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Clinical and radiological results after Internal Brace ® suture versus the all-inside reconstruction technique in anterior cruciate ligament tears 12 to 18 months after index surgery.

Georg Mattiassich (georg.mattiassich@gmx.at)
Trauma Center Linz https://orcid.org/0000-0002-5743-6783
Reinhold Ortmaier
Ordensklinikum Linz GmbH Barmherzige Schwestern
Harald Kindermann
FH Oberosterreich
Jürgen Barthofer
Unfallkrankenhaus Linz
Imre Vasvary
Landeskrankenhaus Salzburg - Universitatsklinikum der Paracelsus Medizinischen Privatuniversitat
Stefan Tino Kulnik
Ludwig Boltzmann Gesellschaft
Klaus Katzensteiner
Unfallkrankenhaus Linz
Iris Leister
Paracelsus Medizinische Privatuniversitat

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Abstract

Background

Anterior cruciate ligament (ACL) injury can lead to reduced function, meniscal lesions, and early joint degeneration. Preservation of a torn ACL using the Internal Brace® technique might re-establish normal knee kinematics, avoid donor-site morbidity due to tendon harvesting, and potentially maintain proprioception of the knee.

Methods

Fifty subjects were recruited for this study between December 2015 and October 2016. Two groups of individuals who sustained unilateral ACL rupture were included: those who underwent surgery with preservation of the injured ACL (Internal Brace® technique; IB) and those who underwent ACL reconstruction using a hamstring tendon graft (all-inside technique; AI). Subjective self-administered scores were used: the German Version of the IKDC Subjective Knee Form (International Knee Documentation Committee), the German Version of the WOMAC (Western Ontario and McMaster Universities Arthritis Index), SF-36 (short form), the German Version of the KOOS (Knee Osteoarthritis Outcome Score), and the German Version of the modified Lysholm-score by Lysholm and Gillquist. Anterior tibial translation was assessed using the KT-1000 arthrometer® (KT-1000 Knee Ligament Arthrometer, MEDmetric Corp., San Diego, CA, USA). Magnetic resonance evaluation was performed in all cases.

Results

Twenty-three subjects (46%) were men, and the mean age was 34.7 years. The objective IKDC scores were “normal” in 15 and 14 patients, “nearly normal” in 11 and 7 patients, and “abnormal” in 1 and 2 patients, in the IB and AI groups, respectively. KT-1000 assessment showed a side-to-side difference of more than 3 mm on maximum manual testing in 11 (44%) and 6 subjects (28.6%) in the IB and AI groups, respectively. In the postoperative MRI, 20 (74%) and 22 subjects (96%) in the IB and AI groups showed an intact ACL. Anterior tibial translation was significantly higher in the IB group compared to the AI group in the manual maximum test.

Conclusions

Preservation of the native ACL with the Internal Brace ® primary repair technique can achieve comparable results to ACL reconstruction using Hamstring autografts over a short term. Clinically relevant limitations such as a higher incidence of pathologic laxity, with patients more prone to pivot shift phenomenon were observed during the study period.

Introduction

Anterior cruciate ligament (ACL) injuries are very common and can lead to reduced function of the knee, meniscal lesions, and early joint degeneration [1]. Subjective and objective criteria of joint instability, a patient's activity level, age, pre-injury knee status, and possible procedural complications must be considered in clinical decision making for each patient individually. Muscle strengthening, or post-traumatic use of a motion restricted brace might lead to acceptable knee stability in general [2]. A major concern regarding ACL reconstruction is, that it cannot prevent the development of early-onset knee osteoarthritis (OA) after ACL injury [3]. Because the native ACL also contains sensory nerve fibers, almost complete removal of the native ACL tissue during ACL reconstruction impairs proprioception and muscular stabilization, and consequently, adversely affects rehabilitation and sports performance [4].

