

Original Research Article

Prospective randomised comparison of femoral transfix versus endobutton with constant tibial fixation in hamstring tendon ACL reconstruction: a preliminary study

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Received: 14 June 2017

Accepted: 19 July 2017

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ABSTRACT

Background: The purpose of this study is to evaluate clinico radiological outcome of hamstring tendon ACL reconstruction using femoral Transfixation and Endobutton with identical Tibial fixation.

Methods: A Prospective randomized clinical outcome study was done from January 2002 to June 2008, a total of 132 patients with quadruple hamstring ACL reconstruction using a femoral fixation group A Endobutton (n=68; median age=27.4) and group B with Transfix (n=64; median age=26.1) and identical Tibial fixation with Biointerference screw and bone staple were studied. Patients in each group had a clinical and radiological assessment at <3, 3-12, 12-24 and >24 months after surgery.

Results: The mean Lysholm Knee score has improved significantly with time within these groups but no difference on comparison between groups. Ninety percent of all patients had functionally normal or near normal International Knee Documentation Committee (IKDC) knee ligament ratings. IKDC Subjective Knee evaluation mean score has progressively increased significantly from pre op values of 37.58 and 36.55 to about 74.51 and 75.85 in group A and group B respectively. The tibial and femoral tunnels also showed widening of about 9.64% and 7.79% in group A as compared to 7.71% and 7.27% in group B at >24 months follow-up, which was statistically insignificant. MRI done in limited patients showed good graft incorporation in both groups.

Conclusions: So keeping the tibial graft fixation constant, the two different femoral fixation methods, Endobutton and transfixation have not influenced in the clinical outcome in this short term preliminary study. But long term follow up of these is necessary to evaluate the significance of tunnel widening and its final outcome.

Keywords: ACL, Endobutton, Transfix

INTRODUCTION

Arthroscopic assisted Reconstruction of torn ACL with an intraarticular graft has become the most common method in ACL surgery.¹ The various choices of autografts include bone patellar tendon bone (BTB), quadrupled semitendinosus (ST), or gracilis tendon (GT) auto grafts and quadriceps tendon. Allograft options include Achilles tendon, bone patellar tendon bone (BTB)

and hamstring tendons.² Among these, bone patellar tendon bone (BTB) autograft was considered the gold standard procedure in 1990s.³ However, anterior knee pain, risk of patellar fracture and patello-femoral problems are often associated with this procedure.⁴ So, recently attention has moved towards the use of semitendinosus and gracilis tendon autograft because of relatively low donor site morbidity and high level of patient acceptance. Among these quadruple

semitendinosus tendon is considered the graft of choice today.⁵

Numerous tibial and femoral fixation techniques have been described, which differ considerably with respect to the site of fixation (cortical, tunnels, near the joint line) and biomechanical parameter. Most commonly used femoral fixation techniques include button fixation (Endobutton), transfixation technique and interference screws (titanium or biodegradable).⁶ The femoral sided Endobutton and tibial sided screw and washer have been used to achieve good hamstring tendon graft fixation.⁷ However, bone tunnel enlargement has been reported after using this technique for ACL reconstruction, but the importance of tunnel enlargement is not clear, because clinically these patients did well after the ACL reconstruction.⁸

As loosening and the failure of the neo ACL graft are more common at the femoral site, more information is needed about the femoral site fixation.⁹ So keeping the tibial site fixation identical, a comparative study is needed, of the outcome of the two techniques of femoral site fixation i.e. Endobutton fixation and transfixation.

METHODS

The prospective study was conducted from January 2002 to June 2008. The patients subjected to this study were those who had chronic ACL tear and had undergone arthroscopic ACL reconstruction with quadruple semitendinosus tendon fixed at femoral site by either Endobutton or transfixation techniques. Patients with either transfix or Endobutton fixation at femoral site has an *identical tibial site fixation* of graft by biodegradable interference screw and bone staple fixation. All the patients were explained about the study and written and informed consent was taken from them. In this study a total of 132 patients were enrolled two groups, 68 patients in group A (Endobutton technique) and 64 patients in group B (Transfixation technique). The exclusion criteria for the study include patients who are previously operated to the knee, with other ligament injuries (PCL, MCL, LCL), with other types of grafts used and with any other type or combination of graft fixation methods. The patients were subjected to clinical and radiological examination preoperatively as well as postoperatively and findings documented.

