Original article

Biomechanical assessment of an alternative method of staple fixation for anchoring the Bone Patellar Tendon Bone graft to the tibia

Matthai Thomas^a, George Vinu M.^a, Rao Anbu S.^a, Oommen Anil T.^a, Korula Ravi J.^a,
Devasahayam Suresh^b, Poonnoose Pradeep M.^{a,*}

^a Department of Orthopaedics, Christian Medical College, Vellore, Tamil Nadu, 632004, India

^b Department of Biomedical Engineering, Christian Medical College, Vellore, Tamil Nadu, 632004, India

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ABSTRACT

Introduction: The Anterior cruciate ligament (ACL) is the most commonly injured ligament around the knee and is best reconstructed with a biological graft. For ideal graft fixation, there should be sufficient initial strength to avoid failure of fixation and sufficient stiffness to restore the stability of the knee and to avoid gradual loosening in the post-operative period.

When considering fixation of Bone Patellar Tendon Bone (BPTB) grafts to the tibia, the interference screw is considered to be the gold standard. As an alternative, we have used of staples and stainless steel (SS) wire to anchor the BPTB graft to the tibia and femur. The aim of this study was to assess the biomechanical efficacy of this fixation technique for anchoring the BPTB graft to the proximal tibia. We used a bovine model to compare three fixation techniques –interference screw, braided polyester sutures tied to a screw post and SS wire tied to a staple.

Materials and methods: Fifteen fresh bovine knees specimens were used for the study. The patella was fixed to a load cell and the construct was pre-tensioned to 40N to allow for creep of the tendon. The BPTB graft was fixed to the tibia using the three fixation techniques – the interference screw, polyester suture tied to a post, and SS wire anchored to a staple. After fixation, the graft was subjected to a single load to failure test, and the forces generated were recorded. The ultimate failure load (the pullout strength), stiffness, and mode of failure were noted.

Results: In the single load-to-failure biomechanical testing, the ultimate failure load and stiffness for Staple with SS wire were 726.40N and 61.9N/mm respectively. For the screw post and polyester suture, it was 733.20N and 53.22N/mm, and for Interference screw – 594.00N and 79.50 N/mm respectively. There was no statistically significant difference in the stiffness or ultimate failure load between the three fixation techniques. The graft fixation using interference screws failed at the bone- tunnel interface by slippage of the bone block from the tunnel in all 5 specimens. In all 5 of the specimens fixed with polyester suture and the screw post, the fixation failed when the polyester suture snapped. When the SS wire and staple construct was stressed, the graft failed as the SS wire cut through the graft in 4 specimens, and in the fifth construct, the knot over the staple unraveled as the load was applied.

Conclusion: The biomechanical properties of BPTB graft fixation with SS wire tied to a staple is similar to that of other fixation devices like the interference screw and suture post. This technique provides a simple, yet effective fixation for the graft – but needs further clinical assessment.

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1. Introduction

Anterior cruciate ligament (ACL) injury is the most common ligament injury around the knee joint.¹ Reconstruction with a biological graft is the preferred treatment for rupture of the ACL. For an ideal graft fixation, there should be sufficient initial strength

to avoid failure of fixation (i.e. high pullout strength or ultimate failure load of graft fixation), and sufficient stiffness to restore the stability of the knee to avoid gradual loosening in the early post-operative period.²

When considering fixation of Bone Patellar Tendon Bone (BPTB) grafts to the tibia, the interference screw is considered to be the gold standard for graft fixation.³ Though, the interference screw provides good fixation strength, it has its own drawbacks like graft laceration and need for hardware removal.⁴ It also has its

* Corresponding author.

