ORIGINAL REPORT

Comparison of Different Methods of Femoral Fixation Anterior Cruciate Ligament Reconstruction

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Abstract- The aim of this study is to compare three modes of femoral fixation, namely Aperfix, Rigidfix and Endobutton, in anterior cruciate ligament (ACL) reconstruction. 120 patients were randomly assigned to three groups, each consisting of 40 patients, and each group was treated by one of the above mentioned methods of femoral fixation. All patients were examined prior to and 24 months after surgery, and they were compared for anterior tibial displacement using the Lysholm score and KT-1000. The three modes of femoral fixation were not significantly different in terms of time of surgery. In the Endobutton group, the Lysholm score rose from 63.21±18.59 prior to ACL reconstruction to 90.64±9.47 after the surgery, while it rose from 65.72±18.74 to 96.22±5.35 in the Aperfix group and from 69.21±17.45 to 90.64±9.47 in the Rigidfix group. Anterior tibial displacement was 3.96±1.58 mm for Endobutton, 4.28±1.48 mm for Rigidfix and 4.03±1.79 mm for Aperfix. Aperfix was indicated to yield a better outcome in terms of instant stability and general results.

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Introduction

Anterior cruciate ligament (ACL) tears constitute the most common ligament injury of the knee (1), necessitating more than 100,000 cases of reconstruction in the United States annually **(**2). ACL graft fixation has been proposed to exert an essential influence on the mechanical behavior of the graft during the early period after reconstruction. Clinically, the biomechanics of the final graft construct will be determined by multiple factors including tibial fixation, femoral fixation, graft characteristics, and surgical technique.

Femoral fixation of quadrupled hamstring grafts is the key element to a durable ACL reconstruction, and there are many options available to achieve it; including interference screw, Endobutton, femoral cross-pin (TransFix & Biotransfix), Rigidfix and Aperfix, each bearing its own cons and pros (3). Early instability (less than 6 months) may occur after surgery due to flawed surgical technique, inappropriate graft fixation, premature exercise or inappropriate physiotherapy, whereas delayed instability (beyond one year) develops as a result of repeated trauma to the ACL tissue (4).

Endobutton (Smith & Nephew, Andover, MA, USA) is a device placed against the anterolateral cortex of the distal femur, suspending the graft inside the femoral tunnel. In this type of fixation, vectors of resistance are parallel to and opposite the external forces, and they concentrate on the cortical bone of the distal femur, on the bone-device surface.

Rigidfix **(**DePuy Mitek, Raynham, MA**)** is a transcondylar fixation system which uses one or more horizontal bars that cross the graft and femoral tunnel and create a bulge in graft. In this type of fixation, resistance is distributed along the surface between the device and bone and it depends on osseous density and length of the lever arm, considering the use of pulling forces (graft suspension point).

Aperfix (Cayenne Medical, Inc, Scottsdale, Arizona) is another system for femoral fixation in which the femoral fixation device in cancellous bone is pulled alongside the shaft, opening like a wing, thus preventing

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the graft from moving back. It is made of polyether ether ketone: a non-absorbable radiolucent substance which does not provoke inflammatory response.

A powerful and stable fixation will prevent graft rupture and loss before it is fixed biologically. In addition, a weak initial fixation may compromise graft repair as stresses cause micro-motions of the graft, thus delaying or jeopardizing graft integration in the osseous canal (5-9). There is no consensus as to which of the methods mentioned above is superior. The aim of this study is to compare biomechanical characteristics of some of the more popular fixation devices (Endobutton, Rigidfix and Aperfix). It was hypothesized that there are significant differences between different methods of femoral fixation and newer methods may have a better outcome.

Materials and Methods

We conducted our study on 120 patients admitted to our referral orthopedic hospital for ACL reconstruction from January 2008 to May 2009.

Patients aged over 45 years, those with symptoms of knee osteoarthritis and those with other injuries of knee ligaments requiring repair were excluded from the study. Based on the order of referral, patients were randomly assigned to three groups, each holding 40 patients; the first patient was assigned to Aperfix group, the second patient to Rigid fix group, the third to Endo button group and so on.