Concomitant and secondary injuries, such as meniscal tears and cartilage lesions also play a role in the development of post-traumatic OA. Currently, the complex individual three-dimensional anatomy of the ACL, and therefore knee proprioception, and kinematics cannot be completely restored by surgical reconstruction [5, 6]. Nevertheless, a repair of the torn ACL prevents donor-site morbidity associated with tendon harvesting, and might potentially enable preservation of the ligament's proprioceptive function [7–12]. Tendon harvesting results in a weakening of active knee stabilizing structures, and leads to consecutive problems, together with tunnel-widening, in revision cases after ACL reconstruction.

Synthetic materials have been used to reduce donor-site morbidity, although previous studies have shown major disadvantages in terms of longevity and biocompatibility [45–57].

Knee stabilization using a tear-resistant tape as a safety belt for the healing area, together with bone marrow stimulation (under the supposition that stem cells will foster tendon-to-bone healing), are two influential factors. Applying these principles, researchers have reported promising results after ACL repair using dynamical fixation with a polyethylene braid [48].

One of the main arguments for repair is that novel fixation methods and suture materials are not comparable to historical open methods. Immediate initiation of functional therapy may lead to better muscle function, an earlier return to sports, and better proprioception. Even though many studies have reported high subjective satisfaction rates after ACL reconstruction, in a meta-analysis, Biau et al. reported full recovery to pre-operative range of motion and a return to pre-injury sport level in only 40% of patients [49–51].

The greatest disadvantage of using autologous tendons is the loss of extrinsic knee stabilizers [52–54], which may also increase the risk of re-rupture. Ruptures of the ACL with direct or indirect sequelae, such as meniscal tears, are predisposing factors for the development of OA. Morbidity at the harvest zone, loss of proprioception, elongation and progredient loosening are further unsolved complications of ACL reconstruction [49, 55–58].

The primary objective of this study was to determine whether a difference in clinical outcomes exists between the Internal Brace® surgical technique and the all-inside ACL reconstruction surgical technique at 12–18 months after ACL surgery. The secondary objective was to compare the extent of graft healing between the two surgical techniques based on magnetic resonance imaging (MRI).

Materials And Methods

Study design and participants

Patients fulfilling the following criteria were included: (1) ACL total rupture at the femoral insertion on MRI and confirmed during arthroscopy. Patients who were operated within the first six weeks after trauma, showed a solid stump to anchor reasonable sutures, and consented to the IB-technique, were operated in this manner. All other patients received ACL reconstruction by the AI technique. The other two criteria were as follows: (2) patients who were available for the 12–18 months of follow-up and (3) no known previous injuries to the contralateral knee. Exclusion criteria were concomitant total collateral ligament rupture, or a full-thickness cartilage lesion on MRI or arthroscopy. If meniscus refixation or repair was performed, patients were excluded if the post-operative rehabilitation protocol was different from the standard local rehabilitation protocol after ACL reconstruction. Additional eligibility and exclusion criteria are listed in Table 1.

Table 1

Inclusion and exclusion criteria

Inclusion	Exclusion
1. Isolated ACL injury 2. If the ACL injury was combined, the following circumstances were required: • Meniscus tear treated with partial resection • A small stable meniscus tear treated with fixation that did not interfere with the rehabilitation protocol • Cartilage lesions on MRI without pathologic intra-operative findings tested using a probe 3. Agreement to participate in the study and signed informed consent before inclusion	1. Presence of one of the following associated injuries to the index knee as visualized on MRI and/or arthroscopically: • An unstable longitudinal meniscus tear requiring repair in which subsequent post-operative treatment (i.e. bracing and limited range of motion [ROM] interfered with the standard rehabilitation protocol • Grade IV cartilage injury • Injury to the posterior cruciate ligament (PCL), complete medial collateral ligament (MCL), or lateral collateral ligament (LCL) as visualized on initial MRI

Participants were recruited from the patient database at the Trauma Center Linz. Operation theatre protocols were reviewed to confirm the type of surgery. Participants were selected after all standard clinical after-care examinations were completed without any additional tests. None of the questionnaires and clinical tests included in this study was used in the standard post-operative documentation of these patients. Seventy-two eligible patients who underwent surgery between July 2014 and August 2015 were identified and invited to participate in the study, of which 27 agreed to participate. Based on this IB group, 23 age- and sex-matched subjects who underwent AI reconstruction were selected.