E-mail address: pradeep.cmc@gmail.com (P.M. Poonnoose).

limitations in revision surgeries and in patients with poor proximal tibial bone stock.⁵ As an alternative to the interference screw, we have used staples and stainless steel (SS) wire to anchor the BPTB graft to the tibia and femur. The graft is prepared by passing a 20G SS wire through the patellar and tibial bony ends of the graft. The BPTB graft is then passed through the bony tunnels made in the femur and the tibia and the SS wires at the two ends are tightened over staples placed perpendicular to the bony surface at the tunnel exit. In this technique, the staple is not used to fix the graft to the bone, but serves as a post for tensioning the graft. While similar to the suture post fixation technique, the SS wire has better stiffness and is biologically more inert than the suture material. This technique is simple, less expensive, technically less exacting, and posterior blow out of the femoral tunnel does not impede fixation. The aim of the study was to assess the biomechanical efficacy of this fixation technique in anchoring the BPTB graft.

2. Materials and methods

Fifteen fresh bovine knees were obtained from a local abattoir. The soft tissues and menisci were dissected off the tibia and the femur and discarded. The patella and the patellar tendon were left attached to the tibia. The bone mineral density of the proximal tibia was assessed using the DEXA scan. Only tibiae with trabecular bone density greater than 0.8gm/cm³ were selected.⁶ After the DEXA scan was performed, the ACL graft was harvested from the mid portion of the patellar tendon (10 mm in width), with a 30 mm x 10 mm quadrilateral bone plug from the bovine tibia. The patella was left intact and not fashioned into a bone plug. It served as a fixation point for the load cell.

2.1. Tibial specimen preparation

A 10 mm diameter bone tunnel was drilled from the tibial ACL insertion, directed inferiorly and antero-medially, in an inside out fashion. The tibia was mounted on the testing apparatus and fixed using a modified vice grip and further stabilized by two 3.5 mm cross pins that were passed through the vice grip into the tibial specimen.

2.2. Patellar tendon graft preparation

A 7 mm hole was made in the patella –to serve as a fixation point to the load cell. The 30 x 10 mm tibial bone plug was then prepared for fixation with the different techniques. Two 2 mm holes were drilled in the bone block. The proximal hole was placed 1 cm from the bone tendon junction and the second hole was 1 cm from the first. The distal hole was used to pass a stay suture (No.5 polyester) that served to pretension the graft at 40N. The proximal hole was used for fixation of the graft with either a 20 gauge SS wire or a 5'ethibond suture as explained below (Fig. 1).

2.3. Testing apparatus

The tibial portion of the graft was passed through the 10 mm tunnel in the tibia. A 7 mm thick 'S' shaped hook was passed through the patellar end of the graft, and attached to the load cell. The load cell – a standard cantilever load cell with a maximum sensing load of 1000N – was mounted on the mobile carriage of a lathe and could be moved at a constant rate of 1.6 mm/s (Fig. 2a). The load cell was connected to the bridge amplifier and the output recorded on a digital storage oscilloscope. The polyester stay suture attached to the distal tibial bone plug was fixed to a post and the graft was preloaded to 40N. This was done by moving the load cell mounted carriage mechanically, to stretch the tendon. After a

Fig. 1. Fixation technique-SS Wire to Staple: A 20G SS wire is passed through the bone plug 1 cm from tendon bone junction. The stay suture is used to pretension the graft at 40N.

period of 15 min to allow for “creep” of the graft, the specimen was reloaded to 40N before starting the experiment. A schematic of the experimental arrangement is shown in Fig. 2b.

2.4. Graft fixation

The tibial bone plug was then fixed to the tibia by means of three different fixation techniques i.e. interference screw, No.5 Ethibond tied to a screw fixation post and using SS wire fixed to a staple (Fig. 3).

- **Interference screw fixation:** A 9 x 30 mm softsilk titanium interference screw (Smith and nephew, London, UK), was inserted over a guide wire placed parallel to the graft in the tibial tunnel until the end of the screw was flush with the end of the bone block. While inserting the screw, the changes in the graft tension were recorded.
- **Polyester suture (No.5'Ethibond) to screw fixation post:** Two No.5'Ethibond sutures were passed through the tibial bone plug, and were used to secure the graft to a screw fixation post (55 x 6.5 mm AO cancellous screw with a 1.5 mm SS washer). The screw was inserted distal to the bone tunnel outlet at 65° to the bone surface, directed distally. The screw was tightened after the No.5'Ethibond was tied to the screw.
- **SS Wire to Staple:** The 20G SS wire placed in the tibial bone plug was tied to the 20 x 20 mm staple, which was placed distal to the bone tunnel. After knotting the SS wire on to the staple, it was tightened and tensioned using nose pliers.

