学位論文

Effect of fixation angle and graft tension in double-bundle anterior cruciate ligament reconstruction on knee biomechanics (膝前十字靱帯再建術における靱帯の脛骨固定手技が膝安定性に与える 影響について、人屍体膝を用いたバイオメカニクスに関する研究)

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(Shih-Sheng Chang, Masataka Fujii, Daisuke Araki, Junjun Zhu, Brandon Marshall, Monica Linde-Rosen, Patrick Smolinski, Freddie H. Fu) 1 Effect of Fixation Angle and Graft Tension in Double-Bundle Anterior Cruciate Ligament Reconstruction

2 on Knee Biomechanics

3 Abstract

- 4 *Purpose* To compare the effect of graft fixation angle and tension in double-bundle ACL reconstruction
- 5 on knee biomechanics.
- 6 Methods Fourteen cadaver knees were tested using a robotic system under two loadings: (1) an 89-N
- 7 anterior tibial load (ATL) at full extension (FE), 15°, 30°, 45°, 60°, and 90°, and (2) combined 7 N·m
- 8 valgus and 5 N·m internal tibial torques (simulated pivot-shift test) at FE, 15°, 30°. Four graft fixation
- 9 angles and tensions were used for the anteromedial (AM) and posterolateral (PL) bundles, respectively:
- 10 (Recon 1) 30°/20N and FE/20N, (Recon 2) 30°/30N and FE/10N, (Recon 3) 45°/20N and 15°/20N,
- 11 (Recon 4)  $45^{\circ}/30N$  and  $15^{\circ}/10N$ .
- 12 Results All fixation protocols closely restored the intact knee kinematics under ATL and simulated pivot
- 13 shift loading. For the AM bundle under ATL, the in situ force (ISF) with Recon 3 at the FE was
- 14 significantly lower than that of the intact knee. For the PL bundle under ATL, the ISF with Recon 3 at
- 15 the FE,  $15^{\circ}$  and  $30^{\circ}$  was significantly higher than that of the intact knee. In PL bundle under simulated
- 16 pivot shift loading, the ISF with Recon 1 and Recon 2 at FE, was lower and the ISF of the PL bundle with
- 17 Recon 3 at the  $15^{\circ}$  was higher than that of the intact knee.
- 18 Conclusion The AM-45°/30N and PL-15°/10N fixation most closely matched intact knee kinematics,

19	however, stabilizing the knee during anterior tibial translation may risk an imbalance of the AM and the			
20	PL bundle loading. The results indicate that ACL bundle forces many not be restored even if the clinical			
21	assessment shows good results with the Lachman test and pivot-shift test. This may alter the loading on			
22	other structures of the knee.			
23				
24	Keywords: Double-bundle, anterior cruciate ligament, graft tension, fixation			
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## 37 Introduction

38	Anatomical observation has shown that the anterior cruciate ligament (ACL) consists of two bundles, the				
39	anteromedial (AM) bundle and posterolateral (PL) bundle [6,11]. Many biomechanical studies have also				
40	found that double bundle (DB) ACL reconstruction was better able to restore knee kinematics to that of				
41	the native ACL than single-bundle (SB) reconstruction [8,24,27,30,32,33,38,43,46,49]. However, in				
42	these studies, the fixation protocol varied widely and there was no consensus on the amount of graft				
43	tension applied or the knee flexion angle when the grafts are fixed. Many studies have reported the				
44	importance of the tension on the graft during tibial fixation [2,4,5,19,21,25-27,32,35,41,42,47].				
45	In biomechanical laboratory studies, some results showed an effect of graft fixation angle in DB ACL				
46	reconstruction on knee kinematics [20,30,33,43]. Miura et al. reported on the biomechanical comparison				
47	between two fixation protocols at different knee flexion angles [30]. Their protocol compared the fixation				
48	angles of $30^{\circ}/30^{\circ}$ and $60^{\circ}$ /full extension (FE) for the AM/PL grafts. They concluded there was an				
49	excessive force on the PL bundle with the $30^{\circ}/30^{\circ}$ protocol and an excessive force on the AM bundle				
50	with the $60^{\circ}$ /full extension (FE) protocol. Vercillo et al. also reported that when the PL graft is fixed at				
51	$15^{\circ}$ of knee flexion, the AM graft should be fixed between $15^{\circ}$ and $45^{\circ}$ [43]. However, a three-tunnel				
52	procedure with two femoral tunnels and one tibial tunnel was used for DB ACL reconstruction in both				
53	studies and the use of the single tibial tunnel may have affected the graft fixation tension. Having the				
54	independent tibial tunnels in a four tunnel DB ACL with two femoral tunnels and two tibial tunnels may				

