Two-year Outcome With the AperFix System for ACL Reconstruction

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Abstract

The purpose of the study was to assess the fixation durability of the AperFix System (Cayenne Medical, Inc, Scottsdale, Arizona) used in arthroscopic reconstruction of the anterior cruciate ligament. The AperFix System consists of a femoral and tibial component designed to secure either allograft or autograft. The outcomes of 185 knees (180 patients) were retrospectively reviewed at a minimum of 2 years postoperatively. Mean age at surgery was 31±12 years (range, 16-68 years). Of these, a convenience sample was seen prospectively to obtain radiographs and to assess functional status. No cases occurred of fixation failure involving loss of graft positioning or pullout. No patients required revision anterior cruciate ligament reconstruction. In 2 knees, the tip of the central fixation pin had to be modified as a result of hardware prominence and soft tissue irritation at 434 and 159 days postoperatively, respectively. In 4 knees, tibial screw removal occurred secondary to local discomfort (mean, 239 days; range, 105-371 days). No other recurring adverse events or problems associated with the implants were identified. Forty-four patients were evaluated prospectively at a mean follow-up of 32±7 months. Lysholm scores and patient satisfaction scores were positively and significantly correlated with Tegner activity scores (r=0.61; P<.0001). Eighty-two (82%) patients had a KT-1000 (Medmetric Corp, San Diego, California) side-to-side difference of less than 3 mm (average, 0.4 mm). No indications of femoral device migration existed when comparing follow-up and immediate postoperative radiographs. The AperFix System provides durable femoral aperture fixation during anterior cruciate ligament reconstruction with excellent clinical outcome scores and a low complication rate.

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Strength of graft fixation to bone, rather than the strength of the graft, is considered to be the weakest link in the stability of an anterior cruciate ligament (ACL) reconstruction during the early postoperative period. This concept applies to both femoral and tibial fixation. However, tibial fixation can be more problematic than femoral fixation because forces on the ACL graft may be parallel to the tibial drill hole, the quality of tibial metaphyseal bone may be inferior to that of femoral bone stock, and the 4-tailed end of the tendon graft fixed to the tibia is more difficult to secure. In an effort to improve graft fixation, new systems are continually being introduced by the medical device industry. These fixation systems vary considerably with respect to implant hardware and fixation procedures.

The purpose of this study was to report the 2-year outcome of a novel device, the AperFix System (Cayenne Medical, Inc, Scottsdale, Arizona), which consists of both femoral and tibial components (Figures 1-3). This fixation system is designed to decrease graft laxity, increase pullout strength, and augment bone–tendon healing with circumferential compression forces. The components consist of the bioinert polymer polyetheretherketone (PEEK), which is characterized by an ideal modulus of elasticity that theoretically provides stiffness and strength while minimizing stress shielding and tunnel widening. It has become a prominent choice in medical device implants in spinal fusions. In the current authors’ practice, it has been used successfully for autograft, allograft, and hybrid ACL and posterior cruciate ligament reconstructions.

 MATERIALS AND METHODS

 Study Design

This was an outcome study with retrospective and prospective arms. The primary objective was to assess the fixation durability of the AperFix System used in arthroscopic ACL reconstruction. The retrospective arm involved a review of all patients who were at least 2 years postoperative. The prospective arm consisted of a convenience sample of patients from the retrospective arm who were available to return to the clinic for a free 1-time follow-up visit expressly for the purpose of this study. This study was approved by the institutional review board, and patients in the prospective arm signed an informed consent form.

 Study Cohort

Use of the AperFix System in the current study began in 2007. Only patients at a minimum of 2 years postoperative were included in the data analyses (thus, only patients operated on between 2007 and 2010). No other exclusion or inclusion criteria existed.

