

Outcome of transtibial AperFix system in anterior cruciate ligament injuries

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ABSTRACT

Background: The anterior cruciate ligament (ACL) is one of the major stabilizing factor of the knee that resist anterior translation, valgus and varus forces. ACL is the most commonly ruptured ligament of the knee. The graft fixation to bone is considered to be the weakest link of the reconstruction. According to the parallel forces to the tibial drill hole and the quality of tibial metaphyseal bone is inferior to femoral bone stock, graft fixation to the tibia is more difficult to secure. AperFix system (Cayenne Medical, Inc., Scottsdale, Arizona, USA) which consists femoral and tibial component that includes bioinert polymer polyetheretherketone (PEEK) is one of the new choice for ACL reconstruction surgery. aim of this study was to assess the clinical outcomes and fixation durability of the AperFix (Cayenne Madical, Inc., Scottsdale, Arizona, USA) system and to determine the effect of patient's age in arthroscopic reconstruction of the anterior cruciate ligament.

Materials and Methods: Patients with symptomatic anterior cruciate ligament rupture underwent arthroscopic reconstruction. Patients were evaluated in terms of range of motion (ROM) values; Lysholm, Cincinnati and Tegner activity scales; laxity testing and complications. Femoral tunnel widening was assessed by computer tomography scans. Early postoperative and last followup radiographs were compared.

Results: Fifty one patients were evaluated with mean followup of 29 months (range 25–34 months). Mean age at the surgery was 26.5 ± 7.2 years. Lysholm, Cincinnati and Tegner activity scales were significantly higher from preoperative scores (Lysholm scores: Preoperative: 51.4 ± 17.2 , postoperative: 88.6 ± 7.7 [$P < 0.001$]; Tegner activity scores: Preoperative 3.3 ± 1.38 , postoperative: 5.3 ± 1.6 [$P < 0.001$]; Cincinnati scores: Preoperative: 44.3 ± 17 , postoperative: 81.3 ± 13.9 [$P < 0.001$]). The mean femoral tunnel diameter increased significantly from 9.94 ± 0.79 mm postoperatively to 10.79 ± 0.95 mm ($P < 0.05$). The mean ROM deficit (involved vs. contra knee) was -7.2 ± 16 ($P < 0.001$). There was no significant difference for knee score, ROM deficits (<30 years: -7.3 ± 15 and >30 years -7.06 ± 19) and femoral tunnel enlargement (<30 years: 0.83 ± 0.52 and >30 years 0.87 ± 0.43) of the patients with below and above 30 year. There was no significant difference for knee scores and femoral tunnel enlargement between patients with meniscal injuries and don't have meniscus lesions.

Conclusion: The AperFix system gives satisfactory clinical and radiological results with low complication rate. However, long term clinical and radiological results are needed to decide the ideal anterior cruciate ligament reconstruction method.

Key words: Anterior cruciate ligament injury, AperFix system, arthroscopy, ACL reconstruction

MeSH terms: Anterior cruciate ligament injury, ACL reconstruction, arthroscopy

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INTRODUCTION

The anterior cruciate ligament (ACL) is one of the major stabilizing factor of the knee that resist anterior translation, valgus and varus forces. ACL is also a mechanoreceptor of the knee. As the contact sports activities are rising, injuries of the knee joint are more common and ACL is the most ruptured ligament of the knee.¹

Number of patients with ACL rupture is rising and medical device industry introduces new systems for effective graft fixation. After the ACL reconstruction, the strength of the graft fixation to bone is considered to be the weakest link of the reconstruction. According to the parallel forces to the tibial drill hole and the quality of tibial metaphyseal bone

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is inferior to femoral bone stock, graft fixation to the tibia is more difficult to be secure.^{2,4} AperFix system (Cayenne Medical, Inc., Scottsdale, Arizona, USA) which consists femoral and tibial component that includes bioinert polymer polyetheretherketone (PEEK) is one of the new choice for ACL reconstruction surgery. This system PEEK is characterized by an ideal modulus of elasticity that provides strength and stiffness and used, especially in spinal fusions and complex maxillofacial defects.⁵ A stable fixation would prevent graft rupture and knee instability. Also, a weak fixation may compromise graft repair. But, there is no consensus about ideal fixation about ACL reconstruction surgery.^{6,7}

In this study, we aimed to evaluate mid term clinical and radiographic results with AperFix system used in arthroscopic ACL reconstruction and determine the effect of patient's age on deciding surgical treatment.

