

# The Influence of Supplementary Tibial Fixation on Laxity Measurements After Anterior Cruciate Ligament Reconstruction With Hamstring Tendons in Female Patients

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**Background:** Female patients undergoing arthroscopic anterior cruciate ligament reconstruction with a hamstring tendon graft developed increased postoperative laxity compared to male and female patients who had reconstruction using a patellar tendon graft. This difference may be due to graft slippage in less dense female tibial bone.

**Hypothesis:** Reinforcement of tibial fixation of the hamstring tendon graft in women by supplementary methods may reduce laxity.

**Study Design:** Randomized controlled clinical trial; Level of evidence, 2.

**Methods:** Fifty-six female patients divided into 2 groups (standard tibial fixation with  $7 \times 25$ -mm metal interference screw versus metal interference screw with supplementary staple fixation) were followed for 2 years.

**Results:** After 2 years, the mean side-to-side difference using KT-1000 arthrometer manual maximum measurements was 1.8 mm (standard group) and 1.1 mm (staple group) ( $P = .05$ ). The percentage of patients with a side-to-side difference of  $<3$  mm did not differ significantly between the 2 groups ( $P = .66$ ): 88.8% of the standard group versus 90.5% of the staple group. A grade 0 Lachman test result was present in 63% of the standard group and 86% of the staple group ( $P = .04$ ). Kneeling pain was experienced by 7% of the standard group and 29% of the staple group ( $P = .05$ ).

**Conclusions:** Supplementary tibial fixation in female patients undergoing anterior cruciate ligament reconstruction with hamstring tendon graft in addition to a single-size screw significantly improves laxity measurements and clinical stability assessment 2 years after surgery. However, this improvement is at the cost of increased kneeling pain.

**Keywords:** fixation; hamstring; anterior cruciate ligament (ACL); laxity; female patients

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We identified in a previous study comparing the use of either a patellar tendon or hamstring tendon graft for reconstructing the ACL that 2 years after surgery the female hamstring group had increased laxity on KT-1000 arthrometer testing compared to the male hamstring and female patellar tendon reconstruction groups.<sup>8,20</sup> It is thought that less dense bone in the female proximal tibial metaphysis may allow slippage of the tendon graft. There

was no gender difference seen in laxity measurements when a bone–patellar tendon–bone graft was used, which suggests that hamstring graft laxity is dependent on fixation technique rather than gender. The aim of this study was to determine whether reinforcement of the tibial fixation would reduce the increased laxity seen in female patients undergoing ACL reconstruction using hamstring tendon graft.

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## MATERIALS AND METHODS

### Patient Selection

Between June 1997 and December 1998, 58 female patients consented to participate in a prospective, randomized, double-blind study of arthroscopic ACL reconstruction using a hamstring tendon autograft. Sample size

was calculated based on the ability to detect a laxity difference of 1-mm side-to-side difference with a power of 0.90. Patients with an associated ligament injury, chondral damage, previous meniscectomy, excision of more than one third of 1 meniscus, an abnormality seen radiographically, an abnormal contralateral knee, or who were pursuing a claim for compensation or did not wish to participate in a research program were excluded from the study.

Patients were randomized to receive either standard 7 × 25-mm RCI (Smith & Nephew Endoscopy Inc, Andover, Mass) interference screw tibial fixation or 7 × 25-mm RCI interference screw fixation with a supplementary staple. A standard 7 × 25-mm RCI interference screw was used for the left femoral fixation, and a reverse-thread 7 × 25-mm RCI interference screw was used for the right femoral fixation.<sup>18</sup> All patients signed informed consent forms. Ethical committee approval was obtained from the Australian Institute of Musculo-Skeletal Research and Sydney University. One patient declined surgery, and another was excluded before randomization as she was found to have a contralateral ACL rupture making side-to-side assessment invalid. The remaining 56 patients were randomly assigned into 1 of 2 groups using a random number table. Twenty-nine patients received standard tibial fixation and 27 patients received supplementary tibial fixation. Surgery was performed after a period of physical therapy aimed at restoring range of movement of the joint and reducing the amount of swelling.