Graft Source

Selection of the graft source for ACL reconstruction was based on patient age, activity level, and preference. In patients younger than 30 years or with a Tegner activity score of 7, a hybrid graft of a semitendinosus tendon autograft combined with a strip of allograft tendon (either semitendinosus or anterior tibialis) was trimmed to size to create a graft of appropriate diameter for the patient’s bone size (9, 10, or 11 mm) (70% of patients). This hybrid graft usually comprised 50%
Surgical Technique

Endoscopic single-bundle ACL reconstruction was performed in all patients. A minimal notchplasty was routinely performed to enhance visualization, and the insertion stump of the ACL was preserved on both the femur and the tibia. The guide pin for the femur was inserted so that it penetrated the ACL stump as close to the center as possible. Tibial tunnel creation was performed with the guide pin inserted just anterior to the anterior border of the medial collateral ligament insertion and at a 55° angle with the long axis of the tibia. Femoral tunnel creation was performed with the guide pin inserted through the tibial tunnel in the majority of cases and through an accessory medial portal when the transtibial path was not optimal. The diameter of the fluted reamer varied with the size of the graft selected for the patient. In patients shorter than 5 feet, 9-mm tunnels were made; in patients who were 5 feet to 5 feet 6 inches tall, 10-mm tunnels were made; and in patients taller than 5 feet 6 inches, 11-mm tunnels were made.

Prior to placing the guide pins, the semitendinosus tendon was harvested in patients in whom a hybrid graft was used. The same incision was then used to create the tibial tunnel. After the tunnels were created, the AperFix System with the graft complex was inserted through the tibial tunnel and into the femoral tunnel. If the femoral tunnel was created through the medial portal, then the graft complex was passed through the portal and into the femoral tunnel. After the device was located in the femoral tunnel, it was deployed, securing it and the graft complex to the tunnel walls. The knee was taken through a range of motion (ROM) to ensure no roof or posterior lateral ligament impingement was present. Tension was then placed on the graft distally, and the graft was secured within the tibial tunnel with the knee in position of maximum inward positioning of the graft or in extension if no movement of the graft occurred during ROM. The AperFix tibial fixation expansion device was implanted to secure the graft in the tibial tunnel.

The arthroscope was then introduced into the knee to evaluate the tension of the graft and to ensure that the tibial fixation device did not protrude into the joint. The knee was then tested for stability using the Lachman test.

Postoperatively, patients were placed in a hinged knee brace for 7 to 10 days until independent ambulation with a normal gait was achieved. All patients were given the same rehabilitation guidelines, consisting of a progressive exercise program that patients participated in through postoperative week 20. All patients had a course of formal physical therapy, but the amount varied based on insurance carrier. Athletic participation in cruciate-dependent sports was permitted after thigh girth and ROM were symmetric and patients were at least 6 months postoperative.

Retrospective Chart Review

Charts for 180 patients who were at least 2 years postoperative were reviewed to search for cases in which the AperFix System failed or any recurring adverse events occurred.

Prospective Follow-up

Attempts were made to contact all patients who were at least 2 years postoperative. Contact was by telephone or e-mail in chronological order based on surgery date. Patients were asked if they would be willing to return for a free office visit and evaluation. At the prospective follow-up visit, clinical evaluations included assessment of overall knee function, laxity (Lachman and pivot shift tests), tenderness, effusion, girth measurements (3 and 6 inches from the superior pole of the patella), ROM, flexibility, weight-bearing status, and KT-1000 (Medmetric Corp, San Diego, California) measurements. Patients completed validated outcome surveys (Lysholm survey, Tegner activity scale, and visual analog satisfaction scale) to document the presence of pain, activity limitations and extent of return to preinjury sports activities, and satisfaction with the surgical procedure.

Radiographic Evaluation

Anteroposterior and lateral knee radiographs were obtained for patients who returned for the prospective follow-up visit and were compared with radiographs from the first postoperative visit when available. The objective was to assess whether femoral device migration and tunnel widening occurred. A novel root mean square (RMS)/least significant change method was used to determine whether the change in device position or tunnel size from the immediate postoperative radiograph was statistically significant. Specifically, the variability in measurements from duplicate radiographs was used to calculate the root mean square SD and percent coefficient of variation (%CV) of measurements made using the length measurement tool in the digital radiograph software. An adjustment was made for magnification. The least significant change value was then calculated at the 95% confidence interval, and this was used as the threshold for determining whether a change in distance between points was statistically significant at a P value less than .05. One investigator (GMK) performed all measurements to avoid interevaluator variation in technique.

\[
\text{RMS-\%CV} = \sqrt{\frac{\sum CV^2}{N}}
\]

Where \( \Sigma CV^2 \) is the sum of the squared coefficient of variation for each set of radiograph measurements and N is the group sample size. Root mean square-SD was calculated in the same manner using SD instead of %CV. Using this method, a change in width at follow-up had to be more than 1.13 mm (10.15%) to be statistically significant.
Tunnel width was measured at the base of the AperFix System femoral component central pin, and the joint space between the distal femur and superior tibia was measured at the midpoint of the lateral and medial compartments.

