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Knee Surgery, Sports Traumatology, Arthroscopy

Short And Proximalized Interference Screw Fixation Lead To Tibial Tunnel Bone Re-Growth and Better Hamstring Graft Integration in ACL Reconstruction.

--Manuscript Draft--

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Abstract:	Purpose: The stability of the graft in the bony tunnels is of utmost importance in the anterior cruciate ligament (ACL) reconstruction since it ensures safe healing at the tendon-bone interface. The hypothesis was that when a double tibial fixation was used in ACL reconstruction with a short graft of autologous hamstrings, tibial tunnel bone re-growth, and better graft integration would be observed at short-term follow-up. Methods: For the analysis, it was included a cohort of 112 patients after a primary ACL reconstruction with hamstring tendons which underwent postoperative magnetic resonance imaging (MRI) 3.0-Tesla (3.0-T) 6 months after the surgery. The patients were divided into three groups based on the tibial fixation technique: 40 had a screw (group S), 35 had a screw and cortical button (group S+B), and 37 had a screw and anchor (group S+A). The images were independently evaluated by two orthopedic specialists, who measured the screw-free tunnel space and assessed the presence of bone filling in the free tunnel. Furthermore, the Ge's protocol was used to determine the graft healing in the tunnel. Results: In 94 patients a screw-free tunnel space was detected, and a filling of the tunnel was reported in 80.85% of the cases (76 patients), being partial in 15.79% (12 patients) of the cases and complete in 84.21% (64 patients) of the cases. Patients who presented better graft integration (GE1) had significantly higher values of screw-free tunnel length compared to the other ones who had lower graft integration (GE3) ($p < 0.05$). Conclusions: At 6 months postoperative MRI, tibial tunnel bone re-growth and graft-tunnel tibial integration after hamstring ACL reconstruction is significantly associated with the presence of free space between the anterior tibial cortex and the most distal portion of the interference screw, hence the use of a short and proximalized interference screw is suggested to restore bone stock after hamstring ACL reconstruction.

	To Whom It May Concern: We are submitting this original manuscript entitled "Short And Proximalized Interferencial Screw Fixation Lead To Tibial Tunnel Bone Re-Growth and Better Hamstring Graft Integration in ACL Reconstruction" to your journal. This original manuscript is aiming at examining different techniques of tibial fixation used in anterior cruciate ligament reconstructions with hamstrings, their repercussion in tibial bone re-growth and in terms of graft integration, studied by magnetic resonance imaging. We are submitting to your journal this original manuscript entitled "Short And Proximalized Interferencial Screw Fixation Lead To Tibial Tunnel Bone Re-Growth and Better Hamstring Graft Integration in ACL Reconstruction." This original manuscript is aimed to revise different techniques of tibial fixation used in anterior cruciate ligament reconstructions with hamstrings, their repercussion in tibial bone re-growth and in terms of graft integration, studied by magnetic resonance imaging. We believe that the manuscript could be of interest for Knee Sport Medicine community and for Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA) readers. Hoping that this study will reach the standard for publication in your journal we send you our warmest regards. The Authors
Do you or any of your co-authors have a conflict of interest to declare?	No. The authors declare no conflict of interest.
Response to Reviewers:	
Keywords:	ACL reconstruction, double tibial fixation, tibial bone regrowth, graft integration.

Short And Proximalized Interference Screw Fixation Lead To Tibial Tunnel Bone Re-Growth and Better Hamstring Graft Integration in ACL Reconstruction. Francisco J. Simon-Sanchez^{1*}, Simone Perelli¹⁻², Nicola Pizza¹, Michelangelo Delmedico³, Rodolfo Morales-Avalos⁴, Raúl Torres Claramunt¹⁻², Joan Carles Monllau¹⁻²

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Abstract

Purpose: The stability of the graft in the bony tunnels is of outmost importance in the

anterior cruciate ligament (ACL) reconstruction since it ensures safe healing at

the tendon-bone interface. The hypothesis was that when a double tibial fixation was used

in ACL reconstruction with a short graft of autologous hamstrings, tibial tunnel bone re-growth, and better graft integration would be observed at short-term follow-up.