### Surgical Technique

The senior author (L.A.P.) performed minimally invasive arthroscopically assisted ACL reconstruction using the hamstring tendon autograft (gracilis and semitendinosus tendons) with interference screw fixation in all patients. Under general anesthetic, a thigh tourniquet was applied and inflated after exsanguination of the leg with an Esmarch bandage. High anterolateral and low anteromedial portals were made and a diagnostic arthroscopy performed using gravity-fed saline insufflation of the joint. Any meniscal lesions found were appropriately treated. The ACL stump was removed and the intercondylar notch cleared, but a notchplasty was not performed. The position of the femoral tunnel was marked on the posterior cortex with a Steadman pick 5 mm anterior to the posterior capsule reflection and overdrilled with a 4.5-mm AO drill bit with the knee positioned in maximum flexion.

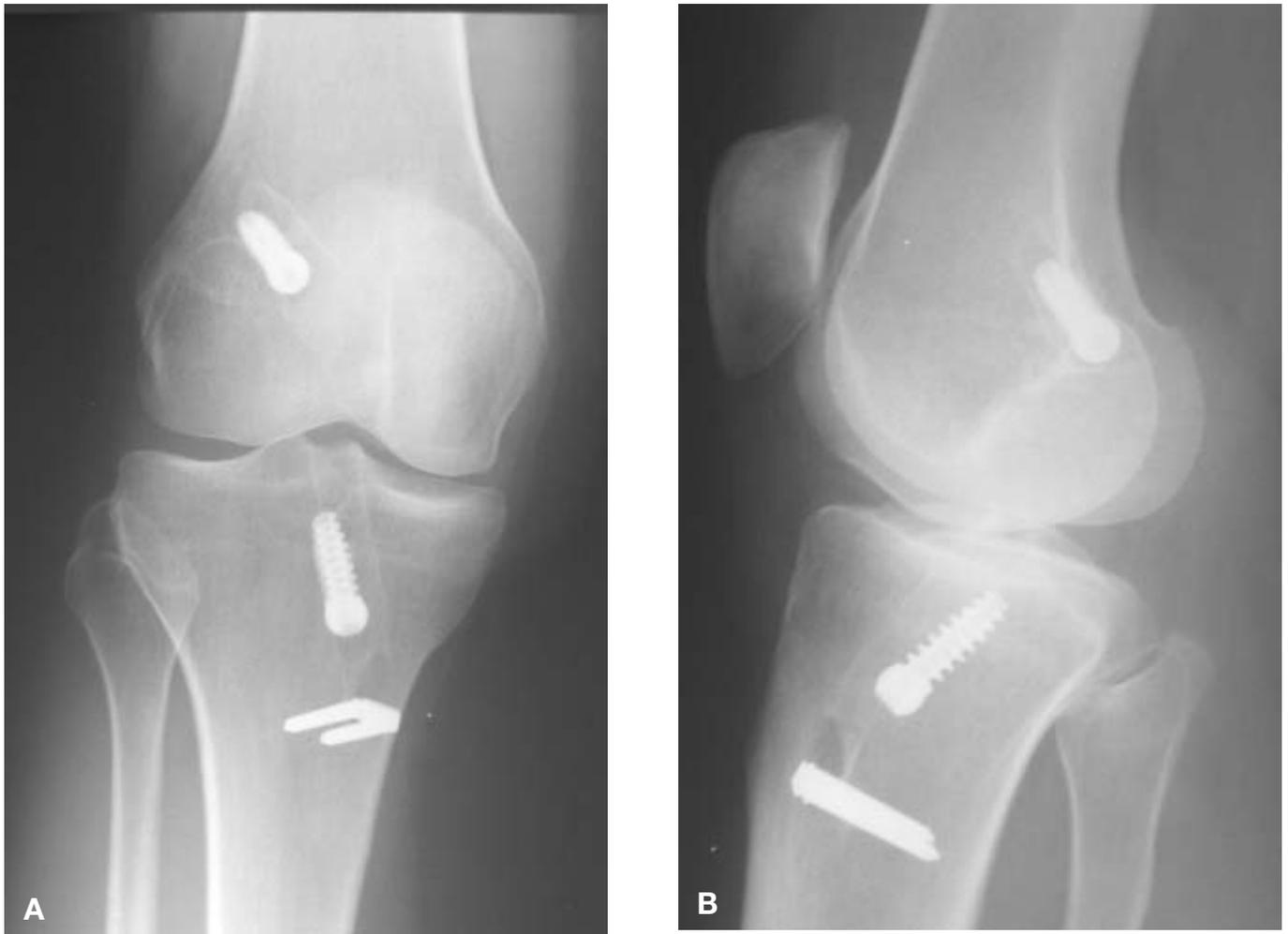
A 2-cm longitudinal ipsilateral incision was made 1 cm medial to the tibial tubercle over the pes anserinus insertion. The semitendinosus and gracilis tendons were harvested to 22 cm using a tendon harvester (Linvatec Inc, Largo, Fla). The tendons were stripped of any adherent muscle and mesotendon and fashioned into a 4-strand graft by folding over a No. 5 Ticron (Sherwood-Davis & Geck, St. Louis, Mo) pull-out suture. The tendon strands were equally tensioned and the free ends of the graft sutured for a distance of 40 mm with a No. 2 Vicryl (Ethicon, Edinburgh, Scotland) suture, and the folded end was sutured for a distance of 25 mm with a No. 1 Vicryl