MATERIALS AND METHODS

83 patients with symptomatic ACL rupture underwent arthroscopic ACL reconstruction by the senior author (GG) between February 2010 and May 2011. Diagnosis was based on clinical examination (anterior drawer, Lachmann, Pivot shift tests) and confirmed by magnetic resonance imaging. Effusion and tenderness were evaluated; range of motion (ROM) value, Lysholm, Cincinnati and Tegner activity rating systems were scored before the surgery.⁸ The inclusion criteria were ACL injury with no other ligament injury of the knee and the exclusion criteria were knee surface related fractures, lower limb alignment deficiencies, prior knee surgery and connective tissue disorders. This study was approved by the institutional ethical committee; all patients were informed and the study was performed in accordance with the declaration of Helsinki as revised in 2000.

Operative procedure

Single bundle, ACL reconstruction was performed. All of the operations were performed under spinal or general anesthesia and pneumatic tourniquet was used in all patients. First the knee joint was arthroscopically evaluated through standard arthroscopy portals. Accompanying meniscus lesions were recorded. Then, semitendinosus and gracilis tendons were harvested using a tendon stripper. Tibial tunnels were laid at 55° to the long axis of the tibia and guide pin was inserted anterior border of the medial collateral ligament insertion. Femoral tunnel opened at 10 or 2 o'clock positions with the knee hyperflexed with the guide pin inserted through the tibial tunnels. 9 mm, 10 mm and 11 mm reamers were selected according to the size of the graft. Notchplasty was not performed during the surgery. After the preparation of the tunnels, the AperFix

system with double looped semitendinosus and gracilis autograft complex was inserted through the tunnels. After the graft had been inserted to the tunnels, flexion and extension was performed to test impingement. Then the knee joint evaluated arthroscopically for the tension of the graft and tibial fixation device's position, to ensure that it was not protruding into the joint. The knee was tested with anterior drawer and Lachmann test.

Postoperative rehabilitation

A knee brace with an angle adjustable hinge was used for 4 weeks postoperatively. The goals were to decrease pain and swelling after the 1st day of the surgery. At the 2–14 days our goals were obtained full extension, minimize swelling, allow wound healing, maintain active quadriceps control and achieve 90° of flexion. At the 2–6 weeks, we aimed to increase flexion to 135 degrees and increase muscle tone. We aimed to progress to full ROM, increase strength and increase functional activities at 6–9 weeks, improve muscle strength and endurance at 9–12 weeks. After 12 weeks we started light sports activities and after 6 months of the surgery vigorous pivoting activities was resumed.

After 2 year of the arthroscopic ACL reconstruction; we were able to contact with 76 of the 83 patients and 51 of them returned to the clinic for the evaluation. Laxity tests (Anterior drawer, Lachmann, Pivot shift), effusion and tenderness were assessed. ROM value was scored using goniometer and differences in maximum ROM between involved and contralateral sides were measured. Lysholm, Cincinnati and Tegner activity scale was scored after 26 months (range 23–28 months) of the surgery. We couldn't use the KT arthrometer to measure the laxity.

Radiographic evaluation

Femoral tunnel widening was assessed by computer tomography (CT) scans. All the examinations were performed using a Toshiba Aquillon 64 Slice CT with postprocessing coronal and sagittal images. Early postoperative and last followup CT results were compared. Femoral tunnel width in the middle point on sagittal image reconstruction was measured by a radiologist who is blinded to cases [Figures 1 and 2]. Enlargement of the tunnel between the early postoperative and the last followup were recorded. The slice thickness was 0.5 mm with retroconstruction of 1 mm made in all patients before postprocessing imaging.

Statistical analysis

Statistical analysis was carried out by using the Statistical Package for the Social Sciences (SPSS) software version 13.0 (SPSS Inc., Chicago, USA) and data are presented as mean \pm standard deviation comparisons



Figure 1: Computed tomography scans in the middle point on sagittal image reconstruction showing femoral tunnel width measurement

between preoperative and postoperative scores (Lysholm, Tegner, Cincinnati), ROM deficits and tunnel widening measurements were analyzed by using paired *t*-test. To analyze results of <30-year patients unpaired *t*-test was performed. Wilcoxon Signed Ranks test was performed to analyze >30-year patients. Unpaired *t*-test was also performed to analyze if meniscal lesions affect outcomes or not. Mann–Whitney U-test was used to evaluate the relationship between this two variable. $P < 0.05$ were considered to be significant.