Data Analysis
Data are presented as mean±SD. Comparisons between ACL-reconstructed knees and contralateral knees were performed using the paired t test; other comparisons were performed using the unpaired t test or Fisher’s exact test. Pearson correlation was used to evaluate the relationship between 2 variables. Results of statistical tests were considered significant if the P value was less than .05.

RESULTS
One hundred eighty patients (185 knees) were a minimum of 2 years postoperative. Mean age at surgery was 31±12 years (range, 16 to 68 years). Regarding knees, 30% belonged to women and 70% belonged to men. Injuries included isolated ACL ruptures (37%) and those with concomitant intra- and extra-articular pathology (eg, meniscal tears and collateral ligament injuries) (63%). All ACL injuries were confirmed by magnetic resonance imaging. Etiology of the injuries was sports-related in 155 (84%) knees, work-related in 6 (3%), and other event (eg, falls, walking, playing with children) in 24 (13%). The type of graft was allograft in 38% of knees and a hybrid graft (allograft plus autograft) in 62%.

Retrospective Chart Review
Knees were a mean of 34±7.6 months postoperative; however, follow-up visits were inconsistent, with 42% of knees returning for a 6-month visit and 30% of knees for a 12-month visit. No cases of fixation failure involving loss of graft positioning or pullout occurred. In the 2 knees, the tip of the central fixation pin had to be revised as a result of hardware protrusion and local soft tissue irritation at 434 and 159 days postoperatively, respectively. Four cases of tibial screw removal occurred secondary to localized discomfort (mean, 239 days; range, 105 to 371 days). No other recurring adverse events or problems associated with the implants were identified.

Prospective Follow-up
Forty-four patients were evaluated at a mean of 32±7 months. Mean age at surgery was 27.3±8.8 years (range, 16.3 to 46.7 years), and mean body mass index was 26.0±4.3 kg/m² (range, 18.6 to 36.6 kg/m²). Table 1 summarizes measured variables. Lysholm and patient satisfaction scores were positively and significantly correlated with the change (postoperative score–preinjury score) in Tegner activity scores (r=0.61 for both correlations; P<.0001). Thirty-six (82%) patients had a KT-1000 side-to-side difference less than 3 mm (average, 0.4 mm). Knees undergoing ACL reconstruction had significantly higher KT-1000 values compared with contralateral knees (6.2 vs 4.8 mm; P=.0005), with a mean difference of +1.29±2.2 mm (range, −2.33 to 7.00 mm; 95% confidence interval, 0.59-1.99 mm). No significant correlation was found between KT-1000 scores and Lysholm scores, patient satisfaction with surgery, Tegner scores, or percent tunnel widening. Eight (18%) patients had ACL-reconstructed knees with KT-1000 measurements more than 3 mm greater than the contralateral knee. However, no significant difference existed in Lysholm scores, patient satisfaction with surgery, Tegner scores, or percent tunnel widening between patients with a KT-1000 displacement difference (involved vs contralateral knee) more than 3 mm and those with a difference less than 3 mm (Table 2). No significant differences existed in overall outcomes, KT-1000 measurements, or relationships between variables between patients with allograft or hybrid grafts.

