A CASE CONTROL STUDY TO COMPARE DISTAL FEMUR TUNNEL WIDENING BETWEEN SUSPENSORY FIXATION AND SUSPENSORY FIXATION AUGMENTED WITH BIOABSORBABLE SCREW FOR ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION WITH HAMSTRING GRAFT



A dissertation submitted in partial fulfillment of

MS (Orthopedics) branch II Examination of Tamil Nadu

DR.M.G.R UNIVERISTY, CHENNAI

To be held in May 2019

## **DECLARATION CERTIFICATE**

I hereby declare that this dissertation titled "A CASE CONTROL STUDY TO COMPARE DISTAL FEMUR TUNNEL WIDENING BETWEEN SUSPENSORY FIXATION AND SUSPENSORY FIXATION AUGMENTED WITH BIOABSORBABLE SCREW FOR ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION WITH HAMSTRING GRAFT " is carried out by me under the guidance and supervision of Dr Anil Thomas Oommen, Professor, Department of Orthopedics Unit II, Christian Medical College, Vellore.

This dissertation is submitted in partial fulfillment of the requirements of the Tamil Nadu Dr M.G.R Medical University for the degree of MS (Orthopedics) examination to be held in May 2019.

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December 27, 2016

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#### Sub: Fluid Research Grant NEW PROPOSAL:

Comparison of distal femoral tunnel widening between suspensory fixation and suspensory fixation augmented with bio-absorbable interference screw for Anterior Cruciate Ligament reconstruction with hamstring graft.

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Dear Dr. Sam James Daniel,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

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1 of 4



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Dear Dr. Sam James Daniel,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Comparison of distal femoral tunnel widening between suspensory fixation and suspensory fixation augmented with bio absorbable interference screw for Anterior Cruciate Ligament reconstruction with hamstring graft" on November 03rd 2016.

The Committee reviewed the following documents:

- 1. IRB Application format
- 2. IKDC and Lysholm Scoring Sheet
- 3. Patient Information Sheet and Informed Consent Form (English and Telugu)
- 4. Proforma
- 5. No. of documents 1-4

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on November 03rd 2016 in the BRTC Conference Room, Christian Medical College, Bagayam, Vellore 632002.



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We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Comparison of distal femoral tunnel widening between suspensory fixation and suspensory fixation augmented with bio-absorbable interference screw for Anterior Cruciate Ligament reconstruction with hamstring graft" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

#### Fluid Grant Allocation:

A sum of 1,00,000/- INR (Rupees One lakh Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an 1st Installment. The rest of the 50,000/- INR (Rupees Fifty Thousand only) each will be released at the end of the first year as 2 nd Installment.

Yours sincerely,

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4 of 4

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11

# CONTENTS

TITLE	
INTRODUCTION	14
ABSTRACT	
ABBREVIATIONS	
AIMS AND OBJECTIVES	
LITERATURE REVIEW	
Introduction	
Global Epidemiology	20
Indian Epidemiology	21
Mechanism of injury	21
Examination	22
Diagnosis	29
Treatment	
Measuring bone tunnel widening	
MATERIALS AND METHODS	
ANALYSIS AND RESULTS	54
DISCUSSION	76
CONCLUSION	80
BIBLIOGRAPHY	81
ANNEXURES	
Questionnaire	88
Patient information sheet	94
Informed consent	
Master sheet	97

# TITLE

A CASE CONTROL STUDY TO COMPARE DISTAL FEMUR TUNNEL WIDENING BETWEEN SUSPENSORY FIXATION VERSUS SUSPENSORY FIXATION AUGMENTED WITH BIOABSORBABLE SCREW FOR ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION WITH HAMSTRING GRAFT

#### **INTRODUCTION**

Among sports related injuries, Anterior Cruciate ligament injuries are the most common among sports related injuries. ACL reconstruction using hamstring grafts is the most common technique followed worldwide (63%)(1). Two common modalities used worldwide for Anterior Cruciate Ligament reconstruction are suspensory fixation with an Endo-button and Aperture fixation with an Interference screw. Endo-button fixation is the most common type of fixation of the hamstring graft (40%) worldwide(1). Hamstring grafts are used as it results in less anterior knee pain which helps in early post operative rehabilitation period and in the long term period compared to patellar tendon autograft.

The patients who undergo ACL fixation with endobutton develop widening of the femoral and tibial tunnel. The widening is more in the femoral tunnel(72%- twice as that of the tibial side) than the tibial tunnel(38%)(2). The widening in the tunnel was found to be due to movement of the graft inside the tunnel, as the tunnel is slightly larger than the graft, a phenomenon called windshield wiper effect(2,3). The tunnel widening happens more when the fixation points are far apart than when the fixation points are close to each other, because when the fixation points are far it causes more mobility of the intervening graft(4). The tunnel widening happens maximum within 6weeks(3)of the surgery and is almost complete by 3 months(5)and remains the same till 12 months after the surgery, hence a 6 month to 2 year follow up was taken.

We place the tunnel in an anatomical position to the original ACL bundle. This study is aimed at studying the bone tunnel widening in the distal femur at 6 months to 2 year follow up using x-ray and CT scans for exact quantification and comparing it with International Knee Documentation Committee (IKDC) and Lysholm scores. The radiation exposure of CT scan is minimal and can be safely used in studying the tunnel widening without causing any adverse effect to the patient(5).

#### ABSTRACT

**Purpose:** Tunnel widening in ACL reconstruction is a common problem noted in suspensory fixation with hamstring grafts. Our hypothesis was that augmentation of the femoral side suspensory fixation with an interference screw (aperture fixation) negates this tunnel widening possibly caused by windshield wiper effect.

**Methods:** In our study we used quadrupled hamstring graft which was fixed with suspensory fixation on both sides with an aperture fixation on the tibial side in both the groups. We observed tunnel widening in patients without augmentation and with augmentation using immediate post operative x-ray and follow up x-ray. A CT scan assessment was also done at follow up.

**Results:** Femoral tunnel widening measured by x-ray in the augmentation group measured at the widest point of the tunnel point 'D' was  $0.74 \pm 1.05$  (AP),  $1.01 \pm 1.04$  (lateral) and in the endobutton only group was  $1.54 \pm 1.48$  (AP) and  $1.79 \pm 1.47$ (lateral), both of which were statistically significant(p-0.038, p-0.038). Widening at the point 'E' (aperture) in the augmentation group was  $1.25 \pm 1.10$  (AP),  $1.09 \pm 0.98$  (lateral) and in the endobutton only group was  $1.53 \pm 1.30$  (AP),  $1.65 \pm 1.29$  (lateral), it was not statistically significant. The values were comparable to CT. There were also better clinical outcomes in the augmentation group

**Conclusion:** Our hypothesis which assumed that tunnel widening would be reduced by the addition of the interference screw on the femoral side in addition to the suspensory fixation contributed to decrease in tunnel widening as well as better functional outcome true. In addition to the radiological improvement, there was also clinical improvement noted in the patients both during immediate post operative period and during their follow up.

#### **ABBREVIATIONS**

- ACL- Anterior cruciate ligament
- PCL- Posterior cruciate ligament
- MCL- Medial collateral ligament
- LCL- Lateral collateral ligament
- IKDC- International Knee Documentation Committee
- BMI- Body mass index
- CT- Computer tomography
- MRI- Magnetic resonance imaging
- RTA- Road traffic accidents
- US- United States; USA- United States of America
- PT graft/ BPTB Patellar tendon graft/ bone-patellar tendon bone
- HS- Hamstring
- HA- Hydroxy-apatite
- PLLA- Poly-L-lactic acid
- PLGA- poly-glycolic acid
- PLGA (TCP)- poly-D,L-lactide-tricalcium phosphate
- PEEK-polyetheretherketone

#### AIMS AND OBJECTIVES

To compare the amount of tunnel widening between suspensory fixation to suspensory fixation augmented with interference screw fixation in the distal femur after hamstring graft Anterior Cruciate Ligament reconstruction,

-To assess tunnel widening using x-ray comparison and CT scan evaluation at 6 month- 2 year follow up

-To compare tunnel widening to functional knee scores like, International Knee documentation committee score and Lysholm score.

-To see if augmentation of the suspensory fixation (endobutton) with aperture fixation (interference screw) results in decrease in femoral tunnel widening in ACL reconstruction

#### LITERATURE REVIEW

#### Introduction

Bone tunnel widening following an anterior cruciate ligament is a commonly encountered phenomenon. The cause of the tunnel widening is multifactorial, a combination of biological and biomechanical factors. Micro motion of the graft within the tunnel is believed to cause inflammatory response(6,7).

Early reports suggested that bone tunnel enlargement is mainly the result of an immune response to allograft tissue; more recent studies imply that other mechanical as well as biological factors play a more important role. Biological factors associated with tunnel enlargement are non-specific inflammatory response (osteolysis around implants), foreign-body immune response (against allograft), cell necrosis due to toxic products in the tunnel (ethylene oxide, metal), and heat necrosis as a response to drilling (natural course)(8). Mechanical factors that contribute to tunnel enlargement include stress deprivation of bone within the tunnel wall, improper tunnel placement, graft-tunnel motion, and aggressive rehabilitation. Grafttunnel motion refers to transverse and longitudinal motion of the graft within the bone tunnel and can occur with various graft types and fixation techniques especially in a suspensory type fixation(9). An aggressive rehabilitation program may contribute to tunnel enlargement as the graft-bone interface is subjected to early stress before biological incorporation is complete(10). Improved and more

19

anatomical surgical fixation techniques may be useful for the prevention of bone tunnel enlargement.

