

A Comparison of Clinical Outcomes of Two Methods of Femoral Hamstring Graft Pin Fixation in Anterior Cruciate Ligament Reconstruction

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ABSTRACT

The outcome of anterior cruciate ligament (ACL) reconstruction with hamstring grafts depends on early rehabilitation and secure graft fixation. Various devices available for graft fixation at the femoral tunnel have different biomechanical properties as demonstrated on cadaveric studies. The aim of this study was to compare clinical outcomes in patients using either of two methods of transfemoral pin fixation for hamstring grafts in ACL reconstruction. Twenty-eight patients undergoing primary ACL reconstruction with hamstring autograft with either transfemoral expansion fixation (Rigidfix) or cortical-cancellous suspension (Transfix) by a single surgeon were analysed including subjective knee scores and objective measurements including range of motion and arthrometer-measured anterior translation. Transfix was used in 14 (50.0%) patients and Rigidfix was used in 14 (50.0%) patients. There was no significant difference in pre-injury Tegner activity scores, pre-operative Tegner activity scores, Lysholm scores and age or in Tegner post-operative activity scores, Lysholm scores, range of motion, Lachman and pivot scores absolute anterior translation and anterior translation compared to the non-operated knee at two years. There was a significant improvement in Tegner (2.6 ± 2.4 , $p < 0.00$) and Lysholm (25.3 ± 21.2 , $p < 0.00$) scores at two years with no significant difference between the two groups. One patient had a broken Transfix cross-pin 13 months after surgery which presented as a subcutaneous swelling which was removed. Although the biomechanical properties of Rigidfix and Transfix differ as demonstrated in cadaveric studies, both devices had similar favourable clinical outcomes in our series.

Keywords: Graft, Trans-tibial, Semitendinosus, Sports surgery

INTRODUCTION

There are various methods of anterior cruciate ligament (ACL) reconstruction of which the two main choices in autograft reconstruction involve the use of the bone-patella tendon-bone or hamstring graft. Early rehabilitation and return to activity with a stable knee are the main goals in ACL reconstruction¹. The weak link in hamstring graft lies in its femoral fixation, for which various devices and techniques have been described. These can be divided into three main types: cortical suspensory devices such as the Endobutton (Smith & Nephew), interference screws, and femoral transfixation devices such as the Transfix (Arthrex) and Rigidfix (Depuy-Mitek)².

These devices work on different mechanical principles and as such have different mechanical properties. Femoral transfixation devices have been

proposed to have mechanical advantages over other femoral fixation methods due to increased pull-out strength and having a fixation point close to the joint. Femoral transfixation devices consist of bioabsorbable pins within the femoral tunnel which either penetrates the four-strand graft, such as the Rigidfix, or the two-strand hamstring graft wrapped 180° around the pin to create a quadrupled graft, such as the Transfix.

The Rigidfix works by crossing the bone perpendicular to the femoral tunnel and passing through the hamstring graft and femoral tunnel, increasing the volume of the graft and therefore causing a pressure effect against the tunnel wall. As the Rigidfix pin passes through the substance of the graft, slippage may occur as the collagen fibres separate³.

The Transfix device is a single cross-pin which engages the graft in the femoral tunnel after passing it over a graft-passing wire with the graft lying perpendicular and over the Transfix device. The pin is inserted laterally through the lateral femoral condyle. When using the Transfix, the graft is wrapped around the pin instead of the pin piercing it and this has been suggested to reduce graft lengthening from slippage³.

Despite having differing mechanical properties, there have been no significant differences in clinical outcome between the different fixation methods in studies comparing Rigidfix with a bio-absorbable interference screw and Endobutton, and bio-absorbable interference screw^{4,5}. However, there is a paucity of clinical data comparing the clinical outcome of the two transfemoral fixation devices with one published study by Choi et al (2013)⁶ comparing Rigidfix with Transfix which reported an increase in tibial tunnel widening with Rigidfix without a difference in clinical outcome.

AIM

The aim of this study was to compare the clinical outcome between Rigidfix and Transfix for soft tissue femoral fixation in primary ACL reconstruction using the autogenous hamstring graft.

MATERIALS AND METHODS

This study was a retrospective study of patients undergoing primary ACL ligament reconstruction by a single surgeon using an autogenous hamstring graft. All patients underwent arthroscopy under general anaesthesia with the operated leg in a leg-holder for preparation of the tibial and femoral footprints using mechanical shavers. Both their semitendinosus and gracilis tendons were harvested. A tourniquet placed around the patient's thigh was inflated at the start of surgery and kept inflated until wound closure and bandaging. Residual muscle and fat over the harvested tendons were removed. Whipstitches were applied at both ends with Ethibond and the graft was then pre-tensioned and doubled to form a four-strand graft. The tibial tunnel was drilled first using a tibial drill guide and a single femoral tunnel was then prepared using the trans-tibial technique where the femoral offset guide, guidewire, and reamer were passed sequentially via the tibial tunnel.