In total, fifty subjects were recruited for this cross-sectional observational study between December 2015 and October 2016. Two groups of individuals who sustained a unilateral ACL rupture participated: 27 subjects underwent ACL primary repair surgery using the Internal Brace ® (IB) method and 23 subjects underwent ACL all-inside (AI) reconstructive surgery using a hamstring autograft.

Patients were eligible for this study when ACL insufficiency was diagnosed by clinical examination (positive Lachman test and/or pivot shift test), with a complete ACL tear at femoral insertion detected on MRI, and not more than 6 weeks from trauma to surgery in cases with Internal Brace ® repair.

Surgical technique

The surgical procedures were performed by two experienced trauma surgeons specializing in knee surgery. The surgeons did not participate in the study related examinations.

All procedures were performed under either spinal or general anesthesia. Patients were placed in the supine position with the knee positioned in a leg holder and a thigh tourniquet was applied. Anterolateral and anteromedial portals were created, and diagnostic arthroscopy was performed according to a standardized protocol. Meniscal lesions were identified and appropriately treated if needed.

Internal Brace®

After a complete ACL tear was confirmed and was localized at the femoral insertion zone, ACL repair using the Internal Brace® technique was performed (Fig. 1).

A malleable passport cannula (Arthrex, Naples, FL) was placed in the anteromedial portal to facilitate suture passage, management, and ligament repair. A 4 mm femoral tunnel was drilled from the anteromedial portal through the center of the femoral ACL insertion area (Fig. 2).

Microfracturing was performed in the femoral insertion zone until bone marrow globules were squeezed out of the drilling tunnel. Suture passage into the ligament remnant was performed with a Scorpion suture passer (Arthrex, Fig. 3).

The ACL stump was then supplied with high-strength non-absorbable sutures (FiberWire, 2.0, Arthex). The initial stitch was placed into the anteromedial bundle fibers of the ACL remnant (Fig. 3). Two sufficient stitches were passed out of the avulsed end and pulled through the femoral drill hole. After that, an incision was made at the anteromedial aspect of the medial tibia. A 4 mm tibial tunnel was then drilled to the center of the tibial ACL footprint using a target device. A FiberTape (Arthrex) was pulled from distal to proximal into the femoral tunnel which traversed the knee through the tibial and femoral footprints of the ACL (Fig. 4).

The tape was fixed in full knee extension distally at the tibial cortex using an anchor system (SwiveLock 4.75 mm, Arthrex), or, if this was not technically feasible, we utilized a Suture button (Arthrex) (Fig. 5). Finally, the tape was tightened with the knee in full extension, and the ACL sutures were fixated proximally at the cortical button at the lateral femoral condyle by knots.

All-inside technique

If an ACL rupture was ineligible for repair, reconstruction was performed. A single bundle of semitendinosus tendon was inserted through retrograde-drilled femoral and tibial sockets in an “all-inside” technique. The semitendinosus graft was harvested over a 1.5 cm long incision posteromedial to the flexion fold of the knee. The semitendinosus muscle tendon was pulled out, and a tendon-stripper was inserted and pushed first at the proximal end and then at the distal end to regain a total length of approximately 24 cm for the graft. After the tendon was debrided of the muscle, the quadrupled tendon had a total length between 6.5 and 7 cm and a diameter between 7 and 10 mm (mean 8 mm). The ends of the tendon were sutured, and the TightRopes (Arthrex) were arranged for further fixation on the tibia and femur. The diameter was measured to determine the appropriate caliper of the FlipCutter (Arthrex) to drill the socket holes. The ends of the graft were marked at a distance of approximately 1.5–2 cm from the ends to obtain the correct length of the intra-articular segment of the tendon. Anatomic insertion sites and the femoral notch were debrided of ligament remnants and soft tissue to gain full access to the medial aspect of the lateral femoral condyle by visualizing the osteochondral border. A femoral drill socket was created using the outside-in-technique with a femoral guide (Arthrex, Inc.) by retrograde drilling with the FlipCutter (Arthrex), the diameter of which was 1 mm less than the measured diameter of the graft to achieve a good press-fit fixation. A 20 or 25 mm-deep socket was formed. The entry point of the tibial tunnel was placed anterosuperior to the medial collateral ligament and pes anserinus using a tibial guide (Arthrex) and was drilled towards the intercondylar eminence.

