

## CLINICAL OUTCOME OF CORTICAL APERTURE VS INTRATUNNEL SUSPENSORY FIXATION IN ACL RECONSTRUCTION – A RANDOMIZED CONTROL TRIAL

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### Abstract

**Background:** -Anterior cruciate ligament reconstruction is the most commonly performed arthroscopic reconstructive procedure and has continued to evolve with regard to the technique, graft selection, graft fixation and post-operative rehabilitation. Early rehabilitation demands rigid intraoperative mechanical fixation of the graft since therapy begins prior to biologic incorporation of the graft in the bone tunnels. **Materials and Methods:** The study included 30 cases each of aperture and suspensory fixation method of anterior cruciate ligament reconstruction, attending the orthopaedics outpatient department. The cases had, initial clinical and radiograph evaluation done followed by subsequent knee arthroscopic reconstruction and were evaluated clinically using knee functional IKDC scoring system postoperatively in OPD

**Result:** IKDC Score preoperatively in aperture group was 45.65 and post operatively at three, six and nine months was 61.14, 73.66 and 80.48 while in suspensory group it was 46.87 preoperatively and postoperatively it was 63.6, 77.17,83 at three, six and nine months, which is not significant.(p>0.05) and improved significantly in both the groups at three, six and nine months post operatively.(p<0.05 ). **Conclusion:** The main finding of our study was no significant clinical difference for ACL auto graft fixed with suspensory button fixation versus aperture screw fixation as measured by IKDC score (pre operatively and post operatively).

## INTRODUCTION

Anterior cruciate ligament (ACL) tear of the knee is one of the most common sports injuries. The injury is common among athletes, and it can also occur at the workplace in jobs that require physical exertion.<sup>[1]</sup> Arthroscopic Anterior cruciate ligament surgery provides the best treatment option to restore active lifestyle. Mechanical strength of Anterior cruciate ligament reconstruction depends upon the Nature of graft, pull out strength of the fixation device and the effect of cyclical loading on the reconstruct. Various fixation devices provide mechanical fixation of the graft to the host bone till biological fixation takes over.<sup>[2-6]</sup>

Biological fixation occurs by two modes, direct or indirect. Direct fixation comprises a four layer interface of tendon, fibrocartilage, mineralized fibrocartilage and bone.<sup>[7]</sup> This transmits tensile forces well and is present at the tendon bone interface of a Patellar Tendon Bone graft. Indirect attachment occurs through Sharpeys fibers and is seen with soft tissue grafts.<sup>[8-10]</sup>

Intratunnel aperture fixation devices such as “Interference screws” directly compress the graft to the bony wall of tunnel and hence promote graft bone healing. Interference screws provide adequate fixation strength and it has been shown that pull out strength is in the range of 450 to 690 N.<sup>[3-6]</sup>

Cortical extra tunnel suspensory devices such as “Endobutton”, available as a continuous loop or the loop can be prepared indigenously using a polyester tape. The pull out strength of Endobutton has been shown to be 530- 1036 N in various laboratory studies.<sup>[3-5]</sup>

The tunnel requirements for the intratunnel aperture fixation devices are: a competent bony cylinder, intact posterior wall of the femoral tunnel and a good bone mineral density while cortical extra tunnel suspensory devices require: a competent bony cortex in the proximal portion of the tunnel and a good Bone Mineral Density.

There is currently no gold standard for the fixation of soft tissue grafts for ACL reconstruction Controversy exists regarding which is a better graft fixation method in ACL reconstruction in terms of Clinical

Outcome. The purpose of our study was to compare ACL soft tissue autograft reconstruction using Cortical suspensory vs Intratunnel aperture fixation at one year follow up.

## MATERIALS AND METHODS

We conducted a randomized controlled trial in 60 patients in which equal number of patients were assigned to Intratunnel aperture fixation group 1(n=30) and Cortical suspensory fixation group 2(n=30). Following approval by the Research Ethics Committee of our institution, signed informed consent was taken prior to inclusion in the study. After informed consent was taken patient were allocated to group by block Randomization method

### Sample Size Calculation

sample size analysis showed that total sample of 60 with 30 patients in each group to show clinically relevant side-to-side difference in knee AP laxity of 6mm((compared with the normal, contralateral knee and based on lachmann test) between the 2 groups, assuming an SD of 3.0 mm. For the power analysis, the alpha value was set at .05 and the beta value at .<sup>[8]</sup>