Anterior cruciate ligament (ACL) reconstruction tunnel widening tends to occur mostly in the early post-operative period within 3months and no significant change is seen from 3 months to 2 years(11). There is no correlation between bone tunnel enlargement and clinical outcome of the patients that has been reported so far (6,12–14)

#### **Global Epidemiology**

The majority of ACL injuries (70%) are sports related. The highest incidence is in the age group 15-25 years old who participate in contact sports involving pivoting movement of the knee (15). The incidence was 33 cases in 100 000 in 1994 and it rose to between 40 and 60 incidents in 100 000 in 2014 in the United States(16). It is estimated that approximately 200 000 ACL reconstructions are performed in the USA alone each year(16). The incidence on Swedish National Knee Ligament Register 2014 was up to 80 ACL disruptions in 100,000 populations. National incidence in New Zealand in 2005 was 1193 per 100,000 person-years(17). This number is expected to increase further as a result of increased participation in athletic activities.

#### **Indian Epidemiology**

In the Indian cohort studies, 58% were associated with sporting injuries, 26% with Road traffic accidents (RTA), and 16% were related to other nonsporting injuries like falls from heights, tripping down stairs, and other causes (18).

#### **Mechanism of injury**

ACL and PCL injuries are one of the most common and significant injuries which can occur with virtually any mechanism of injury, if the force exceeds the ligaments capacity to stretch (10-25% of the usual resting length).

Mechanism of injury can either due be direct or indirect trauma. Palmer described four mechanisms of injury to the ligament(19).

1. Flexion, Abduction and Internal rotation of femur on tibia.

2. Flexion, Abduction and External rotation of femur on tibia.

3. Hyperextension of the knee

4. Antero-posterior displacement.

Abduction, flexion and internal rotation is the most common mechanism and, if the injury is severe it can result in the "O" Donoghue" triad i.e. an injury to ACL, MCL and medial meniscus. The 2nd most common type is due to hyperextension. Usually no single ligament can be disrupted without sustaining some degree of injury to the other supporting structures. The injury to the other supporting structure may be minimal and may heal with conservative measures leaving what is apparently and isolated injury of the ACL on clinical examination.

#### **Examination**

The most commonly used physical examinations are the Lachman test, anterior drawer test, pivot shift test and single foot hopping test. These tests are not only used to diagnose an ACL tear but also used to examine patients post operatively.

#### Lachman test:

The knee is flexed at 20–30 degrees with the patient supine. The examiner should place one hand behind the proximal tibia and the other grasping the patient's distal thigh. The examiner's thumb is placed on the tibial tuberosity and the fingers placed on the posterior aspect of the calf. The tibia is pulled forward to assess the amount of anterior translation of the tibia in comparison to the femur. An intact ACL should prevent forward translational movement ("firm endpoint") while an ACL-deficient knee will demonstrate increased forward translation without a decisive 'end-point' - a soft endpoint indicative of a positive test. More than 2 mm of anterior translation compared to the uninvolved knee suggests a torn ACL.

Lachman test is considered more sensitive as compared to the anterior drawer as it negates the door stopper effect of the meniscus(20). But recent arthroscopic studies show equal sensitivity of lachman and anterior drawer test(21).

Lachman test is graded as follows

Grade 0- proprioceptive appreciation of a positive test (1-2mm translation)Grade I- visible anterior translation of the tibia (3-5mm)Grade II- passive subluxation of the tibia with the patient supine (6-10mm)Grade III- ability of the patient with a cruciate-deficient knee to actively sublux the proximal tibia (more than 10mm)

Gurtler, JS Torg, Dr. John Lachman's colleagues published Dr. Lachman's findings.



#### Anterior drawer test:

The patient should be supine with the hips flexed to 45 degrees, the knees flexed to 90 degrees and the feet flat on table(22). In this position, it is noted that the medial tibial plateau is 1cm anterior to the medial femoral condyle in the normal knee. The examiner sits on the examination table by the patient and over the foot, in front of the involved knee. Both the hands grasp the tibia with both the thumbs just below the joint line of on either side of the patellar tendon. Both the index fingers are placed over the back of the knee to ensure that the hamstrings are relaxed. The tibia is then drawn forward anteriorly. An increase in the amount of anterior tibial translation compared with the opposite limb or lack of a firm end-point may indicate either a sprain of the anteromedial bundle or complete tear of the ACL. The anterior drawer test is done after ruling out a sag sign in the proximal tibia.



Anterior drawer is graded as

Grade 0- drawer same as compared to the opposite knee.

Grade I- proprioceptive appreciation of a positive test,  $1/3^{rd}$  anterior translation compared to the opposite knee. (3-5mm)

Grade II- visible anterior translation of the tibia, $2/3^{rd}$  anterior translation compared to the opposite normal knee. (5-10mm)

Grade III- passive subluxation of the tibia with the patient supine and gross subluxation compared to the opposite knee. (>10mm)

#### **Pivot shift test of Macintosh:**

The patient is supine with the leg extended, and the examiner stands on the affected side of the patient(23). The examiner places the hand (which is toward the head of the patient), over the lateral aspect of the proximal tibia and fibula. The other hand grasp the ankle and internally rotates the foot and make sure that the knee is in starting position of full extension .The knee is subluxed in an anterior cruciate deficient knee. A valgus stress is applied following which the knee is gradually flexed. The knee relocates with a clunk at about 30 degree knee flexion. Reduction is due to the pull of the iliotibial band when its line of pull changes from anterior to posterior to the knee and due to the convexity of the lateral tibial condyle

Grade I: 'glide', when the tibia is held in maximal medial rotation, there is an abnormal movement that can be felt as a small and gentle sliding reduction. This glide does not occur in neutral or lateral rotation. A grade I knee is the result of residual laxity after reconstruction or partial cruciate injury. The result is an instability which is mainly anterolateral.

Grade II: 'clunk', when the tibia is in the medially rotated position and there is an abnormal movement in the neutral position. The test is mostly negative when the tibia is held in a position of definite lateral rotation.

Grade III: 'gross shift', when the tibia is held in neutral or moderate lateral rotation, an abnormal movement with a pronounced clunk takes place.



#### Slocum test:

Slocum reported that more subtle degrees of rotary instability can be detected by this test. The patient is placed in a lateral position with the affected side up. The medial side of the foot is placed on the firm examining table with the knee in full extension. This position eliminates the rotational effects of the hip, internally rotates the tibia on the femur and allows the knee to fall into a valgus position. A thumb is placed on each of the femoral and tibial sides posteriorly, and an index finger is placed across the joint anteriorly. The knee is then pressed gently forward into flexion. A test result is positive if reduction of the subluxed knee occurs as the knee passes the 25- to 45-degree range of flexion.

Grade I- smooth glide

Grade II- sudden palpable glide

Grade III- gross repositioning of the subluxated tibia

Lesser degrees of instability are detected by Slocum's method, which also is not as likely to be painful.



# Single foot hopping test:

The patient is made to hop once to a distance on the affected knee. A patient with a complete ACL tear is unable to do so. Single-legged hop test is also conducted 6 months after ACL reconstruction can predict the likelihood of successful and unsuccessful outcome 1 year after ACL reconstruction. Patients demonstrating less than the 88% cutoff score at 6 months may benefit from targeted training to improve limb symmetry in an attempt to normalize function(25).

#### Diagnosis

#### X-rays:

Bony avulsion of the ACL is ruled out by plain radiograph of the knee. It is also performed together with measurements of the differential anterior translation has been shown to be important for diagnosing ACL injuries. In lateral radiographs, anterior translation of the tibia may be seen in individuals with complete tears, significant translation of the medial and lateral compartments can be seen, while in patients with partial tears, little translation is seen in relation to the normal side.(26)

The Segond fracture due to lateral capsular avulsion may be visualized on an antero-posterior view. Segond fracture occurs in 9-12% of all ACL injuries(27). This is an avulsion fracture of the lateral tibial plateau, located near the joint line and lateral to the Gerdy tubercle. The Segond fracture represents an avulsion of the anterolateral ligament of the knee(28). Segond fracture is direct evidence of a lateral capsule injury and indirect sign of an ACL injury.





The lateral notch fracture is located in the lateral femoral condyle. The likely mechanism is a hyperextension or impaction injury with a collision of the femoral condyle and the anterior tibial plateau during the rotational movement responsible for injuring the ACL, most commonly the pivot-shift. This type of fractures is most commonly seen in chronic ACL-deficient knees. The physician must differentiate lateral notch fractures from osteochondral defects.