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56	studies that have compared the combinations of fixation angle and tension in a four tunnel anatomical DB
57	ACL reconstruction techniques. Graft fixation is an important factor in ACL reconstruction. The
58	relationship between the effect of fixation angle and tension should be evaluated in the restoration of knee
59	biomechanics.
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61	Some investigators have warned that excessive initial graft tension might lead to abnormal joint stiffness,
62	loss of extension, graft failure, and degeneration of articular cartilage [5,28,29,34,48] and it has been
63	suggested that the PL graft is exposed to excessive force. Otsubo et al. reported that 11% of PL grafts
64	were partially or completely damaged at the femoral tunnel aperture in a clinical study and they suggested
65	that the initial graft tension at the time of graft fixation might be reconsidered to avoid excessive loading
66	of the PL graft [37].
67	The purpose of this study is to evaluate the effect of different combinations of knee flexion angles and
68	graft tensions for graft fixation in four tunnel anatomical DB ACL reconstruction on knee biomechanics.
69	It is hypothesized that (1) 45°/15° flexion angles for AM and PL bundle fixation will most closely restore
70	the intact ACL bundle force, and (2) 30N/10N graft tensions will be better than 20N/20N graft tensions.
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allow better control of the graft fixation tension [38]. To our knowledge, there are no biomechanical

# 72 Material and Methods

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73 Fourteen fresh-frozen human cadaveric knees with no evidence of prior injury and a mean age of 7456.7±6.8 years (range, 46-65 years) were used in this study. Computed tomography (CT) scans of the 75specimens were taken and examined to ensure there was no evidence of osteoarthritis or any bony 76abnormalities. Before testing, the knees were stored at  $-20^{\circ}$ C and thawed overnight at room temperature 77 [31,44]. The surrounding skin and muscles more than 10 cm away from the joint line were removed to 78allow for mounting and testing. The femur and tibia were cut approximately 20 cm from the joint line 79and secured within thick-walled custom aluminum cylinders with polyester resin (Bondo®, 3M, USA). 80 The femur was rigidly mounted to a base and the tibia was fixed to a universal force/moment sensor 81 (UFS), (Model 4015, JR3 Inc, Woodland, CA)[9] on the end-effector of the robotic manipulator 82 (CASPAR Stäubli RX90 robot, Orto MAQUET, Germany), that has an accuracy of ±0.2 N and ±0.1 N·m 83 for forces and moments according to the manufacturer. 84 85Using the robotic testing system, the 6-degrees of freedom (dof) knee kinematics, the in-situ forces in the 86 intact ACL, the ACL graft, the AM, and PL bundles and their respective replacement grafts, were 87 measured [9,10,23,39]. Based on the manufacturer specifications, the robotic system is capable of

89 the intact knee from full extension (FE) to  $90^{\circ}$  of knee flexion was first determined by the robotic/UFS

recording and reproducing positions with an accuracy of ±0.02 mm at each joint. The passive path of

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90 testing system in 0.5° increments, by minimizing all other forces and moments at each step [40]. This