A detailed surgical technique guide for both techniques has been provided by Arthrex on their website.

Post-operative treatment

All patients followed a structured rehabilitation protocol according to local guidelines. For the first 10 days post-operatively, partial weight-bearing (15–20 kg) of the operated leg was allowed without orthosis. Physiotherapy started on the first day after surgery with no restriction placed on the range of motion. Muscle strength training began in the third week after surgery under supervision.

Return to non-contact sports was allowed after muscular and proprioceptive conditions were regained at least 6 months after surgical intervention. Return to pivoting sports or high-risk contact sport activities was advised only after at least 12 months and after passing specific return-to-sports criteria [13, 14].

Outcome measurements

Subjective knee scores

The following validated subjective self-administered scores were used: the German Version of the IKDC Subjective Knee Form (International Knee Documentation Committee)[15, 16], the German Version of the WOMAC (Western Ontario and McMaster Universities Arthritis Index)[17, 18], SF-36 (short form), the German Version of the KOOS (Knee Osteoarthritis Outcome Score)[19], and the German Version of the modified Lysholm-score by Lysholm and Gillquist [20].

Clinical outcome

Anterior tibial translation was assessed using the KT-1000 arthrometer® (KT-1000 Knee Ligament Arthrometer, MEDmetric Corp., San Diego, CA, USA). A side-to-side difference in anterior-posterior translation of three or more millimeters is considered to be indicative of knee joint laxity. [21, 22]

Radiological outcome

All follow-up MRI scans were performed using a 1.5-Tesla MRI unit (Magnetom VISION; Siemens AG, Erlangen, Germany) equipped with a dedicated multi-channel knee coil with the patient lying in the supine position.

The MRI knee protocol was standardized, and axial, sagittal and coronal planes were acquired in all patients. Additionally, oblique-paracoronal planes following the anatomic course of the ACL were observed for better evaluation of ligament integrity.

The following sequences were acquired:

- T1 TSE (SL 3 mm, TE 16 ms, TR 727 ms)
- fat-saturated (FS) proton density-weighted (PDw) TSE (SL 3 mm, TE 34 ms, TR 3000 ms)
- FS PDw TSE (SL 3 mm, TE 36 ms, TR 3670 ms)
- Axial FS PDw TSE (SL 3.5 mm, TE 33 ms, TR 4400 ms)
- Oblique-paracoronal FS PDw TSE (SL 2 mm, TE 36 ms, TR 2000 ms)
- Oblique-paracoronal FS T1 TSE (SL 2 mm, TE 11 ms, TR 630 ms)

AI and IB groups were differentiated according to post-operative changes, with wider drill holes observed in AI reconstructions than those in IB.

Continuity of the ACL-reconstructed fibers seemed to be the most accurate and reliable sign for assessing ligament integrity for both the autograft and the IB. In the IB-reconstructed ACL tears, the FiberWire appeared as a thin, linear T1 and as a PDw hypointense string-like structure following the femoral and tibial drill holes and the anatomic course of the original ACL; the FiberWire must not be mistaken for intact ACL fibers. Fibers running parallel to the FiberWire were declared intact.

Secondary signs of ACL instability that elicited suspicion of re-rupture of the ACL included bone marrow edema around the tibial or femoral drill holes, tibial translation, a hyperbuckled posterior cruciate ligament (PCL), and uncovering of the posterior horn of the lateral meniscus or secondary atraumatic meniscal tears.

