Original article

Correlation between fixation systems elasticity and bone tunnel widening after ACL reconstruction

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Summary

Background: **Femoral and tibial tunnel widening (TW) after ACL reconstruction is a phenomenon increasing talk in the literature. It is underlying biological and mechanical causes.**
Objective: **The aim of this study was to evaluate the relationship between bone tunnel enlargement and two different ACL fixation systems.**
Patients and Methods**: 40 patient underwent ACL reconstruction with hamstring; randomly divided into group A with 20 patients treated with stiff systems (femoral Rigidfix and tibial interference screw), and into group B, with 20 patients treated with morel elastic system (femoral and tibial Tight-rope). Evaluated postoperatively with knee MRI at 40 days, 3 months, 6 months to measure bone tunnel diameters widening.**
Results: **At 40 days tunnel widening between two groups shows no statistically difference. At 3 months postoperatively, femoral bone tunnel widening amounted on average to 1.84 mm in middle of tunnel and 1 mm at the mouth in joint in group A, and respectively 3.2 mm and 2.5 mm in group B ($p<0.05$). Tibial tunnel widening was 1.24 mm at the mouth in joint and 1.3 mm in middle in group A and respectively 2.26 mm and 2.43 mm in group B ($p<0.05$).**
At 6 months femoral tunnel widening amounted on average to 2.45 mm in middle and 1.35 mm at the mouth in joint in group A and respectively 3.5 mm and 2.7 mm in group B ($p<0.01$). Tibial tunnel widening amounted on average to 1.27 at mouth in joint and 1 mm in middle of tunnel in group A and respectively 2.6 mm and 2.3 mm in group B ($p<0.01$).
Conclusions: **This study results suggest elastic fixation system increases bone tunnel enlargement after ACL reconstruction with hamstring without correlation with worse clinical performance.**
Level of evidence: IV.

KEY WORDS: anterior cruciate ligament reconstruction, graft fixation methods, tunnel widening, clinical outcome.

Introduction

There are many graft materials available for the treatment of an ACL-deficient knee. ACL reconstruction in the last 20 years has seen many changes on best graft to use (BTB, hamstring, synthetic devices), on surgical technique (transtibial, anteromedial, over-the-top, single or double bundle, all-inside technique). Some studies reported as one of the complications the a gradual widening of the drilled femoral and tibial tunnels in ACL-reconstructed knees[1-4]. There seems to be a significantly greater risk of TW when using hamstring grafts compared with patellar tendon bone graft[5]. The bone tunnel remodeling is significantly different with regards to the fixation method, graft and tunnel diameter[6]. Many studies describe the mechanical explanations for TW as the windshield-wiper effect and the bungee cord effect [1] that are based on the hypothesis that the graft slides inside the tunnel during the motion of the knee, in either a longitudinal or a transverse direction[5] (Fig. 1 a, b).
Comparative studies between vary fixation systems are encumbered by intrinsic limits as they often compare systems with biomechanical characteristics and engineering philosophy completely different, implanted on bone with density and biomechanical property far away from those young typical patient that under-