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91 path serves as the reference position from which external loads are applied and kinematics data are 92collected. Two external loading conditions were tested in all knee states: (1) 89 N anterior tibial load 93 (ATL) at FE, 15°, 30°, 60°, and 90° of knee flexion, and (2) combined rotational loads of 7 N·m of valgus 94torque and 5 N·m of internal tibial rotation torque at FE, 15° and 30° of knee flexion for a simulated 95 pivot-shift test [17,18,46]. The anterior tibial translation (ATT) was calculated by comparing the tibial 96 antero-posterior positions before and after loading, and in situ force of the ACL or ACL graft was also 97determined by comparing the force of the ACL-intact or DB-reconstructed knee to that of the 98ACL-deficient knee using the principle of superposition [23,39,40]. The AM and PL bundles of the 99 ACL were separated and transected using a previously described technique, which resulted in two knee 100 states, namely, AM bundle deficient and PL deficient knee [12]. The testing was repeated in ACL-intact, 101 AM bundle deficient (or PL bundle deficient, alternated), ACL-deficient, and four reconstruction knee 102states. A single surgeon (YS) performed all the ACL reconstructions arthroscopically, and the order was 103 alternated. The semitendinosus and gracilis tendons were chosen as ACL replacement grafts, which 104 were harvested using a tendon stripper from each knee. A double strand semitendinosus tendons and 105gracilis tendons were used for the AM and the PL grafts, respectively. 106 Each ACL reconstruction was performed in an anatomic fashion using a 3-portal technique [7]. The 107 femoral and tibial bone tunnel locations of both the AM and PL bundles were determined by the

108 arthroscopic inspection. First, the AM bundle was identified and dissected, then the bone tunnels were

109	created at the center of the insertion site and the same procedure was applied to the PL bundle. These
110	femoral tunnels were created by free pin placement and over-drilling through the accessory medial portal
111	and a direct drill guide (ACUFEX, Smith & Nephew Endoscopy, Andover, MA) was used for tibial
112	tunnels. (Fig. 1) For both grafts, the femoral side was fixed using an extra-cortical button (EndoButton
113	CL, Smith & Nephew, USA) and the tibial side was fixed using two spiked washers and two screws
114	(Arthrex, Naples, FL).
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116 For the first and second fixation protocols, the flexion angles of 30°/FE were selected for AM/PL graft 117fixations. These angles were selected to simulate a clinical fixation procedure [16]. For the third and 118 fourth fixation protocols, the angles of 45°/15° were selected for AM/PL graft fixation, respectively. 119 These angles were selected to copy a previously reported protocol [43]. In addition, different graft 120 fixation tensions for the AM and PL bundles, 20N/20N and 30N/10N, were used for 30°/FE and 45°/15° 121protocols in order to investigate the effect of reduced graft tension of the PL bundle [37]. Thus, four 122fixation protocols were used for the AM/ PL grafts: (Recon 1) 30°/20N and FE/20N, (Recon 2) 30°/30N 123and FE/10N, (Recon 3) 45°/20N and 15°/20N, (Recon 4) 45°/30N, and 15°/10N. Prior approval was 124obtained for this study from the University of Pittsburgh Committee for Oversight of Research and 125Clinical Training Involving Decedents (CORID) # 396.

## 126 Statistical Analysis

- 127 An a priori power analysis was performed (G\*power 3.1.9.2 Dusseldorf, Germany) using significance
- 128 level of 0.05, a power of 0.80 and based on being able to detect a difference in graft force of 10 N based
- 129 on previous data [42] and resulted in N = 13.
- Statistical analysis of the ATT and in-situ forces was performed using a 2-factor repeated measures analysis of variance (ANOVA) with knee state and knee angle as the factor, followed by Scheffé's post hoc test because all variables were measured on the same specimen and multiple contrasts were
- 133 performed. The two factors evaluated were the condition of the knee and the knee flexion angle with
- 134 statistical significance set at P<0.05. All tests were performed using SPSS version 18.0 (SPSS Inc,
- 135 Chicago, Illinois).
- 136

