The “all crosspin” fixation technique in anterior cruciate ligament reconstruction: a clinical comparison between two tibial fixation methods using quadrupled hamstring tendon graft.

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Abstract

The purpose of this paper was to prospectively compare two series of 160 Anterior cruciate ligament (ACL) reconstructions. Four-strand hamstring tendon grafts were used in each group. The same femoral fixation was used in both groups and a clinical comparison was made between two types of tibial fixation. In one group the intrafix system was used and in the other, the rigidfix cross-pin system.
Hypothesis: The clinical results between the two groups are similar with the cross-pin method of fixation on both sides of the joint providing satisfactory stability in the ACL reconstructed knee.
Results: The hypothesis was correct and both methods of fixation were found to be satisfactory in providing an acceptable degree of stability following ACL reconstruction at 1 year post-op.
Key words: ACL reconstruction-hamstring - tibial fixation – intrafix - rigidfix

Introduction

Soft tissue grafts such as the quadrupled hamstring tendon graft (STG) are increasingly being used for anterior cruciate ligament (ACL) reconstruction. The tibial tunnel and hence the graft fixation in the tibial tunnel has been referred to as the weak link in these reconstructions. **[4, 14]** Over the last 10 years the tibial fixation has evolved. Initially, extracortical fixation was used, then indirect repair with linkage materials. Direct fixation within the tunnel in an anatomic position, such as with an interference screw was introduced as they exhibited improved structural properties and less frequent loss of fixation. Direct fixation, however, resulted in comparatively lower ultimate loads to failure during biomechanical testing. **[16,19,23]**
One of the methods used to remedy the ultimate load to failure problem was the introduction of material between the interference screw and the graft. The screw was then placed concentrically, allowing for more exposure of the graft to the bone, providing semi-aperture fixation**[14]** and resulting in improved construct stiffness**[20]** The Intrafix device (Innovasive Devices, Mitek, Westwood, Mass) is an example of this method of fixation. **[14] (Fig. 1)**

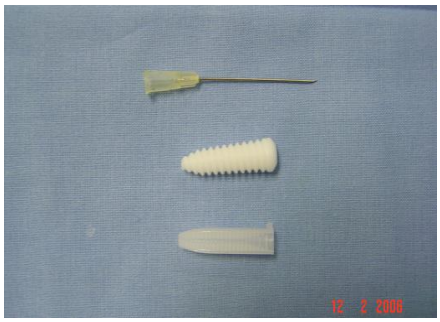

Figure 1: The Intrafix system and a hypodermic syringe needle, for size comparison.

The problem of tunnel widening has become a topic of interest recently. The exact cause is unknown but interference screws have been implicated in this, as have the “windscreen wiper” and “bungee” effects due to non-anatomic graft fixation **[11, 17]**

Another way of achieving an anatomical fixation of a hamstring graft is to fix the graft with two biodegradable pins (length, 42mm; diameter, 3.3mm; Rigidfix, Ethicon, Mitek Division, Norderstedt, Germany). These pins pierce the graft perpendicular to its long axis and are held by whip-sutures placed in the graft. **(Fig. 2)**

Figure 2: The Rigidfix crosspins and a hyperdermic syringe needle, for size comparison.

The purpose of this study was to clinically evaluate the results of two groups of ACL reconstructed knees using the Rigidfix and Intrafix methods of tibial fixation.

Materials and methods

160 ACL reconstructions were performed on 159 patients over a period of 3 years . These patients were prospectively and randomly divided into 2 groups based on the method of tibial fixation of the ACL graft (Table 1). In one group, an Intrafix system was employed and in the other, Rigidfix crosspins. All ACL reconstructions were carried out arthroscopically by the senior author in the standard way, using a quadrupled hamstring tendon graft. In all cases the hamstring grafts were harvested through a single vertical incision over the pes anserinus insertion on the proximal tibia, 2cm medial to the midline. Number 2 Ethibond whip sutures were used to prepare the graft appropriately in each group.

Reaming of the tibial and femoral tunnels was carried out after insertion of guidewires using the appropriate jigs, under arthroscopic guidance. The diameter of the tunnels was matched to the cross-sectional diameter of the prepared graft. Femoral fixation was carried out with the use of the Rigidfix cross-pins in all cases.
A routine accelerated rehabilitation protocol was used in all cases.
Inclusion criteria included “isolated ACL ruptures”, no articular surface damage or damage of less than grade 3 Outerbridge. All patients with meniscal injuries were included.
73 Patients were lost to follow-up. (50-Intrafix, 23-Rigidfix)

Assessments were carried out at 6 months and again at 12 months using a manual maximum KT1000 arthrometer test (Medmetic Corp, San Diego, Calif) **[6]**, one-legged hop test for distance as a percentage of the distance jumped on the contralateral leg, Lysholm **[15]** and Tegner **[25]**activity scores.

TABLE 1
Demographic data

	Rigidfix	**Intrafix**
Total number of patients in study	30	57
Male:female	28:2	34:23
Average age	35.3 (20-55)	34.8 (21-56)
Number of patients with 6 months follow-up Number of patients with 6+12 months follow-up	14 16	32 25

Results

1. Hop tests

When comparing the operated and normal knee, > 80% is regarded as sufficient pivoting function to allow twisting and turning with confidence. Table 2 summarises the hop test results, comparing the 2 groups. It was interesting to see that there was an improvement in results, in both groups, from the 6 month to the 12 month mark. It was also interesting to note that both groups demonstrated satisfactory results, even though the intrafix group fared slightly less well. This difference was not statistically significant, making the results comparable.

