

## Comparison of the effectiveness of femoral fixation techniques (Aperfix and Endobutton) in anterior cruciate ligament surgery: A clinical trial in men with complete anterior cruciate ligament rupture

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### RESEARCH

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### ABSTRACT

#### Background

Anterior cruciate ligament (ACL) is a Strengthener ligament of the knee. About 50 persons per 100,000 annually counter ACL rupture. Based on studies, the majority of people who have high mobility jobs, and had reconstruction surgery after ACL rupture, have returned to pre-injury level of activity.

#### Aims

We compared two methods of surgery (aperfix and endobutton) in this article. We want to answer these two main questions in this study:<sup>1</sup> is the effectiveness of surgical methods (aperfix and endobutton) in patients with anterior cruciate ligament rupture, the same?.<sup>2</sup> Are the aspects of

the knee function, in two surgical methods (aperfix and endobutton) after ACL reconstruction surgery, the same?

#### Methods

This study is a prospective clinical trial on patients who had complete ACL rupture in an isolated trauma, who were nominated for ACL reconstruction surgery. We excluded the cases that had underlying disease or other damages from the study. 100 patients were randomly divided into two groups of 50 individuals. Then each group underwent surgery. The femoral fixations were by the two common methods of "Aperfix" or "Endobutton". We followed up, the cases one year after surgery and evaluated them by lysholm score as well as with IKDC score.

#### Results

The mean lysholm score and IKDC score do not have statistically significant difference in the two groups. (Mean lysholm score in Aperfix group=95.66 vs. 94.56 in Endobutton group ( $p=0.057$ ) and IKDC score=92.32 in Aperfix group vs 92.20 in Endobutton group ( $p=0.28$ )). However, in some aspects of knee function, such as locking, Swelling, and climbing stairs, patients who had undergone Aperfix approach, had better results.

#### Conclusion

Surgical methods have little difference however due to better results in some aspects of knee functions in this study and due to other studies, it can be said Aperfix method slightly has more benefits. Further investigations with larger number of cases and longer duration of follow-up are recommended.

#### Key Words

Anterior cruciate ligament, surgical reconstruction, arthroscopy, knee

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## What this study adds:

### 1. What is known about this subject?

Surgical methods have little difference however due to better results in some aspects of knee functions in this study and due to other studies.

### 2. What new information is offered in this study?

This research provides information on comparison of two methods of surgery (Aperfix and Endobutton) in Men with Complete Anterior Cruciate Ligament Rupture.

### 3. What are the implications for research, policy, or practice?

It can be said Aperfix method slightly has more benefits. Further investigations with K-T device and with larger number of cases and longer duration of follow up are recommended.

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## Background

Anterior cruciate ligament (ACL) in the knee is an important strengthener ligament. ACL rupture is common in athletes, soldiers and seen in patients with trauma and about 50 per 100,000 annually encounter this.<sup>1,2</sup> The primary function of this ligament is fixation of Tibia against moving forward. In the second task, the ligament stops the rotation of tibia (varus or valgus stress, for example).<sup>3,4</sup>

Recently, knee injuries have increased because of various reasons such as professional sports, especially football. This causes morbidity and disablement. Rehabilitation of the injured people has always been of interest to specialists and significant effort has been made to repair it in the world.

Treatment consists of supportive therapy or surgical treatment that is based on the amount of tears, the job of the patients, the mobility of the patient and the patient's expectations.<sup>5</sup>

According to the studies, most people who have stirring jobs, after anterior cruciate ligament reconstruction surgery, have returned to pre-injury activity level.<sup>6</sup>

There are various surgical techniques for femoral fixation, after anterior cruciate ligament repair. Two common methods are Aperfix and Endobutton. Endobutton is a hardware that placed on the anterolateral cortex of distal femur and hangs the graft into the femoral tunnel. In Aperfix technique, external hardware opens in cancellous bone and stretches across the length of the body, and then wings open and prevent returning of the graft. This study

aimed to evaluate and compare the two methods of femoral fixation.

We want to answer these two main questions;

1. Is the effectiveness of surgical methods (Aperfix and Endobutton) in patients with anterior cruciate ligament rupture, the same?
2. Are the aspects of the knee function such as symptoms, ability to climb the stairs and so on, in two surgical methods (Aperfix and Endobutton) after ACL reconstruction surgery, the same?

## Method

This prospective clinical trial study was conducted on 100 patients referred to the orthopaedic clinic of Tehran Imam Reza Hospital in 2015-2016 who had complete ACL rupture in an isolated trauma, who were nominated for ACL reconstruction surgery. All patients were men. Mean age of cases was 26.45 years old.

Patients randomly divided into two groups and surgery was performed by a skilled orthopaedic surgeon, by special surgical techniques. We excluded the cases that had underlying disease or other damages, from the study. Patients aged over 45 years, or with symptoms of osteoarthritis in the knee, or with other knee Components injuries, were excluded from the study. It should be noted that according to Imam Reza hospital (military hospital), all patients in our study were male.

