

Comparative Study after Hamstring Anterior Cruciate Ligament Reconstruction with Endobutton and Rigidfix: A Clinical Trial Study

Abstract

Background: One of the most common orthopedic clinic visits involves direct and indirect knee trauma leading to rupture of anterior cruciate ligament (ACL). Endobutton and Rigidfix are most frequent treating methods that used by orthopedic surgeons. Thus the aim of this study was compare the clinical results of reconstructing arthroscopic ACL of the knee through two methods namely Rigidfix and Endobutton. **Materials and Methods:** In a clinical trial study, a total of 40 patients with rupture of ACL were selected and randomly divided into two groups. The groups were treated through fixation procedures either Endobutton or Rigidfix. Prior to surgery and then at least 2 years after surgery, the patients were under physical examination in terms of knee range of motion, knee stability, knee pain, ability to perform daily activities and exercises and compared between the two groups. **Results:** The knee range of motion in Endobutton and Rigidfix were 135.73 ± 2.63 and $129.87 \pm 7.14^\circ$ respectively ($P = 0.06$). comparing two groups, during last month in Endobutton and Rigidfix the frequency of knee pain were 2.5 ± 1.4 and 3.4 ± 1.4 respectively ($P = 0.08$). Moreover, the pain intensity score were 2.9 ± 1.5 and 2.6 ± 1.1 ($P = 0.49$). But there was a significant difference observed in patients' satisfaction and ability to perform sports activities. **Conclusions:** The two fixation methods namely Endobutton and Rigidfix are not preferred over one another. But patients' satisfaction and ability to perform sports activities in Endobutton was better than the Rigidfix.

Keywords: Anterior cruciate ligament reconstruction, Endobutton, hamstring tendon, Rigidfix

Introduction

Nowadays, one of the most common orthopedic clinic visits involves direct and indirect knee trauma leading to rupture of anterior cruciate ligament (ACL). Due to the low average age of the population and the great enthusiasm of young people for doing sports such as football, as well as traffic accidents, the frequency of ruptured ACL is remarkable. Although there are no estimates of the disease available in Iran, it is argued there are 200,000 ACL ruptures occurring annually in the USA, and there are approximately 100,000 ACL reconstruction surgeries.^[1]

The reconstruction of ACL ruptured in the knee is strongly recommended for an active patient, because it will prevent any knee instability and further injuries and early osteoarthritis and meniscal damage. Both open surgery and arthroscopic surgery are successful for reconstruction of the ligament through various grafts.^[2]

There have so far been several methods proposed for reconstruction of arthroscopic ACL, where ligament grafts are fixed with through various procedures. The method used for ACL graft fixation should be strong enough to maintain the stability of the knee as well as strength enough so as to prevent giving way in knee for initiating motions.^[3-6]

The graft fixation can be done on the femur side through several devices such as screw interference, Rigidfix, femoral cross pin (Transfix and Biotransfix) Endobutton, Aperfix, etc.^[7]

A strong and firm fixation would prevent the rupture and loss of graft as long as the biological fusion between the graft and the bone is in the right place. Additionally, a poor initial fixation would, due to micro-motions inside the intercanal graft, lead to postponement or even lack of biological fusion, thus increasing the risk of treatment failure.^[8-12]

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Numerous studies have compared various methods of fixation each yielding different results.^[13-16]

Since the success rate of each of these approaches depends on surgeon's experience and skillfulness, intensity on injury, available medical instruments, level of postoperation care and etc., this study was done to evaluate and compare two common procedures namely Rigidfix and Endobutton to determine the preferred technique.

Materials and Methods

This is a double-blind randomized controlled clinical trial study conducted in Isfahan Medical Centers during 2012 to 2013. The target population was patients who suffered a ruptured ACL, admitted to Isfahan Medical Centers during June 2012 to May 2013.

Inclusion criteria were the age range 20–45 years old, suffered a ruptured ACL, admitted to Isfahan Medical Centers during June 2012 to May 2013 and parents' consents to participate in the study. In this study, also patients who had history of knee surgery, patients with experienced significant damage to other knee ligaments, patients who had degenerative changes in a joint or had a psychiatric illness and patients who discontinued participate in the study, were excluded.

The sample size was obtained based on the formula for comparison of two mean and based of 95% confidence level. Eighty percent power, twenty subjects in each group.

The patients were divided based on the chronological order of hospital admission. All patients initially underwent diagnostic arthroscopy for evaluation of ACL and posterior cruciate ligaments as well as the medial and lateral menisci, which was administered in supine position through tourniquet. In case the ACL rupture and incompetence were proved, the hamstring autograft on the same side (including gracilis and semitendinosus ligaments) was applied to treat one group by Rigidfix and the other by Endobutton [Figure 1].