RESULTS

Fifty one male patients were evaluated in our study. The right knee was operated in 35 patients and left knee in 16 patients. The mean time from injury to surgery was 9.2 months (range 1–42 months). Mean followup time was 29 months (range 25–34 months). Mean age was 26.5 ± 7.2 years (range 18–49 years). Of the 51 patients 16 had medial, 9 had lateral and 6 had both meniscus tears. Partial meniscectomy was performed for the meniscus lesions. Sports related injury was common (82%) as most of the patients were soldiers (34/51).

In the postoperative period Lysholm, Cincinnati and Tegner activity scores were significantly higher from preoperative knee scores [Table 1]. The mean ROM deficit (involved vs. contra knee) was -7.2 ± 16 ($P < 0.001$). There was no significant difference for knee scores, ROM deficits and tunnel enlargement of the patients with below and above 30 year [Table 2].

No implant breakage, deep vein thrombosis, implant failure, patellar fracture, joint infection, ligamentous instability or rupture occurred after the surgery. Three patients had significant hemarthrosis after 2 weeks of the surgery and aspiration was required.

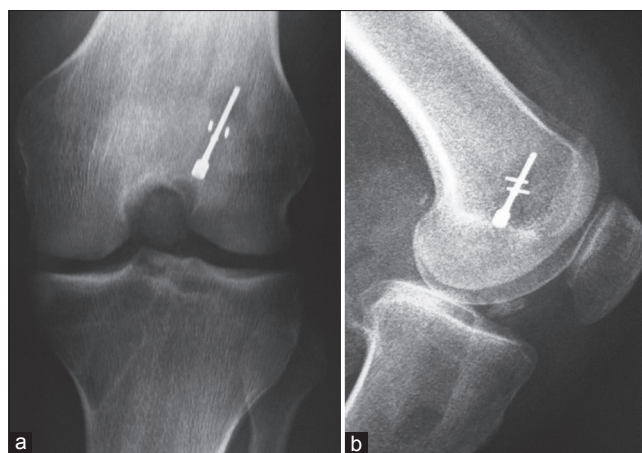


Figure 2: (a) Anteroposterior (b) lateral radiographs of the knee joint showing implanted AperFix system (Cayenne Medical, Inc., Scottsdale, Arizona, USA)

Table 1: Knee scores

| Knee scores | Preoperative | Postoperative | P |
|-------------|--------------|---------------|-------|
| Lysholm | 51.4±17.2 | 88.6±7.7 | <0.05 |
| Tegner | 3.3±1.38 | 5.3±1.6 | <0.05 |
| Cincinnati | 44.3±17.4 | 81.3±13.9 | <0.05 |

Table 2: Comparison of outcomes between <30 years and >30 years patients

| Variables | <30 years | >30 years | P |
|----------------------------|-----------|-----------|----|
| N | 40 | 11 | |
| Lysholm scores* | 36.6±16.1 | 38.7±20.6 | NS |
| Tegner activity scores* | 2.05±0.78 | 2.0±1.0 | NS |
| Cincinnati scores* | 37.4±8.8 | 35.5±10.6 | NS |
| ROM deficits | -7.3±15 | -7.06±19 | NS |
| Femoral tunnel enlargement | 0.83±0.42 | 0.87±0.43 | NS |

N=Number of patients, *Postoperative-preoperative knee scores±standart deviation, NS=Nonsignificant ($P>0.05$), ROM=Range of motion

Comparing immediate CT scans (mean, 4 ± 3 days after the surgery) and followup CT scans (mean 30 ± 5 months after the surgery) the mean femoral tunnel diameter increased significantly from 9.94 ± 0.79 mm postoperatively to 10.79 ± 0.95 mm ($P < 0.05$). The mean femoral tunnel enlargement was 0.85 ± 0.44 mm. There was no significant correlation between tunnel enlargement and patient scores. There was no femoral device migration or implant breakage. There was no significant difference for knee scores and femoral tunnel enlargement between patients with meniscal injuries and don't have meniscus lesions [Table 3].

DISCUSSION

Anterior cruciate ligament is the most commonly damaged ligament and ACL reconstruction is one of the most commonly performed surgery in orthopedic surgery.⁹⁻¹³ Many surgical procedures are performed in ACL reconstruction surgery and which technique is most suitable is still controversial. In a prospective randomized

Table 3: Comparison of outcomes between patients with or without meniscus lesions

| Variables | With meniscus lesion | No meniscus lesion | P |
|----------------------------|----------------------|--------------------|----|
| N | 29 | 22 | |
| Lysholm scores* | 36.9±14.3 | 36.8±20.3 | NS |
| Tegner activity scores* | 2.13±0.81 | 1.86±0.83 | NS |
| Cincinnati scores* | 37.7±8.92 | 35.04±10.4 | NS |
| Femoral tunnel enlargement | 0.77±0.38 | 0.96±0.5 | NS |