Methods: For the analysis, it was included a cohort of 112 patients after

a primary ACL reconstruction with hamstring tendons which underwent postoperative

magnetic resonance imaging (MRI) 3.0-Tesla (3.0-T) months after the surgery. The

patients were divided into three groups based on the tibial fixation technique: 40 had a

screw (group S), 35 had a screw and cortical button (group S+B), and 37 had a

screw and anchor (group S+A). The images were independently evaluated by two

orthopedic specialists, who measured the screw-free tunnel space and assessed the

presence of bone filling in the free tunnel. Furthermore, the Ge's protocol

was used to determine the graft healing in the tunnel.

Results: In 94 patients a screw-free tunnel space was detected, and a filling of the tunnel

was reported in 80.85% of the cases (76 patients), being partial in 15.79% (12 patients)

of the cases and complete in 84.21% (64 patients) of the cases.

Patients who presented better graft integration (GE1) had significantly higher

values of screw-free tunnel length compared to the other ones who had lower graft

integration (GE3) ($p < 0.05$)

Conclusions: At 6 months postoperative MRI, tibial tunnel bone re-growth and graft-tunnel tibial integration after hamstring ACL reconstruction is significantly associated

with the presence of free space between the anterior tibial cortex and the most distal portion of the interference screw, hence the use of a short and proximalized interference screw is suggested to restore bone stock after hamstring ACL reconstruction.

Level of evidence: Level IV, retrospective comparative cohort study.

Keywords: ACL reconstruction, double tibial fixation, tibial bone re-growth, graft integration.

List of Abbreviations

Anterior cruciate ligament (ACL)

Anterior cruciate ligament reconstruction (ACLR)

Magnetic resonance imaging (MRI)

Body mass index (BMI)

Computed tomography (CT)

Introduction

When a hamstring graft is used for ACL reconstruction, it can be adjusted in terms of length and size depending on the surgical technique and the patient's anatomy [5].

Furthermore, fixation devices are used accordingly to the length and position of the graft to ensure good stability of the construct. Several studies showed that the tibial side is the weakest point of the ACL reconstruction construct [17,21,22] and different solutions have been suggested to face this point.

If a shorter graft is preferred, interference screws should be positioned closer to the joint line when a complete tibial tunnel is performed. Additionally, a cortical fixation may be used as a second tibial fixation to reduce the micro-movement at the graft bone interface of the tibial tunnel [2,20].

Alternatively, some authors advocate for using of all inside techniques when a short hamstring graft is used [15]. This technique involves the use of specific retro-drills devices and relies on adjustable loops fixed on the tibial cortex far from the graft, as the only bony fixation. This type of tibial fixation increases the working arm of the device and, consequently, the risk of micromovements [15]. Nonetheless, the all-inside users prefer this technique thanks to the possibility to save bone stock at the tibial side. In the existing literature, there is limited documentation regarding bone regeneration within the tibial tunnel following the drilling of a complete out-in tibial tunnel.

The purpose of the present study was to review the postoperative MRI of ACL reconstructed with a short graft of hamstring tendons autograft using a complete out-in tibial tunnel in a single high-volume institution center. The hypothesis was that when a double tibial fixation was used, tibial tunnel bone re-growth and better graft integration

would be observed at short-term follow-up.

Materials and Methods

This retrospective comparative cohort study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines. The study was based on data collected for clinical purposes in patients who had undergone an anatomic ACL reconstruction (ACLR) performed in a single University Teaching Center. The present retrospective study was conducted following the Declaration of Helsinki Ethical Principles and Good Clinical Practices. Institutional review board (IRB) approval was obtained to use data from an IRB-approved research registry (protocol number LCA-2017-01). Informed consent was obtained to enroll participants in this research registry, but additional informed consent was not required to include participants in the current exempt study. All patients who underwent primary ACLR with hamstring tendons between January 2021 and September 2022 and had undergone postoperative MRI (3.0-T) 6 months after the surgery were considered for study eligibility.