The Rigidfix technique (DePuyMitek, Raynham, MA), the upper end (femoral) graft hamstring were fixed by two biosynthetic pins passed through the femur condylar, femoral canal and tissue graft [Figure 2].

As for the Endobutton technique (Smith and Nephew, Andover, MA, USA) the upper end (femoral) graft were fixed by a polyethylene bonding and metal button in the femoral canal [Figure 3].

In both procedures, grafts were fixed in tibia with biosynthetic interference screws for all patients.

The physiotherapy on the patients knees were administered after 24 h, consisting of isometric quadriceps exercise, hamstring and quadriceps strengthening.

Both procedures were conducted by one surgeon while the data were collected through orthopedic residents unaware of the type of surgery. Before surgery and 2 years after

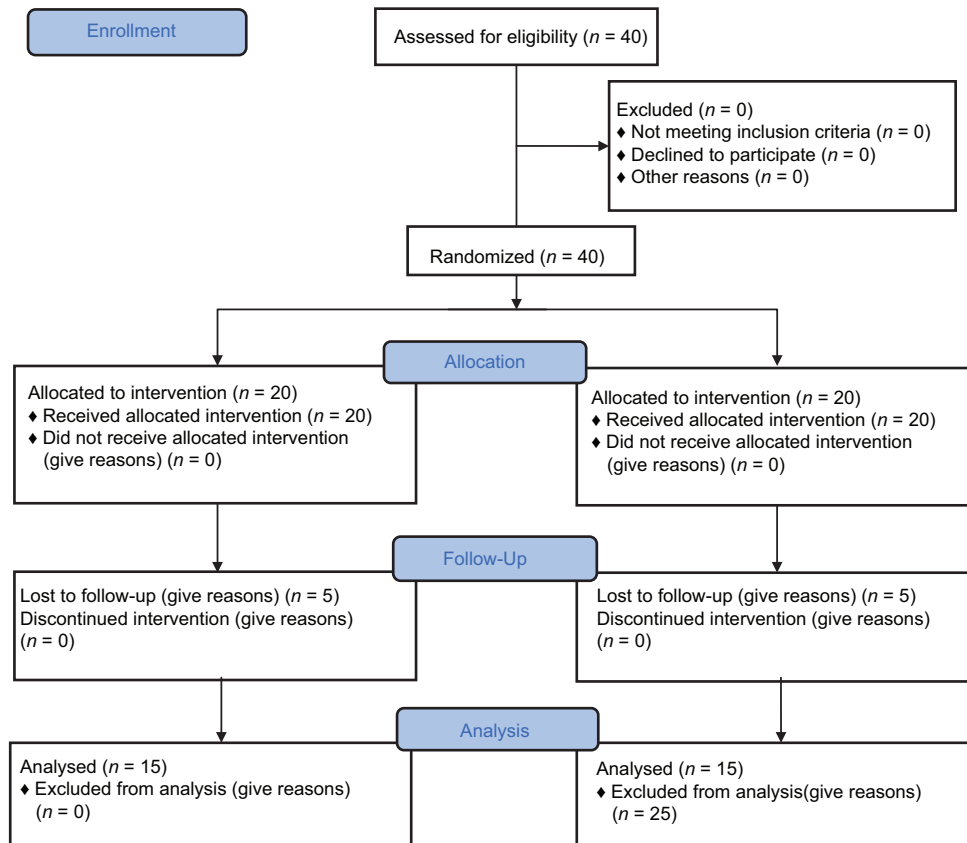


Figure 1: CONSORT study flowchart

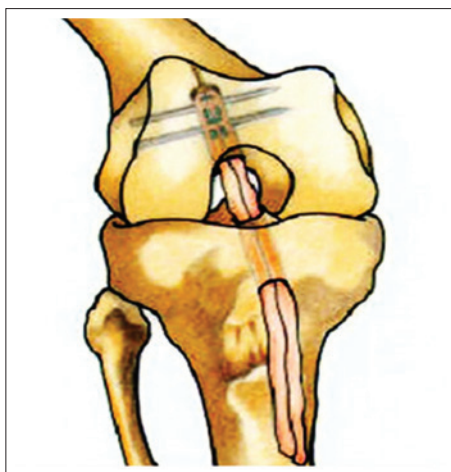


Figure 2: Rigidfix technique

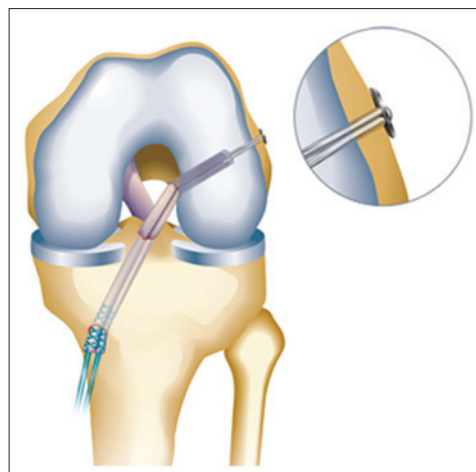


Figure 3: Endobutton technique

surgery, the patients were called to be examined in terms of knee range of motion, stability, knee pain, ability to perform daily activities and exercise.

In determining the knee range of motion, the patient used in active state the maximum amount of extension for knee flexion, where the range of motion was measured and recorded in degrees. Then, the same process was administered in passive state by the examiner.

The lack of extension was measured as the patient's knee was kept in passive state under maximum tolerable so as to reach full extension (0°) for measurement and recording. Then, any limitation equal or lower than 5° took a score of 3, 6 to 10° took 2 points, and over 10° took 1 point.

The stability of the knee was determined according to Lachman test, anterior drawer test (ADT) and pivot shift test. In the ADT and Lachman test, the displacement for 5 mm or lower took a score of 3, displacement for 6 to 10 mm took 2 points, and displacement more than 10 mm took 1 point. In the pivot test, the instability were measured and recorded under four ratings equal (-), glide (+), clunk (++) and gross (+++).

Knee pain, knee stiffness, giving way, ability to perform daily activities and exercise were determined along with criteria visual analog scales (VAS) and questionnaire (International Knee Documentation Committee) IKDC 2000.