Surgical procedure

All the patients in this study underwent arthroscopically assisted ACL reconstruction for symptomatic chronic ACL deficient knees. All operative procedures were performed by one arthroscopic surgeon. In both the groups after general anesthesia or regional anesthesia, the examination of the affected knee was done and findings documented. After positioning of the patient diagnostic arthroscopy was done to confirm ACL tears and associated meniscal injuries, which were managed

simultaneously. The semitendinosus and gracilis grafts were harvested through a 3-cm oblique incision over the pes anserinus. The STG tendons are then quadruple looped and then its diameter measured for tunnel preparation. The tunnel diameter was usually between 7 to 9 mm. Then using standard techniques and Jigs the Tibial and femoral tunnels were prepared and graft passed through the tunnels.

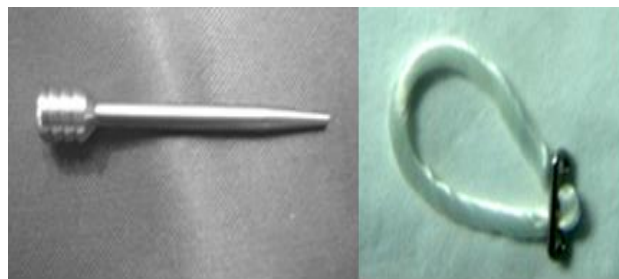


Figure1: Showing metallic transfix pin and endobutton with closed loop.

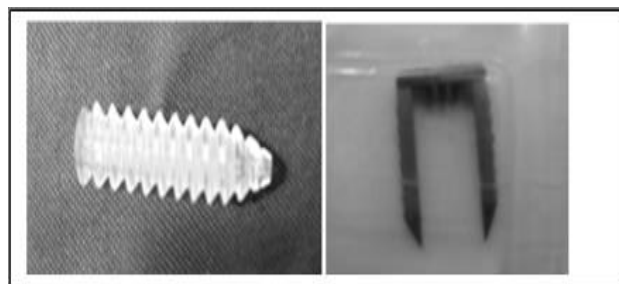


Figure 2: Showing bioabsorbable interference screw and bone staple.

The femoral end of graft was fixed with Endobutton (Smith Nephew – Acufex) in group A patients and by transfix pin (Arthrex) in group B patients (Figure 1). In both the groups the tibial end was kept same and fixed with a cannulated bio-interference screw (arthrex) and spiked ligament staple (arthrex) as in Figure 2. Both the groups had a standard similar post-operative regime. Patients were encouraged early weight bearing with hinged knee brace and crutches. Patients were put on standard closed chain exercises for 4 to 6 weeks and then open chain exercises. Running and light sports activities were started between 4 to 6 months.

The patients in both the groups were followed at regular intervals. At each visit the patients were evaluated both clinically and radiologically. The patients were enquired about any specific complaints and documented the findings. Both groups of patients were evaluated preoperatively once and postoperatively immediate, within 3 months, 3 to 12 months, 12 to 24 months and more than 24 months by the following standard methods.

1. Lysholm knee scoring scale
2. Modified* 2000 IKDC knee examination form
3. 2000 IKDC subjective knee evaluation form

(*2000 IKDC knee examination form has been modified due to non-availability of KT-1000 arthrometer in our setup and other unavoidable reasons).

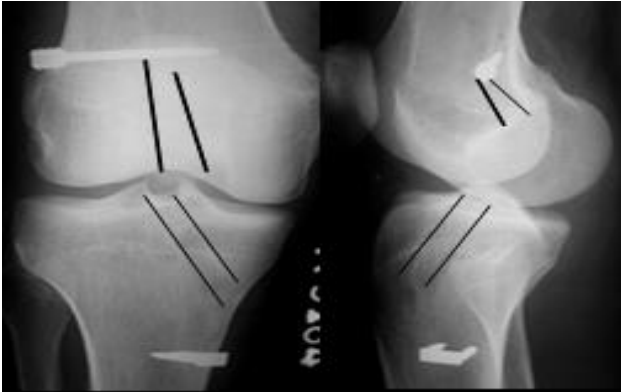


Figure 3: Showing the enlarged tibial and femoral tunnels marked for measurement in antero-posterior and lateral radiographs of knee joint.