Exclusion criteria were: multiligament knee surgery, previous knee surgery, patients younger than 18 years-old, and secondary tibial tunnel drilling different from the ACL one (meniscal root tear, meniscal radial tear). Additionally, patients who received an anterolateral procedure at the same time as the ACL surgery were also excluded, given that some studies suggested that the maturation of the ACL is influenced by the anterolateral procedure [19].

A cohort of 112 patients was included for analysis, the patients were divided into three groups based on the fixation technique used at the tibial side: 40 patients had an interference screw (group S), 35 had an interference screw and cortical button (group S+B) and 37 had an interference screw and anchor (group S+A). Homogeneity and comparability of the groups were evaluated looking for any difference in terms of sex, age, graft diameter, BMI, and preoperative KT1000 value. Demographic and surgical data are resumed in Table 1.

Magnetic Resonance Imaging (MRI) evaluation:

All participants underwent knee MRI using a 3.0-T magnet (Signa HDxt; GE Healthcare) running software Version HD 23 equipped with a 4-channel transmit receive knee coil. Standard, oblique sagittal, T1 proton density-weighted images with a 3-mm slice thickness were used to maintain the obliquity in line with the ACL.

The best single slice that demonstrated the full length of the ACL tibial

tunnel was selected for analysis. To assess interobserver reliability, the images were independently measured by 1 orthopedic surgeon and 1 orthopedic radiologist. To assess intraobserver reliability, for each case measurements were repeated 4 weeks later by 1 assessor who was blinded to the result of the first measurement.

In all MRIs, Proton Density weighted images were used to evaluate the distance between the distal part of the interference screw and the anterior tibial cortex. When this distance was 2mm or less, it was deemed insufficient to evaluate bone re-growth. When the distance was more than 2mm, the screw-free tunnel was divided in two parts and the assessment of bone growth within the tunnel was conducted as follows no

re-growth when both parts were empty, partially re-growth when only one of the two parts was filled by bone, completely re-growth when both parts were filled by bone.

(Figure 1)

Furthermore, the protocol described by Ge et al. [8] to measure graft healing in the tunnel (signal intensity at the bone-graft interface) was adopted in the present study.

Based on this protocol, the patients were assigned to 1 of 3 grades. (Figure 2):

The analysis was performed using a picture archiving and communication system workstation (Horizon Rad Station; McKesson).

Surgical technique:

Both semitendinosus and gracilis tendons were harvested in all cases. Subsequently, they were triplicated and assembled on an adjustable cortical-suspension device (Ultrabutton, Smith & Nephew) always leaving 2 couple of high-resistance sutures free at the tibial side used to pull the graft during tibial screw insertion. The goal for the graft length was 7 cm for the S and S+A groups and 6.5cm for the S+B group. This is to avoid any protrusion of the graft from the tibial tunnel which could prevent from the use of the second fixation.

Aiming at the center of the native

ACL footprint, the femoral socket was drilled using a cannulated drill from the anteromedial portal. The diameter was chosen according to the dimensions of the final graft, always drilling a 20mm length blind tunnel. For the tibial tunnel, the tip of a standard tibial guide was placed at the center of the ACL footprint.

The graft was then passed through the tibial tunnel, across the joint, and into the femoral tunnel. After the graft was tensioned several times, graft fixation to the tibia was achieved at between 20 and 30° of flexion using an absorbable interference screw (Biosure HA; Smith & Nephew) of the same diameter as

the graft's. The position of the screw in the group S+B was more proximal with respect to group S and S+A to avoid screw protrusion at the tibial cortex which can cause impingement with the second fixation device. For the same reason in this group of patients, a shorter screw was normally used. After interference screw positioning, patients in group S+A received a second fixation at the tibial side by the use of an anchor device (Footprint; Smith and Nephew) that permit to bury under the tibial cortex the high-resistance sutures free at the tibial head of the graft.