All operation were done by one surgeon but patients improvement was done by another surgeon who wasn't had roles in the study.

Finally the data entered to IBM SPSS statistics v.23 (Armonk, NY: IBM) software and were analyzed through independent *t*-test, Mann-Whitney test.

Results

Out of 40 patients, 10 patients (5 out of Endobutton and 5 out of Rigidfix) were excluded from the study for failing to

visit for the examination, thus, the study completed with a total of 30 patients, that is, 15 patients in Endobutton and 15 in Rigidfix [Figure 3].

Thirteen patients in Endobutton and 12 patients in Rigidfix groups were male (86.7% vs. 80%) and no statistically difference between the two groups ($P = 0.99$). The mean age of patients in Endobutton and Rigidfix groups were 30.5 ± 7.2 and 29.3 ± 7.7 years respectively and no statistically difference between the two groups was seen ($P = 0.56$). The duration of ACL injury was 2.03 ± 0.84 and 1.7 ± 0.91 years in the Endobutton and the Rigidfix groups ($P = 0.36$). The range of follow up time in the both groups were 24.1-35.6 and 24.2-35.8 months respectively ($P = 0.8$). [Table 1].

Active range of motion in Endobutton and Rigidfix groups were 135.73 ± 2.63 and 129.87 ± 7.14 degrees respectively ($P = 0.06$). Also passive range of motion in the both groups were 140 ± 0 and 140 ± 0 respectively ($P = 1$) [Figure 4].

The results of treatment after 2 years are shown in Table 2. According to the results, 1 patient of each group had mild limitation of extension ($P = 1$). According to Lachman test, mild displacement of tibia (≤ 5 mm) in 6 patients of Endobutton and 5 patients of Rigidfix groups were seen (40% vs. 33.3%). Also 9 patients of Endobutton and 10 patients of Rigidfix groups had moderate displacement of tibia (60% vs. 66.7%) and no statistically difference was seen between the two groups ($P = 0.71$).

In examination of Ant. drawer test, 8 (53.3%) patients in Group Endobutton and 10 (66.7%) in Rigidfix, experienced tibial displacement for 5 mm or less, 7 (46.7%) patients in Endobutton and 5 (33.3%) patients in Rigidfix experienced displacement within the range of 6 to 10 mm. The displacement in none of the patients was over 10 mm. ($P = 0.46$).