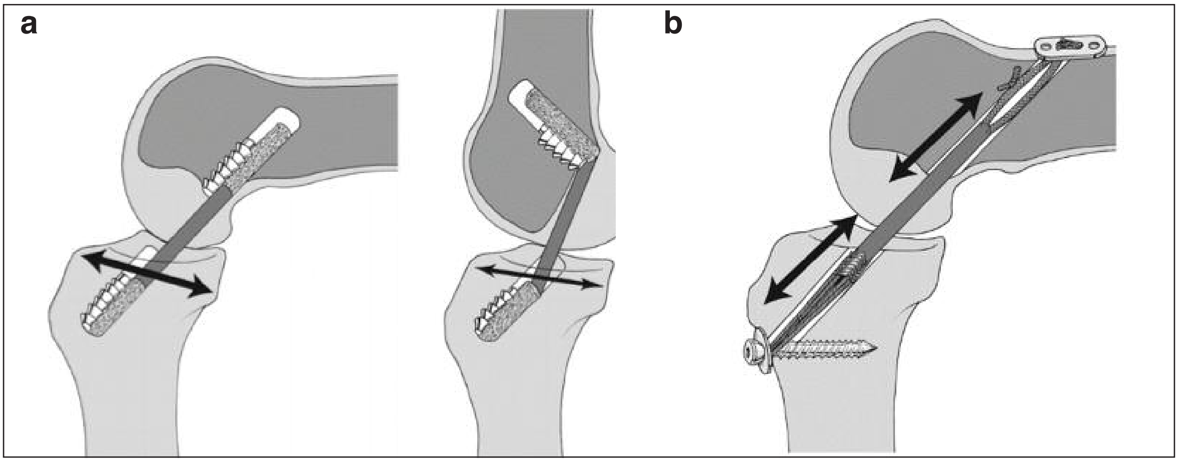


Figure 1a, b. a) Windshield wiper effect. b) -Bungee cord effect.

went ACL reconstruction (bone to elderly or donor animal)[7,8]. The direction of force application in tests to evaluate ultimate tensile load or pull-out strength is only in one direction, while other movements are excluded; or femoral and tibial fixation systems are tested separately, forgiving the complexity of femoral and tibial bone-graft-device system[9].

Laboratory studies suggest grafts homogeneity in terms of stiffness and ultimate tensile load compared to native ACL; whereas are not so clear the mechanicals property devices should have in the "system".

Native ACL has an ultimate tensile load of 2160 N and a stiffness of 242 N/mm[10].

The current substitutes are all able to provide adequate values at time zero: 2977 N e 455 N/mm for patellar tendon[11]; 4140 N e 807 N/mm for hS quadrupled 2353 N e 326 N/mm for quadriceps tendon[12].

About fixation systems, literature evidences that less than 500 N are adequate for early rehabilitation protocol and daily living.

Fixation systems divide into three main groups: compression, expansion and suspension.

Compression systems use interference screw. Last upgrades made this system more reliable, because less aggressive screw threads reduced tendon tear risk. However, fixation with this device is affected by bone density, direction of insertion, diameter (increasing it improves the strength), length, material and screw design.

In some studies, it has been reported that resorbable screw average ultimate tensile strength and stiffness (ranging from 341 and 576 N, and from 29 and 252 N/mm respectively) is higher than metal screw (ranging from 240 and 617 N, and 71 and 257 N/mm respectively). In other studies, there was no statistical difference in stability and in the incidence of complications. Graft interference fixation perform an anatomical fixation near the joint and improve isometric implant[13].

Expansion fixation, is made up by one or more transverse pins that pass-through graft, properly prepared, leading graft swelling in bone tunnel. This system depends by primary graft press-fit, bone density, right pin position. Eccentric pin implant would lead an unbalanced load distribution, compromising graft integration and system failure.

Suspension fixation is indirect system that hang graft on sutures or polyester connected to metal button (e.g. endobutton) with ultimate tensile load of 850±189.8 N and stiffness of 112.5±9.7 N/mm; or completely metal systems (e.g. Swing Bridge) with ultimate tensile load of 1359±214.1 N and stiffness of 162.6±45.8 N/mm. Device is implanted on antero-lateral femoral cortex or outside tibial tunnel.

Possible problems of this technique can be lateral skin incision, uncomfortable presence of foreign body that irritates antero-lateral soft tissues bringing to metal removal, difficulties in removing the system, bone loss management in revision surgery[14].

The Endobutton® has an easy technique, fast and reproducible. Its disadvantage is relating to longitudinal and sagittal graft movements and the concomitant synovial fluid entrance in the tunnels. These movements create shear forces that could delay the graft healing and comport the tunnel widening. It has been shown that loads between 100 N and 300 N, induce 0.3 mm graft motion respect tunnel. In our study was used Tight-rope system, an upgrade of the concept of endobutton, that can intraoperatively adapt polyester loop length to improve tension graft.

Cortico-cancellous suspension fixation use a transcondilar device that crosses bone tunnel and graft overhangs it with orthogonal pullout forces. Transfix® (ultimate tensile load 1469.7±315.5 N; stiffness 206.7± 9.7 N/mm), Bio-transfix® (ultimate tensile load 1491.6±87.6; stiffness 210.1± 67.9) and Sling Shot Crosspin (Mitek) belong to this class. Mechanical property depends on bone density, length of the lever arms respect to suspension point of graft. Potential risks are saphenous and peroneal nerve injury, lateral collateral injury, iliotibial band syndrome that in some studies get to 16% of incidence[15,16].

