Comparison of Outcomes of Two Femoral Fixation Devices in Hamstring Anterior Cruciate Ligament Reconstruction

Abstract

Background: Tear of the anterior cruciate ligament (ACL) is a common ligamentous injury of the knee. Reconstruction of this ligament is often required to restore functional stability of the knee. Outcome of ACL reconstruction is significantly affected by how the graft is fixed to the bone. This study is to determine if there is a different clinical outcome after cortical versus cortical-cancellous suspension femoral fixation in hamstring based anterior cruciate ligament (ACL) reconstruction.

Materials and Methods: This is a retrospective comparative study conducted between 2006 and 2010. We enrolled patients who underwent arthroscopic ACL reconstruction. Sixty two patients met inclusion criteria and 41 agreed to come for followup assessment. Median age was of 28 years (range 18–39 years). Demographic baseline profile of both groups was similar. Femoral fixation devices were cortical (n = 16) and cortical-cancellous suspension techniques (n = 25). The average period of evolution at the time of assessment was 40 months (range 12–72 months). The patients were examined according to Lachman test (using Rolimeter knee tester), anterior drawer test, pivot shift test, International Knee Documentation Committee questionnaire, and Tegner-Lysholm knee scoring scale.

Results: The objective evaluation of the patients (Lachman test) showed better results in terms of stability in the group of patients who underwent the cortical-cancellous suspension method. These differences were not reflected in the assessment of activity level (Tegner-Lysholm), where both groups showed the same results.

Conclusions: ACL reconstruction with both cortical and cortical-cancellous suspension femoral fixation techniques show the same clinical results at medium long followup. However, cortical-cancellous fixations seem to provide greater stability to the reconstruction.

Keywords: Anterior cruciate ligament reconstruction, arthroscopy, femoral fixation device, knee, RetroButton, TransFix

MeSH terms: Arthroscopic surgical procedures, arthroscopy, anterior cruciate ligament, cruciate ligament

Introduction

Tear of the anterior cruciate ligament (ACL) is a common ligamentous injury of the knee. Reconstruction of this ligament is often required to restore functional stability of the knee. The outcome of this procedure has been well documented in a variety of studies, with good-to-excellent results in approximately 85%–95% of patients.1,2 Outcome of ACL reconstruction is significantly affected by how the graft is fixed to the bone. In the last years, different methods of fixation for ACL reconstruction have been reported.3–4 These methods can be classified as:

(a) Those in which the graft is fixed in suspension fashion outside both the femoral and tibial bone tunnels (extratunnel fixation) (b) Those in which the graft is fixed inside the bone tunnels, in closer proximity to the intraarticular apertures (intratunnel fixation) (c) A combination of these methods, in which one side of the reconstruction is fixed in the bone tunnel and the other outside the tunnel.5

It should also be noted that factors other than site and type of graft fixation contribute to tunnel widening. These include mechanical factors, such as improper graft placement and accelerated rehabilitation and biological factors, such as synovial fluid propagation within the tunnels and increased cytokine levels within the knee.6 The extratunnel systems, RetroButton system (Arthrex, Naples, FL, USA)-a cortical suspension technique-and TransFix system (Arthrex, Naples, FL, USA)-a cortical-cancellous suspension technique-are the available devices. RetroButton’s loop and metal plate is relatively cheap, and its point of fixation

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is some distance from the joint. The TransFix implant is inserted through the lateral femoral condyle and the graft passes around the implant and the point of fixation is closer to the joint. Its insertion requires dissection of the iliotibial band and placement of the implant adjacent to it. It is also more expensive than the RetroButton system.\textsuperscript{7,8}

The purpose of this study was to compare clinical outcome of two different extratunnel femoral fixations: cortical and cortical-cancellous suspension techniques, in hamstring ACL reconstruction. Null hypothesis is that the outcomes of ACL reconstruction with both techniques are similar.

Materials and Methods

Hospital records were reviewed, looking for patients who underwent arthroscopic primary ACL reconstruction between January 2006 and December 2010.

