A COMPARATIVE STUDY OF FUNCTIONAL OUTCOME BETWEEN BIOABSORBABLE INTERFERENCE SCREW AND ENDOBUTTON FIXATION ON FEMUR IN ARTHROSCOPIC ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

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Abstract

Background: This prospective clinical study was performed to compare the Functional outcomes between Bioabsorbable Interference Screw And Endobutton Fixation On Femur In Arthroscopic Anterior Cruciate Ligament Reconstruction .

Methods: from April 2018 to June 2019, 126 patients (16 females and 110 males) aged 18 to 50 years were enrolled in this study. Patients were randomly divided into two groups including Anterior Cruciate Ligament (ACL) reconstruction with Bioabsorbable interference screw fixation called group A (N=63) and other group B that underwent ACL reconstruction with Endobutton fixation (N=63). Functional outcomes were compared for TL (Tegner Lysholm) Score preoperatively, at 3 months and 6 months. All data were collected and analyzed with the help of suitable statistical parameters.

Results: The endobutton fixation yielded better outcome in terms of instant stability of the graft and functional outcome at the end of 6 month. We are currently awaiting long term results to verify whether or not these early results persist.

Key words: Bioabsorbable Interference Screw, Endobutton Fixation, Anterior Cruciate Ligament, TL Score.

Introduction

The knee joint is commonly injured during sports activities. Anterior cruciate ligament injury, alone or in conjunction to injury of other ligaments or menisci, is a very commonly involved ligament in these injuries. Nowadays, Ligamentous injuries of the knee are being diagnosed frequently due better understanding of the complexity of knee joint and also due the advanced technology.¹

The ACL is the primary static restraint to anterior translation of tibia and bears 75-85 % of load when an anterior force is applied to tibia in vitro.^{1, 2} ACL tears usually caused by deceleration with twisting, pivoting, or a change in direction, or by hyperextension of knee.³ Perhaps the most common mechanism is valgus stress in flexion along with external rotation of tibia.

The history can be a valuable adjunct to diagnosis and the mechanism of injury should be specifically asked. Nearly 40 % of patients may report a 'pop' at the time of injury and are unable to continue further participation. Gross swelling due to hemarthrosis usually develops within 2-3 hours. In chronic tears, the chief complaint is recurrent episodes of 'giving way' of knee, associated with pain, swelling and stiffness.²

The patient's level of activity, occupation, and future aspirations are very important considerations in coming up with a rational individualised treatment plan.

The goal of management is to prevent recurrent instability of knee so that the patient can resume his or her pre-injury activities. The most common group of patients requiring surgical management are young people who are unwilling to modify their active lifestyle or who are professional athletes. Obtaining a normal range of motion and regaining strength equal to opposite side are of utmost importance before any surgical intervention is contemplated.

Arthroscopic ACL reconstruction is now the gold standard technique for management due to its advantages of smaller incisions without damaging adjacent uninvolved structures, the ability to deal with associated meniscal and articular cartilage lesions in the same sitting, and shorter post-operative recovery period.

Traditionally, bone-patellar tendon-bone grafts were used for reconstruction and are still used by many surgeons. But the trend is slowly evolving towards quadrupled hamstring graft due to the following reasons:

1. Less donor site morbidity

2. Less complications like anterior knee pain, pain while kneeling, patellar fracture, patellofemoral crepitation.⁴

The strength of quadrupled hamstring graft has now been proven to be comparable to bone tendon bone grafts. There were concerns about weakness of knee flexion following harvest of both semitendinosus and gracilis tendons, but it has been hypothesized that these tendons actually regenerate after harvest and Ferretti et al surgically visualized fibrous bands reproducing the path of native semitendinosus tendon.⁵

Anatomic graft placement is recongized as important for good clinical outcome after surgery and non-anatomic reconstruction is cited as the most common cause of failure. Single incision ACL reconstruction has traditionally been performed using Transtibial tunnel technique in which femoral tunnel is drilled through the tibial tunnel. This results in the graft being placed too far anteriorly on the femur, resulting in a vertical orientation of graft, which is non-anatomic for obvious reasons. A vertically oriented graft does not reproduce the oblique orientation of native ACL, which limits its ability to restore normal knee kinematics.^{6,7,8} Grafts placed near the center of ACL attachment site on femur more closely restore normal knee translation and rotation than a more vertically oriented graft.⁹