Optimal graft positioning for ACL reconstruction is being thoroughly investigated in the literature[17] and mechanical properties of fixation systems are overall still inadequate; therefore, still represent the weak link: proper stiffness would restore normal knee kinematic on load and reduce graft motion in the tunnel. For integration of a grafted tendon with bone, the mechanical environment at the tendon-bone interface is one of the major contributory factors[18].

It is easy to think that graft motion is caused by low stiffness systems as extra cortical fixation (far from the origin of bone tunnel) and hamstring[19]. We remember that the graft necrosis usually observed in the initial two weeks of the healing process is averted by inducing gaps into the tendon graft prior to ACL reconstruction[20].

This phenomenon is determined by the position of the tunnel in reciprocal movement between them (windshield wiper effect), and by implant elasticity (bungee cord effect).

An excessive movement can prejudice graft healing, induce bone tunnel widening (evidenced with BtB and hS) and affect knee biomechanics[21].

Ideal fixation should minimize graft motion, prevent synovial fluid access in bone tunnel and increase anterior stability of the knee[22]. Bone loss following surgical reconstructions of the ACL is mostly not caused by the immobilisation before and after the surgery, but rather due to limitations of the functional result with regards to tendon stiffness and muscle force[23].

Most of the studies confirm that bone tunnel enlargement is not connected to worse clinical performances[21,24].

The objective of our study is to understand correlation between different stiffness fixation systems and femoral and tibial tunnel widening.

Patient and method

We conducted a prospective study[25] on patients with ACL-deficient knees. From April 2014 to December 2015, one surgeon (L.M.) performed 73 ACL reconstruction using double Semitendinosus and Gracilis Tendon (ST/G). Inclusion criteria were: symptomatic instability due to ACL deficiency, age lesser than 60 years old, no metabolic bone disease. Patients with associated posterior cruciate ligament injuries, previous knee surgeries were excluded.

Forty patients with age between 17 and 51 years, 80% males and 20% females, were included in the study. They were randomly divided into group A with 20 patients treated with “stiff” systems (femoral Rigidfix and tibial reabsorbable interference screw), and into group B, with 20 patients treated with more elastic system (femoral and tibial Tight-rope).

A standardized post-operative and rehabilitation protocol was used. Full weight bearing was allowed immediately after surgery. A brace allowing full range of motion and crutches were used during the first 15 postoperative days.

Post-operative follow-up was performed with MRI at 40 days, 3 months, 6 months in the same radiological institute using MRI Siemens 1.5 tesla machine, with dedicated knee coil.

The imagin was performed in supine position after routine patient preparation. All patients were imaged in sagittal and coronal STIR (TR: 4100 ms; TE: 30 ms; Slice thickness 3 mm), sagittal PD (TR: 2000 ms; TE: 17 ms; Slice thickness 3 mm) Sagittal and axial T2 (TR: 3000 ms; TE: 90 ms, Slice thickness 3 mm).

A third operator (P. P.) acquired femoral and tibial tunnel diameter measure, in middle and in mouth in joint, in MRI scans. The IKDC classification and Lysholm scores were recorded for each patient. Statistical analysis was performed using R Studio (Version 1.0.40). The comparison of quantitative data and the paired comparison of normally distributed parameters were performed using the Student *t* test.

Results

At 40 days tunnel widening between two groups shows no statistically difference. At 3 months postoperatively, femoral bone tunnel widening amounted on average to 1.84 mm in middle of tunnel and 1 mm at the mouth in joint in group A, and respectively 3.2 mm and 2.5 mm in group B ($p<0.05$). Tibial tunnel widening was 1.24 mm at the mouth in joint and 1.3 mm in middle in group A and respectively 2.26 mm and 2.43 mm in group B ($p<0.05$) (Fig. 2 a-d).