2.5. Evaluation of pullout strength, stiffness and mode of failure-

After fixation of the graft to the tibia with the fixation device, the stay suture used to pretension the graft was cut, and the graft

Fig. 2. a) Experimental set up with patella tendon graft attached to the load cell placed on the mobile carriage of a lathe, which is moved at a rate of 1.6 mm/s. b) Schematic representation of the experimental arrangement.

Fig. 3. Three different fixation techniques for tibia. Testing was done for stiffness and pull out strength and mode of failure.

was re-tensioned to a load of 40N, applied axial to the tibial tunnel. The force recorded at the onset of the study was 40N in all cases. The tendon graft was then stretched at a rate of 1.6 mm/sec, by moving the mobile platform on which the load cell was attached, with the aid of an electrical motor. The tendon was stretched till failure of the fixation. The **ultimate failure load** (the **pullout strength**) – i.e. the maximum tension generated in the graft at the time of failure of fixation – was recorded on the oscilloscope and the **mode of failure** of the graft was noted. The **stiffness** of the graft was assessed by calculating the slope of the linear portion of the force-displacement curve generated during the biomechanical testing (Fig. 4).

2.6. Statistics

Multiple comparisons using the Bonferroni post hoc test was used to analyse statistical significant difference between the stiffness and ultimate failure load of the three fixation devices. P values less than 0.05 were considered significant.

3. Results

Using interference screws for tibial graft fixation, the pull out strength (**Ultimate Failure Load**) varied from 384N to 752N (mean 594N). The pull out strengths were higher when the graft was fixed

Fig. 4. Force displacement curve, showing the relation between Ultimate Load strength and Stiffness.

Table 1

Biomechanical properties of the fixation devices.

Biomechanical properties	Staple with SS wire (Mean $\pm$ SD) N = 5	screw fixation post with ethibond suture (Mean $\pm$ SD) N = 5	Interference screw (Mean $\pm$ SD) N = 5
Ultimate Failure Load (N)	726.40 ($\pm$ 60.24)	733.20 ($\pm$ 72.77)	594.00 ($\pm$ 173.61)
Stiffness (N/mm)	61.90 ($\pm$ 13.13)	53.22 ($\pm$ 10.18)	79.50 ($\pm$ 28.24)

with SS wire and staple (640N–776N), and with the suture post (608N–776N) (Table 1), but the difference in the ultimate failure load between the three fixation devices was not statistically significant.

Stiffness of the graft-device construct was highest with interference screw. Table 1 shows the mean stiffness of the three

constructs used in the study. However, the differences in stiffness were not statistically significant.

Fig. 5 illustrates different force-displacement graphs that were generated while testing the three fixation devices and shows the relationship between the ultimate failure load and stiffness.

Fig. 5. Force displacement graphs for fixation with (a) interference screw, (b) stainless steel wire on a staple and (c) 5'0' ethibond on a suture post..

The graft fixation using interference screws failed at the bone-tunnel interface by slippage of the bone block from the tunnel in all 5 specimens. In all 5 of the specimens fixed with the screw post device, the fixation failed when the ethibond suture ruptured. When the SS wire and staple construct was stressed, the graft failed as the SS wire cut through the graft in 4 specimens, and in the fifth construct, the knot over the staple unraveled as the load was applied.