Other accompanying post-traumatic findings included chondral defects, meniscal tears, collateral ligament tears, bone marrow edema, microtrabecular bone fractures, joint effusion, and suspected PCL tears.

All MRI scans were reviewed by a radiologist who specialized in musculoskeletal MRI, especially of the knee (I.V.). The radiologist had no access to any patient information or records to ensure an unbiased review of the scans. Pre-operative MRI examinations from various MRI units using different scanners were also analyzed retrospectively by the same radiologist to compare pre- and post-operative status.

The study was registered with the ClinicalTrials.gov database (unique identifier: NCT02760589).

Data analysis

Statistical methods

To examine the difference in clinical outcomes between the two surgical groups, the following clinical outcome measures were compared: IKDC, WOMAC, KOOS, Lysholm, and SF-36 scores, KT-1000 assessment, and the IKDC pivot shift result. Graft healing was compared based on MRI findings.

Statistical analysis

Statistical analysis was performed using SPSS statistical software (version 20.0, SPSS Inc., Chicago, Illinois, USA). Descriptive statistics, including the means and SDs for continuous variables (such as age, BMI, IKDC subjective score, WOMAC, KOOS, Lysholm, and SF-36 scores, and KT-1000 anterior knee translation) and frequency counts for categorical variables (such as sex, IKDC pivot shift result and IKDC objective score, and radiological findings in terms of ligament continuity), were calculated. Depending on the variable, the chi-square test or the independent t-test was used to determine differences in patient characteristics between patients undergoing IB versus AI. The Wilcoxon matched-pairs signed-rank test was applied for paired comparisons between the pre-operative and post-operative MRI findings for *menisci (medial and lateral)* for each subject. The Kolmogorov-Smirnov test was used to determine whether the data were normally distributed. The calculated effect size of 0.72 was based on a sample size of $n = 50$, an assumed power of 0.8 and an alpha of 0.05.

Results

Fifty subjects were included: 27 who underwent Internal Brace® ACL primary repair and 23 who underwent all-inside ACL reconstruction. All patients were available for follow-up at 12–18 months. The time from injury to surgery ranged from 1 day to 2 months (mean = 16.04 days, SD = 15.1, median = 13.55), 46% (23) of the subjects were men, the mean age was 34.7 years (SD = 10.81), the mean weight was 74.5 kg (SD = 12.01), and the mean BMI was 24.6 (SD = 2.99). IB and AI subjects did not differ in terms of important demographic variables (Table 2). None of the patients in our study presented post-operative complications like bleeding, infections, re-ruptures, or nervous lesions.

Table 2
Demographics of the all-inside (AI) and Internal Brace ® (IB) patients.
Results are expressed as mean and standard deviation (SD)

Variable	IB (n = 27)	AI (n = 23)	P
Age [years]	35.44 (SD = 11.84)	33.83 (SD = 9.66)	0.603[a]
Height [cm]	170.85 (SD = 8.83)	173.39 (SD = 9.63)	0.336 [a]
Weight [kg]	71.37 (SD = 12.04)	75.09 (SD = 11.93)	0.280 [a]
BMI	24.36 (SD = 3.16)	24.89 (SD = 2.91)	0.537 [a]
Male	10	13	0.137[b]
Female	17	10	

[a] t-test for independent samples

[b] Chi-square test

Subjective knee scores and anterior knee translation

Subjective self-administered scores and patient satisfaction were generally high in both groups. The objective IKDC score was “normal” in 15 and 14 patients, “nearly normal” in 11 and 7 patients, and “abnormal” in 1 and 2 patients in the IB and AI groups, respectively (Table 3). In the pivot shift test, 14 subjects in each group showed a smooth glide of the tibia during reduction (51.9% of IB patients and 60.9% of AI patients). In 11 subjects (40.7%) in the IB group and in 9 subjects (39.1%) in the AI group, an abrupt reduction of the tibia was observed, and in 2 subjects (7.4%) from the IB group, the tibia momentarily locked in a subluxed position (Table 3).

