Original Article

Anterior cruciate ligament reconstruction using autologous hamstring single-bundle Rigidfix technique compared with single-bundle Transfix technique

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Abstract

Background: Initial fixation strength is critical for the early post-operative rehabilitation of patients with anterior cruciate ligament (ACL) reconstructions. However, even the best femoral fixation devices remain controversial. We compared the results of 2 of the femoral fixation techniques,Rigidfix and Transfix.

Materials and Methods: A total of 30 patients with unilateral ACL deficiency were randomly assigned to 1 of 2 groups. In Group A an anatomic single-bundle ACL reconstruction was performed using Rigidfix technique(Mitek, Norwood,MA), Group B were treated by a single bundle using Transfix technique(Arthrex, Naples, FL, USA). For tibial fixation, a bioabsorbable Intrafix interference screw was used for all the groups and the graft was fashioned from the semitendinosus and gracilis tendons in all patients. The patients were subjected to a clinical evaluation, with assessment of the anterior drawer, Lachman's and the pivot-shift tests. They also completed the International Knee Documentation Committee (IKDC) score.

Results: At a mean of 14 months (12–17) followup there were no significant differences concerning time between injury and range of movement between the 2 groups. However, the Rigidfix group showed significantly better results for the subjective assessment of knee function ($P = 0.002$). The Lachman, anterior drawer, and pivot-shift tests also showed no significant difference between the 2 groups. The IKDC scale showed no significant difference among the groups ($P < 0.001$).There was no difference regarding duration of operation and cost of the operation between the 2 groups.On clinical evaluation there was no significant difference between the 2 groups. However, regardless of the technique, all knees were improved by ACL reconstruction compared with their preoperative status.

Conclusion: Both techniques can be used for reconstruction of ACL. Other factors, such as psychic profile of the patients should be considered for surgery planning.

Key words: Anterior cruciate ligament, reconstruction, Rigidfix, Transfix, hamstring

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INTRODUCTION

Anterior cruciate ligament (ACL) injuries are a significant cause of disability in active individuals with an estimated incidence of 80,000–200,000 ACL injuries occurring in the United States each year.[1] With approximately 100,000 graft reconstructions performed in the United States annually.[2] There is a

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variety of techniques available with respect to the type of fixation and choice of graft tissue. While the choice of graft tissue has received considerable attention in the context of patient outcomes, the method by which a graft is fixed is of paramount importance in dictating the robustness of the graft construct; the fixation device may represent the weakest link in the ACL reconstruction. Optimal graft fixation should be structurally secure, recapitulate normal tendon healing and allow for the graft construct to replicate the biomechanical properties and biological composition of the native ligament. It is imperative that the mechanical fixation device offers these properties until full incorporation of the graft and biological fixation have occurred. Single-bundle ACL reconstructions successfully restore anterior stability but not rotational stability.[3,4] There are numerous single-bundle reconstruction techniques, two of them are Rigidfix and Transfix techniques.[5-11] This new techniques have been compared biomechanically, but biomechanical studies showed mixed results for different techniques.[12-14] Because of novelty of these techniques, long-term results of them, such as osteoarthritis prevention are lacking.

The aim of this study was to compare the results of ACL reconstruction using Rigidfix technique with Transfix technique. Our hypothesis was that postoperative anterior laxity, the pivot-shift test, and subjective evaluation after the Rigidfix ACL reconstruction with hamstring graft, would be significantly better than Transfix reconstruction using the same graft. The second hypothesis was that there would be no significant differences in the other clinical measures between the procedures.

MATERIALS AND METHODS

We randomized 30 men with ACL deficiency into 2 groups, each using a different technique to secure their hamstring tendon grafts. The randomization was by a closed envelope method. None of the patients had medial, lateral, or posterior laxity on physical examination. The mean time between injury and operation was 5 months.

There was no difference regarding the delay between the injury and operation, operative findings, followup time, age, and gender between the groups [Table 1].

Table 1: Patient data

Patients	Group A	Group B
Time range between injury and operation (months)	4–6.5	4–6
Operative finding meniscus injury		
Medial	6	6
Lateral	4	3
Age range in years	21–32	22–30

All the reconstructions were undertaken by an orthopedic surgeon. An orthopedic resident who was blind to the procedure, performed followup examinations.

Surgical technique

A diagnostic arthroscopy was performed through standard anteromedial and anterolateral. The gracilis and semitendinous tendon grafts were then harvested through a longitudinal incision 2–3 cm medial to the tibial tuberosity, the harvested tendons were folded 4 times.

Group A (n = 15). The tibial hole was made in a standard fashion using the Mitek aiming guides (Johnson & Johnson), which enable transtibial drilling of the femur at the correct position to a depth of 30 mm. Using the Mitek cross-pin guide, 2 cross-pin locking holes were fashioned from the lateral aspect of the femur. This allowed transfixation of the femoral end of the graft with 2 RigidFix cross-pins (Mitek) once the graft had been drawn into the femoral tunnel to a depth of 30 mm. After tensioning, the tibial end of the graft was secured with an Intrafix screw.

Group B (n = 15). The tibial tunnel was drilled in a standard fashion at the site of ACL footprint, creating a tunnel that matched the diameter of the graft. A transtibial femoral tunnel was prepared using the Arthrex guide enabling correct positioning of the prepared graft. The femoral end was secured with a TransFix II screw (Arthrex) and the tibial end with an Intrafix screw (Mitek). In both groups the graft was tensioned to 20–30 lb of force.

