

## Comparison of Clinical Outcomes Following Anatomic Single vs. Double-Bundle ACL Reconstruction: A Randomized Clinical Trial

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**Objectives:** The shortcomings of anterior cruciate ligament reconstruction (ACL), including failure to restore normal structure and function of the knee, limited return to pre-injury level of sports participation and failure to prevent the development of post-traumatic knee osteoarthritis (OA) have recently been recognized. Anatomic methods to reconstruct the ACL, including anatomic single-bundle (SB) and double-bundle (DB) reconstruction, have been proposed to improve clinical outcomes after ACL reconstruction. We performed a double-blinded randomized clinical trial to compare clinical outcomes of anatomic SB to anatomic DB ACL reconstruction. We hypothesized that anatomic DB ACL reconstruction with a quadriceps tendon autograft with bone block would result in reduced knee laxity, better range of motion, patient-reported outcomes (PROs), return to sports and reduced risk of re-injury compared to anatomic SB ACL reconstruction.

**Methods:** Individuals between 14 and 50 years of age participating in at least 100 hours of Level 1 or 2 sports activities that presented within 12 months of injury to both bundles of the ACL with or without injury to the medial or lateral meniscus were eligible to participate in this study. Individuals with prior injury or surgery of the ipsilateral or contralateral knee or greater than a grade 1 concomitant knee ligament injury were excluded. If the ACL insertion sites were between 14 and 18mm, as measured with an arthroscopic ruler at the time of arthroscopy, the subject was randomized to undergo SB or DB ACL reconstruction with a 10 mm quadriceps tendon autograft harvested with a patellar bone block. A single, anatomically placed femoral tunnel was used for all cases. For DB ACL reconstruction, the graft was split into two arms and passed through two anatomically placed tibial tunnels. Subjects were followed at 3, 6, 12 and 24 months after randomization, with the primary endpoints occurring at 24 months. Outcome measures included the KT-1000 (side to side difference) and pivot shift tests, range of motion (ROM), IKDC Subjective Knee Form (IKDC-SKF) and return to pre-injury level of sports participation.

**Results:** Fifty-seven subjects were randomized (29 DB) and two-year follow-up was attained from 51 (89.5%). There were no differences between groups in terms of age, proportion of males, body mass index (BMI), participation in competitive or recreational sports or concomitant meniscus procedures. At 24-month follow-up there were no between groups differences for the pivot shift and KT-1000 tests, ROM and IKDC-SKF scores (Table 1). Twenty-three (85.2%) DB's and 24 (87.5%) SB's reported returning to pre-injury level of sports 2 years after surgery ( $p=0.81$ ). Three subjects (2 SB's, 5.9% of total) suffered a graft rupture and 5 individuals (4 SB's, 9.8% of total) had a subsequent meniscus injury.

**Conclusion:** With the available sample size, we were unable to demonstrate significant differences in clinical outcome between anatomic SB and DB ACL reconstruction when performed with a quadriceps tendon autograft with a bone block in individuals with ACL insertion sites that ranged from 14 to 18 mm. Furthermore, both anatomic SB and DB ACL reconstruction lead to clinical outcomes that are comparable or superior to those reported for non-anatomical ACL reconstruction with minimal recurrent instability.

Table 1 - Clinical Outcomes at 24 Months

	<b>Double Bundle (n=27)</b>	<b>Single Bundle (n=24)</b>	<b>p value<sup>6</sup></b>
Normal Pivot Shift (n, %)	25, 92.6%	23, 95.8%	0.48
KT Arthrometer <sup>1</sup> (30 lb) (mean $\pm$ SD)	0.5 $\pm$ 1.3	0.6 $\pm$ 1.6	0.80
KT Arthrometer <sup>1</sup> (max manual) (mean $\pm$ SD)	0.7 $\pm$ 1.2	0.8 $\pm$ 1.5	0.79
Passive Extension of Involved Knee <sup>2</sup> (mean $\pm$ SD)	3.9 $\pm$ 3.0	3.8 $\pm$ 2.8	0.90
Passive Extension Difference <sup>3</sup> (mean $\pm$ SD)	2.1 $\pm$ 1.9	1.7 $\pm$ 2.6	0.53
Active Flexion of Involved Knee <sup>4</sup> (mean $\pm$ SD)	140.7 $\pm$ 5.7	140.2 $\pm$ 6.3	0.76
Active Flexion Difference <sup>5</sup> (mean $\pm$ SD)	0.3 $\pm$ 4.2	-1.1 $\pm$ 9.0	0.47
IKDC Subjective Knee Score (mean $\pm$ SD)	89.4 $\pm$ 10.3	90.2 $\pm$ 11.1	0.79

<sup>1</sup> Values are involved minus non-involved side to side difference in millimeters

<sup>2</sup> Values are in degrees. Positive values indicate hyperextension <sup>3</sup> Non-involved minus involved knee difference in passive knee extension. Values are in degrees. Positive values indicate a loss of extension of the involved knee <sup>4</sup> Values are in degrees <sup>5</sup> Non-involved minus involved knee difference in active knee flexion. Values are in degrees. Positive values indicate a loss of flexion of the involved knee. <sup>6</sup> Independent t-tests were used for continuous variables and Fisher Exact Tests were used for nominal variables. p values were not adjusted for multiple comparisons.