### Inclusion and Exclusion criteria-

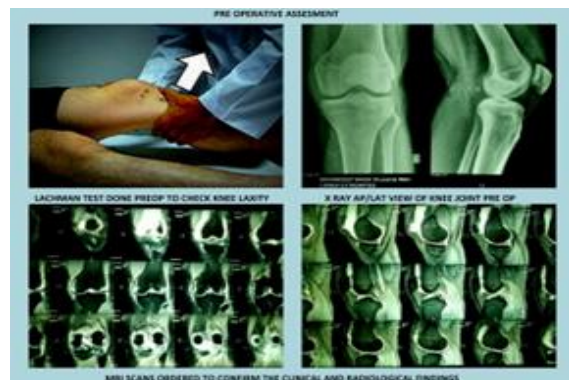
The inclusion criteria was patients aged 19 to 45 years with ACL deficient knee ,with equal eligibility of both gender .ACL injuries included were either “isolated “ or combined with the following injuries visualized on MRI or arthroscopy : A meniscus tear that was either left untreated or treated with a partial resection and cartilage changes verified on MRI with arthroscopically determined intact surface.. Excluded patients had associated injuries to the index knee as visualized on MRI /arthroscopy: An unstable longitudinal meniscus tear that requires repair and where the following post operative treatment (bracing and limited ROM) interferes with the rehabilitation protocol, Osteoarthritis in knee joint (Unicompartmental or Tricompartmental) and a total rupture of MCL/LCL/PCL (Multi ligament Injury) as visualized on MRI

### Pre-operative assessment

The pre-operative assessment included detailed history and physical examination, radiographs and MRI of the involved knee. Anterior drawer test and Lachman test were used for testing ACL injuries. The results of Lachman test were graded and evaluated pre operatively and at final follow up [Table 1]. Grades of laxity was defined by amount of anterior tibial translation relative to contralateral knee.<sup>[11]</sup>

**Table 1**

Grading	Description
Grade 1	1-5mm
Grade 2	6-10mm
Grade 3	>10mm



**Figure 1: Pre-Operative Assessment**

The patient's were further evaluated using International Knee Documentation Committee (IKDC) scoring system preoperatively and postoperatively at three,six and twelve months (1 year) in OPD.

### Surgical technique



**Figure 2: Intraoperative picture showing ACL Reconstruction**

After induction of regional anaesthesia, in supine position with upper thigh tourniquet. Clinical tests were performed under anaesthesia. Initial diagnostic arthroscopy was performed in case the clinical tests ( anterior drawer and lachmann test) were doubtful via anteromedial and anterolateral portal.. Semitendinosus and Gracilis tendon was harvested and prepared. The double stranded graft was looped further to create a total of four strands and graft size measured with the tendon sizer. Femoral sockets were created using the anteromedial portal technique .Graft was fixed with Intratunnel aperture fixation using a femoral and tibial metallic or bioabsorbable interference screw depending on the patients preference in group 1 patients while Cortical suspensory fixation was performed using a femoral, fixed loop length Endobutton(Arthrex or MITEK) and tibial side fixed with metallic or bioabsorbable interference screw in group 2 patients. After fixation of the graft, the knee was taken through approximately 15 to 20 cycles of complete flexion and extension.The joint was cleared off the debris by thorough lavage. Graft harvest site was sutured in layers with no 2-0 vicryl. Skin was sutured with ethilon. Compression bandage dressing was done and long knee extension brace was applied.



**Figure 3: X-rays Pre op and Post op evaluation (Aperture and Suspensory fixation)**

All patients were subjected to four phases (I-IV) of intense rehabilitation<sup>12</sup>, starting from immediate post-operative period till nine months, to restore the function and stability of the joint, gait, pain reduction, restore and enhance the strength and endurance through active physiotherapy. Data were collected and recorded at 3, 6 and 12 months (for patient-reported knee IKDC outcome measures and knee examination follow-up).

## RESULTS

In both the groups' male patients were more commonly affected than female patients. Mean age, BMI, Time since injury and Mean surgery time was not statistically significant in both the groups. ( $p>0.05$ ) [Table 2] At 12 months of follow up, two patients in the Group 1 and one patient in the group 2 were lost to follow-up.