#### 137 **Results**

- 138 In response to the two loadings, the ATT and coupled ATT for all the fixation protocols was not
- 139 significantly different from the intact knee at the all knee flexion angle (n.s.). (Fig.2)
- 140 The *in-situ* force of the AM bundle under ATL with Recon 3 was significantly lower than that of the intact
- 141 bundle at all flexion angles. (Fig. 3, Fig. 4)
- 142 The *in-situ* force of the AM bundle with every reconstruction was significantly lower than that of the
- 143 intact bundle at every flexion angle other than full extension. Under anterior loading, the *in-situ* force of
- 144 the PL bundle with Recon 3 at the  $0^{\circ}$ ,  $15^{\circ}$  and  $30^{\circ}$  was significantly higher than that of the intact knee

151	Discussion
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149	3 at the $15^{\circ}$ was greater than that of the intact knee (P=0.01).
148	FE was lower than that of the intact knee (P=0.02 and 0.01, respectively) and the <i>in-situ</i> force with Recon
147	5) For the PL bundle under simulated pivot shift, the ISF of the PL bundle with Recon 1 and Recon 2 at
146	force of each reconstruction at the all angles was significantly lower than the intact bundle (P<0.05). (Fig.
145	(P=0.02, 0.00 and 0.00, respectively).For the AM bundle under simulated pivot shift loading, the <i>in-situ</i>

- 152 The most important finding of this study is that while different ACL reconstructions can restore knee
- 153 kinematics and certain fixation protocols can restore the PL bundle *in situ* force, the AM bundle force is
- 154 more difficult to restore. Vercillo et al. showed that three-tunnel DB reconstruction restored normal
- 155 knee kinematics in a biomechanical study, [43] while Petersen et al. showed that four-tunnel DB
- 156 reconstruction more closely restored the intact ACL kinematics than three-tunnel DB reconstruction [38].
- 157 This study assessed different combinations of knee flexion angles and graft tensions at fixation in
- 158 anatomical four-tunnel DB ACL reconstruction.
- 159 The *in-situ* force analysis in this study found that the PL graft had a different pattern in each
- 160 reconstruction. Both the 30°/FE fixation protocols, Recon 1 (30°/20N and FE/20N) and Recon 2
- 161 (30°/30N and FE/10N), had a lower PL bundle *in-situ* force than the intact state, while Recon 3 (45°/20N
- 162 and  $15^{\circ}/20N$ ) gave a higher *in-situ* force than the intact state. Recon 4 ( $45^{\circ}/30N$  and  $15^{\circ}/10N$ ) was able

163	to restore the PL bundle <i>in-situ</i> force better than the other reconstructions. Thus, graft fixation with 10N
164	was enough to restore the <i>in-situ</i> force of the PL bundle. Mae et al. indicated that anatomic DB ACL
165	reconstruction with a total of 20 N of initial tension yielded good clinical outcomes [26] if the PL graft
166	fixation was tensioned at 10N or less. Thus, depending on the flexion angle, a PL bundle fixation
167	tension of 10 N may be adequate.
168	For the AM bundle, neither of the reconstructions restored the <i>in situ</i> force of the bundle to the intact state
169	under anterior tibial nor simulated pivot shift loading scenarios. The difference in <i>in situ</i> forces under
170	simulated pivot shift may indicate that AM bundle should to be fixed at lower flexion angle, as described
171	in some clinical studies, in order to restore the rotational function [15,22]. This result is different from
172	previous studies using ACL reconstruction with three tunnels procedure that found 45°/15° protocol for
173	AM/PL bundle was able to restore the native kinematics of the knee. Therefore, anatomical DB
174	reconstruction may require a different fixation protocol than the three-tunnel procedure. Hoher et al.
175	found that the tibial position at the time of graft fixation was an important factor for ATT and <i>in-situ</i> force
176	results during ACL reconstruction and stated that a 67 N posterior tibial load should be applied during
177	graft fixation for normal knee kinematics, which was not done in this study [13]. In this study, the
178	reduced <i>in situ</i> force of AM bundle might be caused by the tibial position at the time of graft fixation.
179	This study found that the <i>in-situ</i> force of AM bundle and PL bundle varied by reconstruction, however, all
180	of the fixation protocols reproduced the knee kinematics within 3 mm of those of the intact knee during in