Several studies suggest that the transtibial technique might not be able to center the graft near the anatomic center of ACL at femoral attachment^{10,11}. The solution to this problem was the Accessory Anteromedial Portal technique¹², in which femoral tunnel is drilled separately through an anteromedial portal. Another advantage of this portal is the less chance of posterior wall blowout on femoral side¹³. Furthermore, transtibial technique may control Antero-posterior translation but fails to control tibial rotation adequately resulting in patients having a positive Pivot shift test and giving way after reconstruction.¹⁴

In the present study, all cases (end button and bioabsorbable interference Screw) have been performed through Accessory Anteromedial Portal technique.

Cortical fixation (ENDOBUTTON) or Suspensory fixation: This system consists of a metal device that is placed flat against the anterolateral cortex of the lateral condyle. The graft is attached to the button by a 5-mm polyester tape or by a braided suture of the surgeon's choice.

Interference screw fixation (aperture fixation): Metallic (Titanium) or Bioabsorbable (Poly-l-lactic acid-PLLA), or Femoral Intrafix.

The present study is planned to determine whether bioabsorbable interference screw fixation on femur provides equal strength, stability and effect on functional outcome in comparison to endobutton fixation on femur in arthroscopic ACL reconstruction.

Material and Methods

Study Area: This study was conducted in the Department of Orthopaedics, S.M.S Medical College and attached group of hospitals, Jaipur with due permission from the institutional ethical committee and review board and after taking written informed consent from the patient

Study Period: Data collection for study started from April 2018 to June 2019, or till the sample size is achieved (whichever is earlier). Then it took another two months to process and analyse data.

Study Type and Design: Hospital based prospective randomized, comparative interventional study.

Sample size: The sample size required is 63 in each group at alpha error 0.05 & 80% power to verify the expected difference of 5.5(+/-2.63) in change of TLS score from base line at 6 month in both groups.

Randomisation Method: The patients were randomized in 2 groups through chit box method.

Study Universe: Patient who met the inclusion criteria (A complete ACL tear patients, clinically and radiologically) and reported at department of Orthopaedics, SMS Hospital, and Jaipur, included.

The study was prospective and all patients were followed up by an independent observer, who was not involved in the surgical procedure. The 126 patients aged 18 to 50 years were allocated randomly to the two groups, either to Screw group (group I-63) or to Endobutton group (group II-63) using. All patients were informed about the randomization procedure and only those patients who accepted this randomization were included in our study.

Ethics Statement: The study protocol was approved by the institutional ethical committee. Informed consents were obtained in written form from patients and all clinical investigations were conducted according to the standard protocol.

Data Analysis: Data was recorded as per Performa. SPSS-22 was used for analysis. For categorical variables chi-square test was used. For continuous variables independent samples *t*-test was used. Significance of difference in means were assessed by un-paired *t*-Test and ANOVA. *P*-value <0.05 was considered as significant.

Assessment of Patients:

All patients were evaluated clinically at the time of admission to elicit mode of injury, date of injury, previous history and any other associated medical/ surgical illness and will be given primary treatment. History, general examination and local examination of both the sides was done and recorded on the Proforma attached.

Patients were investigated completely for operative and anaesthesia purpose. Any associated medical problem was taken care of before the patient was taken for surgery. A.P. and lateral radiographs of the knee were done to rule out any

fractures around the knee joint. We did an M.R.I. scan of knee joint to know the status of all the ligaments and soft tissues around knee joint. Standard operative protocol followed as advised by the American knee society.

The rehabilitation protocol was same for patients of both groups.

Follow Up Schedule:

All the patients were discharged at 3rd day post-op, with a knee brace in full extension and were called on the 14th day

for the suture removal. Thereafter the patients were supposed to come every 2 weeks till a total of 12 weeks, every month till next 2 months and every 3 months thereafter.

Evaluation in the follow up period is carried out through Tegner-Lysholm score which is a subjective score, patient's range of motion and post-op stability is assessed by Lachman test and Pivot shift test. Tegner Lysholms scoring system is used for knee examination.