In examination of knee stability using the pivot shift test and comparison of the two groups, showed that 4 patients

Table 1: Distribution of basic data of study patients

Variables	Groups		P
	Endobutton	Rigidfix	
Sex n (%)			
Male	13 (86.7)	12 (80)	0.99
Female	2 (13.3)	3 (20)	
Mean±SD of age (years)	30.5±7.2	29.3±7.7	0.56
Mean time injury to surgery (years)	2.03±0.84	1.73±0.91	0.36
Mean of follow-up time	24.1-35.6	24.2-35.8	0.8

SD: Standard deviation

Table 2: Results of treatment after 2 years

Variables	Groups		P
	Endobutton	Rigidfix	
Limitation of extension			
No	14 (93.3)	14 (93.3)	1
Mild	1 (6.7)	1 (6.7)	
Lachman test			
≤5 mm	6 (40)	5 (33.3)	0.71
6-10 mm	9 (60)	10 (66.7)	
Anterior drawer test			
≤5 mm	8 (53.3)	10 (66.7)	0.46
6-10 mm	7 (46.7)	5 (33.3)	
Pivot shift test			
Equal	4 (26.7)	5 (33.3)	0.99
Glide (+)	9 (60)	8 (53.5)	
Clunke (++)	2 (13.3)	2 (13.3)	
Gross (+++)	0 (0)	0 (0)	
Mean of patients satisfaction	89±4.3	85±2.9	0.006
Last month symptoms score	89.8±4.6	88.1±5.2	0.34
ability to perform sports activities	85.2±4.6	80.5±4	0.006
Mean of knee pain intensity	2.9±1.5	2.6±1.1	0.49
Number of knee pain			
Mean±SD	2.5±1.4	3.4±1.4	0.08
No	1 (6.7)	1 (6.7)	0.33
1-2	6 (40)	2 (13.3)	
3-4	7 (46.7)	8 (53.3)	
≥5	1 (6.7)	4 (26.7)	

SD: Standard deviation

in Endobutton and 5 patients in Rigidfix obtained test result equal (26.7% vs. 33.3%), 9 patients in Endobutton and 8 patients in Rigidfix obtained glide (60% vs. 53.5) and 2 (13.3%) from each group obtained clunk. The pivot test did not yield any gross (+++). The comparison of the two groups was not statistically significant ($P = 0.99$).

In order to compare the satisfaction with surgery results, a subjective questionnaire IKDC 2000 was used. In comparison of the scores from both groups, the mean scores for Endobutton and Rigidfix were 89 ± 4.3 and 85 ± 2.9 respectively and patients satisfaction in Endobutton was statistically higher than the Rigidfix group ($P = 0.006$). The last month symptoms score was

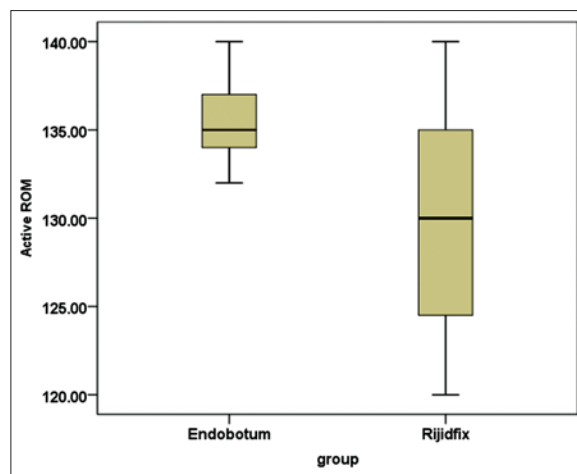


Figure 4: Median, range and 25–75 percentile of active read only memory

89.8 ± 4.6 in Endobutton and 88.1 ± 5.2 in Rigidfix and there isn't statistically difference between the two groups ($P = 0.34$). The ability to perform sports activities was 85.2 ± 4.6 in Endobutton and 80.5 ± 4 in Rigidfix and there is an statistically difference between the two groups ($P = 0.006$).

The frequency and intensity of pain in patients was assessed through the VAS questionnaire. In examination of the two group for the frequency of knee pain over the last month, the two groups Endobutton and Rigidfix experienced pain respectively 2.5 ± 1.4 and 3.4 ± 1.4 ($P = 0.08$), and the pain scores were 2.9 ± 1.5 and 2.6 ± 1.1 in the two groups and the difference was not statistically significant ($P = 0.49$).

Discussion

Reconstruction of the ACL is one of the most common sports injury treatments.^[17] The applied graft depends on the surgeon's preference and available tissues.^[18] Among the autogenous tissues, patellar tendon and hamstring are most commonly used. Furthermore, the method of fixation is vital. Selection of an adequately firm graft with fixation plays a key role in the patient's return to daily activities and sports.^[19]

There are different techniques to repair the ACL discussed in the present study through comparison of two fixation methods; Endobutton and Rigidfix.