suture. The graft diameter was measured by passing it through a sizing block (6 to 8.5 mm in 0.5-mm increments), and this measurement was used to select the size of the stepped router (Smith & Nephew Endoscopy Inc), which was used to make the tibial and femoral tunnels. The femoral end of the graft was marked 30 mm from the tip with methylene blue to equal the length of the femoral tunnel. A 2.4-mm Beath pin was inserted into the 4.5-mm femoral drill hole under arthroscopic guidance and with the knee positioned in maximum flexion. The femoral tunnel was drilled to a depth of 30 mm using the appropriate-sized router. A heavy nylon suture was folded double and threaded through the end of the Beath pin and pulled through the knee to emerge on the anterolateral surface of the distal thigh. The ends were looped over and secured with a clip. The tibial tunnel location was identified in the posterior footprint of the ACL stump on an imaginary line from the anterior horn of the lateral meniscus to the medial tibial spine. A 4.5-mm drill hole was made using a drill guide (Smith & Nephew Endoscopy Inc), and a 2.4-mm guide wire was inserted and overdrilled with the appropriate-sized router.

The hamstring tendon graft was delivered through the tibial and femoral tunnels using the pull-through suture and tensioned by traction on both ends. The graft was snugged into place in the femoral tunnel until the methylene blue mark was flush with the inner cortex. A guide wire was placed in the femoral tunnel anterior to the graft, and a 7 × 25-mm cannulated titanium interference screw (RCI, Smith & Nephew Endoscopy Inc) was inserted over the wire and countersunk 5 mm. Graft fixation was tested by manual tension. Similarly, tibial fixation was achieved with a 7 × 25-mm cannulated titanium RCI screw inserted over a guide wire placed posteriorly in the tibial tunnel. The graft was tensioned manually, and the screw was engaged in 60° of knee flexion with the final seating of the screw in full extension. The screw was countersunk at least 1 cm into the tibial tunnel. The remaining graft was cut off flush with the tibial cortex in the standard group. In the group receiving supplementary tibial fixation, a Richards staple (Smith & Nephew Richards, Memphis, Tenn) was inserted distal to the RCI screw to pin the graft into the subcortical cancellous bone at the opening of the tibial tunnel (Figure 1). The whipstitch sutures were tied over the staple for further fixation.

### Postoperative Rehabilitation

Patients in both groups had identical postoperative rehabilitation, consisting of immediate weightbearing with the aid of crutches after surgery. No brace was used, and patients were encouraged to discard crutches as soon as possible after surgery, usually within 3 to 4 days. Patients attended daily physical therapy sessions for the first week, focusing on achieving full extension and co-contraction of quadriceps and hamstring muscles. Jogging was commenced after 6 weeks, but return to competitive sport was restricted until 6 months after surgery and only after clinical examination.