*Differences between postoperative and preoperative knee scores±SD. N=Number of patients, NS=Nonsignificant ($P>0.05$), SD=Standard deviation

study Zhang *et al.* compared single and double bundle techniques and think that both techniques are suitable for reconstruction.¹⁴ Nohet *et al.* compared transtibial and anteromedial portal techniques and there were no statistically significant differences between two groups.¹⁵ In a controlled laboratory study, no significant differences in anterior translation were found between the anatomic single bundle and anatomic double bundle ACL reconstructions for simulated pivot shift or anterior tibial loading.¹⁶

AperFix system is a relatively new implant system used in ACL reconstruction. This system consist a poly-eter-eter-ketone (PEEK) biomaterial. PEEK is a member of polyaryletherketone family and it is used in not only in dental and trauma medicine, but also in spinal and orthopedic surgery.¹⁷ PEEK is accepted as a radiolucent alternative to metallic biomaterials in spine surgery and especially useful biomaterial for interbody fusion cages.^{5,18} To investigate the suitability of the PEEK polymer for use in highly stress, a combined experimental and analytical study was performed by Ferguson *et al.* The investigators concluded that the results verified the mechanical stability of the polymer in a simulated physiological environment and over extended loading periods.¹⁹ Cooper *et al.* used this system in a failed primary ACL reconstruction in a 23 year old man due to a single traumatic event without any morbidity to femoral and tibial tunnels, they were able to remove the device by using the necessary tools.²⁰

Uzumcugil *et al.* compared the outcomes of TransFix (Arthrex Inc., Naples, Florida, USA) and AperFix system on 38 patients. The mean Lysholm score was 82.42 ± 8.5 in TransFix and 88.68 ± 9.4 in AperFix group ($P < 0.022$). But, there was no significant difference in arthrometric evaluation. They concluded that in the early postoperative period satisfactory clinical results were achieved with AperFix system.²¹

Uribe *et al.* published the 2 year outcome with AperFix system for ACL reconstruction on 185 knees whose mean age was 31 ± 12 months. After 34 ± 7.6 months followup, the mean Lysholm score was 85 ± 18 , Tegner activity score was 5.0 ± 1.3 . On their radiographic evaluation, the mean femoral tunnel enlargement was 1.49 ± 0.49 mm. and they

found no significant correlation between tunnel enlargement and patient scores. They concluded that the AperFix system provides durable fixation for ACL reconstruction with a low complication rate and good clinical results.²²

Bone tunnel enlargement is a major problem after ACL reconstruction surgery and causes of enlargement are controversial. Mechanical (motion of the graft, accelerated rehabilitation, location of fixation, fixation devices) and biological (heat necrosis while tunnel drilling, graft swelling, the synovial fluid propagation within the tunnels, inflammatory response) factors may provide tunnel widening.²³ Peyrache *et al.* reported the average proximal tunnel diameter did not significantly change from 3 months to 2-year.²⁴ But Fink *et al.* reported the enlargement of the tunnel was higher within the first 6 weeks after the surgery.²⁵ According to this study we didn't measure at the highest tunnel widening period and that is the weak point of our study (We measured the tunnel widening at a mean of 19 months followup). In our study, consistent with the literature, there was no relationship between tunnel widening and clinical results.^{26,27}

The most important factors for ACL reconstruction is patient's age, activity level and degree of instability.²⁸ There was no significant difference between <30-year and >30-year' patient's groups. According to our results, we think that patient's age is less important than activity level for the surgical treatment decision. According to Lysholm, Cincinnati, Tegner activity scores we think that ACL reconstruction with the AperFix system demonstrates good clinical results in terms of patient satisfaction and outcome. There is no fixation failure and no femoral device migration occurred at 2-year followup.

Our study has many limitations and weak points. Retrospective nature of the study is one of our weak points because prospective followup results would be better to advice this fixation method. We evaluated the patients with 2 year followup results, but long term followup results needed to decide if this fixation method is ideal or not. Not to measure the tunnel widening at the highest widening period is our another weak point. To evaluate knee laxity with subjective scale we have to measure with KT arthrometer but our clinic don't have a KT arthrometer. Not to measure knee laxity by using KT arthrometer is one of the limitations of our study.

The AperFix system gives satisfactory clinical and radiological results in the early postoperative period. But it is difficult to talk about ideal ACL reconstruction with just one method. According to our results with <30-year and above >30-year patient comparison we think that patient's age is less important than activity level for the surgical treatment decision.

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