181	response to the two applied loads. With arthrometer testing, ACL deficiency is defined as a side-to-side
182	difference of greater than 3 mm [3]. This discrepancy between restoration of the knee kinematics and <i>in</i>
183	situ forces of the ACL was similar to that seen in other studies. Vercillo et al. showed that although
184	statistically significant differences in the <i>in situ</i> force were found between their fixation protocols and the
185	intact knee, while the maximum difference in anterior translation of 2.2 mm was still within the clinically
186	acceptable range [43]. A study by Murry et al. showed that normal knee kinematics were restored with
187	both tensioning protocols even though the loading of the individual bundles differed significantly [33].
188	Yasuda et al. also showed that differences in initial tension applied to the two grafts significantly affected
189	the absolute value of each graft force at each knee flexion angle but did not significantly affect the force
190	versus flexion curve pattern [47].
190 191	versus flexion curve pattern [47]. Some clinical studies have reported that anatomical double-bundle reconstruction resulted in better
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191 192 193 194	Some clinical studies have reported that anatomical double-bundle reconstruction resulted in better restoration of knee kinematics than the anatomical single-bundle reconstruction [1,14,16] however; factors other than knee kinematics may affect clinical results. It has been found that re-injury of the reconstructed ACL occurred in 11% of the PL grafts after DB ACL reconstruction, and the authors
191 192 193 194 195	Some clinical studies have reported that anatomical double-bundle reconstruction resulted in better restoration of knee kinematics than the anatomical single-bundle reconstruction [1,14,16] however; factors other than knee kinematics may affect clinical results. It has been found that re-injury of the reconstructed ACL occurred in 11% of the PL grafts after DB ACL reconstruction, and the authors reasoned that high tension in the PL graft caused this partial rupture in DB ACL reconstruction [37].

199 function of ACL including stability, *in-situ* force pattern and graft tension.

200	The main limitation of this stud	v is that it is a time zero stud	v and graft healing an	d graft remodeling

- 201 under in vivo conditions were not considered. In addition, graft tension can decrease due to repeat
- 202 loading during testing. Numazaki et al. showed that the peak load of the ACL graft dramatically
- 203 decreased five thousand cyclic loadings, even though a bone patella bone graft was fixed with
- 204 interference screws [36]. This effect may need to be considered with the graft tensioning. Furthermore,
- 205 the cadaver specimens were older than the typical age of ACL injury and differences of in bone quality
- and ligament properties may affect the results.
- 207 This study found that all the tibial fixation protocols reproduced the kinematics of the intact knee during
- 208 ATT in response to anterior tibial and combined rotatory loads. However, the *in-situ* force of the AM
- 209 graft was low in all reconstructions and the *in-situ* force of the PL graft had a different pattern in each
- 210 reconstruction. These results indicate that bundle forces may not be restored after ACL reconstruction,
- 211 even if the clinical assessment show good result with the Lachman test and pivot-shift test.

### 212 Conclusion

- 213 In anatomic double bundle ACL reconstruction, using hamstring tendons, fixing the AM graft with 30 N
- at a knee flexion angle of 45° and the PL graft with 10 N at 15° best restored the intact in situ forces of
- 215 the bundles under two different loadings among four different fixation protocols.
- 216 **Conflict of Interest**

The authors have no conflict of interest to report.