#### Magnetic resonance:

*In* spite of all the technological development that has taken place, it is still difficult to diagnose partial ACL tears. The imaging slices of 3mm are necessary in order to make a distinction between complete and partial tears using a 3 Tesla MRI. Van Dyck et al.(29) suggested that certain axial and perpendicular views would be more accurate in making diagnoses based on 3T magnetic resonance imaging.

The signs on an MRI are categorized into primary and secondary signs.

## **Primary signs:**(30)

increased signal/ hyper intense signal of the ACL fibers on T2 images

#### ACL discontinuity

Change in the course of ACL- ACL angle that is less steep than Blumensaat's line: when drawing a line in the course of a normal ACL on the sagittal image the angle should be steeper than the intercondylar roof, so the apex is pointing posterior. If the line of the ACL is less steep than the intercondylar roof (i.e. the apex of the angle points anteriorly instead of posterior) means that ACL is

completely torn and collapsed. If the angle is normal and there is a hyper intense signal, a partial rupture is more likely than a complete rupture.

Empty notch sign, in case of avulsion of the ACL at the femoral attachment

ACL tears typically occur in the middle portion/ the midsubstance of the ligament and appear as discontinuity of the ligament or abnormal contour. If the angle is still normal and there is a hyper-intense signal, a partial rupture is more likely than a complete rupture(30).

#### **Secondary signs**(31)

bone contusion in lateral femoral condyle and posterolateral tibial plateau (at the origin and insertion of the ACL

>7 mm of anterior tibial translation

uncovered posterior horn of the lateral meniscus

Reduced PCL angle due to buckling of PCL, the PCL looks like a J shaped structure. This is also called unfolding of the PCL.

positive PCL line sign(31)

#### Arthroscopic evaluation

Arthroscopic evaluation has been proposed by some authors for diagnosing partial tears, however, in the light of the current knowledge; there is no indication for routine

arthroscopic evaluations for diagnosing such injuries. Arthroscopy makes it possible to diagnose the type of partial tear and, together with the clinical and imaging examinations; it determines the best type of reconstruction needed in cases if surgical treatment is indicated.

#### Treatment

The treatment needs to be appropriate and individualized for each patient's needs. Identifying patients with high and low risk of progression of the clinical deficiency of the ACL is fundamental for providing therapeutic guidance. Low-risk patients are the ones with low physical demands, without complaints of instability or associated injuries, whose clinical tests are negative. These patients' symptoms and signs generally tend not to progress and can be treated conservatively(26). High-risk patients are the ones with proven clinical instability and lifestyles that present a high risk of new torsion injury. In these cases, the best option would be to perform surgical reconstruction of the ACL(32). The treatment strategy needs to take into consideration the symptoms, clinical examination, percentage of fibers remaining, associated injuries, length of time since the injury and daily physical work demands.

#### **Conservative treatment**

Conservative treatment includes immobilization using a knee brace for a period of 4-6 weeks while the patient remains symptomatic. The individual is advised to use

crutches and protected weight bearing for 2 weeks. After 2 weeks once the acute inflammation subsides, stimulation of complete movement and muscle strengthening is started. He is asked to slowly weight bear as tolerated with the knee brace till symptoms subside(26). The aim of treatment is ensure the return to full range of movement by 6 weeks . The principles of rehabilitation for patients with partial tears are the same as those for patients with complete tears. This rehabilitation consists of exercises for muscle strengthening and stretching and cardiovascular, proprioceptive and adaptive training. Pujol et al.(33) Demonstrated that partial ACL tears may have the capacity to heal in terms of clinical findings like pain, instability and laxity, but radiological healing may not happen.

Conservative treatment produces good results when indicated correctly, with minimal reduction of activity level and without impairing stability(32). Other authors have suggested that partial tears are functionally equivalent to complete ACL tears and that conservative treatment would imply worse clinical and functional results. Pujol et al(33), described a series in which 25% of the patients with partial ACL tears evolved with functional instability over a medium to long term. Serial assessments would be necessary in order to monitor the rehabilitation and residual laxity, which thus would enable evaluation of whether conservative treatment should be maintained or whether it should be changed over to a surgical approach(34).

34

#### Surgical treatment

On a 11 year follow up of patients with 'complete' ACL rupture, non-operative treatment resulted in poor and fair functional outcome scores that prevented a return to pre-injury activities in the majority of patients, as well as an increased incidence of secondary ACL surgery, meniscus surgery and osteoarthritis knee(35).

- a. Aperture and suspensory fixation
- b. Tunnel widening
- c. Type of grafts
- d. Surgical technique

Anterior cruciate ligament (ACL) reconstruction with hamstring tendon autograft has become a popular choice among orthopedic surgeons(36,37). Previous studies have shown that a hamstring graft is superior or equivalent to a bone–patellar tendon–bone (BPTB) autograft(38,39).Advantages of hamstring grafts include less donor site morbidity, less kneeling pain, less quadriceps weakness and fewer sensory deficits associated with graft harvest(40). Although there is a clear trend toward the increased use of hamstring tendon autograft, the best fixation method for this soft tissue graft is still being debated by orthopedic surgeons worldwide.

In general, soft tissue graft fixation can be classified as suspensory or aperture based on the location of the fixation point and the method of securing the graft. Multiple studies have found no significant difference between suspensory fixation and aperture fixation. In this study we are combining aperture and suspensory fixation. Graft fixation should be (41)

Strong enough to avoid failure of the graft or the fixation.

Stiff enough to restore load displacement and allow biological

incorporation of the graft into the bone tunnels.

Secure enough to resist slippage under cyclic loading (during the first 1 to 2 months when conversion from mechanical to biologic fixation occurs )



Image shows black circles where grafts are fixed . Left- aperture fixation, Right-Suspensory fixation

If the graft was fixed at the cortex it called suspensory fixation and if was fixed

near the joint it is called aperture fixation.

## a. Aperture fixation
In aperture fixation a headless screw is used to fix the graft, where the threads of the screw engage the graft and the cancellous bone. It is maintained by friction and interference fit between the graft and the tunnel wall (cancellous bone). These screws are called interference screws. Interference screws are commonly used for fixation of both soft tissue (hamstring) and BPTB grafts in ACL reconstruction, but unlike in BPTB grafts in which fixation is applied to the bone, in soft tissue/hamstring grafts, the threads of the interference screws engage the graft.

Currently, two types of interference screw technologies are used: metallic and bioabsorbable. Metallic screws are used because of their strength, longevity and are used while fixing bone patellar tendon bone grafts(42). But metal screws are not recommended while using hamstring grafts. Bio-absorbable screws are more commonly used as they damage the graft less, and they create fewer artifacts on magnetic resonance imaging (MRI) and computed tomography (CT) than metal screws, allowing clinicians to assess the anterior cruciate ligament (ACL)–reconstructed knee for subsequent injury and to plan revision surgery if required.

One of the common problems with the interference screws was slippage of the graft. It was proposed that metal screws resisted graft slippage than bio-absorbable, but biomechanical studies show that bio-absorbable screws equally prevented graft slippage compared to metal screws(41)

Metals screws were the first generation. Second generation was PLLA (poly- Llactic acid) bio-absorbable interference screws. Third generation were the HA (hydroxylapatite) coated PLLA bio-absorbable screws(43). The fourth generation are the poly-D,L-

37

lactide-tricalcium phosphate(PLLA-TCP) and calcium sulphate composite or polyglycolic acid (PGA-TCP and calcium sulphate).

When a bio-absorbable implant is placed into bone, it becomes surrounded by a fibrous layer, followed by a nonspecific response from fibroblasts, macrophages, polymorphonuclear leukocytes and multinucleated giant cells, which resorb bone(43,44). Hydrolysis then breaks down these polymers, resulting in an accumulation of breakdown products (glycolic acid, lactic acid)(45). These breakdown products create a locally acidic environment, lowering the pH around the screw, which inhibits bone formation and stimulates resorption(46). The presence of a fibrous layer may hinder bone in-growth around the screw. The newer screws are coming with a hydroxyl-appetite composite and show better bone formation around the screw(47)

The length of the screw did not affect displacement, load to failure and stiffness (porcine ) between interference screws of length 12.5, 15 and 20 mm(48,49). It is preferred to use 9mm diameter screws on both the tibial and femoral sides than a smaller 7mm screws(49).

Thus interference screws are relatively easy to use, provide aperture fixation, excellent stiffness, minimal slippage after cycling.

#### **Suspensory fixation**

Suspensory fixation can be classified into cortical and cancellous. Cortical fixation includes endobutton, tight rope, rigid loop, staples, screws and washers. Cancellous fixations include transfixation pins.

Endobutton is a first generation type cortical fixation. The initial endobutton technique used a polyester tape that needed to be tied at the desired length before



insertion into the tunnel(50). However, biomechanical studies showed slippage of the polyester tape by 2 to 4 mm so they changed over to closed loop polyester tape(50). The second generation used an adjustable tight rope or a rigid loop in which knot has to be tied after the endobutton is inserted and flipped.



#### b. Tunnel widening

There are 2 types of graft motion which causes tunnel widening

### Bungee effect

#### Windshield wiper effect

**Bungee effect-**This phenomenon of the "bungee cord effect"(51) leads to secondary to longitudinal graft motion, which may reduce stability and construct stiffness and also lead to tunnel widening.