At 6 months femoral tunnel widening amounted on average to 2.45 mm in middle and 1.35 mm at the mouth in joint in group A and respectively 3.5 mm and 2.7 mm in group B ($p<0.01$). Tibial tunnel widening amounted on average to 1.27 at mouth in joint and 1 mm in middle of tunnel in group A and respectively 2.6 mm and 2.3 mm in group B ($p<0.01$) (Tab. I).

Furthermore, bone tunnel enlargement on suspension fixation appears greater on femoral side than in tibial side. No early and late complications were detected.

Discussion

In our study we compared 2 different fixation systems, each with its characteristics and we found that the TW appear to be influenced by the intrinsic mechanical properties of the implants. The use of a more elastic fixation systems (Tight Rope) is associated with more laxity and determinate a bigger tunnel widening.

In literature number of studies about tunnel widening after ACL reconstruction has a little but increasing trend in last ten years.

Other Authors studied correlation between different fixation systems and bone tunnel enlargement. Many TC, MRI, X-ray studies suggest that suspension systems (e.g. endobutton) lead to bone tunnel increase respect other concepts of fixation[26,27]. Common element of these studies is that tunnel enlargement is not connected to worse clinical performances.

Our results assessment shows no statistical difference at 40 days. A possible hypothesis comes from a

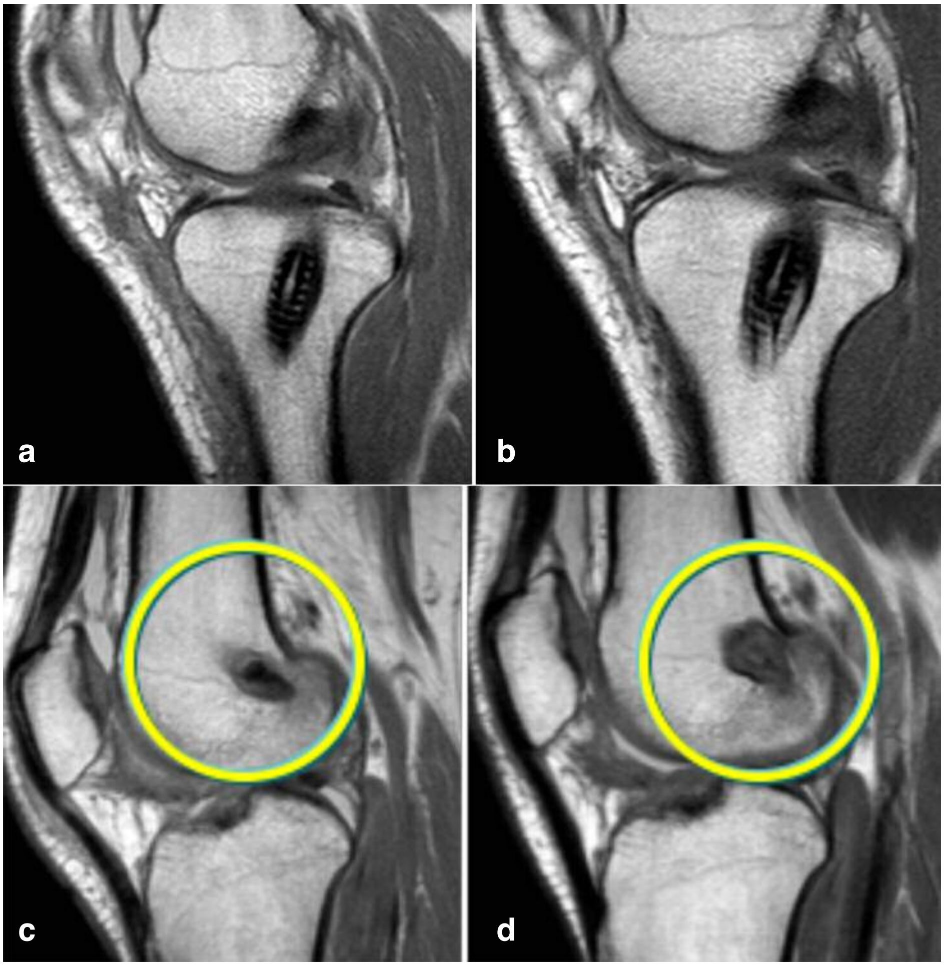
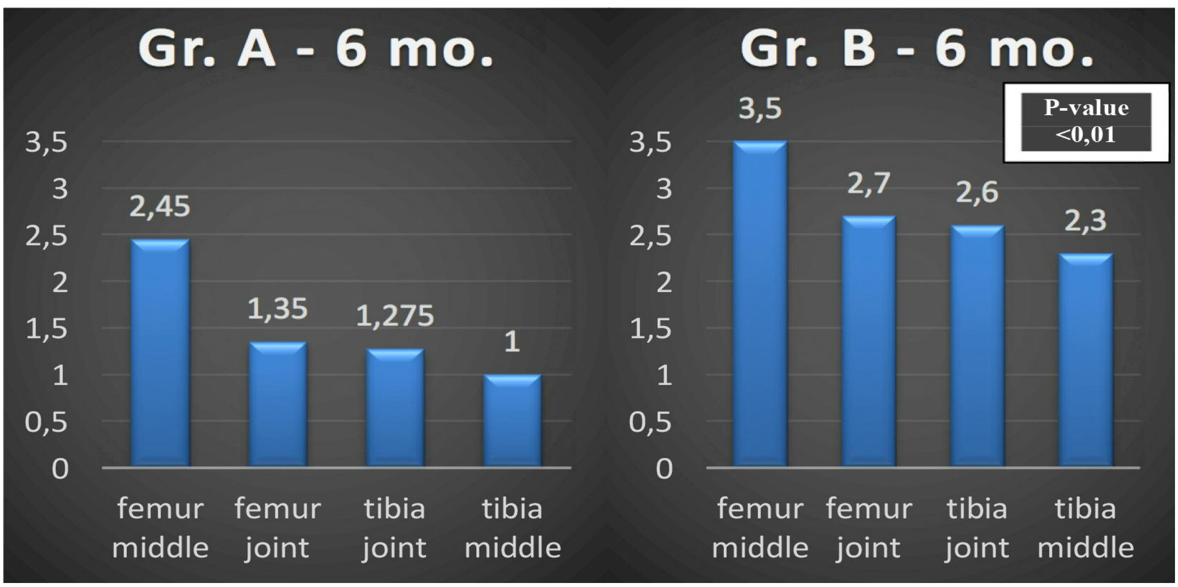