Patients in group S+B received a second cortical fixation engaging the Ultrabutton of the tibial head of the graft to a round-medium Xtendobutton (Smith and Nephew (Figure 3).

All patients participated in the same standardized postoperative rehabilitation protocol. Progression through each phase of rehabilitation was based on each patient's status and the physician's guidance.

Statistical analysis:

The data were presented as median and interquartile range due to their distribution. To conduct multiple comparisons, a Kruskal-Wallis analysis was conducted, followed by Dunn's post hoc tests. Exact Fisher tests or Chi-square tests were conducted based on the type of contingency table used. Logistic regression analyses were carried out, considering dichotomous variables as a function of a continuous variable. In all cases, a p-value of <0.05 was considered statistically significant.

The interobserver agreement between the 2 independent observers was assessed using the Lin concordance correlation coefficient and the 95% CI for continuous measures. The intraclass correlation coefficient values were classified as follows: values less than 0.40 indicate poor agreement, values ranging from 0.40 to 0.75 suggest fair to good agreement, and values greater than 0.75 reflect excellent agreement [9].

The analysis was conducted using GraphPad Prism version 9.3.

Results

Tibial tunnel bone re-growth:

In 94 patients a screw-free tunnel space was detected and a filling of the tibial tunnel was reported in 80.85% of the cases (76 patients), being partial in 15.79% (12 patients) of the cases and complete in 84.21% (64 patients) of the cases. 18 patients didn't show a screw-free tunnel space, 9 in group S and 6 in group S+A, 3 in group S+B.

The mean screw-free tunnel length was being significantly higher in S+B group ($p<0.001$) (Figure 4).

A logistic regression analysis was conducted to examine the relationship between the length of the screw-free tunnel space and the presence of complete filling.

It showed that longer screw-free tunnel lengths were associated with a higher probability of complete bone re-growth observed in MRI. The logistic regression indicated an X value at 50% of 5.82.

The type of tibial fixation was not significantly associated with the presence of complete tunnel filling even though it was more represented in group S+B (group S 16.21%, group S+A 21.16%, group S+B 30.49% ; $p > 0.05$).

Graft integration:

When evaluating the graft healing in the tunnel, 56.36% of the patients were assigned to group GE1, 23.64% to group GE2 and 10% to group GE3. Patients which presented better graft integration (GE1) had significantly higher values of screw-free tunnel length compared to the other ones that had lower graft integration (GE3) ($p < 0.05$) (Figure 5). Again, no correlation between GE group and the type of tibial fixation was observed ($p > 0.05$).

The intraclass correlation coefficient obtained was considered excellent (0.92; 95% CI, 0.90-0.95), and the high calculated k coefficient (0.90; 95% CI, 0.88-0.95) showed excellent agreement between the observers.

Discussion

The most important finding of this study was that in 6 months postoperative MRI a tibial tunnel bone re-growth was observed in 80,85% of the patients with the presence of free space between the anterior tibial cortex and the most distal portion of the interference screw used for tibial fixation. The second finding of this study was that longer screw-free tunnel lengths were associated with a higher probability of complete bone re-growth and better graft-tunnel MRI integration months after surgery. These findings rejected our initial hypothesis given that no correlation was demonstrated between the number or kind of tibial fixation and the radiological findings described. Nonetheless, both bone re-growth and optimal tibial graft integration were more represented in the group S+B;

To the best of the authors' knowledge, this study is the first to evaluate tibial tunnel bony re-growth associated with various ACL fixation methods at a 6-month follow-up. Several different tibial graft-fixation methods exist for hamstring ACL reconstruction. Although indirect methods as suspensory fixation allows the possibility of a thicker graft with greater graft-to-bone contact area [4,7], graft elongation as well as

longitudinal and transverse movements appear to be lower when an interference screws (direct method) is used [12,14,18].

Considering that, some authors suggested the use of a double tibial fixation with both interference screw and cortical suspensory fixation to provide a strong and stiff fixation, minimizing the risk of graft slippage, graft movement, as well as influx of synovial fluid into the bone tunnel. This could result in a better graft integration [1,3,10].