Figure 1: Endobutton

Figure 2: Bioabsorbable interference screw

Results

A hospital based prospective randomized comparative interventional study was conducted in the Department of Orthopedics, SMS Medical Hospital, Jaipur, where patients with complete ACL tear were taken. Randomization of the complete ACL tear patients into two groups based on surgical intervention using chit method was done. One group that underwent ACL reconstruction with Bioabsorbable interference screw fixation called Procedure A group ($N_1=63$) and other group that underwent ACL reconstruction with Endobutton fixation called Procedure B group ($N_2=63$) were compared for TL Score preoperatively, at 3 months and 6 months.

Right (29.37%) and left knee (20.63%) were involved in group A. In group B, (30.16%) were right knee only (19.84%) were left knee. The mode of injury in majority was twisting injury during activities 61 [48.41%] and RTA 48

[38%]. Additional injuries in group -A 11 (8.73%) had medial meniscus tear and 28 (22.22%) had lateral meniscus. In group B 9 (7.14) had medial meniscus tear, 31 (24.60%) had lateral meniscus tear.

At follow up Group A mean Tegner lysholm knee scores at pre, 3, and 6 month follow up were 73.52, 76.44, and 92.11 respectively. Group B The mean Tegner lysholm knee score were 74.06, 77.86, and 93.94 respectively. Both the groups were comparable with respect to pre-operative variables. (Table-1, 2 &4)

In each group, there were significant improvements in functional outcomes over successive follow-ups. The comparison of functional outcomes between the two groups statistically same for base and 3 month but for group 2 it is almost significant for 3 months and 6 month whereas it is not for group 1.

There were no major complications in our study. The most common complication was hypoaesthesia around anterolateral aspect of upper leg which occurred in 8 patients (6.35%) in group A and in 3 patients (2.38%) in group B. This is because of injury to cutaneous nerves while making anteromedial and anterolateral portal incisions. (Table-3) Anterior knee pain was observed in 6 (4.76%) patients in group A and in 5 (3.97%) patients in group B. Graft impingement in roof of intercondylar notch was seen in none of the patients. Posterior wall blowout during drilling and loss of 5 degree of extension not occurred in patients of both groups. Retear also occurred in one patient (0.79%) with interference screw in a group A. This case was reoperated

but not included for further analysis in either of the groups. No re-tear occurred in group B pts. (Table-3)

Primary objective of the study, that is, comparison of TL Scores at 6 months yields significant difference of means in two groups (p value < 0.001) on applying two tailed unpaired t-test with 124 degrees of freedom at 5% level of significance.

Secondary objective of the study, that is, comparison of TL Scores at 3 months yields no significant difference of means in two groups (p value $= 0.083$) on applying two tailed unpaired t-test with 124 degrees of freedom at 5% level of significance.

Table 1: Distribution of subjects according to TLS Score at 3 months

TLS Score at 3 months	Group-A (BIS)(N=63)	Group-B (EF)(N=63)	Total(N=126)	P-Value*
Mean $\pm$ SD	76.44 $\pm$ 3.91	77.86 $\pm$ 5.13	77.15 $\pm$ 4.60	0.083

*Unpaired 't' test

The TLS score at 3 months was 76.44 $\pm$ 3.91 in Group-A while it was 77.86 $\pm$ 5.13 in Group-B. The difference was non-significant ($P>0.05$) in both the groups.

Table 2: Distribution of subjects according to TLS Score at 6 months

TLS Score at 6 months	Group-A (BIS)(N=63)	Group-B (EF)(N=63)	Total(N=126)	P-Value*
Mean $\pm$ SD	92.11 $\pm$ 2.77	93.94 $\pm$ 2.85	95.76 $\pm$ 1.40	<0.001

*Unpaired 't' test

The TLS score at 6 months was 92.11 $\pm$ 2.77 in Group-A while it was 95.76 $\pm$ 1.40 in group-B. The difference was significant ($P<0.05$) in both the groups.