Rigidfix is a transcondylar fixation system based on the use of one or more horizontal suspension rod passing through the graft and femoral tunnel. In this stabilization procedure, resistance is distributed across the interface between the hardware and the bone, strength of which depends on the bone density and length of the lever arm, considering the use of pulling forces (graft suspension point).

The Endobutton is a hardware placed on the anterolateral cortex at the femoral end suspending the graft into the femoral tunnel. In this type of stabilization, the resistance vectors are parallel and opposite to external forces

concentrating on the cortical bone at the end of the femur where the bone and hardware join. Moreover, this method is less expensive in terms of costs.

The results showed that there are no statistically differences between the two groups in demographic data and probably these variables didn't have confounding effects on the results of the treatment.

Based our data the gender distribution of patients participating in the study represents the higher vulnerability in males. Since the most common cause of injury in Iran involves nonprofessional football and other sports trauma, and given the lack of women's participation in such common activities, the gender distribution of ACL rupture can be justified. The mean age was 30.5 ± 7.2 years in group Endobutton and 28.9 ± 7.7 in Rigidfix. The mean age of patients in the two groups is consistent with other studies such that conducted by Tu Jun *et al.* (2011) in China where the mean age of participating patients in the study was 30.1 years old.^[19]

The current study indicated that both methods of ACL reconstruction lead to significant improvement in performance and physical abilities of patients and their satisfaction after a minimum of 2 years (according to the IKDC 2000 form), (although patients satisfaction and ability to perform sports activities in Endobutton method was better than the Rigidfix method) even though none of them was preferred over the other.

The knee active range of motion in Endobutton was $135.73 \pm 2.63^\circ$ and $129.87 \pm 7.14^\circ$ in Rigidfix.

Also comparing the two groups, the frequency of knee pain in Endobutton and Rigidfix were 2.5 ± 1.4 and 3.4 ± 1.4 , respectively. Moreover, the score for pain intensity were 2.9 ± 1.5 and 2.6 ± 1.1 . Basad *et al.* carried out a study in 2010 so as to examine the fixation of ACL through two techniques of Rigidfix and Endobutton, finding out that 6 months after surgery, the Rigidfix showed a higher stability than the Endobutton, even though there was no significant difference between the two groups 12 months after surgery, there was.^[13] In another study conducted in South Korea in 2012, no significant difference in the results was observed between the two techniques after a 4-year follow-up period.^[14] In 2004, another study was conducted in the US to compare the two techniques, where again no preferred method was demonstrated over another.^[15] In another study conducted in 2010 in China, Rigidfix was introduced as a technique yielding better results and more benefits.^[20] In a study conducted in the United States in 2004, the biomechanical properties of these two methods were assessed to find out the amount of slip and displacement of graft in Rigidfix was more than Endobutton.^[3]

In the present study, there was no significant difference between the two groups in terms of the amount of anterior displacement of the tibia relative to the femur (ADT) after

surgery. In examination of the ADT, Lachman test, pivot shift test and the amount of lack of extension showed no significant difference in the two groups. Asik *et al.* (2007) examined the mid-term and long-term effects of reconstruction in the ACL of the knee through Rigidfix in 271 patients (198 men and 73 women). After surgery, 14 (5%) of the patients experienced displacement by more than 5 mm in anterior tibial, while 161 patients (59%) experienced displacement before surgery by more than 5 mm.^[21]

Plaweski *et al.* Conducted a study in 2009 were 29 patients were with rupture of the ACL were treated randomly through Endobutton system (16 patients) and Rigidfix system (13 patients). After 2 years of follow-up, 11 patients treated through Endobutton procedure and 11 patients treated through the Rigidfixed procedure remained in the study. Moreover, there was no significant difference between the two methods.^[22]

In this study, the average delay in surgery was 1.8 years, while it was roughly 5–6 months in other studies. The need for early action does not, however, imply within the first few weeks because joint inflammation and effusion during this period is likely to remain and acute synovitis would not heal and the knee range of motion would not return to normal. In such a condition, surgery would not bring about a desirable outcome for the patient.

Conclusions

In summary, the results of this study showed that the two discussed fixation methods namely Endobutton and Rigidfix are not preferred over one another, but patients satisfaction and ability to perform sports activities in Endobutton was better than the Rigidfix.

The limitation of our study was amal sample size and lost to follow-up of some of patients, even though it is recommended to carry out farther research with greater sample size and longer follow-up period. Moreover, it is suggested to better analyze the results of surgery through the IKDC 2000 form as well as other scoring procedures such as Tegner and Lysholm scores.

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Conflicts of interest

There are no conflicts of interest.

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