**Figure 1.** Postoperative AP (A) and lateral (B) radiographs showing the positions of the femoral and tibial screws and the tibial staple.

### Assessment

All patients were assessed by an independent examiner before surgery and at 3, 6, 12, and 24 months after surgery. Symptoms and signs of knee function were assessed to determine the International Knee Documentation Committee (IKDC) grade. The Lysholm knee score was obtained by means of a self-administered questionnaire. The Lysholm knee score is designed to evaluate specific symptoms relating to knee function (limp, need for support, locking, instability, pain, swelling, and impairment of stair climbing or squatting ability). The highest obtainable score is 100. Instrumented laxity testing was determined with the KT-1000 arthrometer (MEDmetric Corp, San Diego, Calif) by measuring side-to-side differences in displacement at 9.1 kg (20 lb) and on manual maximum testing. Thigh atrophy was measured as the difference in circumference between the sides at a point 10 cm proximal to the superior pole of the patella. Kneeling pain on a standard carpet surface and hamstring muscle discomfort were recorded for site and severity using a visual analog scale from 0 (*no pain*) to 10 (*most severe pain*).

### Statistical Analysis

For the purposes of analysis, all data were assumed to be nonparametric. The Mann-Whitney  $U$  test was used for ranked continuous data (Lysholm knee score) and the unpaired Student  $t$  test for continuous data (KT-1000 arthrometer comparison). The Wilcoxon signed rank test was used for related ordinal or interval data. The  $\chi^2$  test was used for categorical data, using A and B against C and D (normal or nearly normal versus abnormal or severely abnormal) in the IKDC data. Statistical significance was assessed at the 5% level.

### RESULTS

Forty-eight patients (85.7%) were available for review 2 years after surgery. Seven patients were lost to follow-up, and 1 patient suffered a contralateral ACL rupture during the follow-up period and was excluded. Twenty-seven patients had standard RCI interference screw fixation (standard group), and 21 had supplementary tibial fixation with a staple (staple group). The mean age of the stan-

TABLE 1  
Baseline Variables for Patients With  
Standard Tibial RCI Screw Fixation  
and Supplementary Tibial Staple Fixation

	Standard Group	Staple Group
Number of patients	27	21
Mean age, y	25.8	32.5
Side		
Left	17 (63.0%)	18 (85.7%)
Right	10 (37.0%)	3 (14.3%)
Chronicity		
Subacute	17 (63.0%)	14 (66.7%)
Chronic	10 (37.0%)	7 (33.3%)
Strands		
3	1 (3.7%)	2 (9.5%)
4	26 (96.3%)	19 (90.5%)
Meniscectomy		
Previous	1 (3.7%)	1 (4.8%)
At surgery	6 (22.2%)	4 (19.0%)
Repair	1 (3.7%)	0

Standard group was 26 years (range, 15-41 years) and of the staple group was 32 years (range, 28-38 years) ( $P = .02$ ). No pregnancies occurred during the follow-up period.

The ACL was reconstructed in the subacute phase (3 to 12 weeks from injury) in 31 patients and during the chronic phase (>12 weeks from injury) in 17 patients. The median femoral graft diameter was 7.5 mm (range, 6.5-8.0 mm). Forty-five patients had 4 strand grafts, and 3 patients had 3 strand grafts due to suboptimal graft harvest. A meniscectomy was performed in 10 patients at the time of reconstruction, whereas 2 patients had previously undergone a meniscectomy (Table 1). There was no statistically significant difference between the 2 groups in any of the following variables:

- time between injury and surgery,
- articular cartilage surface damage,
- femoral or tibial graft size,
- incidence of meniscectomy,
- side of operation, and
- number of patients receiving a reverse-thread RCI femoral screw.

However, the power of the study does not allow one to draw the conclusion that no significant difference truly exists between the 2 groups in these variables (1.0 vs 2.0; SD = 1; power = 0.9654)

### Lysholm Knee Score

Subjective assessment was performed using the Lysholm knee score (Table 2). The median Lysholm knee score was 95 in both groups (range, 81-100 in the standard group and 86-100 in the staple group). Ninety-six percent of the standard group and 100% of the staple group reported good or excellent results after 2 years.