TABLE 2
Hop test results

		6 months	12 months
Rigidfix	Straight	(30) 87%	(16) 94.8%
	Cross over	86.5%	93.3%
Intrafix	Straight	(57) 82%	(25) 89.6%
	Cross over	79.6%	89.3%

2. KT1000 machine testing

An ideal result is regarded as a side to side difference of <3.5mm.
With this test it was noted that both groups were satisfactory with regards to maximum manual measurement, but the Intrafix group showed an increase in average stability compared to the Rigidfix group. Table 3 summarises these results.

TABLE 3
KT1000 results

	6 months	12 months
Rigidfix	(30) Average 3.5mm	(16) Average 3.2mm
Intrafix	(57) Average 2.4mm	(25) Average 2.4mm

3. Lysholm score

These results show that the scores tend to improve marginally from 6 months to 12 months, with the Rigidfix showing a slightly greater increase, but one that is not statistically significant. They also show comparable results between the two study groups. Table 4 summarises these results.

TABLE 4
Lyshom score

	6 months	12 months
Rigidfix	(30) Average 87.7	(16) Average 90.5
Intrafix	(57) Average 87.5	(25) Average 88.5

4. Tegner activity level

Tegner activity score improves from 6 to 12 months and the results are comparable in both the groups. A greater improvement occurred in the Rigidfix group, once again, not statistically significant, and both groups showed comparable results. Table 5 summarises these results and table 6 shows the overall Tegner grading.

TABLE 5
Tegner activity level

	6 months	12 months
Rigidfix	(30) Average 4	(16) Average 5

Intrafix	(57) Average 4.8	(25) Average 5

TABLE 6
Overall grading

	6 mths	12 mths		6 mths	12 mths
Rigidfix			Intrafix		
Excellent	5	9	Excellent	17	9
Good	20	6	Good	31	13
Fair	3	-	Fair	7	2
Poor	2	1	Poor	2	1
Total	30	16	Total	57	25

Intra-operative complications
Both methods of fixation proved to be reliable. No specific complications relating to the fixation were encountered. The clinical impression one encounters when inserting the Rigidfix pins is that the tibial bone is not dense enough compared to the femoral side, but this did not appear to make a difference in the overall results.

Discussion

Quadrupled hamstring tendon grafts have become the graft of choice for ACL reconstructrion. They have shown to have inherent size, stiffness and ultimate strength equivalent or greater than bone-patellar-tendon-bone grafts **[3,5,10,12,18,21,24,26]**
The concerns with the hamstring graft lie ultimately with the fixation. Femoral fixation using the Rigidfix method of crosspins has been shown to be acceptable and compares favourably to other methods of femoral soft-tissue fixation.**[28]** and the stiffness values of the graft-fixation device-bone constructs closely resemble the stiffness of the native tibia-ACL-femur complex (242N) as described by Woo et al.**[27]**
Numerous reports have indicated that the weakest link of the hamstring tendon ACL construct is the initial fixation of the tibial side. **[2,5,9, 13,24, 26]**
The intrafix method of fixation is a central fixation system that incorporates a handheld tensioning device and uses a four-quadrant sleeve and screw to facilitate equal tensioning, to protect grafts from damage, and to increase the contact area between graft and bone for osseointegration. Starch et al also found the intrafix method of fixation to have an increased strength of fixation compared to metal interference screws. **[22]**
Biomechanical tests have been performed on human cadaver tibias, showing that the initial fixation strength and the cyclic stability of the Rigidfix pins, when used for hamstring tendon grafting for ACL reconstruction, is superior to a bioabsorbable interference screw. **[7,8]**

Antonogiannakis et al described the surgical technique of crosspin fixation on both sides of the joint using a quadriceps autograft and the Rigidfix method of fixation. **[1]**
As far as we are aware, there is no study comparing the clinical results of the intrafix and rigidfix methods of fixation on the tibia in ACL reconstruction, with rigidfix femoral fixation in both groups.
This study demonstrated that the clinical outcomes are comparable in both groups with good to excellent Tegner activity scores in 83% at 6 months and above 87% at 1 year. The Lysholm scores were greater than 87% in both goups and the KT1000 testing demonstrated satisfactory results in both groups.
Functionally both groups faired well with, if anything, the Rigidfix group being slightly better. This was not statistically significant though.
One criticism of the study is the disparity of numbers between the two groups which is as a result of the loss of patients to follow-up. This also resulted in the overall study numbers being significantly reduced, especially in the Rigidfix group.
In conclusion, our clinical data suggest that hamstring graft fixation using the Rigidfix method of fixation on the tibial side provides a reasonable alternative to the Intrafix system for quadruple hamstring graft fixation.
A criticism of this study is that only clinical relevance was assigned to the results rather than a full and comprehensive statistical analysis. There was a large loss of patient numbers to follow-up which reduces the reliability of the study, but within the patient groups looked at in the study, the results have been reported, confirming the hypothesis.
More research into this subject would have to be done to properly assess the hypothesis statistically.

Summary

- Despite the tibial bone being less dense than the femoral bone, the crosspin technique in this study proved effective as a fixation device.
- The crosspins should be aimed in a direction away from the midline, ie from anteromedial to posterolateral.
- No complications occurred intraoperatively with the tibial RigidFix group relating to neurovascular injury or fixation problems.

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