blinding was successful for the patients and independent assessor with only 51% and 46% being able to determine the correct group designation, respectively.

CONCLUSIONS: At two-years there was no difference in disease-specific quality-of-life outcome or IKDC grades between the Patellar Tendon, Hamstring Tendon and Double-Bundle techniques for ACL reconstruction. Based on mean KT measurements, patellar tendon reconstructions had significantly lower side-to-side-differences. There were more traumatic graft injuries in the HT and DB groups, but similar atraumatic graft “failures” between groups. Blinding of the patients and independent assessor was achieved.