4. Discussion

The bone patellar tendon bone (BPTB) graft is considered by many as the gold standard for ACL reconstruction. The popularity of BPTB graft is based on excellent long-term clinical success and the fact that it provides bone-to-bone healing.^{7–9}

Graft fixation has been found to be the weakest link in the ACL reconstruction during the immediate postoperative period until graft integration occurs.¹⁰ Evolving methods of graft fixation have been paralleled by marked changes in the post-operative rehabilitation program, with a shift towards early weight bearing.¹¹

For an ideal graft fixation, there should be sufficient initial strength to avoid failure of fixation (i.e. high *pullout strength* or *ultimate failure load* of graft fixation), and sufficient *stiffness* to restore the stability of the knee to avoid gradual loosening in the early post-operative period. The graft and its fixation have to resist repetitive forces, ranging from 150 N up to 450 N, that are encountered while walking and climbing steps.⁸

Interference screws have been the most popular method of fixing the BPTB graft to the tibia. Though it provides reasonable fixation strength, the screw has its limitations. They include graft laceration, distortion of magnetic resonance imaging,¹² and the occasional need for hardware removal. In the case of a posterior femoral tunnel blow out during surgery, the screw cannot be used. Interference screw divergence – the angle of the interference screw with respect to the bone block, is another clinical concern. It has been shown that an increase in the divergence angle greater than 20° decreases the fixation strength.¹³ This is a major concern when inserting a screw in a femoral tunnel that has been drilled through a transtibial portal, as the angle of screw insertion (transportal), is not the same as the angle in which the tunnel was drilled.¹⁴ It also has limitations in revision surgeries and in patients with poor proximal tibial bone stock, as the screw may not be able to compress the bone adequately to get good fixation, resulting in a wide variability of the pull out strength.^{5,15} Additionally, while drilling the femoral canal for the BPTB in an arthroscopic surgery, there could be a mismatch between the length of the graft and the length of the canal, and the tibial bone plug could protrude from the tunnel opening, precluding the use of an interference screw.⁴

These limitations led to the development of other methods of fixation, whose biomechanical properties have been extensively studied. While indirect methods of fixation like the endobutton and screw post have good pull out strengths, the stiffness of the construct has been a limiting factor, as the fixation devices are placed at a distance from the joint cavity.¹⁶ The low stiffness of the graft and the connecting materials allow motion of the graft within the bone tunnel wall, leading to the bungee cord and windshield wiper effect.⁷

In this study, we have assessed the biomechanical properties of a cheap and simple method of indirect graft fixation using stainless steel (SS) wires and staples that anchor the BPTB graft to the bone. The SS wire graft construct is passed through the tibial and femoral tunnels, and the SS wire is tightened over a staple placed perpendicular to the bony surface at the tunnel exit (Fig. 6).

On studying the biomechanical properties, the staples and SS wire construct was observed to withstand higher loads than the

Fig. 6. ACL reconstruction with BPTB graft, fixed with SS wire and staples at both tibial and femoral tunnels. Patient had an MCL reconstruction during the same surgery.

interference screw before failing. All the three devices studied were able to withstand loads that were higher than that encountered in activities of daily living. However, as expected with the indirect nature of fixation, the stiffness of the SS wire staple construct was marginally less than that of the interference screw. It was higher than the screw post system that used a less stiff ethibond suture material. The SS wire construct has all the advantages of an indirect fixation, in that it can be used even in situations of femoral tunnel blow out, and the graft position can be adjusted in the tunnels before fixation to avoid mismatch between the tunnel length and graft size. It is also less expensive than the interference screws and endobutton. However, it could require hardware removal if pain is associated with the staples or wires. In osteoporotic bone, the SS wire could potentially fail by cutting through the graft as seen in the study.

Although this study was not powered to demonstrate equivalence, the results revealed no difference in efficacy between the interference screw and SS wire staple construct. The SS wire staple construct demonstrate good ultimate failure loads and adequate stiffness, and appear to be more consistent in the results produced as is evident from the lower standard deviations. We conclude that fixation with staples and SS wire is a good, cost effective alternative for fixation of the ACL graft.

Conflicts of interest

None.

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