TABLE 2  
Lysholm Knee Scores For Patients With  
Standard Tibial RCI Screw Fixation and Supplementary  
Staple Tibial Fixation 2 Years After Surgery

Score	Standard Group (n = 27)	Staple Group (n = 21)
Excellent (95-100)	16 (59.3%)	13 (61.9%)
Good (84-94)	10 (37.0%)	8 (38.1%)
Fair (65-83)	1 (3.7%)	0
Poor (<64)	0	0
Median	95	95
Range	81-100	86-100

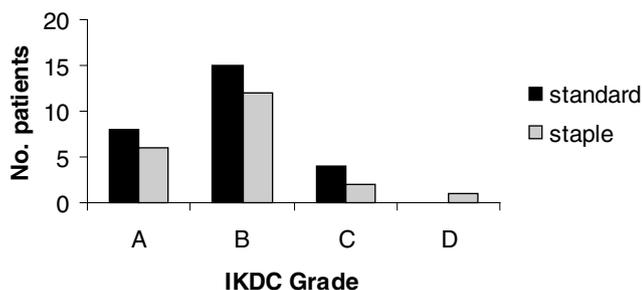
### IKDC Assessment

Overall IKDC assessment revealed 23 patients (85.2%) in the standard group and 18 patients (85.7%) in the staple group with normal (grade A) or nearly normal (grade B) results (Figure 2). On subjective functional assessment, patients in both groups reported their results as either normal or nearly normal. With regard to symptoms, there was no significant difference between the 2 groups for pain, swelling, and partial or full giving way with moderate to strenuous activities. Measurement of range of motion revealed that no patients exhibited an extension loss of >3° or a flexion loss of >5°.

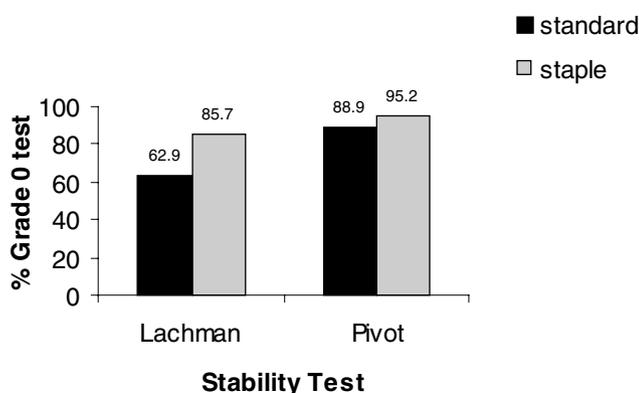
There were similar activity levels within the 2 groups, with 44.4% of the standard group and 52.4% of the staple group participating in level 1 (jumping, pivoting, hard cutting) and level 2 (heavy manual work) activities. The incidence of kneeling pain was 7.4% in the standard group but significantly increased in the staple group to 28.6% ( $P = .05$ ) (mean = 0.48 in the standard group and 1.00 in the staple group; SD = 1.9 in the standard group and 1.7 in the staple group;  $P = .33$ ; range, 0-9 for the standard group and 0-5 for the staple group). There was no significant difference between the groups for the variables of range of knee motion or thigh atrophy.

### Ligament Laxity Testing

The results of manual ligament examination are shown in Figure 3 and Table 3. The Lachman test revealed a difference between the 2 groups ( $P = .04$ ), whereas the pivot shift test revealed no difference, with 88.9% of the standard group and 95.2% of the staple group having a grade 0 pivot test result. Instrumented testing revealed less laxity in the staple group compared to the standard group, which was evident early and was still present at the 24-month review. A significant difference was demonstrated between the mean anterior displacement of the 2 groups on testing at 9.1 kg (20 lb) ( $P = .03$ ) and on manual maximum testing ( $P = .05$ ) (Figure 4 and Table 4). However, when analyzed as a subgroup of patients with <3-mm side-to-side movement, there was no significant difference. On 9.1 kg (20 lb) testing, 88.8% of the standard group (24 of



**Figure 2.** International Knee Documentation Committee (IKDC) scores for patients with standard tibial RCI screw fixation and supplementary staple tibial fixation.



