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.

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.