Based on the study number (2) that was conducted in 1999 by carpenter et al. The incidence of anterior cruciate ligament rupture is 50 per 100,000 and the variance is 3.1. Using the formula of sample size in quantitative studies, with assurance of 95per cent and error of 1/5per cent, a minimum of sample size is:

$$d=0.85$$

$$\alpha=0.05$$

$$\delta=3.1$$

$$n=\delta^2(z_{1-\alpha/2})^2/d^2=47$$

The sample size for the project, including the loss, was considered 100 cases taken advantage of Orthopaedic Clinic of Imam Reza Hospital. Patients randomly divided into two groups and surgery was performed by a skilled orthopaedic surgeon, by special surgical techniques. After a specified time (about one year later), patients were followed up.

First, diagnostic arthroscopy was performed in all patients. And anterior and posterior cruciate ligaments of the knee,

as well as medial and lateral meniscus of the knee were evaluated. After confirming complete ACL rupture, we have an incision and semitendinosus tendon was released from the junction of the tibia. Then the tendon was exited. The tendon graft was provided to reconstruct the ACL. We used medial portal technique. In this technique, the ACL femoral tunnel is drilled through an accessory anteromedial (AAM) portal. The ACL femoral tunnel is drilled independently of the tibial tunnel, then prepared graft, was passed through the Canal with single-bundle method.

In this study, radiographic control was not used in the operating room. In all patients, we didn't use knee drains. After surgery cold compresses and knee elevation and knee braces were used in all patients. No complication was seen during the study. All patients have used three doses of prophylactic antibiotic therapy (cephalosporin); one dose immediately before induction of anaesthesia and two doses after surgery. We used betadine solution for preparing the surgery site. Patients in the extension mode with a brace were transferred to the ward. Physiotherapy in the day after surgery if able began. The patients were allowed to stand with the aid of two crutches and a brace. While the brace is locked in full extension, they were allowed to walk. After reaching 90-degree range of motion of the knee, the patients were discharged. Two weeks later, the stitches were removed.

After about one year, the questionnaires were completed by telephone.

The cases were followed up one year after surgery and evaluated by lysholm questionnaire as well as with IKDC questionnaire.

After data collection, the data stored in SPSS databases and then descriptive statistics and analysis were extracted by T-test.

In our study, results yielding a p-value of 0.05 are considered on the borderline of statistical significance.

We gave all information about the surgery methods to the patients and explained the differences between two methods. All patients entered the study knowingly. In addition, there is no confirmed theory on the preferred surgical procedure. So, none of the patients have not been disadvantaged.

## Results

50 patients with rupture of the anterior cruciate ligament who were operated by Aperfix method, with 50 patients

who were operated by Endobutton method were compared together.

All the patients were men. In our study, results yielding a p-value of 0.05 are considered on the borderline of statistical significance.

Statistically, the average age that could be a confounding factor, was not different between the two groups. (Mean age 25.96 for Aperfix vs. 26.94 for Endobutton ( $p=0.88$ )).

The mean Lysholm score (from 100 points) in Aperfix group was 95.66, and 94.56 for Endobutton, that despite higher score in the Aperfix group, statistically significant difference was not seen. ( $p=0.057$ ) (Table 1 and Figure 1).

Average IKDC score (from 97) in Aperfix group was 92.32 and 92.20 in the Endobutton group that despite higher score in Aperfix Group, statistically significant difference in the groups was not seen. ( $p=0.28$ ) (Table 2 and Figure 2).

Average score of "limp" (from 5) based on Lysholm score, in the Aperfix group was 4.88 and 4.92 in Endobutton group, that did not have, statistically, significant difference. ( $p=0.36$ ).

Average score of "using support" (from 5) based on Lysholm score, in the Aperfix group was 4.92 and 4.92 in Endobutton group, that did not have, statistically, significant difference. ( $p=1$ ).

Average score of "locking the knee" (from 15) based on Lysholm score, in the Aperfix group was 14.50 and 14.02 in Endobutton group that had a significant difference that indicates the situation is better in the Aperfix group in this aspect. ( $p=0.041$ ).

Average score of "giving way" (from 25) based on Lysholm score, in the Aperfix group was 23.30 and 22.60 in Endobutton group, that did not have, statistically, significant difference. ( $p=0.06$ ).

Average score of "pain" (from 25) based on Lysholm score, in the Aperfix group was 23.50 and 23.84 in Endobutton group, that did not have, statistically, significant difference. ( $p=0.50$ ). Average score of "swelling (from 10) based on Lysholm score, in the Aperfix group was 9.92 and 9.52 in Endobutton group that had a significant difference that indicates the situation is better in the Aperfix group in this aspect ( $p<0.01$ ).