Inclusion criteria were as follows: (1) primary ACL reconstruction; (2) patients older than 18, with closed epiphyseal plates; (3) ACL reconstruction using extratunnel femoral fixation; and (4) no affectation of contralateral knee. Exclusion criteria were as follows: (1) the presence of additional fractures around the knee joint; (2) knee multiligamentous injury; (3) chondral lesions diagnosed by arthroscopy (ICRS Grade 2 exceeding 3 cm\textsuperscript{2}) or ICRS Grade 3 and 4; and (4) more than 50% of the medial or lateral meniscus resected.

Sixty two patients met inclusion criteria, only 48 could be contacted by telephone, there was no answer from the remaining 14. Forty one agreed to come for followup assessment. There were 37 males and 4 females. The average age was 28 years (range 18 to 39 years).

The study was approved by the hospital ethics committee, and participation in the study required informed consent.

Operative procedure

The patients were operated under spinal or general anesthesia and positioned supine on the operating table and using a tourniquet on the proximal thigh. Intravenous antibiotic prophylaxis was given. The operative leg was stabilized with an arthroscopic leg holder, and the distal extremity of the bed was dropped to achieve 120° of knee flexion. A thorough examination under anesthesia was essential to confirm ACL tear and rule out concomitant ligament injuries.

During hamstring harvesting, a 3–4 cm longitudinal skin incision was made on the anteromedial (AM) aspect of the tibia. The incision was placed 2 cm medial to the tibial tubercle, started 3 cm below the joint line and prolonged distally. The sartorial fascia was incised proximally and parallel to the tendons with a number 15 blade first and then with Metzenbaum scissors. Deep to the retracted sartorial fascia, the gracilis tendon was visualized proximally and the semitendinosus tendon distally. The semitendinosus tendon was then pulled out with a blunt hook. When the distal insertion of the tendon was left intact, like in this technique, an open tendon stripper was used. Alternatively, the tendon could be distally detached, armed with a leading suture, and harvested with a closed tendon stripper. The gracilis tendon was harvested using the same technique. The tendons were then distally detached and taken to the back table for preparation.

A complete diagnostic arthroscopy was performed through standard AM and anterolateral portals. Any associated pathology (meniscal or chondral injuries) was identified and treated at this point. The remaining ACL stump was removed with a mechanical shaver until the tibial and femoral footprints were well visualized. No notchplasty was required unless osteophytes were visualized in the intercondylar notch.

We performed the singlebundle anatomic ACL reconstruction with AM portal femoral tunnel drilling; the femoral tunnel was done in first place, followed by the tibial tunnel. The tunnel positions were decided based on the native ACL footprint in both femur andibia. The knee position was: (a) 90° flexion knee: in the tunnels drilling. The drilling guides used varied according to the technique used (RetroButton system vs. TransFix system); transportal femoral tunnel was performed regardless of the femoral fixation device. (b) 20° flexion knee and external rotation were used to fix and give tension to the graft.

For the graft fixation, in the femoral tunnel, we used a pin or a bottom device, depending upon the group. However, a biointerference screw was used for tibial fixation in all patients.

Sixteen patients underwent an ACL reconstruction with a cortical suspension technique (RetroButton system) [Figure 1] and 25 with a cortical-cancellous suspension technique (TransFix system) [Figure 2].

The operations were performed by a single surgeon, who was equally familiar with both forms of femoral fixation.

Figure 1: Diagramatic representation showing retro button system (cortical suspension technique)
Patients from both groups followed the same postoperative rehabilitation program. The rehabilitation program was quadriiceps and hamstring isometric exercises, progressing to closed chain exercises, and undergoing range of motion physiotherapy with the aim of regaining full range of motion by 6 weeks. Partial weight bearing was allowed at 3–4 weeks and light running on even ground, cycling, semi-squats, and step exercises after 8 weeks.

