

Effect of Initial Graft Tension on Knee Osteoarthritis Outcomes after ACL Reconstruction: A Randomized Controlled Clinical Trial with 15-Year Follow-Up

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INTRODUCTION: ACL reconstruction is currently the gold standard treatment for ACL rupture. Despite this restorative procedure, patients have been found to have a higher propensity for post-traumatic osteoarthritis (PTOA), possibly due to abnormal knee kinematics compared to their non-injured counterparts.[1] The “initial graft tension” administered during graft fixation affects joint mechanics and may also influence the development of PTOA. This prospective, randomized controlled trial compared the clinical, functional, patient-reported, and imaging outcome measures of PTOA between a high-tension and low-tension group, and a matched control group. The laxity-based tension protocols were set: 1) to restore normal anteroposterior (AP) laxity at the time of surgery relative to the contralateral uninjured knee (low-tension group), or 2) to constrain AP laxity by 2 mm (high-tension group).[2] We hypothesized that there will be no difference in outcomes between the low- and high-tension groups and the control group at the 15-year follow-up.

METHODS: The study was approved by the IRB and all participants granted informed consent. Between February 2004 and February 2007, ninety patients were randomized between the two tension groups (low-tension, n=46; high-tension, n=44). Sixty control subjects were selected to match the patients by age, sex, race, and activity level. Patients had the option of choosing between a bone-patellar-bone or a four-stranded hamstring tendon autograft. Patients assigned to the low-tension group had their grafts tensioned at 0° flexion, whereas high-tension group assignments were tensioned at 30° flexion. AP laxity at 20° flexion was monitored intra-operatively using a knee arthrometer (KT1000S; MEDmetrics Inc; San Diego, CA) to verify graft tension. The following outcomes: 1) clinical (AP laxity [KT-1000 Knee Arthrometer], International Knee Documentation Committee [IKDC] Knee Examination Score); 2) functional (1-leg hop test); 3) patient-reported (Knee Osteoarthritis Outcome Score [KOOS], SF-36v2, Tegner activity scale); and 4) OA imaging (modified Osteoarthritis Research Society International [OARSI] radiographic grading score, Whole Organ Magnetic Imaging Score [WORMS]) were measured pre-operatively and out to 15 years post-operatively. One-way analysis of variance (ANOVA) was used to analyze the effect of tension group on 15-year post-operative outcomes followed by pairwise comparisons using Fishers LSD procedure.

RESULTS: At 15-year follow-up, 20 patients from the low-tension group (43.5%), 23 patients from the high-tension group (52.3%), and 30 patients from the control group (50%) were lost to follow-up. There were no significant differences in AP laxity between the two tension groups and the matched control (p=.146). The IKDC examination scores were similarly non-significant (p=.34). Of note, there were 4 subjects (22.2%) in the low-tension group, 2 subjects (15.4%) in the high-tension group, and one subject in the control group (5.00%) with an IKDC clinical examination grade of C or D. For the one-hop test, there was no significant difference between the tension groups or control group (p=.14). There were significant differences between groups for each of the KOOS subscores (symptoms [symp], pain, activities of daily living [adl], sport, quality of life [qol]) with p<.01. Subsequent pairwise testing indicated that the low-tension group was inferior to the control in all subscores (p<.01), while the high-tension group was inferior to the control in KOOS-symp, KOOS-pain, and KOOS-qol (p<.03). There were no significant differences between the high and low-tension groups. No significant differences were observed in all but one SF-36 category, namely emotional role functioning (SF36e; p=.033). Pairwise comparison showed that the low-tension group was inferior to both the high-tension and control groups (p<.04). No significant differences were found between groups in the Tegner activity scale (p=.08). OARSI and WORMS differences were nonsignificant with p=.067 and p=.051 respectively.

DISCUSSION: The results do not support the hypothesis that there are no differences in 15-year outcomes between the high- and low-tension groups and the matched control. The results from the KOOS indicated inferior results for the high- and low-tension groups compared to the control for 3 of the 5 subscores. Given that the low-tension group performed significantly worse in each of the categories compared to the control, it can be postulated that the low-tension group had slightly worse performance at this time point. This is supported by the emotional role functioning category of the SF-36, as there was significance between the low-tension and control groups, but not between high-tension and control. Though not significant, there was a higher percentage of patients with IKDC ratings of C or D in the low-tension group than the high-tension or control groups, which has been shown to contribute to the development of PTOA.[3] Additionally, both the radiographic and MRI based outcome measures trended toward significance, and subsequent pairwise tests indicated significant differences between the low-tension and control groups in OARSI (p=.024) and WORMS (p=.025) respectively. A limitation of the study was the high loss to follow-up at 15 years. Thus, the study had reduced power to detect potentially meaningful differences.

CLINICAL SIGNIFICANCE: The results of this study indicate that both high- and low-tension outcomes remain inferior to the uninjured, matched control 15 years post-surgery. The low-tension group had slightly worse outcomes than the high-tension group compared to the control, which supports the use of the higher tensioning protocol during ACL reconstruction.

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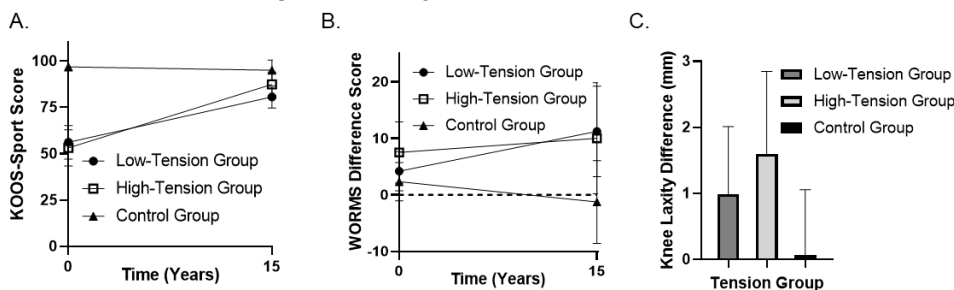


Fig. 1. A. Mean KOOS-sports score ± 95% confidence intervals.

B. Mean difference ± 95% confidence intervals for WORMS score.

C. Mean difference ± 95% confidence intervals (surgical – contralateral knee) for AP knee laxity at 15-year follow-up.