Table 1
Outcome Variables for 44 Patients Returning for a Mean 32-month Follow-up

<table>
<thead>
<tr>
<th>Variable</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Lysholm score</td>
<td>85.1±18</td>
</tr>
<tr>
<td>Mean Tegner activity score</td>
<td>5.0±1.3</td>
</tr>
<tr>
<td>Mean patient satisfaction with surgery</td>
<td>9.0±1.7</td>
</tr>
<tr>
<td>Mean knee ROM deficit (involved vs contra knee), deg</td>
<td>−5.8±13*</td>
</tr>
<tr>
<td>Mean hamstring flexibility deficit (involved vs contra knee), deg</td>
<td>−1.5±6.5*</td>
</tr>
<tr>
<td>Knee pain with activity, No. of patients</td>
<td>7/44</td>
</tr>
<tr>
<td>Mean quadiceps girth deficit of involved knee, cm²</td>
<td>0.6±0.7*</td>
</tr>
<tr>
<td>3 in above knee</td>
<td>6 in above knee</td>
</tr>
<tr>
<td>Mean hamstring flexibility deficit</td>
<td>0.7±0.8*</td>
</tr>
<tr>
<td>Ratio of return to limited or full sports activity, No. of patients</td>
<td>34/44</td>
</tr>
</tbody>
</table>

Abbreviations: contra, contralateral; deg, degrees; ROM, range of motion.
*Maximum score = 100.
**Maximum score = 10.
***Maximum score = 10.
†Difference in maximum range of motion between involved and contralateral sides.
‡Yes or no question on whether patient had pain with exertion.
§Difference in girth measurement between involved and contralateral sides.
¶Yes or no question on whether patient returned to preinjury sports activity.
*Paired t test; statistically significant difference, P<.05.
Radiographic Evaluation

No evidence existed of femoral device migration when comparing follow-up radiographs (mean, 32±6 months postoperatively) with immediate postoperative radiographs (mean, 6±6 days postoperatively). Twelve (27%) patients had statistically significant tunnel enlargement (mean, 1.49±0.49 mm; 14.6%; range, 10.4% to 29.4%). No significant correlation existed between tunnel width at the widest point and patient satisfaction or functional scores. Moreover, no difference existed in satisfaction or functional scores or KT-1000 measurements between patients with significant tunnel widening and those with no significant widening.

Discussion

The results of this study suggest that the AperFix System provides durable fixation for ACL reconstruction. No outright fixation failures where implants released from bone occurred. Moreover, radiographic analysis showed no evidence of femoral device migration over a mean 32 months. Clinically, the involved knees did as well as those in other studies in the literature with regard to postoperative Lysholm scores, ROM, and other parameters.3–10

To the authors’ knowledge, one other report exists on the outcome of the AperFix System for ACL reconstruction. Uzumcugil et al9 compared the outcomes of the TransFix fixation method (Arthrex Inc, Naples, Florida) and the AperFix System after arthroscopic ACL reconstruction. A total of 38 patients with isolated complete ACL ruptures underwent reconstruction using hamstring autografts (n=19 with each fixation system). Mean follow-up was 19 months in the TransFix group and 15 months in the AperFix group. Average flexion was slightly better in the TransFix group (137°) compared with the AperFix group (126°) (P<.001). However, mean Lysholm score in the TransFix group was slightly worse (score, 82) compared with that in the AperFix group (score, 89) (P<.02). No significant difference existed in laxity testing or complication rates between groups. The investigators concluded that the AperFix System had a satisfactory performance comparable with that of cross-pin fixation.9

Three additional clinical studies report on the AperFix System. Cooper et al11 described the successful removal of AperFix femoral and tibial components due to traumatic injury requiring a revision ACL procedure. Despite the need to replace the damaged graft, the femoral and tibial fixation had remained in the original position.11 Uribe et al12 reported successful use of the AperFix System for posterior cruciate ligament repair. Uzumcugil et al9 recently reported a comparison of the AperFix System (n=18), the TransFix method (n=29), and the EndoButton (Smith & Nephew, Mansfield, Massachusetts) (n=20) on tunnel widening after hamstring ACL reconstruction. All 3 graft fixation devices resulted in significant tunnel widening in both tibial and femoral tunnels at 30-month follow-up. The degree of widening was not significantly different between implants except for smaller tibial tunnel diameter in the sagittal plane for the EndoButton compared with the other fixation types.9

Tunnel widening has been recognized as a potential problem with certain types of fixation systems.7,8,13,14 Possible causes