Both the groups of patients are subjected to X-rays of the knee, anteroposterior and lateral views, once preoperatively and then in postoperative follow up periods. Magnetic resonance imaging (MRI) was done in *limited* number of patients once preoperatively and in postoperative period as it was very expensive. Once all the x rays were chosen for measurements, the points for measurements were located by senior radiologists (Figure 3). Also the MRI of limited number of patients was discussed with the Radiologist to evaluate the Graft status and incorporation. On repeated measurements, the intra observer variation was found to be less than ± 0.5 mm. On an average the measurements were repeated thrice for reliability of measurements.

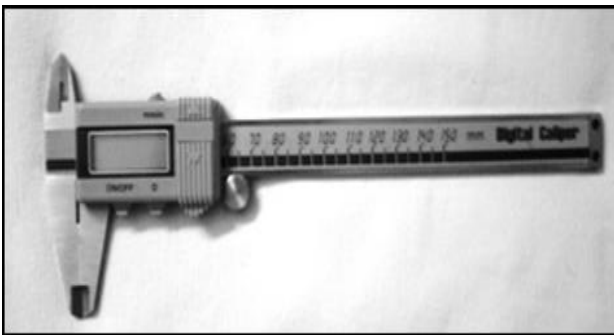


Figure 4: Digital calliper.

Since computerized distance measurements using siemens evaluation unit was limitedly available and restricted in our institute an alternative but effective tool had to be chosen for reliability of measurements. The digital caliper (Figure 4) from the Mitutoyo Company suited our purpose excellently. It has accuracy up to 0.01 mm. All the tunnel diameters were done at one centimeter from the joint line in AP view. The sclerotic tunnel margins were marked, measured and corrected for

magnification. The original tunnel diameter was obtained from the surgical notes or in immediate postoperative X-rays. Bone tunnel enlargement was expressed as a percentage of the original tunnel diameter:

Bone tunnel =

$$\frac{\text{measured dimensions - operative (imed post op) tunnel diameter}}{\text{enlargement operative (imed post op) tunnel diameter}}$$

Statistical analysis was done using Mann Whitney test using the Microsoft Excel software in the Statistical department and results analysed.

RESULTS

In our study we included a total of 132 patients, 68 patients in group A, Endobutton and 64 patients in group B, Transfix. It was observed that 90% of our patients were males, mostly involved in Sports and Military or Security forces. A total of 14 female patients were included with 4 in group A and 10 in group B 9 (Table 1). The mean age in group A was 27.41 years (range from 16 yrs to 36 yrs). In group B the mean age was about 26.15 yrs (range 14 yrs to 43 yrs). Patients in both the groups were followed up to an average of about 25 months, i.e. in group A average follow up period was 25.35 months (range from 8 to 56 months) and in group B they were followed for a mean period of about 26.25 months (range 5 to 48 months).

Table 1: Showing clinical data, associated injuries and complications in both the groups.

	Group A Endobutton	Group B Transfix
Number of patients n=132	68	64
Male: Female	64:4	54:10
Mean age (range) in years	27.4 (16-36)	26.1 (14-43)
Side operated-right: left	50:18	28:36
Average follow-up (range) in months	23.3 (8-56)	26.2 (5-48)
Associated injuries		
Medial meniscal tear n=62	30	32
Lateral meniscal tear n=30	12	18
Complications		
Persistent paraesthesia on leg	6	4
Infection	2	2
Implant problems	0	2

Patients in both the groups had associated injuries/lesions along with ACL tear. It was documented either preoperatively on MRI or intraoperatively (Table 1).

Most of the patients had medial meniscal tear (Total 62, 30 in group A and 32 in group B), followed by lateral meniscal tear (Total 30, 12 in group A and 18 in group B). One patient in group A had Baker's cyst and one in

group B had a non-ossifying fibroma, both are an incidental finding clinically asymptomatic. Meniscal injuries were treated simultaneously before reconstruction in all these patients.

Table 2: Showing the distribution of Lysholm knee score in group A during various follow up and their significance.

	Pre op	Immd	<3 mth	3-12 mth	12-24 mth	>24 mth
No of patients	68	68	18	34	34	24
Minimum	34	34	37	57	81	90
Maximum	69	72	75	80	95	100
Mean	48.21	48.09	62.56	72.06	90.12	94.67
P value		0.954	0.05	0.00	0.00	0.00

p<0.05 is significant.

Table 3: Showing the distribution of Lysholm knee score in group B during various follow up and their significance.