For patients who underwent fixation with Rigidfix,

the Rigidfix cannulated rod was inserted into the femoral tunnel via the tibial tunnel and the guide frame was then attached to this rod. Next, trocars were inserted according to the guide frame via the lateral side of the femur. The graft was then pulled up into the femoral tunnel via the tibial tunnel with the aid of a guide pin with a loop of Ethibond. The two Rigidfix pins were then inserted.

For patients who underwent fixation with Transfix, the Transfix tunnel hook was inserted into the femoral tunnel via the tibial tunnel. The Transfix drill guide and guide pin sleeve was then attached to the tunnel hook. The femoral cortex was broached with a drill pin which was drilled across the femoral tunnel from lateral to medial. A nitinol passing wire was drawn across the femoral tunnel with the aid of the drill pin. The middle of this wire was pulled out of the femoral tunnel through the tibial tunnel by the extraction of the tunnel hook. Next, the tendons were passed through the wire loop with the middle of the semitendinosus and gracilis tendons in the wire loop forming a four-strand graft which was then pulled into the femoral tunnel with the pulling of the free ends of the passing wire. The Transfix pin was inserted across the femoral tunnel over the passing wire after creating a pilot hole for the pin.

Tibial fixation of the graft was performed with an absorbable Milagro bio-interference screw in the tibial tunnel in all cases with the graft under tension after cycling the knee 20 times.

All patients were discharged home on a knee brace after surgery and underwent the same physiotherapy rehabilitation programme at our hospital. Objective and subjective data was collected before surgery and at two years after surgery at our department's Orthopaedic Diagnostic Centre. Objective data included range of motion, Lachman's and Pivot shift tests, and anterior translation measured by the KT 2000 arthrometer. Subjective data included Lysholm and Tegner knee scores. The Lachman's and Pivot shift tests were graded from A to D according to the 2000 International Knee Documentation Committee Knee Examination Form by a trained observer from the Orthopaedic Diagnostic Centre.

Statistical analysis was performed using SPSS for Windows 17.0 (SPSS Andover) using the independent t-test to compare continuous variables

Table 1. Patient Demographics.

	Rigidfix n=14 (50.0%)	Transfix n=14 (50.0%)	p-value
Male gender	9 (64.3%)	11 (78.6%)	0.69
Age	2.2 ± 0.6 years	2.4 ± 0.7 years	0.29
Tegner (pre-injury)	7.1 ± 1.2	6.8 ± 1.8	0.54
Tegner (pre-operative)	3.1 ± 1.9	3.0 ± 1.2	0.07
Lysholm (pre-operative)	63.0 ± 23.4	60.6 ± 21.7	0.78

Table 2. Results.

	Rigidfix n=14	Transfix n=14	p-value
Tegner (post-operative)	5.9 ± 2.1	5.3 ± 1.7	0.37
Lysholm (post-operative)	88.6 ± 16.1	86.2 ± 17.2	0.62
Range of motion (post-operative)	144.4 ± 10.2°	143.0 ± 12.3°	0.73
Anterior translation (post-operative)	11.1 ± 2.5 mm	11.0 ± 2.3 mm	0.82
Anterior translation side-to-side difference (post-operative)	2.7 ± 2.6 mm	0.8 ± 2.2 mm	0.07
Lachman score (post-operative)			
A (normal/firm)	7 (50.0%)	5 (35.7%)	0.26
B (nearly normal)	4 (28.6%)	8 (57.1%)	
C (abnormal/soft)	3 (21.2%)	1 (7.1%)	
D (severely abnormal)	0 (0.0%)	0 (0.0%)	
Pivot shift (post-operative)			
A (normal equal)	8 (57.1%)	6 (42.9%)	0.33
B (nealy normal/glide)	1 (7.1%)	4 (28.6%)	
C (abnormal/gross)	5 (35.7%)	4 (28.6%)	
D (severely abnormal/marked)	0 (0.0%)	0 (0.0%)	
Improvement in Tegner score	2.9 ± 2.7	2.3 ± 2.0	0.29
Improvement in Lysholm score	25.6 ± 15.8	24.9 ± 26.1	0.65
Operative time	71.8 ± 16.1 minutes	71.1 ± 13.3 minutes	0.9

between groups and the paired t-test to compare pre- and post-operative continuous variables. Non-parametric continuous variables were compared using the Mann-Whitney U-test. The Chi-squared test was used to compare categorical variables.