Average score of “climbing stairs” (from 10) based on Lysholm score, in the Aperfix group was 9.76 and 9.52 in Endobutton group that had a significant difference that indicates the situation is better in the Aperfix group in this aspect ( $p<0.01$ ).

Average score of “symptoms” (from 37) based on IKDC score, in the Aperfix group was 35.56 and 35.50 in Endobutton group, that did not have, statistically, significant difference ( $p=0.46$ ).

Average score of “sport activities” (from 40) based on IKDC score, in the Aperfix group was 37.72 and 37.56 in Endobutton group, that did not have, statistically, significant difference ( $p=0.125$ ).

Average score of “overall knee function” (from 20) based on IKDC score, in the Aperfix group was 19.00 and 18.94 in Endobutton group, that did not have, statistically, significant difference ( $p=0.28$ ).

## Discussion

This study showed that the mean Lysholm score and IKDC score after surgery, that are indicators of knee and ACL performance, in both Aperfix and Endobutton femoral fixation technique is the same.

In a study by Deniz and his colleagues in 2015 on 31 patients with Aperfix method and 35 patients with Endobutton method in Turkey, IKDC scoring system was used, there is no difference between the two methods.<sup>7</sup> In another study conducted by Price et al. in 2010, 29 patients who were referred with anterior cruciate ligament rupture were operated randomly in two groups. After examining the patients, no significant differences were observed between the two groups.<sup>8</sup> Our study also confirms it; in addition our study had greater number of people.

Uribe et al. in 2010 studied cruciate ligament reconstruction using Aperfix method, found that this restructuring method provides a safe and timely surgery that reduces bone and soft tissue injuries.<sup>9</sup> But unfortunately they didn't compare various methods with each other.

In The article which doctor Madadi and colleagues carried out in 2010, 96 patients in three groups; Endobutton ( $n=33$ ) and Rigidfix ( $n=29$ ) and Aperfix ( $n=34$ ) were operated. This study showed that Lysholm score after surgery, in Aperfix method had better results than any other methods.

Unfortunately, none of the studies evaluate aspects of knee

function. In our study we check these aspects of knee function. Based on the results, in the following aspects of knees function, Aperfix method had better prognosis:

- climbing stairs
- swelling
- locking

The other aspects are the same in two groups.

Unfortunately, despite conflicting results, other studies don't have been done in this area and this study could provide the basis for future studies.

This study had extenuations because of limited resources, file deficiencies, deficiencies in access to patients, lack of cooperation from some patients and so on. A major limitation of the study was the lack of kt-1000 or kt-2000 device in Iran, which can measure the mechanical strength of the ACL. These limitations could be compensated in larger and future studies; this study could be groundwork for future studies. Prospective studies with more cases and better resources are recommended.

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## Conclusion

In general, we can say that there is little difference between two surgical methods (Aperfix and Endobutton) and depending on the surgeon and the facilities, we can benefit from both methods. Surgical methods have little difference however due to better results in some aspects of knee functions in this study and due to other studies, it can be said Aperfix method slightly has more benefits. Further investigations with K-T device and with larger number of cases and longer duration of follow up are recommended.

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**PEER REVIEW**

Not commissioned. Externally peer reviewed.

**CONFLICTS OF INTEREST**

The authors declare that they have no competing interests.

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None

**ETHICS COMMITTEE APPROVAL**

This study obtained ethical approval from AJA University of Medical Sciences Ethics Committee.

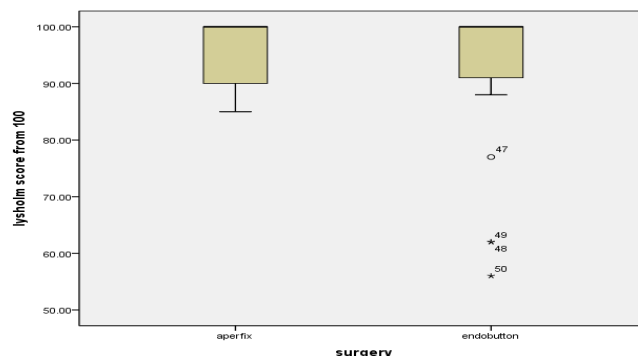
**Table 1: Comparison of lysholm score in two groups**

Group Statistics					
Surgery		n	Mean	Std. Deviation	p-value
Lysholm score from 100	Aperfix	50	95.66	5.43462	0.057
	Endobutton	50	94.56	10.1703	

**Table 2: Comparison of IKDC score in two groups**

Group Statistics					
IKDC score from 97	Surgery	n	Mean	Std. Deviation	p-value
	Aperfix	50	92.32	5.92277	0.282
	Endobutton	50	92.2	7.92568	

**Figure 1: Comparison of lysholm score in two groups**



**Figure 2: Comparison of IKDC score in two groups**