	Pre op	Immd	<3 mth	3-12 mth	12-24 mth	>24 mth
No of patients	68	68	18	34	34	24
Minimum	31	34	51	58	58	69
Maximum	59	75	81	84	100	100
Mean	45.59	47.2	66.42	70.95	88	94.63
P value		0.527	0.00	0.00	0.00	0.00

p<0.05 is significant.

Table 4: Showing distribution of IKDC subjective knee evaluation score during follow up and their significance in group A.

	Pre op	Immd	<3 mth	3-12 mth	12-24 mth	>24 mth
No of patients	68	68	18	34	34	24
Minimum	28.73	13.79	13.79	25.28	48.27	63.21
Maximum	48.27	32.18	56.32	60.91	80.45	85.05
Mean	37.58	17.97	35.88	44.14	69.43	74.51
P value		0.00	0.963	0.02	0.00	0.00

p<0.05 is significant.

Table 5: Showing distribution of IKDC subjective knee evaluation score during follow up and their significance in group B.

	Pre op	Immd	<3 mth	3-12 mth	12-24 mth	>24 mth
No of patients	64	60	24	38	32	32
Minimum	20.68	10.34	11.49	18.39	35.63	47.12
Maximum	54.02	43.67	70.11	78.16	90.8	94.25
Mean	36.55	17.63	36.89	44.63	66.44	75.28
P value		0.00	0.967	0.01	0.00	0.00

p<0.05 is significant.

Few complications were observed during our study, although paresthesia or numbness over proximal leg were seen in 10 patients (group A -6, group B - 4) all of them gradually improved. Two patients in both groups had post op knee infections which were treated with Arthroscopic lavage and antibiotics. One patient had persistent swelling and fever was diagnosed has Tuberculosis of knee and was treated with Antitubercular drugs, following which patient improved. In Transfix group B two patients had wasting of hamstring muscles, but had

no functional loss and four patients had wrong placement of Transfix screw.

All the patients were evaluated using Lysholm Knee score both pre op and at various post op periods during their follow up. It was observed that the mean Lysholm Knee score has been progressively increasing from pre op to post op in subsequent follow ups in both the groups. The mean Lysholm Knee score has improved significantly in both groups from <50 in pre op to >90 in

more than 24 months follow up. The distribution has been shown along with comparison in Table 2 for group A and Table 3 for group B.

Modified 2000 IKDC Knee examination form was used for Clinical evaluation of the patients. On comparing the pre op and post op follow up gradings it was observed

that majority of the patients in pre op had Grade “C” (group A 40, group B 48), and few were in Grade “B” (group A 14, group B 8) or “D” (group A 14, group B 8). None of the patients had Grade “A” in pre op. In post op most patients were in Grade “A” with only few patients had Grade “B” on follow up at different intervals. None of the patents of both groups had Grade “C” or “D”.

Table 6: Showing the comparison of percentage of tibial tunnel enlargement.

Group	<3 mth		3-12 mth		12-24 mth		>24 mth	
	A	B	A	B	A	B	A	B
No of patients	18	22	36	38	32	34	24	30
Minimum (%)	0	0	0	0.17	1.59	1.37	1.71	1.89
Maximum (%)	0.58	0.66	2.97	5.1	19.74	17.23	21.29	16.8
Mean (%)	0.22	0.22	0.81	1.12	6.32	6.64	9.64	7.79

Table 7: Showing the comparison of percentage of femoral tunnel enlargement.

Group	<3 mth		3-12 mth		12-24 mth		>24 mth	
	A	B	A	B	A	B	A	B
No of patients	18	22	36	38	32	34	24	30
Minimum (%)	0	0	0	0	1.19	1.46	2.26	1.69
Maximum (%)	0.99	0.53	6.37	3.24	12.8	16.66	13.57	14.23
Mean (%)	0.33	0.17	1.34	1.03	5.17	5.97	7.71	7.27

Table 8: Showing the significance of tunnel widening at different follow-ups.

Follow up	Tibial tunnel	Femoral tunnel
	P value	P value
<3 mth	0.568	0.152
3-12 mth	0.465	0.727
12-24 mth	0.885	0.732
>24 mth	0.558	0.696

p<0.05 is significant.

These patients were also functionally assessed using questionnaire format of 2000 IKDC Subjective Knee evaluation form. It was observed that the mean score has progressively increased significantly from pre op values of 37.58 and 36.55 to about 74.51 and 75.85 in group A and group B respectively. There was decreased score in immediate post op period due to pain and swelling as patients were not able to do most of the activities as depicted in Table 4 for group A and Table 5 for group B.