<table>
<thead>
<tr>
<th>Variable</th>
<th>&lt;3 mm (n=36)</th>
<th>&gt;3 mm (n=8)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up, mo</td>
<td>32±8</td>
<td>32±6</td>
<td>NS</td>
</tr>
<tr>
<td>KT-1000 measurement, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACL-reconstructed knee</td>
<td>5.5±1.6</td>
<td>8.8±1.7</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Contralateral knee</td>
<td>5.0±1.7</td>
<td>4.0±1.9</td>
<td>NS</td>
</tr>
<tr>
<td>Difference</td>
<td>0.43±1.3</td>
<td>4.8±1.5</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Femoral tunnel widening, %</td>
<td>4.9±8.3</td>
<td>3.3±9.0</td>
<td>NS</td>
</tr>
<tr>
<td>ROM deficit (involved vs contralateral knee), deg</td>
<td>−5.6±10</td>
<td>−6.0±15</td>
<td>NS</td>
</tr>
<tr>
<td>Satisfaction with surgery score</td>
<td>9.2±1.3</td>
<td>8.5±3.1</td>
<td>NS</td>
</tr>
<tr>
<td>Lysholm score</td>
<td>87±15</td>
<td>81±27</td>
<td>NS</td>
</tr>
<tr>
<td>Postop Tegner activity score change</td>
<td>−1.4±1.9</td>
<td>−1.8±2.9</td>
<td>NS</td>
</tr>
</tbody>
</table>

Abbreviation: ACL, anterior cruciate ligament; deg, degrees; NS, not significant; ROM, range of motion.
of widening include heat necrosis from tunnel drilling, movement of the graft inside the tunnel, location of fixation points with respect to the articular surface, and nonspecific inflammatory response. Most studies in the literature report no clinical effect of widening. However, Jarvela et al\textsuperscript{13} reported that patients with the greatest widening had more anterior and rotational laxity at 27-month follow-up. The current authors found that although a statistically significant increase in femoral tunnel widening occurred in 8 patients, no correlation with any other outcome variable existed. The extent of tunnel widening observed in the current study’s patients was consistent with that in previous reports.\textsuperscript{14} Various material properties of a PEEK implant may provide a favorable biomechanical environment, lessening the propensity for conditions leading to tunnel widening\textsuperscript{5}; however, this was not evident in the study performed by Uzumcugil et al.\textsuperscript{8} Further study is necessary to determine if the use of a hybrid graft may promote earlier healing of the graft to femoral tunnel walls, resulting in better overall stability and discouraging conditions favorable for widening.

To better define the mechanical stability of the AperFix System, Gadikota et al\textsuperscript{6} evaluated single-tunnel, double-bundle, and single-bundle ACL reconstructions using fresh-frozen human cadaveric knee specimens. Robotic testing investigated the kinematic response of the knee joint under anterior tibial load (130 N), simulated quadriceps load (400 N), and combined torques at various degrees of knee flexion. The AperFix System reliably held the grafts in place during testing.\textsuperscript{6}

Clinical results in the current study mirrored the findings of others in that full return to the preinjury level of sports activity occurred in the minority of patients\textsuperscript{16}; however, 34 of 44 patients in the prospective arm returned to at least limited noncompetitive sports activities. Discussion of this observation is beyond the scope of this study, but the limited return to sports does not seem to be influenced by inadequacies of the fixation system. Similarly, the authors\textsuperscript{10} found that, over the long term, Lysholm scores decreased in some patients as they experienced new problems unrelated to the original injury, thus depressing the group mean Lysholm score. However, in the current study’s prospective cohort, Lysholm scores and patient satisfaction scores were positively and significantly correlated with the post-ACL repair change (postoperative—preoperative score) in Tegner activity scores. Although KT-000 measurements were significantly higher for the involved knee, this was not unexpected and had no discernible effect on ROM or Lysholm, Tegner, or patient satisfaction scores.\textsuperscript{14-16}

Limitations of this study included the inconsistent data records typically obtained with retrospective studies, a lack of survey scores for all longitudinal follow-up visits, and the limited sample size of the prospective group. Also, the radiographic review and measurements for tunnel widening were not planned prospectively, so matching device and tunnel angles between the last prospective follow-up and the immediate postoperative radiograph series was difficult; this explains the substantial measurement error.

**CONCLUSION**

The AperFix System performed satisfactorily with no outright failures and no apparent migration of the femoral fixation.

**REFERENCES**