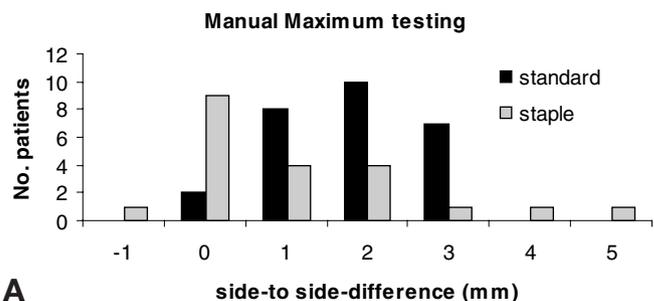
**Figure 3.** Percentage of patients with grade 0 ligament test for patients with standard tibial RCI screw fixation and supplementary staple tibial fixation.

27, power = 0.06) and 90.5% of the staple group (19 of 21, power = 0.27) scored  $\leq 3$ -mm side-to-side difference. On manual maximum testing, 74.1% of the standard group (20 of 27) and 85.7% of the staple group (18 of 21) scored  $\leq 3$  mm ( $P > .05$ ).

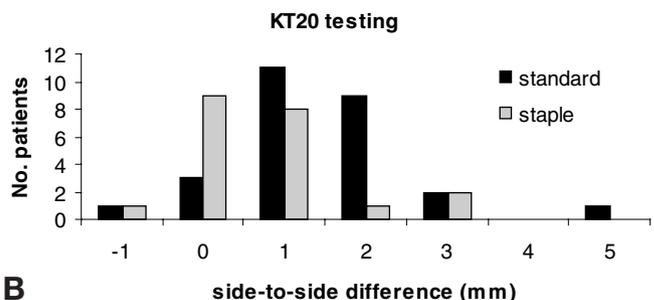
**DISCUSSION**

In a previous study, we identified that 2 years after surgery, female patients with ACL reconstruction using hamstring tendon grafts had increased laxity compared to male patients treated identically and when compared with both male and female patients using patellar tendon grafts.<sup>8,20</sup> The increased laxity was thought to be due to poor fixation of the 7 × 25-mm interference screw in soft tibial bone stock. To assess the effect on laxity of supplementary tibial fixation, a randomized controlled trial was designed in which the only variable that differed between the 2 groups was the use of a supplementary tibial staple.

Randomized controlled trials enable the most valid estimate of the efficacy of any health care intervention to be made. However, most studies published in the orthopaedic literature are nonrandomized, which leads to the potential for bias.<sup>3</sup> Four types of bias have been described: susceptibility, performance, detection, and transfer.<sup>21</sup> In this study,



**A**



**B**

**Figure 4.** Number of patients in both the standard and staple groups with a side-to-side difference using the KT-1000 arthrometer at (A) manual maximum testing and (B) 20-lb (KT20) testing.

**TABLE 3**

Ligament Clinical Evaluation Findings for Patients With Standard Tibial RCI Screw Fixation and Supplementary Staple Tibial Fixation 2 Years After Surgery

Test	Standard Group (n = 27)	Staple Group (n = 21)
Lachman		
Grade 0 <sup>a</sup>	17 (62.9%)	18 (85.7%)
Grade 1	10 (37.0%)	3 (14.3%)
Pivot shift <sup>b</sup>		
Grade 0	24 (88.9%)	20 (95.2%)
Grade 1	3 (11.1%)	1 (4.8%)

<sup>a</sup> $P = .04$ .