Necessary radiographies were prepared prior to surgery. A data sheet, containing demographic data, examination findings and Lysholm score, was completed for each patient. Surgery was performed using tourniquet and in the supine position. All surgeries were performed by one single orthopedic surgeon and his team. All patients initially underwent diagnostic arthroscopy for evaluation of anterior and posterior cruciate ligaments as well as the medial and lateral menisci. Those patients whose ACL rupture was confirmed on arthroscopy underwent surgery as follows: initially, an anteromedial incision was made on the proximal tibia and the gracilis and semitendinosus tendons were detached from their insertions on tibia. Subsequently, the tendons were removed to fashion the graft for ACL reconstruction. A tibial canal was established; through this canal, the femoral canal was created under arthroscopy guide. Finally, the graft was passed through the canals as a single bundle. Based on the patient's group, the grafts were fixed in femur using Rigidfix, Aperfix or Endobutton.

Grafts were fixed in tibia with interference screws for all patients. We did not use control radiography in the surgery room. Knee drains, inserted for all patients, were removed after 24 hours. After surgery, all patients were ordered to receive cold compression and limb elevation as well as conventional supportive knee braces. All complications of surgery were documented during and after surgery.

All patients received prophylactic antibiotics for 48 hours. Knee physiotherapy, consisting of isometric quadriceps exercise, 2 to 1 hamstring/quadriceps strengthening, and continuous passive motions were initiated 24 hours after surgery. Once a range of motion of 90 degrees was achieved for the knee, the patient would be discharged with a recommendation for continuing physiotherapy. Sutures were removed after 2 weeks.

Two years after the ACL reconstruction surgery, the patients were summoned for examination, control radiography and determination of anterior tibial displacement using KT-1000. Out of 120 patients, 96 returned for follow-up, comprising 34 in the Aperfix group, 33 in the Endobutton group, and 29 in the Rigidfix group. In addition to the items mentioned above, the Lysholm chart was completed for these patients.

Once the data sheets were completed, their data were classified for analysis. Statistical analysis was performed on SPSS statistical software (version 15.0; SPSS, Chicago, Illinois). Kruskal-Wallis test, ANOVA and other tests were utilized to compare variables between the groups. *P*-value <0.05 was considered significant.

Results

Ultimately, 96 patients participated in the final follow-up of our study. The basic data of the study patients has been shown in table 1.

Our participants consisted of 93 men and 3 women, with 42 cases of injury in the left knee and 54 cases of injury in the right knee. The duration of time from the knee injury to ACL reconstruction ranged from 1-84 months, with no significant difference observed among the groups ($P>0.05$). On follow-up examination, all patients enjoyed complete range of motion in their knees, and no case of stiffness was observed.

We studied the Lysholm score before and after surgery in different groups of ACL reconstruction. The results are presented in table 2.

Table 1. Basic data of study patients.

	Aperfix	Rigidfix	Endobutton	*P*-value
Number of patients (%)	34 (35.4%)	29 (30.3%)	33 (34.3%)	>0.05
Mean age of patients	26.3	23.6	26.2	>0.05
(Range) /Years	(17- 40)	(19-31)	(18-44)	
Time from injury to surgery	12.5	14.1	14.5	>0.05
(Range)/Months	(1-60)	(1-84)	(2-80)	
Duration of surgery (Min) ±SD	73.8±25.4	73.2±17.1	78.6±22.8	>0.05

M: Male, F: Female, SD: Standard Deviation, Min: Minute

Table 2. Lysholm score and anterior tibial displacement measurements in the study patients.

Type of fixation	Lysholm Score		*P*-value	Ant tibial displacement Post op (mm)		*P*-value
	Preoperative	Postoperative		Excluding failures	Including failures	
Aperfix	65.72±18.74	96.22±5.35	<0.05	4.79±2.04 (2-9)	4.03±1.79	>0.05
Rigidfix	69.21±17.45	90.64±9.47	<0.05	4.89±2.14 (2-11)	4.28±1.48	>0.05
Endobutton	63.21±18.59	90.64±9.47	<0.05	4.96±2.7 (2-13)	3.96±1.58	>0.05

Ant: Anterior, mm: Millimeters, Post op: Post operative

In addition, we evaluated the anterior tibial displacement using KT-1000 to observe displacements in the groups (Table 2).

Re-examination of patients two years after surgery revealed 6 cases of failure in the Endobutton group, with failure defined as an anterior tibial displacement of more than 7 mm using KT-1000. There were 4 cases of failure in the Rigidfix group, whereas only one case of failure was observed in the Aperfix group.

Provided that we eliminate the cases of failure and then compare anterior tibial displacement using KT-1000, we would obtain new mean values of anterior tibial displacement, which indicate no significant difference among these different methods of femoral fixation (Table 2).