RESULTS

We had 28 patients in total, eight (28.6%) were female and 20 (71.4%) were male. The mean age at surgery was 27.6 ± 8.0 years and they were followed up for 2.7 ± 0.5 years. There was no significant difference between the two groups in terms of pre-operative scores and demographics (Table 1).

After surgery, there was no significant difference between the two groups with respect to Tegner and

Lysholm scores. There was no significant difference in the post-operative range of motion, Lachman's and Pivot shift tests. There was no significant difference in absolute anterior tibial translation on arthrometer reading of the operated knee and in the anterior tibial translation when compared to the non-operated knee between the two groups (Table 2).

There was a significant improvement overall between pre-operative and post-operative Tegner 2.6 ± 2.4 ($p < 0.00$) and Lysholm 25.3 ± 21.2 ($p < 0.00$) scores at two years. There was no significant difference in the improvement between the two groups (Table 2).

The mean operative time was 71.4 ± 14.5 minutes and there was no significant difference in operative time between both groups (Table 2). One patient presented with a subcutaneous swelling at the Transfix pin insertion site 13 months after surgery due to a broken Transfix pin which was removed surgically. The patient had an otherwise uneventful recovery.

DISCUSSION

The different biomechanical properties between the various femoral fixation devices for ACL reconstruction have been described previously in both cadaveric and animal studies using porcine parts^{1,3}. The Endobutton has the reported disadvantage of tunnel widening by the bungee effect due to its fixation point being far from the joint line⁷. Aperture fixation devices such as the interference screw are the weakest in terms of pull-out strength and the pull-out strength can be further weakened by divergent placement of the screw relative to the femoral tunnel which can occur in trans-tibial femoral tunnel preparation with trans-portal screw insertion^{3,8}. Hence the reported advantage of transfemoral fixation devices such as the Transfix and Rigidfix which are closer to the joint line compared to the Endobutton⁹. Being bioabsorbable, these devices do not have to be removed if further surgery is required in the future such as knee arthroplasty and they do not cause interference if subsequent magnetic resonance imaging scans of the operated knee are required.

The Transfix can cause iliotibial band friction syndrome due to prominent lateral hardware though this was not found in our series of patients¹⁰⁻¹². The Rigidfix pins can theoretically spear the graft which has been hypothesised to result in increased graft slippage compared to Transfix due to splitting of the collagen fibres of the graft³. This difference could explain the difference in anterior translation between the two groups in our study. Both devices require their own respective insertion techniques and apart from missing the femoral tunnel altogether during graft placement which can occur with both devices, other device-specific complications have occurred with the Transfix device during insertion such as broken or twisted graft-passing wires¹²⁻¹⁴. Supracondylar femur fractures have been described with the use of Transfix too though this was not encountered in our study^{15,16}. We had one patient which had a broken Transfix pin which presented as subcutaneous

swelling necessitating surgical removal. The lateral-most part of the Transfix pin broke off and settled in the subcutaneous tissue of the lateral distal thigh. Breakage of pins have been reported previously in both Rigidfix and Transfix¹⁷⁻²⁰.

In our series of patients comparing Transfix and Rigidfix, we report no significant difference in the favourable clinical outcome despite differences in biomechanical properties between the two devices. This is in agreement with other studies which do not show any clinical difference between the different femoral fixation devices^{4-6,21,22}. The ultimate load to failure leading to breakage of cross-pins for Rigidfix and Transfix has been reported to be 737 N and 746 N respectively which exceeds the estimated strength of the ACL required for activities of daily living at 454 N. This could explain the lack of difference in clinical outcome^{3,23}. Although Choi et al (2012)²⁰ reported tibial tunnel widening with the use of Transfix as compared to Rigidfix, the study did not report any significant difference in Lachman and pivot-shift tests and mean KT-1000 measurements. Any differences observed in our study between the two groups were neither statistically significant nor clinically important with regards to outcome at two years.

Our study protocol employed validated knee scores as an instrument to measure pre-operative and post-operative function as well as objective clinical measurements with all surgery performed by a single-surgeon. All patients followed a standardised rehabilitation protocol administered at our institution and were followed-up for at least two years. However, our study population was not randomised between the two femoral fixation devices and the small number of subjects in our population may not be able to demonstrate statistically significant, though clinically small, differences in outcome. Another limitation of our study is the absence of knee muscle strength and single-leg hopping data.

CONCLUSION

There is no significant difference in the favourable clinical outcome between Rigidfix and Transfix for femoral tunnel graft fixation for ACL reconstruction in our study despite the different biomechanical properties of the two devices.

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