In the ACL reconstruction surgery, soft tissue grafts are commonly fixed with suspensory devices (a rope with a loop) on the end of the graft that is suspended outside the cortical bone. These devices are less stiff than interference screws, but avoid disruption of the insertion of the ACL graft. However, a micro-motion of the graft inside the bone tunnel in a longitudinal (up and down) fashion causes widening of the tunnel. With "poor fitting" oversized tunnels, there is potential for graft motion or a bungee cord effect along with the seepage of synovial fluid into the tunnel from the sides. This is called "Bungee effect"(52,53).

*Wind shield wiper effect*- There was tunnel widening around the graft due to far points of fixation of the graft and was noted and reported by L'Insalata et al(54). Tunnel expansion was significantly greater following ACL reconstruction using HS (hamstring) autograft than in those using BPTB (bone patellar tendon bone)autograft. He noted that thought the tunnel in a hamstring tendon fixation was of same size of the graft (as hamstring graft was of uniform diameter) the tunnel widening was more than using a BPTB graft which was not of a uniform diameter. This is because the points of fixation

40

for the hamstring grafts are at a greater distance from the normal insertion site of the normal ACL and biomechanical point of action of the normal ACL than the points of fixation for BPTB grafts. It is suggested that this greater distance creates a potentially larger force moment during graft cycling which may lead to greater expansion of bone tunnels.

Webster et al stated that the bone tunnel widening stabilized after the first few weeks to months, possibility indicating graft-tunnel incorporation(14). The longer the time for graft-tunnel incorporation resulted in more time available for graft-tunnel micro-motion. Thus Morgan et al claimed that aperture fixation of the tibial and femoral side tunnels may prevent bone tunnel enlargement(55).

c.	Types	of	Grafts
<b>U</b> .	Types	<b>UI</b>	Ulans

	Patellar tendon	Hamstrings
Advantages	<ul> <li>Higher strength</li> <li>Lower re-tear rate</li> <li>Earlier graft remodeling and healing</li> <li>Better knee stability</li> </ul>	<ul> <li>Smaller incision/better cosmesis</li> <li>Minor functional impairment from graft harvesting</li> <li>Earlier regeneration of hamstrings</li> </ul>
Disadvantages	<ul> <li>Higher incidence of anterior knee pain and kneeling pain</li> <li>Increased incidence of OA post-ACL reconstruction</li> <li>Higher rate knee extension deficit due to adhesions</li> </ul>	<ul> <li>Higher incidence of tunnel widening</li> <li>Electromechanical delay in knee flexors/weakness</li> </ul>

OA, osteoarthritis; ACL, anterior cruciate ligament

### Advantages of the patellar tendon graft

Both patellar tendon and hamstring grafts used in ACL reconstruction exceed the biomechanical strength and stiffness of native ACL and this has been proven to be safe approach in an attempt to eliminate the risk of graft tear(56). The use of multiple stands resulted in doubling of the maximum load and stiffness for both semitendinosus and gracilis tendons.

The graft fixation is also an important aspect of surgical failure. It is suggested that, depending on the graft going to be used, the type of fixation should be adjusted accordingly. Specifically, it was found that interference screw offer the maximum load and stiffness properties for PT grafts, resembling those of native ACL. This is extremely important since PT graft is suggested to promote graft healing and remodeling due to the presence of the bone plug. In a recent long-term RCT with follow- up at 15 years, suggesting that a higher percentage of patients reconstructed with PT graft participated in sports-related activities (p = 0.05)(57,58).

## Disadvantages of patellar tendon graft

Patellar tendon is associated with a higher incidence of anterior knee pain and kneeling pain. A recent metaanalysis of 12 studies, with data from 850 patients, showed a significantly higher incidence of anterior knee pain and kneeling pain in PT patients(59). The disadvantages with PT grafts include anterior knee pain , pain during kneeling as well as reported increased incidence of osteoarthritis reported when compared with hamstring grafts (45% *versus* 14% respectively)(60). This was confirmed in a meta-analysis of studies with more than five-year follow-up, where patellar graft was associated with higher incidence of radiographic osteoarthritis(61).

### Advantages of hamstring tendon

The main advantage of the hamstring tendon graft is that it has lower donor site morbidity associated with its harvesting. Hamstring harvesting might be a technically challenging technique, but it causes a smaller incision which results in better cosmetic appearance of the wound, an outcome that may be important in young female patients. It causes significantly less anterior knee pain and less incidence of kneeling pain, as described above(62,63). Complications associated with hamstring graft are rather minor (for example, electromechanical delay in knee flexors and weakness) and are not proven to cause any functional impairment(64,65). Interestingly, most reports suggest a regeneration of hamstrings within two years of surgery, while patellar tendon reconstitution may be a more prolonged process.(64)

### Disadvantages of hamstring tendon

Tunnel widening is reported more frequently with the use of hamstring grafts. This was against the initial belief that, since hamstring graft fills the drilled tunnels completely, it would be associated with lesser tunnel widening. It was found that tunnel increase was approximately double compared with patellar tendon graft (~20% *versus*~10% and 25% *versus* 15% increase in tibial tunnel increase for anteroposterior and lateral views. Three randomized controlled studies showed a higher percentage of tunnel widening on the femoral side in patients treated with hamstring graft(66,67); however, only one of them reported significantly higher knee laxity in the 402 hamstring group(66). Compaction of an autologous bone dowel into the tibial tunnel was shown to reduce the cross-sectional area of the tibial side tunnel and prevent tunnel expansion in approximately 90% of patients after one to two years post-period(68).

J. Dargel et al.: Biomechanics of the anterior cruciate ligament

Table 2 Biomechanical data on graft material and fixation devices currently used in ACL reconstruction

	Fixation technique	Ultimate failure load [N]	Stiffness [N/mm]	Reference
Intact ACL		2160±157	242±28	[33]
Quadrupled hamstring tendon graft		4140±n.n.	807±n.n.	[26]
Tibial	Interference screw Suture/post Washer (20 mm)	776±155 830±187 930±323	226±56 60±14 126±28	[96] [96] [96]
Femoral	Interference screw (b) Interference screw (b) Interference screw (t) Interference screw (t) Cross-pin Endobutton Transfix	507±93 621±139 419±77 774±154 737±140 864±164 746±119	58±14 76±20 40±11 80±15	[91] [104] [99] [104] [108] [108] [108]
Patellar tendon-bone graft		2376±151		[94]
Tibial	Interference screw (b)	718±219	46±5	[104]
Femoral	Interference screw (b) Interference screw (b) Interference screw (t) Press-fit Cross-pin	707±169 702±168 681±146 571±109 639±156	115±26 190±78 107±25 125±29 226±63	[106] [107] [106] [106] [107]

# Published by Dargel et al(53)

The quadrupled hamstring graft has proven biomechanical advantages as reported and hence being use widely for ACL reconstruction. We have been using the quadrupled graft in our unit for the past 10 years.

## d. Surgical technique

L'Insalata et al described use of cortical fixation when he used a hamstring graft and aperture fixation when he used patellar tendon bone graft(54).



Figure 1: Hamstring graft fixation using cortical fixation

We routinely use quadrupled hamstring grafts for ACL reconstruction. We were using suspensory fixation routinely in our unit for the femoral fixation till early 2017 following which we changed our practice to using aperture fixation to augment the femoral tunnel.

#### Measuring bone tunnel widening

Tunnel widening is a frequently encountered phenomenon following ACL reconstruction. A variety of different algorithm of measuring the tunnel widening using x-ray, CT scan and MRI has been described. X-ray measurement consist of weight bearing anteroposterior and lateral views of the knee(69,70). In the last decade CT and MRI has been increasingly used for the evaluation of tunnel widening, as these promise higher accuracy and lower inter and intra-observer variability(70,71).

Fauno and Kaalund measured femoral tunnel width 1cm above the femoral tunnel aperture and tibial tunnel 1cm below the joint surface(72). Peyrache at al measured both the tibial and femoral tunnels at 3 different heights(11). Nebelung at al measured both the tunnel width at both ends of the tunnel(73).

Fink et al measured 5 levels of the tunnel on CT scans(74).

A recent 2018 meta-analysis of femoral tunnel widening in ACL reconstruction using antero-medial portal by Ra et al(75)was **3.5 mm, 95% CI 0.8–6.3 mm.** We measured and compared immediate post operative x-rays and x-rays at follow up. We also did a CT at follow up to corroborate the x-ray findings, however there was no immediate post operative CT to compare the findings.

#### **MATERIALS AND METHODS**

### Study design

Case control study: To investigate the difference in tunnel widening on the femoral side in ACL fixation between two groups, one group with suspensory fixation only and the other with a combination of suspensory fixation and aperture fixation. The other objective was to assess the clinical difference in terms of functional outcome between these groups using Lysholm and IKDC scores. Patients from both the groups were evaluated.