Table 3: Distribution of subjects according to post-operative complications

Post-operative Complications	Group-A (BIS) (N=63)		Group-B (EF) (N=63)		Total(N=126)		P-Value*
	n	%	n	%	n	%	
Re-tear	1	0.79	0	0.00	1	0.79	1.000
Hypoaesthesia	8	6.35	3	2.38	11	8.73	0.207
Anterior knee pain	6	4.76	5	3.97	11	8.73	1.000
Loss of terminal flexion	5	3.97	3	2.38	8	6.35	0.715
Posterior wall blow out	0	0.00	0	0.00	0	0.00	NA
Loss of 5 degree of extension	0	0.00	0	0.00	0	0.00	NA

*Chi square test

Table 4: Intra group comparison of TLS Score

TLS Score	Group-A (BIS) (N=63)	Group-B (EF) (N=63)	Total (N=126)
Preoperative	73.52 $\pm$ 3.53	74.06 $\pm$ 4.18	73.79 $\pm$ 3.86
3 Months	76.44 $\pm$ 3.91	77.86 $\pm$ 5.13	77.15 $\pm$ 4.60
6 Months	92.11 $\pm$ 2.77	93.94 $\pm$ 2.85	95.76 $\pm$ 1.40
P-Value*	< 0.001	< 0.001	< 0.001

*ANOVA test

Table-4 shows the intragroup comparison of TLS Score in both the groups at pre-operative stage, 3 months and 6 months. It was observed that the intragroup difference in TLS score was highly significant in both groups ($P<0.001$).

Discussion

Anterior Cruciate Ligament tear is a very common diagnosis these days due to increase in number of vehicles and increasing road traffic accidents especially motor cycle accidents in the young population and increasing participation of public in sports. Diagnostic & interventional

arthroscopy has been going on at our institute for many years now. We decided to take up this study to address the problem of the vast number of patients attending the out-patient department in our hospital.

Recent long-term outcome data have suggested that the overall progression of degenerative osteoarthritis of the knee joint after ACI injury is not stopped. The impact of the initial trauma after ACL injury may set off a cascade of humoral changes within the joint that ultimately leads to osteoarthritis.

Cameron et al have pointed out that synovial fluid from arthritic knees contains high concentrations of cytokines as well as degenerative enzymes that may play a role in early cartilage damage. Some of these factors may be released early on in the process after a knee ligament injury and may be irreversible by the time an ACL reconstruction is performed. A major goal of surgical ACL reconstruction is restoration of normal knee stability and normal knee kinematics. Thus to achieve this goal, the Antero medial portal technique is proposed, in which femoral tunnel is drilled through an accessory Antero medial portal at 10 /2 o'clock position for right / left knee respectively. This oblique orientation of femoral tunnel ensures rotational stability and better restoration of normal knee kinematics. Equally important is adequate fixation of the graft to femur as well as tibia so that graft properties can be maintained till graft incorporation occurs.

Range of motion after Anterior Cruciate Ligament reconstruction

Most of the Patients (92% in Group A and 96% in Group B) regained a very good range of motion (0°-120 degrees or above). None of the patients had more than 5 degrees loss of terminal extension.

Daniel B O'Neill and Nassau Bay¹⁵(1996) in their series of 45 patients found that 4.44% had restriction of terminal flexion. There was no loss of extension & the remaining 91.27% patients had full range of motion. 416

Jonathan M. Webb, Ian S. Corry, Amanda J. Clingeleffer & Leo A. Pinczewski¹⁶ (1999) in their series of 82 patients had 90% patients with full range of motion, 4.4% with terminal restriction of extension & 5.6% with terminal restriction of flexion

Loss of terminal extension is a very disabling complication as even a 10 degree loss of extension will cause the quadriceps to fatigue much more quickly if the patient's knee cannot lock fully during stance phase. Loss of extension may be due to improper graft placement; the so called high noon placement, it may also be due to an abundance of fibrous tissue anterior to the graft at the tibial tunnel, the so called Cyclops lesion.

Overall results of ACL reconstruction in both Groups

The difference was not significant. Considering each group alone, there was a significant increase in score after the surgery, when compared to the score before the surgery.