Other published techniques even suggested that adding autologous (and possibly allogeneous) cancellous bone inside the tibial tunnel could secure a reduction of the tunnel widening. In addition, this bone grafting abolishes bone gap between the distal end of the interference screw and the cortical bone of the tibia, presumably facilitating graft incorporation [20].

With the data we present in the current study we can state that bone re-growth in the tibial tunnel and graft tibial integration doesn't correlate with the three kinds of tibial fixation studied. At 6 months follow up, the bone regrowth is more related to the free space in the tunnel than to the type of fixation. With this study, we cannot draw a conclusion about the correlation about stiffness and strength of the different fixation methods, but we found that patients with better graft integration (GE 1) had significantly higher values of free tunnel space compared to the others that had lower graft integration (GE3). On these findings we can speculate that the tibial fixation with an interference screw close to the joint line provides stiffness and shorten working length, decreasing graft micromovements and windshield-wiper effect and this could result in a better graft integration.

The data we present suggest a clinically relevant conclusion: to restore the tibial bone stock in ACL primary reconstruction a short and proximalized interference screw is preferable. When using the "all-inside" ACL reconstruction technique, the use of a double cortical suspensory fixation was associated with reduced tibial tunnel widening and smaller tunnels after 2 years compared to tibial tunnel in ACL reconstruction using screw fixation [7,15,16].

Furthermore, this type of reconstruction claims to provide bone sparing which is a crucial in case of a future ACL revision [7]. However, this procedure has some disadvantages since is more technically demanding, relies on the use of retro-drills, and adjustable loop possible failure has been reported due to its loosening [12].

The data we described in the study suggest that when a short and proximalized interference screw is used, the tibial bone stock is restored in few months

postoperatively even without the use of “all-inside” technique.

The current study had several limitations that should be acknowledged. Firstly, patients were not randomized; however, we compared the 3 groups on several variables that can influence graft maturation and found that the groups had comparable results.

Secondly, this was a radiological study, and radiological findings were not correlated with the clinical and functional evaluation of the patients. This was not the goal of the study, but prospective studies that examine the association between these radiological findings and clinical outcomes are needed to confirm whether these two aspects can be related.

Thirdly, as with all radiological studies, it has an intrinsic limitation for the subjective interpretation of the images: to limit this bias, all the MRI evaluations entailed the same magnet strength and followed the same MRI protocol under the supervision of a skilled musculoskeletal radiologist. Furthermore, the images were analyzed by different evaluators checking for inter and intra-rate reliability.

Finally, in our study, we only evaluated bone re-growth and tibial ACL integration at 6 months follow-up given that in several studies it had been suggested that fixation methods directly affect timing and quality of graft-tunnel healing [3,6], for this reason, we wished to identify the earliest signs of osteointegration. Future research should assess whether the findings reported are sustained over longer follow-up periods. Additionally, it may be beneficial to evaluate quantitative bone regrowth using more precise methods, such as CT scans [13].

Conclusion

At 6 months postoperative MRI, tibial tunnel bone re-growth and graft-tunnel tibial integration after hamstring ACL reconstruction is significantly associated with the presence of a free space between the anterior tibial cortex and the most distal portion of the interference screw, hence the use of a short and proximalized interference screw is suggested to restore bone stock after hamstring ACL reconstruction.

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Table 1: Demographic and surgical patients' data