#### Location

Orthopedic out-patient department (OPD) unit II of Christian Medical College (CMC), Vellore

### Recruitment

Patients who underwent ACL surgery from January 2016 to March 2018 were recruited. Both the group of patients were asked to follow up at 6 months but some didn't hence they were contacted by phone, e-mail or registered post. The initial recruitment period was from October 2016 to March 2018 and the period was extended 6 months retrospectively to January 2106 as many patients failed to turn-up after they were asked to come for review. The study was approved by the institutional review board(IRB).

## Sample size

Historical data collection and pub-med search was done. The sample size was calculated with statistical input from the following reference article "*Bone Tunnel Enlargement After Anterior Cruciate Ligament Reconstruction With Semitendinosus Tendon Using Endobutton Fixation on the Femoral Side* ". The sample size was calculated using nMaster software version 2.0.

Formula:

$$n = \frac{Z_{1-\alpha_{2}}^{2} p(1-p)}{d^{2}}$$

Where,

p : Expected proportion

d : Absolute precision

 $1 - \alpha/2$ : Desired Confidence level

With 72% of expected proportion of the femoral tunnel widening, 10 % precision and 95 % desired confidence level, the study requires totally 77 subjects for prospective arm. As we might not be able to get adequate sample size of 77 in 2 years, we expected a minimum of 30, as 30 is required for making a normal distribution curve.

### **Inclusion criteria**

Patients who underwent ACL reconstruction with suspensory fixation (rigid loop or endobutton) only on the femoral side.

Patients who underwent suspensory and aperture fixation on the femoral side. Patients who had a bioscrew and a screw post for suture anchor on the tibial side. Patient who consented for the study

### **Exclusion criteria**

Patients who underwent revision ACL reconstruction

Patients who had bone staples on the tibial side instead of screw post were excluded.

## Methodology

Informed consent was taken from all the patients. Both the group of patients were asked to follow up 6 months as routine. Patients who did not come for follow up at 6 months in both the groups were contacted by phone, e-mail and through registered post. They underwent plain radiograph, anteroposterior and lateral view of the knee and CT scan of the knee at follow up. X rays were done as a part of their routine follow up and CT scans were done as a part of the study from the fluid grant. Height and weight of the patient were measured in a standardized fashion. CT scan machine used was General Electronics- Discovery 750 helical CT. Both the patients IKDC scoring and Lysholm scoring was done. A single leg hop test was also performed.

CT scan measurements, for the study was done by an experienced radiologist who was blinded to the different types of ACL graft fixation. The tunnels were measured after reconstruction of the tunnel in the oblique coronal and saggital planes, which was standardized for all patients. X rays were measured by the principal investigator with the radiologist. The initial tunnel diameter was measured from the immediate post operative x-rays. The follow up measurements to look for tunnel widening were done from the follow up x-ray. A CT scan was also done to corroborate the follow up x-ray findings. There was no immediate post operative CT scan.

### **Tunnel measurements**

CT scans were taken with 2.5mm slice cuts. Axial, saggital and coronal images were taken and 3D reconstruction was done. The femoral and tibial tunnels were reconstructed in the axis of the tunnel in the coronal-saggital plane.



Figure 1: Femur-- Left- anteroposterior reconstruction, right- lateral reconstruction

Femoral side- On the femoral side the diameter of the tunnel was measured at 5 different points; A,B,C,D and E which were equidistant from each other.



Figure 2: Tibia-- Left- anteroposterior reconstruction, right- lateral reconstruction

Tibial side- On the tibial side the diameter of the tunnel were also measured at 5 different points; F, G, H, I and J which were equidistant from each other(74).



X-ray measurements were also done in the same points but for the study purpose only points D and E were quoted as mentioned by the other authors(75).

Data analysis was done using SPSS 21.0. Mean and standard deviation was used to describe continuous variables, while frequency and percentages were obtained for categorical data. The chi square test and the student t test were employed to study the statistical significance of categorical and continuous variables respectively.

# **ANALYSIS AND RESULTS**

A total of 48 patients were included in the study.

Group 1: On the endobutton only group 15 patients reported.

Group 2: On the endobutton + screw fixation group 33 were taken.

## **Table 1: Age distribution**

	Frequency	Percent
Male	45	93.8
Female	3	6.3
Total	48	100.0

Out of the 48 injured 3(6.3%) were women and 45(93.8%) were men.

In Endobutton group- there was 1 female

Endobutton & screw group- there were 2 females

Table 2: Mean follow up after surgery



	In months mean± SD(range in months)
Endobutton group	21.33 ± 11.14 ( )
Endobutton & screw group	9.12 ± 3.83 ()

The interval from surgery to follow up was longer in the endobutton group. This was due to the time of assessment, which was done only when the patient had visited the hospital for follow up.





Majority of the patients (72.9%) presented within 2 years of injury,

- 17 patients (35.4%) presented within 6 months of injury
- 7 patients (14.6%) presented between 6 to 12 months
- 11 patients (22.9%) presented between 12 to 24 months
- 9 patients (18.8%) presented between 2 yrs to 5 years

Some patients even presented after 5 years (8.4%)

On an average, review since injury in both the groups was (mean  $31.23 \pm 50.48$  SD)

## months

# **Table 4: Presentation since injury**



In the Endobutton group8 patients (53%) presented within 6 months of injury On an average, review since injury was (mean  $10.33 \pm 9.55$  SD) months Endobutton & screw group mean presentation since injury was  $40.73 \pm 58.36$ months. They presented quite late since the time of injury. Table 5: Mechanism of injury



4 patients (8.3%) were slip and fall at home (out of which 2 were females)

26 patients (54.2%) of the injuries were sports related

14 patients (29.2%) were during road traffic accidents

4 patients (8.3%) were injuries at work

# Table 6: Type of injury



Both twising injury and contact injuries were almost equal in number but twising injury was more commonly associated with ACL injuries

- 27 patients (56%) of the injuries were due to twisting type
- 21 patients (44%) of the injuries were due to direct contact





Sports related injuries were majority twisting type 76.92%

In RTA majority of the injury was contact type 92.86%

# Table 8: Mechanism of injury - side of injury



In slip and fall 75% involved the left knee

In sports left and right knees were equally involved (50% on both sides)

In RTA right knee (85.71%) was more involved, as the oncoming vehicle is from the right side

In work related injury 75% injuries were on the left knee

Table 9: BMI comparison at review



In the endobutton group, 1 patient (6.67%) was underweight, 4 patients (26.6%) were of normal weight,6 patients (40%) were of overweight, and 4 patients(26.6%) were obese, mean BMI was  $26.90 \pm 4.41$  SD Majority of the Endobutton & screw group were of normal weight 18 patients (54.5%), 12 patients (27.9%) were overweight, 3 patients (9.09%) were obese. Mean BMI was  $25.47 \pm 2.91$  SD

The average BMI between both the groups was  $25.92 \pm 3.46$  (mean  $\pm$  SD)

# **Table 10: Generalized ligamentous laxity**



There were 4 patients with generalized ligamentous laxity in the endobutton group and 5 patients in the endobutton & screw group.





There were totally 9 patients with generalized hyper-laxity

Out of which 7 patients (77.8%) had grade I laxity and 2 patients (22.2%) had

grade II laxity, no one had grade III laxity

Out of the patients who had no generalized laxity, 14 patients (35.9%) had grade 0 laxity and 25 patients (61.5%) had grade I laxity and 1 patient (2.6%) had grade II laxity.



Table 12: Generalized laxity and anterior drawer- group wise

In endobutton group among the normal patients majority had grade I anterior

drawer - 10 patients (66.7%), 1 patient had grade 0 drawer

Among the endobutton and screw group patients, 13 patients (39.4%) had grade 0 drawer and 14 patients (42.4%) had grade I drawer.

In both endobutton and endobutton & screw group the drawer percentage was equal in the hyper-laxity group

## Table 13: Anterior drawer- group wise

Anterior drawer was measured as mentioned in review of literature

In the endobutton & screw group the anterior drawer had reduced compared to the endobutton only group.

Endobutton group- grade 0- 6.7%, grade I- 86.7%, grade II- 6.7%

Endobutton & screw group- grade 0- 39.4%, grade I- 54.5%, grade II- 6.1%

Grade II laxity was found in patients with hyper-laxity

group		Frequency	Percent
Endobutton only	Grade 0	1	6.7
	Grade I	13	86.7
	Grade II	1	6.7
	Total	15	100.0
Endobutton + screw	Grade 0	13	39.4
	Grade I	18	54.5
	Grade II	2	6.1
	Total	33	100.0

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	5.441 <sup>ª</sup>	2	.066
Likelihood Ratio	6.435	2	.040
Linear-by-Linear Association	3.719	1	.054

## Table 14: Lachman - group wise distribution

Lachman was measured as mentioned in review of literature

Lachman was reduced in endobutton & screw group – grade 0- 27.3%, grade I- 66.7%, grade II -6.1%

In endobutton group lachman was more pronounced- grade 0- 6.7%, grade I – 80%, grade II- 13.3%

Group		Frequency	Percen	ıt	Valid Perc	ent	Cumulative Percent
Endobutton only	Grade 0	1		6.7		6.7	6.7
	Grade I	12		80.0		80.0	86.7
	Grade II	2		13.3		13.3	100.0
	Total	15	1	00.0		100.0	
Endobutton + screw	Grade 0	9		27.3		27.3	27.3
	Grade I	22		66.7		66.7	93.9
	Grade II	2		6.1		6.1	100.0
	Total	33	1	00.0		100.0	
		V	/alue		df	Asyn	nptotic Significance (2-sided)
Pearson Chi-Square			3.015 <sup>ª</sup>		2		.221
Likelihood Ratio			3.429		2	.180	
Linear-by-Linear Association			2.843		1		.092
N of Valid Cases			48				

## **Table 15: Donor site pathology**



Out of the 48 patients in the study, 39 patients had no donor site pathology, 4 had tenderness at the screw post, 4 patients had numbress in the harvest site and lateral to the harvest site, 1 patient had a hypertrophic scar.