Figure 2 a-d. a) MRI at 40 days. Tibial interference screw. b) MRI at 6 months. Tibial interference screw. c) MRI at 40 days. Femoral tight-rope. d) MRI at 40 days. Femoral tight-rope.

Table I. Tunnel widening at 6 months in group A an B.



recent study on KSSTA, in which have been evaluated biomechanical factors, morphology, and immunohistochemistry in murine model underwent on ACL reconstruction. It shows that peri-implant bone resorbtion a time-depending process, sustained by metalloprotease and CD68+ cells within 6 weeks[28].

Therefore is possible to state, as for graft healing process[29], that femoral and tibial bone tunnel enlargement comes from a balance between biological factors and biomechanical factors. Nowadays radiological imaging upgrade can combine morphology and metabolism of ligaments like in PET-MRI, and some studies suggest that biological rearrangement, after ACL reconstruction, continues up to 24 months postoperatively[30].

However, in literature there are many attempt in order to modify tunnel widening, either from biological side, with the controversial use of PRP[31,32], preserving ACL remnant[33], hybrid graft[34], alendronate[35], manual drilling to reduce termical stress on bone[36]; either from biomechanical side, improving tunnel position[37] and fixation systems stiffness. All these studies are conducted on little patient cohorts or on animal model, therefore it is desirable our little clinical experience would continue to also understand biological factors combined with biomechanical element.

In the current study, only two different femoral fixation implants had been evaluated. This is one of the limitations of the study. Different positioning of the tunnel, correlation between conventional radiography and CT scan and loop length could be added into consideration in a future study.

Conclusion

From the experience of this study, we can conclude that ACL reconstruction with hamstring is subjected to femoral and tibial bone tunnel widening, the most among the use of fixation systems more elastic. Literature revision unanimously suggests that this phenomenon do not correlate to lower clinical performances, at least in the short term.

Conflict of interest

The Authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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