Discussion

Our findings indicate that all three modes of ACL reconstruction are associated with improved function and satisfaction of patients as demonstrated by the increase in Lysholm score. Although the Lysholm scores were not significantly different prior to ACL reconstruction, comparison of Lysholm scores after surgery indicated Aperfix to yield better improvement of Lysholm score compared to Rigidfix, and the two of them yielded better results (in terms of improvement in Lysholm score) compared to Endobutton; the differences among the 3 modes of femoral fixation are not statistically significant.

In a study by Milano et al on 90 porcine knees (10), different femoral fixation devices were compared in a biomechanical analysis. Based on the fixation mechanism used, they classified their fixation methods to compression (Bioscrew), expansion (Rigidfix), cortical (Endobutton), cancellous suspension (Linx-HT) and cortical cancellous (Transfix and Bio-Transfix). They concluded that Cortical-cancellous suspension fixation appears to offer the optimal and most predictable results in terms of elongation, fixation strength, and stiffness. For both compression and suspension, the weakest fixation was attained with cancellous fixation devices. Cortical suspension devices (i.e. Endobutton) demonstrated a greatly variable mechanical behaviour, depending on their design.

Basad *et al.* conducted a study on 67 patients to compare Endobutton and Rigidfix using physical examinations and magnetic resonance imaging (MRI) 6 and 12 months after surgery. Twenty-one patients were in the Endobutton group and 46 in the Rigidfix group. Comparison was made using KT-1000, Lysholm, International Knee Documentation Committee (IKDC) scale and Tegner. Six months after surgery, KT-1000 indicated better stability with Rigidfix compared to Endobutton; however, no significant difference was observed between the two groups 12 months after

surgery. In addition, IKDC, Tegner, and Lysholm scores were similar for both methods (11).

According to our findings, 2 years after surgery, 75% of patients in the Endobutton group, 89% of those in the Rigidfix group and 91% of those in the Aperfix group obtained Lysholm scores of over 80, whereas in a study by Asik, out of 271 patients who underwent ACL reconstruction with Transfix, only 7% achieved Lysholm scores of below 80 (12).

Rigidfix uses two pins across the graft and femoral tunnel. This technique reduces the risk of fracture of the posterior femoral cortex. In addition, there is a decrease in the "windshield wiper effect" associated with the Endobutton system since the Rigidfix system fixes the femoral graft transversally and "in situ", thus preventing mobility between the graft end and the fixation system.

The Endobutton is commonly used and is relatively inexpensive. The point of fixation lies some distance from the joint (13). This technique is prone to drill tunnel enlargement, possibly through the so-called 'bungee' effect (14-16). The resulting bone loss may result in revision surgery (17).

In the present study, we did not observe a significant difference in anterior tibial displacement among the three groups. All three modes of fixation reduced anterior tibial displacement equally.

Sen *et al.*, (2007) conducted a study on 271 patients (198 men and 73 women) who underwent ACL reconstruction with Transdfix to evaluate the medium and long-term outcomes. After surgery, only 14 patients (5%) had an anterior tibial displacement of more than 5 mm, whereas it was observed in 161 patients (59%) prior to surgery (12).

In a retrospective study by Plawaski *et al.* on 105 cases of ACL reconstruction with Endobutton, 59% of patients had laxity values of less than 2 mm, with the overall mean laxity value reported to be 1.8 mm (18).

Price *et al.* conducted a study on 20 patients with ACL tear to perform ACL reconstruction with either Endobutton (13 patients) or Rigidfix (16 patients). After two years of follow-up, 11 patients in the Endobutton group and 13 patients in the Rigidfix group remained in the study, while their findings indicated no significant difference between the two modes of femoral fixation (19).

There are few studies reporting the results of Aperfix system and to the best of our literature investigation there was no study to compare this system with the other methods of femoral fixation.

We found only one study in which Uribe *et al.* studied posterior cruciate ligament reconstruction with Aperfix to report that Aperfix provides a secure and timely system for reconstruction while reducing the risk of bone and soft tissue injury (20).

To the best of our knowledge, this is the only study comparing Endobutton, Rigidfix and Aperfix with each other. There are certain limitations for our study; we only applied the Lysholm score for evaluation of the patients' outcome and did not use other methods of scoring like IKDC or Tegner to assess the patients' outcome more elaborately. Furthermore, the follow-up duration of this study was limited. Future studies on larger populations and with longer periods of follow-up are recommended. We are currently awaiting longer term results to verify whether or not these early results persist. In conclusion, aperfix yields a better outcome compared to the other two modes of femoral fixation in terms of instant stability of the graft and the general results.

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