<sup>b</sup>Not significant.

susceptibility bias was reduced because the 2 groups of patients had a similar prognosis. Any gender bias has been eliminated by selecting only female patients. Performance bias was minimized because the same surgeon operated on all patients using the identical graft fixation technique with 7 × 25-mm RCI interference screws (apart from the use of a tibial staple in the staple group). The postoperative management, activity levels, and follow-up regimens were similar in both groups. Detection bias was reduced by using identical outcome measures and a single independent examiner. However, transfer bias may have occurred because 6.9% of the standard group compared to 22.2% of the staple group was lost to follow-up. This study has shown a statistically significant reduction in laxity with

TABLE 4  
Results of Side-to-Side Difference on KT-1000 Arthrometer for Patients With Standard Tibial RCI Screw Fixation and Supplementary Staple Tibial Fixation 2 Years After Surgery

Arthrometry Test	Standard Group (n = 27)	Staple Group (n = 21)	P
9.1 kg (20 lb)			
Mean (95% confidence interval)	1.4 (1.0-1.9)	0.7 (0.3-1.2)	.03
Percentage <3 mm, power = 0.06	88.8	90.1	.66
Manual maximum			
Mean (95% confidence interval)	1.8 (1.4-2.1)	1.1 (0.4-1.8)	.05
Percentage <3 mm, power = 0.27	74.1	85.7	.20

the use of a supplementary tibial staple in this female population. Sixty-three percent of the standard group and 86% of the staple group had a grade 0 Lachman test at 2 years after reconstruction ( $P = .04$ ). Instrumented testing minimizes the measurement error that occurs because of the subjective nature of clinical ligament testing, and in this study we obtained both manual maximum force measurements and instrumented displacement measurements at a 9.1 kg (20 lb) force. Over the 2-year follow-up period, instrumented testing revealed less laxity in the staple group compared to the standard group at all time periods (Figure 5). However, when analyzed as a subgroup of patients with movement of <3 mm, instrumented testing suggested that there was no difference between the 2 groups. A larger study group would have increased the power of the study and may have detected a difference, but it is debatable whether a side-to-side difference of <3 mm is of clinical relevance.

Surgical reconstruction of the ACL attempts to eliminate instability and reduce the potential for damage to chondral surfaces and the menisci.<sup>9,22</sup> Laxity after ACL reconstruction leads to instability and therefore is considered a failure of treatment. Various factors have been implicated, but anatomical graft placement is probably the most important factor within the surgeon's control that will ensure a successful outcome.<sup>7,10,11,15</sup> The method used to attach the graft to bone can also affect the outcome. Graft fixation on the femoral side may be achieved by either suspensory or aperture methods,<sup>17</sup> and ultimately osteo-integration occurs.<sup>19</sup> Fixation of the graft to the tibia can be achieved with sutures and post screws, interference screws, or staples.<sup>13</sup> Kim et al<sup>16</sup> described the use of 2 staples for tibial fixation without detachment of the tibial insertion of the hamstring tendon. Graft constructs fixed to bone at the intra-articular apertures with interference screws have been shown to undergo less stretching and be stiffer than either suspensory-fixed grafts or grafts fixed externally to the drilled tunnel.<sup>17,24</sup> The shorter distance between fixation points results in less stress and strain that can cause graft elongation and tunnel widening.<sup>12</sup>

The final position of the graft within the tunnel can vary with interference screw fixation, and this has been shown to have an effect on postoperative laxity.<sup>18</sup> In a previous study, it was identified that reverse-thread screws for femoral fixation in right-sided knees allows the graft to