Group S

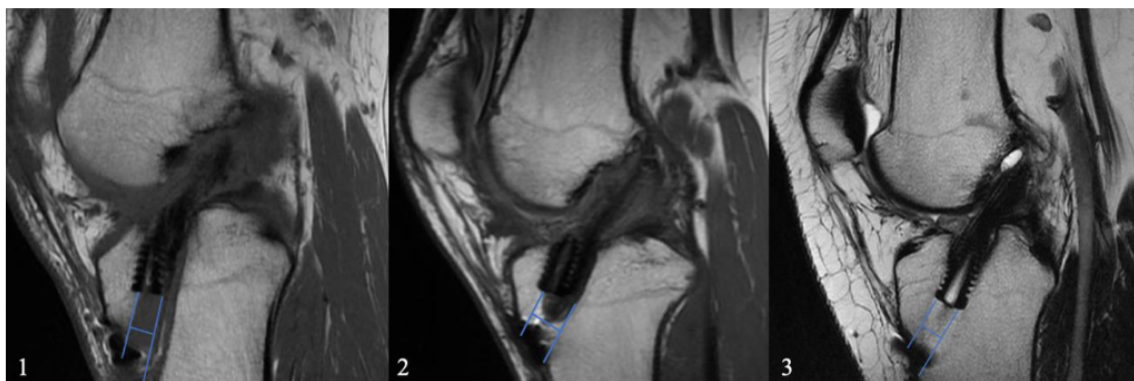
Group S+B

Group S+A

P-value

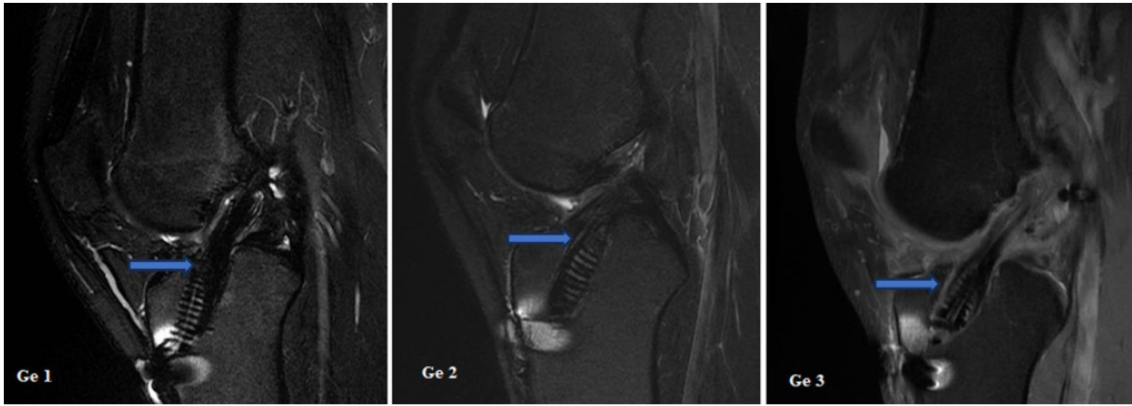
Age	30.59 (SD 10.58)	28.11 (SD 10.44)	29.81 (SD 10.41)	n.s.
Gender				n.s.
Male	24 (60%)	18 (51.4%)	21 (56.8%)	
Female	16 (40%)	17 (48.6%)	16 (43,2%)	
Graft diameter	9.17 (SD 0.97)	9.44 (SD 0.56)	9.67 (SD 0.43)	n.s
Preoperative K1000 values	3.89 (SD 1.05)	3.78 (SD 0.66)	4.06 (SD 0.73)	n.s
BMI				n.s.
18.4 - 24.9	24(60%)	21(60%)	21 (56.8%)	
25 - 29.9	14(35%)	11(31.4%)	12 (32.4%)	
> 30	2 (5%)	3 (8.6%)	4 (10.8%)	

Figure 1



1: No bone regrowth. 2: Partially bone regrowth. 3: Completely bone regrowth.

Figure 2



Ge1. Low intensity, no fibrosis at the bone-graft interface, full attachment.

Ge2. High intensity over a portion of the interface.

Ge3. High intensity over the entire bone-graft interface, poor attachment.