During our follow ups we noticed tunnel enlargement in both the groups at both femoral and tibial side on radiographs. The tunnel diameters were compared with immediate post op to Regular follow up measurements. The measurements were corrected to magnification. The percentage enlargement was compared in both groups. It was observed that the tibial tunnel was comparable till 12-24 months follow-up but in >24 months the mean percentage enlargement was 9.64% in group A as compared to 7.79% in group B as shown in Table 6. Similarly the femoral tunnel diameter was found to enlarging on regular follow up. The enlargement has been

progressive and comparable in both the groups as shown in Table 7.

Statistical analysis was done comparing the tunnel enlargement in both groups at different periods of follow up comparing it with immediate post op or original tunnel diameter measured. It was noticed that the tunnel diameter widening was seen in both Endobutton and Transfix groups at both tibial and femoral side. On analysis it was found that the enlargements in both groups at both sides are comparable and not significant as shown in Table 8.

Postoperative MRI was done in few patients during the follow up; many patients could not afford the MRI due to its high cost. The MRI’s were evaluated in consultation with senior Radiologists regarding the graft status and graft incorporation. A total of 27 MRI’s, 14 in group A and 13 in group B were done during there various follow up and compared. It was observed that the neo graft was found intact in all the cases in both groups in our study. The graft was found incorporated in all most all the cases

as evaluated by previous studies, bone tendon interface was mature, the same has been shown in Figure 3.

DISCUSSION

In this prospective study, we compared the clinical and radiological outcome of quadruple semitendinosus tendon fixed at femoral site by two different methods Endobutton and Transfix, keeping tibial fixation constant. Our results show that fixation with Transfix pin did not lead to any significant differences in the clinical outcome when compared with Endobutton. Although there is definite significant improvement in the clinical scores in both groups compared to pre op scores.

In previous studies showing the evaluation by Lysholm knee score, IKDC knee score or IKDC subjective knee evaluation score comparing the semitendinosus autograft show that there was no difference in the final outcome.¹⁰⁻¹³ In our study the Lysholm knee score had improved significantly and progressively in both the groups on follow up when compared to preoperative score. The mean score has improved from pre-operative level of <50 in both groups to >90 after >24 months follow up. There was no significant difference in the score on comparing the group A (Endobutton) and group B (Transfix).

Tibial tunnel enlargement has been seen in our study in both the groups, the average percentage enlargement at >24 months show no significant difference in the Endobutton group A (9.64%) when compared to Transfix group B (7.71%). Even though there appears to be more tibial enlargement in group A compared to group B, but statistically there is no significance ($p < 0.05$). Similarly the femoral tunnel also showed widening of about 7.79% in group A as compared to 7.27% in group B at >24 months follow-up, which was statistically insignificant. The tunnel enlargement at both femur and tibia has been progressive as noticed at various follow-up intervals.

Post-operative MRI was done in only 27 patients due to its cost. As only limited MRI was done we could not calculate the tunnel diameter on MRI. We have assessed the status of the graft during various follow ups; in almost all the cases the graft was intact with no tear. This was supported by our study that none of our patients who are followed till date as per our knowledge has undergone revision surgery.

The grafts within both the tunnels were well incorporated in all the patients of both groups. This was documented after discussing with senior radiologists. The bone tendon interface was partially or fully mature as per T2-weighted images. There was no fluid signal around the graft. Our study was correlating with the previous study by Jansson on MRI which showed that the ligamentous graft itself was not enhanced by the contrast medium whereas periligamentous tissue within and around the STG graft bundles showed mild contrast enhancement associated with tunnel expansion.¹⁴

The study by Ma using the IKDC subjective knee form showed that scores were normal or near normal.¹⁵ Our study also showed that the IKDC scores and IKDC knee examination scores, Even though on examination the patients had laxity in follow up but they did not have any functional loss or impairment whatsoever. Their study correlates well with our present study.¹⁴ There average IKDC subjective knee form scores were 85 ± 11 versus 81 ± 17 (BIS vs. ENDO) and side-to-side KT differences were 3.2 ± 2.6 mm versus 2.4 ± 1.8 mm ($p > 0.05$). For both groups, tunnel enlargement was present on radiographs at both femoral and tibial sides (36% to 77%). Tunnel enlargement was more significant at the femoral tunnels (53% to 77%) than the tibial tunnels (36% to 42%). But in our study there was no significant difference in tunnel enlargement at both tibial and femoral sides. They had kept the minimum follow up to 2 years, with 15 patients in each group, whereas in our study which was a short term one had more number of patients (total 132, group A=68, group B=64).