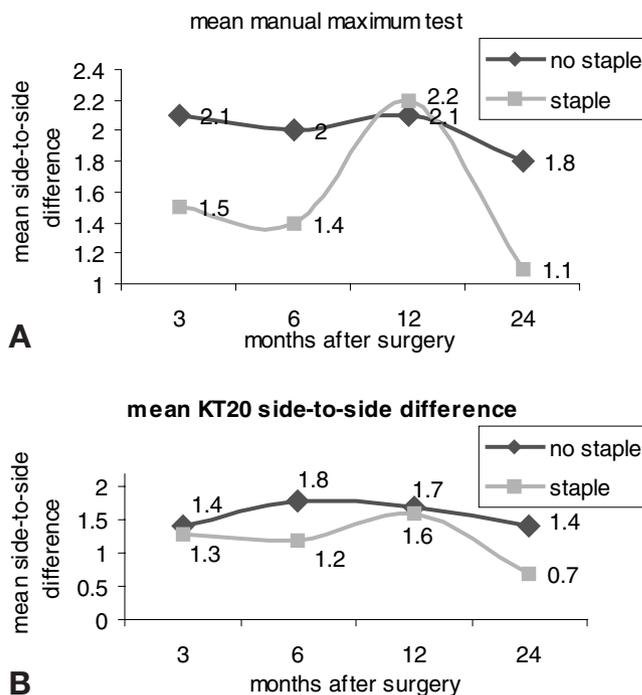


Figure 5. Mean laxity over time in both the standard and staple groups using the KT-1000 arthrometer at (A) manual maximum testing and (B) 20-lb (KT20) testing.

adopt a posterior position, which has been shown to significantly reduce the laxity seen in right-sided knee patients 12 months after surgery compared to standard screw fixation.<sup>18</sup> By eliminating this disparity between sides, a more valid comparison can be made between left-sided and right-sided knees.

In this study, no significant differences were identified in either group between the percentage of patients who subjectively rate their knee function as either normal or nearly normal. This figure correlated with the high Lysholm knee scores seen in both groups. However, there was a significant difference in kneeling pain, with 7.4% of the standard group and 28.6% of the staple group reporting pain. Kneeling pain may be an important factor in patients who have to kneel as part of their occupation. Other authors have described similar problems with pain

localized to the tibial staple. Bak et al<sup>2</sup> reported discomfort in 15% of patients after reconstruction of the ACL with an iliotibial band autograft, and 25% required removal of the staple. Billotti et al<sup>4</sup> reported the removal of the staple in 7% of patients because of local pain after ACL reconstruction using the semitendinosus and iliotibial band. However, in this study none of the patients required removal of the staple during the follow-up period.

Physiological factors such as hormones and bone density may affect graft fixation and laxity. Recent studies have shown that female athletes suffer a higher incidence of ACL tears than comparable male athletes, and it has been postulated that the presence of sex hormones, particularly estrogen, may predispose females to higher ACL injury rates.<sup>23,25</sup> However, Karageanes et al<sup>14</sup> found no association with the menstrual cycle and laxity of the ACL in adolescent female athletes. Pregnancy studies have intimated a relationship between serum relaxin levels and joint laxity.<sup>1</sup> Transient laxity has been documented around the end of pregnancy in a woman who had undergone an ACL reconstruction 2 months before conception.<sup>5</sup> However, Arnold et al<sup>1</sup> failed to find a relationship between serum relaxin levels and measurements of anterior translation of the knee.

Peak bone density tends to be higher in men than in women, and measurements show that men have a greater bone mineral density than women at almost every region of the body.<sup>1</sup> ACL rupture is known to have a deleterious effect on bone mineral density in the proximal tibia and has been documented clinically<sup>2</sup> and experimentally in a canine model.<sup>6</sup> Disuse of the limb after injury predisposes the proximal tibia to loss of bone mineral density, and all of these factors may explain the clinical observation of poorer bone stock in female patients compared to male patients. In soft tibial bone, a single 7 × 25-mm interference screw is inadequate fixation for the rehabilitation protocol used and leads to an increased incidence of graft laxity. Increasing fixation strength by supplementary tibial fixation with a staple has been shown in this study to be effective in decreasing the incidence of joint laxity after hamstring tendon reconstruction. Increasing fixation strength may be achieved by using other means such as longer screws, increased diameter thread, or both longer and increased diameter screws. These and other methods of fixation require similar clinical evaluation before recommendation can be made for their use.

## CONCLUSION

The results of this study show that supplementary tibial fixation in female patients undergoing ACL reconstruction with hamstring tendon graft and interference screw fixation can reduce the amount of overall laxity seen 2 years after surgery when compared to standard tibial fixation.

The addition of a staple increased the amount of kneeling pain, and further study is required to determine a more effective method of tibial fixation over a single 7 × 25-mm titanium RCI screw.

## ACKNOWLEDGMENT

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