## Lysholm score

Lysholm grading

Poor <64

Fair 65-83

Good 84-94

Excellent 95-100

Endobutton group:

< 7 months- 83.5  $\pm$  0.71 (mean  $\pm$  SD)

>7 months- 94.69 ± 4.80 (mean ± SD)

7 months was chosen as patients didn't start running nor squatted till after 7 months (till their 1<sup>st</sup> follow up).

Endobutton & screw group:

< 7 months-  $87.86 \pm 8.73$  (mean  $\pm$  SD)

>7 months- 92.55  $\pm$  7.11 (mean  $\pm$  SD)

Endobutton & screw group had a better Lysholm scores while compared to the endobutton only group.

# **IKDC** scores

## Endobutton group

< 7 months- 59.2 ± 18.67 (mean ± SD)

>7 months-  $83.39 \pm 8.18$  (mean  $\pm$  SD)

In Endobutton & screw group

 $< 7 \text{ months-} 64.53 \pm 14.58 \text{ (mean} \pm \text{SD)}$ 

>7 months-75.87 ± 11.16 (mean ± SD)





There was effusion in 1 patient, patellar tap was positive in the endobutton group



There was effusion in 1 patient, patellar tap was positive in the endobutton & screw group

## Table 17: hop test

group		Frequency	Percent	Valid Percent	Cumulative Percent
Endobutton	1 (100-90)	4	26.7	26.7	26.7
	2 (89-76)	8	53.3	53.3	80.0
	3 (75-50)	2	13.3	13.3	93.3
	4 (50-0)	1	6.7	6.7	100.0
	Total	15	100.0	100.0	
Endobutton & screw	1 (100-90)	10	30.3	30.3	30.3
	2 (89-76)	12	36.4	36.4	66.7
	3 (75-50)	7	21.2	21.2	87.9
	4 (50-0)	4	12.1	12.1	100.0
	Total	33	100.0	100.0	

In the single leg hop test both the groups had comparable results. Majority of the patients had grade II - 89-76% in both the groups, probably as they were restricted from running or hopping till the 6 month.
# Tunnel widening

Tunnel diameters from CT scan were measured by an experienced radiologist and x-ray diameters were measured by the principal investigator.

Table	18:	Endobutton	group	- Points D	. E	measurements
IUNIC	<b>TO</b> .	LIIGONGLUOII	Pi AMA			incusurence inclus

Endobutton	Immediate post op x-ray measurement (n=15)		
Group	AP (mean $\pm$ SD) mm, range	Lateral(mean $\pm$ SD) mm, range	
D	$7.10 \pm 0.63$ (6.0-8.1)	$7.09 \pm 0.60 \ (6.1 - 8.0)$	
Е	$7.16 \pm 0.61 \ (6.2-8.1)$	$7.17 \pm 0.62$ (6.2-8.2)	

Endobutton	X-ray measurement at review (n=15)		
Group	AP (mean $\pm$ SD) mm, range	Lateral(mean $\pm$ SD) mm, range	
D	8.64 ± 1.46 (6.0-11.7)	8.88 ± 1.45 (6.4-12.0)	
Е	8.69 ± 1.21 (6.5-11.0)	8.81 ± 1.19 (6.5-11.0)	

Endobutton	CT measurement at review (n=15)		
Group	AP (mean $\pm$ SD) mm, range	Lateral(mean $\pm$ SD) mm, range	
D	8.65 ± 1.55 (5.8-12)	8.41 ± 1.40 (5.7-11.4)	
Е	8.60 ± 1.32 (6.0-11.0)	8.33 ± 1.22 (6.0-10.7)	

The initial tunnel diameter was measured from the immediate post operative x-ray, the follow up measurements to look for tunnel widening were done from the follow up x-ray and CT scan

Endobutton	Immediate post op x-ray measurement (n= 33)AP (mean $\pm$ SD) mm, rangeLateral(mean $\pm$ SD) mm, range		
& screw			
D	$9.01 \pm 0.51 \ (7.5 - 9.8)$	8.83 ± 0.55 (7.5-9.8)	
Е	9.17 ± 0.49 (8.0-9.7)	9.11 ± 0.54 (8.0-10.0)	

Table 19: Endobutton &	screw group	- points D, E	measurements
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Endobutton	X-ray measurement at review (n= 33)		
& screw	AP (mean $\pm$ SD) mm, range	Lateral(mean $\pm$ SD) mm, range	
D	$9.75 \pm 0.98 \ (9.8-11.0)$	$9.83 \pm 0.97 \ (9.6-11.2)$	
Е	$10.42 \pm 1.02 \ (9.7-11.0)$	$10.21 \pm 1.07 (9.4-11.2)$	

Endobutton	CT measurement at review (n= 33)		
& screw	AP (mean $\pm$ SD) mm, range	Lateral(mean $\pm$ SD) mm, range	
D	9.27 ± 1.06 (7.2-11.4)	9.37 ± 1.04 (7.5-11.5)	
Е	$10.08 \pm 1.04$ (8.0-12.0)	9.95 ± 1.09 (8.0-11.7)	

## Table 20: Tunnel widening

Endobutton	X-ray	
	AP (mean $\pm$ SD) mm, range	Lateral(mean $\pm$ SD) mm, range
D	$1.54 \pm 1.48$	$1.79 \pm 1.47$
Е	$1.53 \pm 1.30$	$1.65 \pm 1.29$

Endobutton & screw			
	AP (mean $\pm$ SD) mm, range	Lateral(mean $\pm$ SD) mm, range	
D	$0.74 \pm 1.05$	$1.01 \pm 1.04$	
Е	$1.25 \pm 1.10$	$1.09 \pm 0.98$	

Tunnel widening was measured as difference between immediate post op x-ray and x-ray at follow up both in the anteroposterior and lateral views. Follow up CT scan measurements were similar to the follow up x-ray measurements. There was no CT at post op period to compare the follow up CT measurements.

## P-value: measured by t-test

	AP- xray	Lateral- xray
D	P - 0.038	P - 0.038
Ε	P- 0.453	P- 0.107

#### DISCUSSION

Tunnel widening in ACL reconstruction is a common problem noted(72). It is seen mostly in suspensory fixation with hamstring grafts more than aperture fixation in bone patellar tendon bone graft(50). Our hypothesis was that anterior cruciate ligament reconstruction with hamstring graft by suspensory fixation causes femoral tunnel widening, but augmentation with an interference screw does not cause tunnel widening at follow up.

There are recent similar studies, published by Porter and Shadbolt in 2016(76), where they did an in vivo study with computer navigation, they added an aperture interference screw fixation to the femoral side in addition to the suspensory endobutton. Their results showed reduced anterior drawer and pivot shift post addition of the interference screw but they did not evaluate the tunnel widening.

The aim in both the studies was to reduce the distance between the fixation points so that graft motion causing 'bungee cord effect' and 'windshield' effect would be reduced. The addition of the interference screw was also to improve the stiffness of the fixation.

The patients in this study were operated by 2 primary surgeons, who work in the same orthopedic unit. They both use the same technique for ACL reconstruction. There was no discrepancy in the type of graft harvesting, tunnel position, graft fixation devices or rehabilitation protocol. In both the groups, patients were admitted 2 days

76

preoperatively, counseled on ACL surgery and rehabilitation protocol. Both the groups underwent preoperative MRI scan to look for any associated meniscal or other intraarticular/ juxta-articular ligament injuries. All the patients were advised to come for an assessment at 6 months after surgery. The time of assessment varied in each group because of the difference in the timing of their follow up visit to this hospital. X-rays were done at their follow up and a CT scan assessment was also done at the time of follow up, but there was no immediate post op CT to compare the findings. There was no difference in rehab protocol between the two groups.

The endobutton with the graft is threaded through the tunnel and appropriate sutures are pulled to ensure flipping of the endobutton after the graft reaches the point marked, and is verified by scopy visualization. The tension on the graft is maintained by pulling the distal strands during cycling of the knee so that the endobutton is flush on the femoral cortex, following which the femoral interference screw is added. The tibial interference screw was inserted while applying a posterior drawer, then the suture screw post was fixed. The interference screw (aperture fixation) was added on the femoral side with the endobutton (suspensory fixation) to add rigidity to the construct and possibly negate the 'windshield wiper effect'. This technique has been performed in our orthopedic unit for the past 2 years.