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- **Fig.1** Completed DB-ACLR with knee at 90° of flexion as viewed from the central portal.
- 368 (AM-anteromedial bundle, PL- posterolateral bundle, PCL- posterior cruciate ligament)

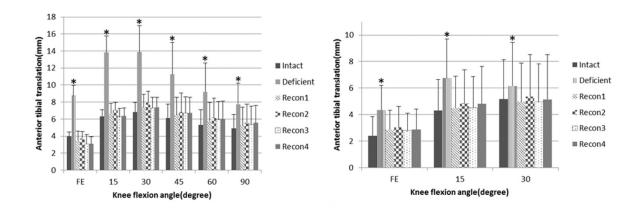


Fig. 2 Anterior tibial translation under an 89-N anterior tibial load (left) and coupled anterior tibial
 translation (right) under simulated pivot shift load with different knee conditions. (\*P<0.05 compared to</li>
 intact ACL and all reconstructions, FE-full extension, Recon 1: 20N/20N-30°/FE, Recon 2: 30N/10N -

 $30^{\circ}$ /FE, Recon 3: 20N/20N -  $45^{\circ}$ /15° and Recon 4: 30N/10N -  $45^{\circ}$ /15°)

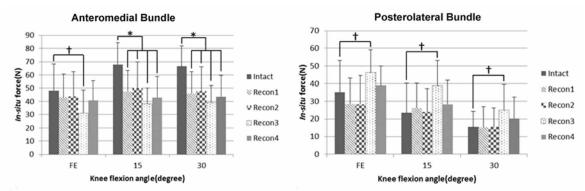


Fig. 3 In situ force in the AM (left) and PL (right) bundles in response to an 89 N anterior tibial load at different flexion angles. (\*P<0.05 compared to ACL intact, <sup>†</sup>P<0.05 between ACL intact and Recon 3, FE-full extension, Recon 1: 20N/20N-30°/FE, Recon 2: 30N/10N-30°/FE, Recon 3: 20N/20N-45°/15° and Recon 4: 30N/10N-45°/15°)</li>

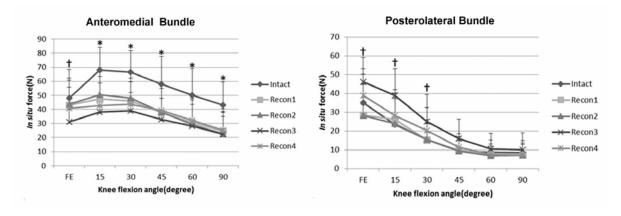


Fig. 4 In situ force in AM (left) and PL (right) bundles in response to an 89-N anterior tibial load at the all knee flexion angles (mean ± SD). (\*P<0.05 between intact ACL and all reconstructions, <sup>†</sup>P<0.05 between intact ACL and Recon 3, FE-full extension, Recon 1: 20N/20N-30°/FE, Recon 2: 30N/10N-30°/FE, Recon3: 20N/20N-45°/15° and Recon4: 30N/10N-45°/15°)</li>

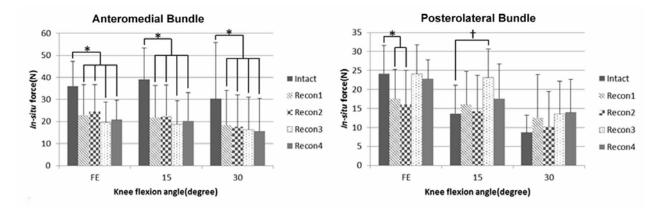


Fig. 5 In situ force in AM (left) and PL (right) bundles in response to simulated pivot shift load.
(\*P<0.05 compared to ACL intact, <sup>†</sup>P<0.05 between ACL intact and Recon 3, FE-full extension, Recon 1: 20N/20N-30°/FE, Recon 2: 30N/10N-30°/FE, Recon 3: 20N/20N-45°/15° and Recon 4: 30N/10N-45°/15°)</li>