### Knee Laxity

Out of 27 patients in aperture fixation who had grade three knee laxity pre operatively ,six (22.2 %) patients had grade one knee laxity while 21 (77.8%) patients had normal knee laxity post operatively while in suspensory group out of 28 patients who had grade three knee laxity pre operatively ,eight patients(28.5%) had grade one knee laxity and 20(71.5%) patients had normal knee laxity.(Table 3) However , All the patients with grade two knee laxity in aperture and suspensory fixation had normal girding at the final follow up

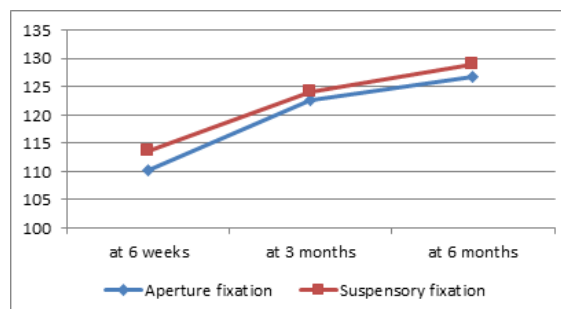
### IKDC Score

IKDC Score preoperatively in (aperture) group 1 was 45.65 and post operatively at three, six and 12 months was 61.14, 73.66 and 80.48 while in (suspensory)

group 2 it was 46.87 preoperatively and postoperatively it was 63.6,77.17,83 at three, six and twelve months, which is not significant. ( $p>0.05$ ) and improved significantly in both the groups at three, six and twelve months.

### Mean range of flexion

The mean range of flexion regained with regular physiotherapy in both the groups after six weeks, three months and six months post operatively and was not statistically significant in both the groups. ( $p>0.05$ )



**Figure 4: depicting Mean range of flexion regained at 6 weeks, 3 and 6 months.**

In our study there were no significant difference on comparing the patient's ability to go upstairs and downstairs at 3 months follow up. [Figure 5]. There was also no significant difference on comparing the patients ability to squat, jump ,jog and run at final follow up of one year.( $p>0.05$ )



**Figure 5: Post-Operative Clinical Assessment: 1. Ability to Go downstairs at three months, 2.Range of flexion regained at six weeks and six months, 3. Ability to Squat at six months**

**Table 2: Comparison of Age, BMI, Time Since injury and Mean Surgery Time**

	Aperture	Suspensory	p value
Age	28.10 ±7.35	27.73±4.90	0.821
BMI	23.23±3.13	23.24±2.91	0.993
Time since injury	7.13±7.31	6.23±5.53	0.593
Mean Surgery time	63	77	0.358

**Table 3: Comparison of knee laxity**

Type of fixation	Lachman Grading Pre Op		Lachman Grading Post Op	
	Grade 3	Grade 1	Grade 1	Normal
Aperture	27	6(22.2%)	21(77.5%)	Normal
Suspensory	28	8(28.5%)	20(71.5%)	Normal

**Table 3: comparison of IKDC Score pre op and post op at 3,6 and 12 months.**

	Aperture	Suspensory	p value
Pre- op	45.65 ± 5.64	46.87±5.15	0.387
Post -op			

3 months	61.14±6.21	63.60±4.39	0.082
6 months	73.66±7.44	77.17±6.52	0.057
9 months	80.48±6.20	83±5.006	0.089

## DISCUSSION

The choice of fixation in ACL reconstruction is still evolving and the current fixation devices, the Cortical Extratunnel Suspensory fixation devices and the Intratunnel Interference fixation devices, have been widely used and have resulted in an improved rehabilitation program post operatively.

However, it is evident that certain fixation devices (staple, screw and washer devices) may not be secure enough to allow accelerated rehabilitation protocol and need supplementary fixation or external protection in the post-operative period.<sup>[8]</sup>

While the behavior of the construct under cyclical loading in suspensory devices behave poorly leading to fixation failure. In suspensory devices like endobutton, the fixation is away from the joint and may lead to sagittal and longitudinal movement in the graft tunnel under cyclical loading.

The purpose of our study was to compare ACL soft tissue autograft reconstruction using Cortical Extratunnel Suspensory fixation vs Intratunnel Aperture fixation at 12 months follow up. The study was conducted in the Department of Orthopaedics at Sri Guru Ram Das Institute of Medical Sciences and Research Amritsar, Punjab. All patients admitted had initial clinical and radiograph evaluation followed by subsequent knee arthroscopic ACL reconstruction and were evaluated postoperatively.