The Lachman and Drawer test were performed immediately after fixation intra operatively. The study done by Porter et al showed improvement in anterior drawer and pivot shift but tunnel widening was not studied(76).

77

This study consisted of 45 males and 3 females. Other Indian studies published also shows male predominance(18). This is because Indian women participate in lesser pivoting sports like basketball compared to the western population(15).

The follow up of the patient in the Endobutton group was between 8-41 month (mean  $21.33 \pm 11.14$  SD), but the endobutton& screw group was between 6-20 months (mean  $9.12 \pm 3.83$  SD).

ACL injuries related to pivoting sports were double compared to the road traffic accidents in the study. 26 patients (54.2%) of the injuries were sports related and 14 patients (29.2%) were during road traffic accidents. These findings are comparable to the Indian data published in 2012 which had sports related ACL injuries double as that of road traffic accidents(18).

Our Lysholm and IKDC scores were dependent on our regular rehabilitation protocol. Our rehabilitation protocol consisted of wearing a knee brace while walking for 4 weeks in a normal patient and up to 6 weeks in a patient with generalized ligamentous laxity. They were ambulated with crutch support during this period of 4-6 weeks. They were started on quadriceps and hamstring strengthening, active range of movement exercises during this period. Squatting, cycling, jogging and running were delayed till 6 months. Hence patient's who came for their 6 month review, had low Lysholm and IKDC scores. The Lysholm and IKDC scores were comparable between the two groups. Anterior drawer had reduced in the endobutton & screw group 0- 39.4%, grade I-54.5%, grade II- 6.1% as compared to endobutton group who had more of grade I laxity. Endobutton group- grade 0- 6.7%, grade I- 86.7%, grade II- 6.7%. P-value was not significant which could be due to difference in sample size. Lachman had also reduced in the endobutton & screw group but was not statistically significant which also may be attributed to the difference in sample size.

Femoral tunnel widening measured by x-ray in the augmentation group measured at a standard point 'D' in the middle of the tunnel was  $0.74 \pm 1.05$  (AP),  $1.01 \pm 1.04$ (lateral) and in the endobutton only group was  $1.54 \pm 1.48$  (AP) and  $1.79 \pm 1.47$ (lateral), both of which were statistically significant(p-0.038, p-0.038). Tunnel widening at the point 'E' (aperture) in the augmentation group was  $1.25 \pm 1.10$  (AP),  $1.09 \pm 0.98$ (lateral) and in the endobutton only group was  $1.53 \pm 1.30$  (AP),  $1.65 \pm 1.29$  (lateral). This was not statistically significant. The follow up x- ray measurements were similar to the follow up CT measurements.

Tunnel widening on x-ray in the endobutton & screw group at points D and E (aperture) on the femoral side was lesser compared to the endobutton-only group. Tunnel widening was measured as difference between immediate post op x-ray and x-ray at follow up. The CT scan measurements at follow up were similar to the follow up x-ray measurements that were done. There was no CT done at the immediate post op period to compare the follow up CT measurements.

79

This is possibly due to negation of the 'windshield wiper' and the 'bungee cord effect' as the fixation points are brought nearer.

The tunnels were measured at points D and E as quoted in the other similar studies which measured distal femur tunnel widening(77,78).

The advantages of the study were that the patients were operated and were followed up by the same surgeons. The limitations of the studies were that the subjects were not well matched on the follow up period. The x-ray measurements were done by the principal investigator and the radiologist together, CT scan measurements were done independently by radiologist.

## CONCLUSION

Our hypothesis which assumed that tunnel widening would be reduced by the addition of the interference screw on the femoral side in addition to the suspensory fixation contributed to decrease in tunnel widening as well as better functional outcome true. In addition to the radiological improvement, there was also clinical improvement noted in the patients both during immediate post operative period and during their follow up.

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## **ANNEXURES**

Questi	onnaire			
Hospital number		NG IN POST-OP ACL RE		SURGERY
Name: Occupation: Place:	Age	: Date of Birth:	//	Sex: M/F
Height:	Weight:	BMI:		
<u>Details of Injury</u> Date of Injury: Mode of Injury:	a. □ ADL □ Sports b. □ Non-trauma □ Non-traumat	□Road Traffic□Work htic gradual onset □Tra ic sudden onset □Trau	umatic non-cont matic contact on	act onset Iset
Side: Right/ Let Duration of symp Pre-op IKDC score Range of motion:	t toms: in months e:			
<u>Details of Surgery</u> Date of Surgery: Surgery:	L			
Ligament Surgery	,			
🛛 ACL Repair 🗳	Intraarticular ACL r	econstruction		
Graft				
□Ipsilateral □Co	ntralateral			
□Single hamstrir	ng graft 🛛 2 Bu	undle hamstring graft	4 Bundle I	hamstring graft
Femoral tunnel lo Femoral tunnel s Graft length: Endo-button size Femoral screw size Tibial screw size Screw post: X-ray/ CT: Femoral tunnel n	ocation: ize: length: : ze:			

#### LYSHOLM KNEE SCORING SCALE

I. LIMP:

\_\_\_\_ I have no limp when I walk. (5)

\_\_\_\_ I have a slight or periodical limp when I walk. (3)

\_\_\_\_ I have a severe and constant limp when I walk. (0)

II. USING CANE OR CRUTCHES:

\_\_\_ I do not use a cane or crutches. (5)

I use a cane or crutches with some weight-bearing. (2)

\_\_\_\_ Putting weight on my hurt leg is impossible. (0)

#### III. LOCKING SENSATION IN THE KNEE:

- I have no locking and no catching sensations in my knee. (15)
- \_\_\_\_\_ I have catching sensations but no locking sensations in my knee. (10)
- \_\_\_\_ My knee locks occasionally. (6)
- \_\_\_\_ My knee locks frequently. (2)
- \_\_\_\_ My knee feels locked at this moment. (0)

### IV. GIVING WAY SENSATION FROM THE KNEE:

- \_\_\_\_ My knee never gives way. (25)
- \_\_\_\_ My knee rarely gives way only during athletics or other vigorous activities. (20)

\_\_\_\_ My knee frequently gives way during athletics or other vigorous activities and in turn, I am unable to participate in these activities. (15)

- \_\_\_\_ My knee often gives way during daily activities. (5)
- \_\_\_\_ My knee gives way every step I take. (0)

#### V. PAIN:

- \_\_\_\_ I have no pain in my knee. (25)
- \_\_\_\_\_ I have intermittent or slight pain in my knee during vigorous activities. (20)
- \_\_\_\_ I have marked pain in my knee during vigorous activities. (15)
- \_\_\_\_ I have marked pain in my knee during or after walking more than 1 mile. (10)
- \_\_\_\_ I have marked pain in my knee during or after walking less than 1 mile. (5)
- \_\_\_\_ I constant pain in my knee. (0)

#### VI. SWELLING:

- \_\_\_\_ I have no swelling in my knee. (10)
- \_\_\_\_ I have swelling in my knee only after vigorous activities. (6)
- \_\_\_\_\_ I have swelling in my knee after ordinary activities. (2)
- \_\_\_\_ I have swelling constantly in my knee. (0)

#### VII. CLIMBING STAIRS:

- \_\_\_\_ I have no problems climbing stairs. (10)
- \_\_\_\_ I have slight problems climbing stairs. (6)
- \_\_\_\_\_ I can climb stairs only one at a time. (2)
- Climbing stairs is impossible for me. (0)

#### VIII. SQUATTING:

- \_\_\_\_ I have no problems squatting. (5)
- \_\_\_\_ I have slight problems squatting. (4)
- I cannot squat beyond a 90 degree bend in my knee. (2)
- \_\_\_\_ Squatting is impossible because of my knee(s). (0)

## 2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

Your Full Name		
Hospital Number:		
Today's Date:///	Date of Injury:///////	-
Day Month Year	Day Month Year	

## SYMPTOMS\*:

\*Grade symptoms at the highest activity level at which you think you could function without significant symptoms, even if you are not actually performing activities at this level.