Average followup was 40 months (range 12-72 months). All patients were assessed by the same evaluator, who was well versed with the technique performed. As clinical evaluations, Lachman test, using arthrometer: Rolimeter knee tester (Aircast, Neubeuern, Germany, Europe), was graded negative (0; side-to-side difference [SSD] <3mm), 1+ (SSD between 3 and 5mm), 2+ (SSD between 5 and 10mm), and 3+ (SSD > 10mm). The contralateral knee in each patient was normal and used for laxity comparisons. Pivot shift was graded as negative or positive. Anterior drawer and knee range of motion were also measured. Participants were assessed with both the International Knee Documentation Committee (IKDC) questionnaire and Tegner-Lysholm knee scoring scale.

Statistical analysis was performed using the IBM SPSS Statistics for Windows, version 19.0 (IBM Corporation, Armonk, NY, USA). Parametric data were assessed using t-test. Contingency tables were assessed with the Chi-squared test. A minimum level of significance was $P = 0.05$.

To determine the calculation of the power for a proportion of 6% in the initial group, estimating that in the experimental group we would had a 44%, we needed 15 patients per group. Assuming a loss of 10%, we would recruit 16 patients per group for a level of signification of 0.05 and a power of 0.8. We recruited 16 in one group and 25 in another group to have a greater capacity in the second group.

**Results**

Demographically, the groups were comparable with respect to age and additional features ($P > 0.05$), except gender where a group had significantly higher male gender ($P < 0.05$) [Table 1].

Clinically, there was no significant difference in range of motion, anterior drawer, the presence of an effusion, or tenderness ($P > 0.05$). In the results of Lachman test, measured with Rolimeter arthrometer, stability in cortical-cancellous suspension group seemed to be greater, but there was no significant difference ($P > 0.05$) [Table 2 and Figure 3]. The end point in Lachman test was much firmer in cortical-cancellous than cortical suspension device ($P < 0.05$) [Table 3 and Figure 4]. A pivot shift was performed at each level patient was reviewed but it was not well tolerated by all of them. As a consequence, the results were not an accurate representation of either patient group.

IKDC classification postoperatively was not significantly different. At the last followup, 15 patients (93.8%) were classified to IKDC A or B in cortical suspension group and 18 (72%) in cortical-cancellous suspension group ($P > 0.05$) [Table 4]. The medium values of Tegner-Lysholm knee scoring scale were 87.25 points (range 50–100) in cortical suspension group and 80.08 points (range 17–100) in cortical-cancellous suspension group ($P > 0.05$) [Table 5].

Patients experienced a similar decrease in activity level in both the groups. Vigorous-moderate activity level was measured in preinjury examination and light activity level in the last followup ($P > 0.05$) [Table 6].

| Table 1: Demographic baseline profile |
|--------------------------------------|
| Variables                            | Transfix (n=25) | Retro button (n=16) |
| Male: Female                         | 23 (92%): 2 (8%) | 14 (88%): 2 (12%) |
| Mean age (years)                     | 33.7 (19-48) | 33.0 (20-47) |
| Body mass index (kg/m²)              | 26.08 (19-35) | 26.19 (21-35) |
| Laterality (right:left)              | 13 (52%): 12 (48%) | 8 (50%): 8 (50%) |
| Preinjury activity level             |                 |                 |
| Vigorous                             | 9 (36%) | 5 (31%) |
| Moderate                             | 10 (40%) | 7 (44%) |
| Light                                | 5 (20%) | 4 (25%) |
| Sedentary                            | 1 (4%) | 0 (0%) |
| Etiology                             |                 |                 |
| Sedentary activity                   | 3 (12%) | 0 (0%) |
| Traffic                              | 4 (16%) | 3 (19%) |
| Contact                              | 6 (24%) | 5 (31%) |
| No contact                           | 12 (48%) | 8 (50%) |

| Table 2: Lachman test at last followup |
|---------------------------------------|
| Lachman test                          | ≤3 mm (-) | 3-5 mm (1+) | 6-10 mm (2+) | >10 mm (3+) |
| 3 (18.8%)                             | 11 (68.8%) | 2 (12.4%) | 0 |
| 11 (44.0%)                            | 11 (44.0%) | 3 (12.0%) | 0 |
Comparison of femoral fixation methods in ACL reconstruction

No surgery-related substantial complications were observed.