The analysis of age distribution in the study showed a range of 19-45 years. The youngest subject was 19 years of age and the oldest subject was of 45 years of age with the average age being 28.10 in the aperture group and 27.73 in the suspensory group of fixation. All the subjects in the study were of active age group, involved in various kinds of day to day physical activities, making them prone to knee injuries. This correlates well with a research article by C. Benjamin Ma et al,<sup>[13]</sup> On analyzing gender distribution of the subjects with knee injuries, it was found male patients were more commonly affected than female patients in both of the groups. Most of the previous studies have documented male preponderance though females are at higher risk.<sup>[14,15]</sup>

The mean surgery time in our study in the aperture group was 66 min and in the suspensory group was 73 mins [Table 2] suggesting decreased operating time in patients with intratunnel interference screw fixation devices which is in contrast to the study by James H. Lubowitz al,<sup>[16]</sup> however statistically no significant difference in the operating surgery time between the two groups were seen( $p>0.05$ )

In our study in aperture group 90% patients had Lachman grade three knee laxity, 10% patients had grade two knee laxity pre operatively while in the suspensory group 93.3% patients had grade three knee laxity and 6.7% patients had grade two knee laxity pre operatively. On final follow up 20%

patients of aperture fixation had grade one knee laxity and 26.7% patients of suspensory group had grade one knee laxity while rest of the patients in both the groups had normal knee laxity.

The mean range of flexion regained with regular physiotherapy after six weeks, three months and six months post operatively in both the groups and was statistically not significant when compared in both the groups. ( $p>0.05$ ) However the range of flexion improved significantly in both the groups. ( $p<0.05$ ) [Figure 4]

In our study the mean IKDC subjective score was 45.6 in the aperture group while it was 46.8 in the suspensory group of fixation preoperatively, At final follow up, the mean IKDC subjective knee score in the aperture group was 80.5 and the mean IKDC subjective knee score in the suspensory group was 83 suggesting no significant difference between the two groups. ( $p>0.05$ ) and improved significantly in both the groups at three, six and twelve months. ( $p<0.05$ ) [Table 4].

Our results are similar to James H. Lubowitz al,<sup>[16]</sup> regarding the clinical outcome in comparison of aperture vs suspensory method in graft fixation. They reported no significant differences in knee IKDC subjective score comparing all-inside ACL allograft reconstruction using aperture fixation and all inside ACL allograft reconstruction using suspensory fixation at the final follow up.

C. Benjamin Ma,<sup>[13]</sup> also in their study compared the bioabsorbable interference screw and endobutton using hamstring as graft of choice with the average IKDC subjective knee form scores as  $85 \pm 11$  in the interference group versus  $81 \pm 17$  in the endobutton group showing no significant difference in clinical outcome similar to the results in our study. All patients in both the groups had functionally normal or near-normal IKDC examination rating at final follow up showing no significant difference.

The main finding of our study was no statistical significant difference for Clinical outcome in ACL hamstring autograft fixed with cortical suspensory button fixation versus Intratunnel aperture screw fixation. These results are clinically relevant to surgeons performing all-inside ACL reconstruction because evolution in the all-inside ACL technique has shown a transition from aperture fixation,<sup>[17]</sup> to suspensory fixation,<sup>[18-25]</sup> which has been described as a simpler and more reproducible technique.<sup>[26]</sup>

### Limitations

Our study had few limitations, Knee Antero-posterior stability was not evaluated pre operatively and post operatively with the help of KT-1000 knee arthrometer. The KT-1000 knee arthrometer (KT-1000) is an objective instrument to measure anterior tibial motion relative to the femur for anterior cruciate ligament (ACL) reconstruction.<sup>27</sup>We also could not analyze femoral and tibial socket widening

using computed tomography in both the fixation methods. Besides we have applied IKDC score for evaluation of the patients outcome and did not use other methods of scoring systems. As the follow up period was small, the graft failure rates could not be assessed accurately.

## CONCLUSION

The main finding of our study was no statistical significant difference for Clinical outcome in ACL auto graft fixed with Cortical extra tunnel suspensory fixation versus Intra tunnel aperture screw fixation as measured by IKDC score (pre operatively and post operatively). These results are clinically relevant to surgeons performing arthroscopic ACL reconstruction because evolution in the all-inside ACL technique has shown a transition from aperture fixation to suspensory fixation, which has been described as a simpler and more reproducible technique.

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