1. What is the highest level of activity that you can perform without significant knee pain?

Uvery strenuous activities like jumping or pivoting as in basketball or soccer

Strenuous activities like heavy physical work, skiing or tennis

□ Moderate activities like moderate physical work, running or jogging

Light activities like walking, housework or yard work

Unable to perform any of the above activities due to knee pain

2. During the past 4 weeks, or since your injury, how often have you had pain?

0 1 2 3 4 5 6 7 8 9 10

Never 🖸 🗖 🗖 🗖 🗖 🗖 🗖 🗖 🗖 🗖

Constant

3. If you have pain, how severe is it?

0 1 2 3 4 5 6 7 8 9 10

No pain

Worst pain

Imaginable

4. During the past 4 weeks, or since your injury, how stiff or swollen was your knee?

Not at all
Mildly
Moderately
Very
Extremely

5. What is the highest level of activity you can perform without significant swelling in your knee?

 $\Box$ Very strenuous activities like jumping or pivoting as in basketball or soccer

Strenuous activities like heavy physical work, skiing or tennis

□ Moderate activities like moderate physical work, running or jogging

Light activities like walking, housework, or yard work

Unable to perform any of the above activities due to knee swelling

- 6. During the past 4 weeks, or since your injury, did your knee lock or catch?
  - □Yes □No

7. What is the highest level of activity you can perform without significant giving way in your knee?
Very strenuous activities like jumping or pivoting as in basketball or soccer
Strenuous activities like heavy physical work, skiing or tennis
Moderate activities like moderate physical work, running or jogging

Light activities like walking, housework or yard work

Unable to perform any of the above activities due to giving way of the knee

## **SPORTS ACTIVITIES:**

8. What is the highest level of activity you can participate in on a regular basis?

□Very strenuous activities like jumping or pivoting as in basketball or soccer

Strenuous activities like heavy physical work, skiing or tennis

□Moderate activities like moderate physical work, running or jogging

Light activities like walking, housework or yard work

□Unable to perform any of the above activities due to knee

		Not difficult at all	Minimally difficult	Moderately Difficult	Extremely difficult	Unable to do
a.	Go up stairs					
b.	Go down stairs					
C.	Kneel on the front of your knee					
d.	Squat					
e.	Sit with your knee bent					
f.	Rise from a chair					
g.	Run straight ahead					
h.	Jump and land on your involved leg					
i.	Stop and start quickly					

9. How does your knee affect your ability to:

#### **FUNCTION:**

10. How would you rate the function of your knee on a scale of 0 to 10 with 10 being normal, excellent function and 0 being the inability to perform any of your usual daily activities which may include sports?

 FUNCTION PRIOR TO YOUR KNEE INJURY:

 Cannot perform
 0
 1
 2
 3
 4
 5
 6
 7
 8
 9
 10
 No limitation

 daily activities
 Image: Im

daily activities

in daily activities

				IKDC KNE	E E)	2000 XAMINATION	FO	RM						
Patie	nt Name:				Dat	e of Birth:		<i>.</i>						
Gend	er: :F :M Age:				Dat	Da e of Examinat	ion	Month Year :/						
Gene	ralized Laxity:	: tight		: normal		: lax		Day Month	Ye	ar				
Align	ment:	A obvious v	/aru	s <b>A</b> normal		A obvio	ous	valgus						
Patel	la Position:	P obvious t	oaja	P normal		P obvie	ous	alta						
Patel	la Subluxation/Dislocation:	: centered		: subluxa	ble	: sublu	uxe	d : dislo	cate	ed.				
Rang	e of Motion (Ext/Flex):	Index Side: Opposite Si	de:	passive passive		·;;	_	active_ active_		- <u>;</u> ;				
SEVE	IN GROUPS		F	OUR GRADE	ES	в						*Gre	oup	
			N	ormal	N N	learly lormal	At	onormal	Se Ab	verely	A	в	C	D
1.	Effusion		E	None	E	Mild	E	Moderate	E	Severe	E	E	E	E
2.	Passive Motion Deficit			-30		2 40 50		6 to 100		- 102				
	ALack of flexion		L	0 to 5°	•	6 to 15°	0	16 to 25°	•	>25°	٠	0	a	0
3.	Ligament Examination													
	ΔLachman (25° flex) (134N)			-1 to 2mm	,	3 to 5mm(1*)	)	6 to 10mm(2*)	)	>10mm(3*)				
	ΔLachman (25° flex) manual max Anterior endpoint:		A	-1 to 2mm firm	'	3 to 5mm	, A	6 to 10mm		>10mm				
	ATotal AP Translation (25° flex)			0 to 2mm		3 to 5mm		6 to 10mm		>10mm				
	ΔTotal AP Translation (70° flex)			0 to 2mm		3 to 5mm		6 to 10mm		>10mm				
	ΔPosterior Drawer Test (70° flex) ΔMed Joint Opening (20° flex/val)	us rot)		0 to 2mm		3 to 5mm		6 to 10mm		>10mm				
	ΔLat Joint Opening (20° flex/varu	s rot)		0 to 2mm		3 to 5mm		6 to 10mm		>10mm				
	ΔExternal Rotation Test (30° flex	prone)		<5°	۰	6 to 10°	0	11 to 19°	۰	>20°				
	△External Rotation Test (90° flex	prone)		<5°	•	6 to 10°	°	11 to 19°	•	>20°				
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4.	Compartment Findings						_	crepitation	wit	h				
	∆Crepitus Ant. Compartment		С	none	C	moderate	C	mild pain	C	>mild pain				
	ΔCrepitus Med. Compartment ΔCrepitus Lat. Compartment		C C	none	C C	moderate moderate	C	mild pain mild pain	C C	>mild pain >mild pain				
5.	Harvest Site Pathology		н	none	н	l mild	н	moderate	н	severe				
6.	X-ray Findings													
	Med. Joint Space		м	none	M	mild	M	moderate	M	severe				
	Lat. Joint Space		L	none	L	mild	L	moderate	L	severe				
	Ant. Joint Space (sagittal)		A	none	A	mild	A	moderate	A	severe				
	Post. Joint Space (sagittal)		Ρ	none	P	mild	P	moderate	P	severe				
7.	Functional Test One Leg Hop (% of opposite side	)	0	≥90%	9	89 to 76%	9	75 to 50%	9	<50%				
**Fin	al Evaluation										*	*	*	*

 Group grade: The lowest grade within a group determines the group grade
 Final evaluation: the worst group grade determines the final evaluation for acute and subacute patients. For chronic patients compare preoperative and postoperative evaluations. In a final evaluation only the first 3 groups are evaluated but all groups must be documented. Δ Difference in involved knee compared to normal or what is assumed to be normal.

IKDC COMMITTEE AOSSM: Anderson, A., Bergfeld, J., Boland, A. Dye, S., Feagin, J., Harner, C. Mohtadi, N. Richmond, J. Shelbourne, D., Terry, G. ESSKA: Staubli, H., Hefti, F., Hoher, J., Jacob, R., Mueller, W., Neyret, P. APOSSM: Chan, K., Kurosaka, M.

## Patient information sheet

# **CHRISTIAN MEDICAL COLLEGE VELLORE**

# COMPARISON OF TUNNEL WIDENING AND FUNCTIONAL OUTCOME BETWEEN SUSPENSORY FIXATION AND SUSPENSORY FIXATION AUGMENTED WITH INTERFERENCE SCREW FOR ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION WITH HAMSTRING GRAFT

We request you to join the study on the comparison of tunnel widening in 2 different types of anterior cruciate ligament reconstruction, being conducted at Christian Medical College, Vellore.

1. This study is being conducted in the Department of Orthopaedics - Unit II. The study is being done by Dr. Sam J Daniel, a post graduate student in Orthopaedics, under the guidance of Dr. Anil Oommen, Professor, Department of Orthopaedics-II

## 2. What is the need for this study?

The study aims to find out the result of surgery done for anterior cruciate ligament reconstruction. Since you had undergone surgery here, we invite you to join this study.

# **3.** Can I refuse to participate in this study or withdraw from participating in this study?

You have the full freedom to decide whether or not to participate in this study. If you decide not to participate in this study, it will not affect your treatment at this hospital by any means.

Any new information obtained from this study will be informed to you as and when the study progresses. You have the full freedom to withdraw from participating in this study at any point of time.

The duration of this study is two years. You are required to sign a consent form to be part of this study. You will be undergoing the same physical examination as

being done on all the other patients who underwent the same anterior cruciate ligament reconstruction with an additional X-ray and CT scan in the study.

The doctors conducting this study will have the right to review your medical records at this hospital, as part of this study.

All the expenses of this study will be borne by Christian Medical College, Vellore.

There are no risks to you in being part of this study.

# What is the usefulness of conducting this study?

This study aims to assess the result of putting an extra interference screw along with an Endobutton for fixation of the hamstring graft. This may help in improving the treatment for this in the future.

You will not have any extra financial burdens by being part of this study.

The identity and the details of the patients taking part in this study will be kept confidential among the doctors conducting this study. The identity of the participants will not be revealed when this study is published. The patient can continue to access treatment at this hospital even after the completion of this study.

For any doubts and clarifications regarding this study, contact Dr. Sam J Daniel P.G. Registrar, Department of Orthopaedics Ph: 8870803937 <u>sam.jd47@gmail.com</u>

Dr. Anil Oommen, Professor, Department of Orthopaedics- II. <u>ortho2@cmcvellore.ac.in</u>

## **Informed consent**

## Study Title: Tunnel widening in distal femur after ACL reconstruction

Study Number: \_\_\_\_\_\_
Subject's Initials: \_\_\_\_\_\_ Subject's Name: \_\_\_\_\_\_
Date of Birth / Age: \_\_\_\_\_\_

(i) I confirm that I have read and understood the information sheet dated \_\_\_\_\_\_ for the above study and have had the opportunity to ask questions.

- (ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- (iii) I understand that, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
- (iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
- (v) I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable signatory:

Date: \_\_\_/\_\_\_Signatory's Name: \_\_\_\_\_\_Signature:

Or	
Representative:	
Date://	
Signatory's Name:	
Signature of the Investigator:	
Date://	
Study Investigator's Name:	

Signature or thumb impression of the Witness: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_/\_\_\_\_

Name & Address of the Witness: \_\_\_\_\_

Master sheet

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