One of the studies which closely resemble ours is by Faunoe from Denmark.¹⁶ In his study comparing the Endobutton and Transfix the tibial fixation was different with interference screw in one group and Bicortical screw with washer in another group respectively. There was no difference with respect to Lysholm, IKDC or arthrometric evaluation thus supporting our study (we have not used Arthrometer). There was significant reduction of tunnel widening in both femur and tibia using fixation points close to the joint. But in our study tibial fixation was kept constant, the tunnel widening is progressive in both groups at both sites till now.

In our study the tibial fixation of graft was kept constant in all our patients in both groups using transparent biodegradable screw and bone staple. For femoral fixation patients were randomly divided into two groups, adhering to standard surgical steps for each type of fixation method. Our sample size is comparatively large enough with almost equal number of patients in both groups, Group A (Endobutton) 68 patients and Group B (Transfix) 64 patients. The study design was such that the patients were followed up at frequent intervals (immediate, <3 months, 3-12 months, 12-24 months and >24 months) to assess the gradual progression of changes clinically and radiologically for comparison thereof. All the surgeries were performed by a single surgeon, thus avoiding the surgeon related variation in fixation methodology. So far to best of our knowledge no similar study keeping the tibial fixation constant and comparing the two different femoral fixation methods has been done.

Cinar et al retrospectively evaluated 35 patients who underwent arthroscopic ACL reconstruction with quadrupled hamstring tendon graft.¹⁷ Fixation was performed in the tunnel using the transcondylar rigid fix pin (group 1) in 18 patients and from outside the tunnel using the Endobutton-CL device (group 2) in 17 patients. The mean follow-up was 24 months (range 21 to 38

months) in group 1, and 24.6 months (range 12 to 36 months) in group 2. This was almost similar in our study. There study showed no significant difference in Postoperative knee scores. Also there was marked and excessive tunnel enlargement in 14 patients (77.8%) in group 1, and in 15 patients (88.2%) in group 2, with no significant difference between the two groups ($p>0.05$). Ligament laxity exceeded 3 mm in eight patients (44.4%) in group 1, and in three patients (17.7%) in group 2 ($p<0.001$). There was no relationship between tunnel widening and ligament laxity ($p>0.05$; $r=0.175$ and $r=-0.01$ for group 1 and group 2, respectively). Our study also shows similar results. They concluded that differences in the localization of the tunnel fixation have no effect on tunnel enlargement and that joint laxity may be affected by biomechanical properties of fixation materials.

The following are the few drawbacks which we had in our present study. The study design was such that the patients were to come for follow up at different periods for evaluation. As most of our patients were living in far off palces they could not come so frequently inspite of trying to contact them through post, telephone, mobile and E-mails. If all the patients had come for the follow up the results might have been influenced. It was not feasible for all the patients to get MRI in post operative period due to its high cost, the evaluation could not be done in all the patients. This would have thrown further lights in our results. Absence of KT-1000 Arthrometer have compelled us to modify the 2000 IKDC knee examination score. So the present study was deprived of the benefit of quantifying the preoperative and post operative knee side to side laxity.

CONCLUSION

Considering the limitations of our study as mentioned under observations, the following conclusions are drawn. The clinical outcome of Arthroscopic ACL reconstruction using quadruple ST auto grafts show definite improvement in both groups (Endobutton - group A and Transfix-group B). There are progressive Tunnel enlargements noticed at both tibial and femoral sites in both group A and group B which have not influenced the clinical outcome. MRI done in limited number of cases show graft incorporation with in the tibial and femoral tunnels. So keeping the tibial graft fixation constant, the two different femoral fixation methods, Endobutton and Transfixation have not influenced in the clinical outcome in this short term preliminary study. But long term follow up of these is necessary to evaluate the significance of tunnel widening and its final outcome.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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Cite this article as: Nataraj AR, Nag HL, Rastogi S, Neogi DS. Prospective randomised comparison of femoral transfix versus endobutton with constant tibial fixation in hamstring tendon ACL reconstruction: a preliminary study. *Int J Res Orthop* 2017;3:1023-30.