With regard to associated meniscal injury, 6 knees in Group A had medial and 4 had lateral meniscal tears. In Group B, 6 had medial and 3 had lateral injuries. All injured menisci were treated with the partial excision. Grade I chondral lesions were seen in 2 patients, 1 in each group. All were treated conservatively without surgery. The same pre- and postoperative program was used for the groups.

Rehabilitation was the same for all patients. Three weeks of splinting was performed. Crutches were employed for 1–2 weeks and braces were not used. Closed-kinetic chain quadriceps exercises were started immediately and sports involving pivoting on the treated knee at 6–9 months.

Evaluation was performed by clinical examination, a patient satisfaction questionnaire, the International Knee Documentation Committee (IKDC) Scale.

Data were analyzed using the SPSS. The difference of means was undertaken by analysis of variance, paired sampled *t* tests and, where appropriate, by the Chi-square test. The significance level was set at $P < 0.05$.

RESULTS

At a mean followup of 14 months,[12-17] rotational stability as evaluated by the pivot-shift test was not different between 2 groups. In Group A, 7 patients (46%) had normal rotational stability, and 6 patients (40%) in Group B, had rotational laxity of Grade I [Table 2]. However, in both groups, the rotational laxity was significantly better at a mean of 14 months than preoperatively ($P < 0.001$) [Table 3]. Manual knee laxity testing with Lachman's and the anterior drawer tests showed no significant difference between the 2 groups [Table 2]. At a mean followup of 14 months (12–17 months) all patients had full extension of the knee. IKDC scores showed no significant difference between the groups, with all showing significant improvements compared with their preoperative scores [$P < 0.001$, Table 4]. Subjective assessment of knee function showed better results in patients treated with Rigidfix technique [Table 5]. There was no difference regarding the duration of operation and the cost of the operation between 2 groups.

Complications

There was no major complication in our study.

DISCUSSION

At short-term followup, this study showed that Rigidfix single-bundle ACL reconstruction had significantly better subjective results than patients with a Transfix single-bundle ACL reconstruction. The assessment of anterior laxity with Lachman's and the anterior drawer test and rotational stability with pivot-shift test showed no difference between the 2 groups.

It has been reported elsewhere that there are no clinically relevant differences between the Rigidfix and Transfix techniques and our study confirmed it.[3,5] Ahmad *et al.* compared different femoral fixation devices and found that Rigidfix technique had inferior results.[10] Harilainen *et al.* in a prospective comparison of 3 hamstring femoral fixation devices found no significant difference between them[13] Wu *et al.* in a porcine model found significant better results by Rigidfix technique.[16] Our results are in contrast with Ahmad *et al.*, and in contrast with other results when considering subjective results. Halewood *et al.* showed that both techniques are better than previous methods.[17] Seo *et al.* showed no significant difference between the 2 groups, but lesser complications were observed by Rigidfix technique.[18] Our results are comparable with results of Seo *et al.*'s study with Rigidfix technique, and lower results by Transfix technique. But these results and those by Seo *et al.*

Table 2: Post-operative results of assessment of knee laxity at a mean of 14 months

Test	Group A (n = 15)	Group B (n = 15)
Lachman's test		
Negative	13	11
Grade I	2	2
Grade III	0	2
Grade IV	0	0
Anterior drawer test		
Negative	13	10
Grade I	2	5
Grade II	0	0
Grade III	0	0
Grade IV	0	0

Table 3: Results of the pivot-shift test performed pre- and post-operatively

Pivot-shift test	Group A (n = 15)	Group B (n = 15)
Pre-operatively		
Normal	0	0
Nearly normal	4	4
Abnormal	8	9
Severely abnormal (%)	3	2
Post-operative at a mean of 14 months		
Normal	7	6
Nearly normal	7	7
Abnormal	1	2
Severely abnormal	0	0

Table 4: Evaluation of the knee by the IKDC score pre-operatively and at a mean 14 months' follow-up

IKDC grade*	Group A (n = 15)	Group B (n = 15)
Pre-operatively		
A	0	0
B	0	1
C	14	13
D	1	1
At mean 14 months follow-up		
A	10	9
B	4	5
C	1	1
D	0	0

*A, normal; B, nearly normal; C, abnormal; D, severely abnormal. IKDC, International Knee Documentation Committee

Table 5: Subjective evaluation of knee function by the IKDC score preoperatively and postoperatively

Patients	Group A	Group B
IKDC score preoperatively (/100)	63	61
IKDC score postoperatively (/100)	95	86

IKDC, International Knee Documentation Committee

are short-time results and should be interpreted cautiously.

In our study, IKDC objective scores were nearly equal in both the groups, whereas subjective assessment of the knee was better in the Rigidfix group. However, the differences in the IKDC scores were not statistically significant and all patients in our study were able to play their original sport. We believe that the superior subjective assessment of the knee in the Rigidfix group might partly be caused by some factors other than stability of the knee, such as psychic profile of the patients.

We accept that our study has some limitations as the numbers of patients in each group was not large and the mean followup was only 14 months. Because of novelty of these techniques and lack of long-term results, comparing these techniques with regard to osteoarthritis prevention should be continued. The pivot-shift test can be difficult to perform but we are unaware of any other simple way of measuring rotational instability of the knee. In contrast, anterior laxity of the knee could be measured with the KT-1000 arthrometer, which is a recognized instrument after ACL reconstruction.

Although all the techniques used gave almost equal clinical results, the method of Rigidfix ACL reconstruction produced better subjective results than Transfix reconstruction.

CONCLUSION

Despite superiority of Rigidfix technique in subjective assessment, we can propose both techniques to the patients, but we think that other factors, such as psychic profile of the patients, should be considered before surgical planning.

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