**Discussion**

After ACL reconstruction, progressive rehabilitation programs and the demands of the patients to participate in sports activities as early as possible require a secure and reliable fixation of the graft. Cortical-cancellous as well as cortical suspension techniques have shown good clinical results and primary stability after ACL reconstruction.\(^5,11-13\) Ilahi \textit{et al.}\(^5\) presented a meta-analysis with 36 studies: 5 intratunnel hamstring graft fixation studies (\(n = 569\)), 10 extratunnel hamstring graft fixation studies (\(n = 604\)), and 24 patellar tendon studies (\(n = 1592\)). There was no significant difference in the percentage of knees restored to normal instrumented laxity measurements among the three groups, nor was there a difference in graft failure rate. Patient satisfaction and return to preinjury activity rates were similar between the intratunnel fixation and patellar tendon groups and were significantly lower for the extratunnel fixation group.

Harilainen and Sandelin\(^12\) presented a 2 year followup of randomized trial including 120 patients, comparing cortical-cancellous and intratunnel (bioabsorbable screw) fixation after ACL reconstruction with hamstring tendons. They found no significant difference at the 1-and 2-year followup evaluation at the clinical examination, knee scores (Tegner-Lysholm, IKDC, and patellofemoral scores), and laxity measurements (Lachman and pivotshift tests). In agreement with the previous, Frosch \textit{et al.}\(^13\) published a prospective nonrandomized study comparing cross-pin femoral fixation with bioabsorbable interference screw fixation in hamstring ACL reconstruction. They also found similar clinical results between the two groups. Cross-pin fixation was superior with regard to the anteroposterior laxity as measured with KT-1000.

Other author\(^14,15\) suggest that both cortical (Endobutton) and cortical-cancellous (CrossPin) fixation techniques may have superior biomechanical properties than the intratunnel ones (interference screws).

In our study, we have compared two methods of fixation, femoral extratunnel (cortical and cortical-cancellous suspension techniques) to evaluate if either one provides better graft stability or clinical results. From study, knee physical examination demonstrated that in the results...
of Lachman test, the laxity of the patients who have undergone cortical-cancellous fixation was greater [Table 2 and Figure 3] even though these differences were not significant. This evaluation showed that in the reconstruction with cortical-cancellous fixation, the end point was much firmer than in those which underwent a different technique (P < 0.05) [Table 3 and Figure 4]. These results suggest that cortical-cancellous fixation provides greater stability to the graft. Despite this apparent difference in stability, the results of IKDC and Lysholm did not demonstrate any difference between the two groups. Hence, both methods of fixation may present a good clinical evolution from a medium to long term, regardless of the degree of laxity in Lachman test.

Consistent with our study, in 2010, Price et al. in a prospective RCT reported no significant differences in clinical outcome after TransFix (cortical-cancellous suspension) versus Endobutton (cortical suspension) femoral fixation in hamstring ACL reconstruction with a 2 year followup. No statistical differences between the two groups were found at the 1- or 2-year followup examinations also. At the 2 year followup, 72.7% of the Endobutton and 84.6% of the TransFix group patients were in the IKDC A or B categories. Additional procedures postoperatively occurred more frequently in the TransFix group. There are some limitations in our study. First, it is a retrospective study with a small sample size. However, despite the small number of patients in our study groups, the trend of outcomes concurs with the literature available. Larger groups could certainly have strengthened our data. Another limitation is that the followup of the patients was of only 40 months. We would like to mention that another limitation could be that the followup of the patients was only clinical; therefore, we did not consider the possible image changes occurred in tunnel or grafts.

**Conclusion**

Cortical-cancellous as well as cortical suspension techniques showed good clinical results and primary stability after ACL reconstruction. The majority of patients in both groups were in IKDC A or B after a followup of 40 months. However, cortical-cancellous fixations seem to provide greater stability to the reconstruction as measured with Rolimeter knee tester. Nonetheless, the same clinical results were obtained after a followup of 40 months in both groups.

More comparative studies are necessary to confirm this trend.

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**Conflicts of interest**

There are no conflicts of interest.

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