Giuseppe Milano et al¹⁷ in 2007 conducted a study entitled "Comparison of femoral fixation methods for anterior cruciate ligament reconstruction with patellar tendon graft: a mechanical analysis in porcine knees". An ACL reconstruction was performed on 40 cadaver porcine knees, using patellar tendon (PT) graft. Specimens were divided into four groups according to the femoral fixation: interference absorbable screw (Group A), metallic setscrew (Group B), absorbable pins (Group C), and a combination of metallic setscrew and pin (Group D). Mean stiffness of group

A (104.3 ± 15 N/mm), group B (117.5 ± 14.5 N/mm), and group C (113.6 ± 12.2 N/mm) did not show significant differences between them. Group D (172.8 ± 40.4 N/mm) was significantly greater than group A. All the groups were not significantly different from normal ACL (162.5 ± 15.9 N/mm).

In 2008, **Wang J and Ao YF**¹⁸ studied the clinical results of anterior ligament reconstruction with Intrafix and concluded that ACL reconstruction with Intrafix can restore the stability of knee, and the clinical result is good. The Lysholm scores were average 89 (83-93), 17 cases excellent and 15 cases good. The results of KT-2000 were average 1.2 mm (0-2.0 mm) at 30 degree 133 N, average 0.5 mm (-0.5-2.0 mm) at 90 degree 133 N. The appearance and tension of reconstructed ACL were good on MRI. The X ray showed good position of bone tunnel. But this study use Intrafix on the tibial side, not on femoral side.

Tsuda et al¹⁹ have shown in 2002 that endobutton fixation allows graft motion in both sagittal and longitudinal planes, and greater anterior knee laxity compared to interference screw fixation.

Arsi Harilainen et al²⁰ conducted a study comparing different fixation devices. A total of 120 patients were randomized into 4 different groups (30 each) for anterior cruciate ligament reconstruction with hamstring tendons: femoral Rigidfix cross-pin and Intrafix tibial expansion sheath with a tapered expansion screw; Rigidfix femoral and BioScrew interference screw tibial fixation, BioScrew femoral and Intrafix tibial fixation; or BioScrew fixation into both tunnels. There were no statistically or clinically relevant differences in the results 2 years postoperatively, and all 4 techniques improved patient performance.

In 2011 **Alexis Colvin MD et al**²¹ did a meta-analysis - What Is the Best Femoral Fixation of Hamstring Autografts in Anterior Cruciate Ligament Reconstruction? And found that the literature suggests a trend toward decreased surgical failures (relative risk = 0.57; confidence interval, 0.1678–1.0918) with femoral fixation at the joint line with an interference screw. However, there is no difference when postoperative functional outcomes are compared.

Flanigan DC et al²² in 2011 did a comparison of ACL fixation devices using cadaveric grafts. They compared Endobutton direct with Femoral Intrafix. They found no significant difference between failure to load ($p=0.42$) or stiffness ($p=0.39$), or peak displacement ($p=0.32$).

Thus there is no study so far which compares the clinical results of Femoral Bioabsorbable interference screw vs Endobutton, though **Flanigan DC et al**²² showed in a cadaveric study no significant difference between failure to load ($p=0.42$) or stiffness ($p=0.39$), or peak displacement ($p=0.32$).

In our study we have used interference screw and Endobutton. Both modes of fixation of ACL reconstruction are associated with improved function and satisfaction of

patients as indicated by Lysholm score and anterior drawer test after surgery.

However by considering the Tegner Lysholm score magnitudes of both the groups we feel the group B Endobutton fixation is better clinically as compared to the group A because the score is statistically same for base and at 3 months between the groups but for group B there is significant improvement in TL score in the duration of 3 month post-operative to 6 month post-operative period where as it is not for group A interference screw fixation.

Conclusion

In our study, we prospectively compared the functional outcomes after doing ACL reconstruction by hamstring graft which was fixed by using bio interference screws and suspensory fixation with Endobutton at femur and bioabsorbable screw at tibia. Functional assessment was done on basis of Tegner Lysholm score. The endobutton fixation yielded better outcome in terms of instant stability of the graft and functional outcome at the end of 6 month.

We are currently awaiting long term results to verify whether or not these early results persist.

Conflict Of Interest

There is no conflict of interest between authors.

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