Figure 3

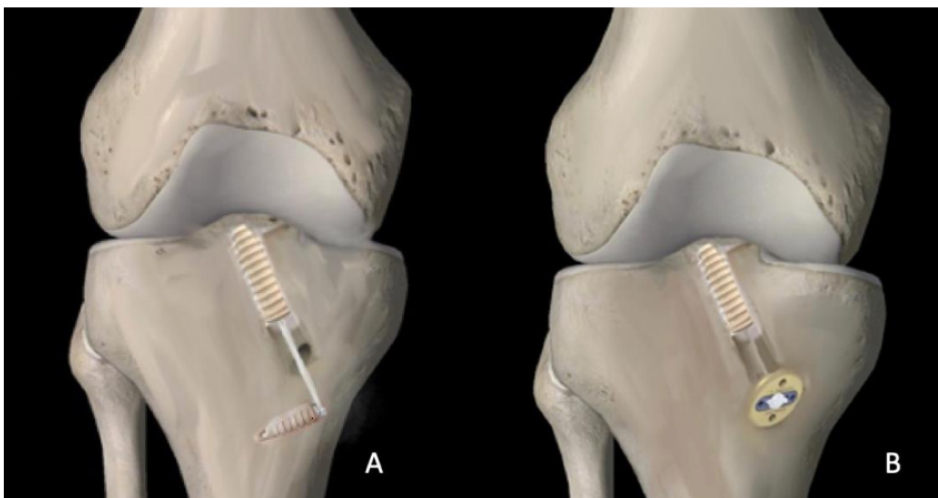
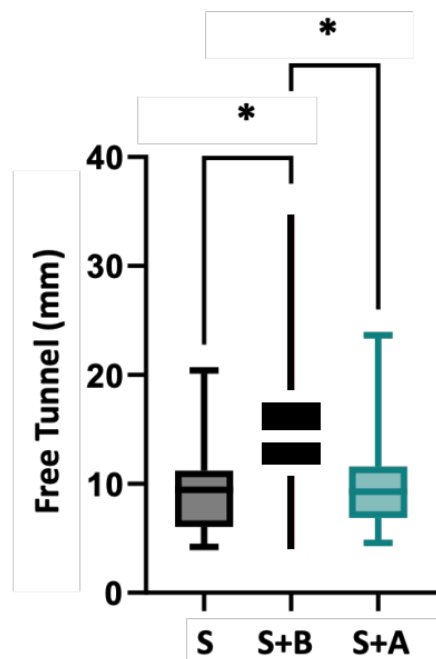


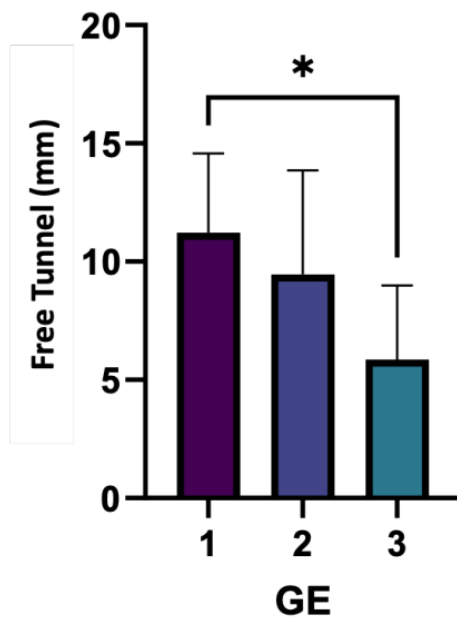
Illustration of tibial ACL fixation with an interference screw plus anchor (A), and an interference screw plus cortical button (B).

Figure 4



The Kruskal Wallis with Dunn post-hoc analysis showed that patients with a hybrid tibial fixation with an interference screw and button (S+B) had a significantly higher free tunnel space compared to the other hybrid fixation patients with interference screw and anchor (S+A) and to the single fixation patients with an Interference screw only (S). The mean screw-free tunnel length was 9.29 mm +/- 3.85 SD in group S, 10.09 mm +/- 4.53 SD in group S+A, and 15.1 mm +/- 5.88 SD in group S+B being significantly higher in this group ($p < 0.001$)

Figure 5



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480 *The Multiple comparison between the values of free tunnel space (**mm**) and the three*
481 *groups based on Ge classification (1,2,3) showed a significant difference between*
482 *patients with highest graft integration (GE1) and patients with the lowest graft*
483 *integration (GE3).*

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