Table 3
Subjective scores of the patients in both the groups. Results are expressed as mean and standard deviation (SD)

Subjective scores [scale: 0–100]	IB (n = 27)	AI (n = 23)	P
IKDC	82.18 (SD = 13.75)	77.27 (SD = 13.66)	0.213 [a]
WOMAC	91.51 (SD = 11.86)	89.54 (SD = 09.66)	0.527 [a]
KOOS overall KOOS symptoms KOOS pain KOOS functions of daily living	83.26 (SD = 14.41) 80.27 (SD = 16.68) 87.96 (SD = 11.98) 90.74 (SD = 13.75)	83.02 (SD = 11.08) 80.13 (SD = 15.82) 84.06 (SD = 16.24) 92.46 (SD = 07.52)	0.949 [a] 0.976 [a] 0.334 [a] 0.596 [a]
Lysholm	86.70 (SD = 10.59)	83.87 (SD = 14.31)	0.426 [a]
SF 36 physical	52.33 (SD = 06.96)	50.96 (SD = 07.89)	0.509 [a]
SF 36 mental	53.76 (SD = 06.62)	51.13 (SD = 08.08)	0.213 [a]

[a] t-test for independent samples

The follow-up examination results revealed that all measured subjective scores did not differ significantly between the groups ($p > 0.05$; Table 3), which was consistent with clinical and instrument-based examination results, except for the manual maximum KT-1000 measurement (Table 4 and Table 5). The difference in anterior knee translation between the operated knee and the contralateral knee revealed a significant difference in the manual maximum test between the surgical groups (MD = 2.01; 95% CI 0.50–3.53; $p = 0.01$). The mean anterior translation was 9.96 mm (SD = 2.71) and 8.00 mm (SD = 2.09) in the IB and AI group, respectively. KT-1000 assessment showed a side-to-side difference of more than 3 mm on maximum manual testing in 11 subjects (44%) of the IB group and in 6 subjects (28.6%) of the AI group. The mean anterior tibial translation values (in millimeters) for both groups are presented in Table 5.

Table 4
Clinical results of the follow-up evaluations in all-inside (AI) and Internal Brace ® (IB) patients. Results are expressed as mean and standard deviation (SD)

Clinical examination	**IB (n = 27)**	**AI (n = 23)**	**P**
IKDC objective score, n			
A = normal	15	14	0.527 [a]
B = nearly normal	11	7	
C = abnormal	1	2	
IKDC pivot shift, n			
Tibia glides smoothly during reduction	14	14	0.388 [a]
Tibia abruptly reduces	11	9	
Tibia momentarily locks in a subluxed position	2	0	

[a] Chi-square test

Table 5
Results of instrument-based examinations of the anterior tibial translation

Healthy knee [mm]	**IB (n = 27)**	**AI (n = 23)**	**P**
KT-1000 Anterior Drawer	3.70 (SD = 1.79)	3.39 (SD = 1.70)	0.532 [a]
KT-1000 Compliance Index	5.37 (SD = 2.40)	4.91 (SD = 2.11)	0.482 [a]
KT-1000 Manual Maximum	6.30 (SD = 2.45)	6.35 (SD = 2.71)	0.944 [a]
Operated knee [mm]			
KT-1000 Anterior Drawer	5.11 (SD = 2.15)	4.48 (SD = 1.76)	0.266 [a]
KT-1000 Compliance Index	7.22 (SD = 2.68)	6.13 (SD = 2.36)	0.136 [a]
KT-1000 Manual Maximum	9.96 (SD = 2.71)	8.00 (SD = 2.09)	0.007 [a]
Side-to-side difference [mm]			
KT-1000 Anterior Drawer	1.41 (SD = 1.72)	1.09 (SD = 1.56)	0.496 [a]
KT-1000 Compliance Index	1.85 (SD = 2.03)	1.22 (SD = 1.86)	0.258 [a]
KT-1000 Manual Maximum	3.67 (SD = 2.91)	1.65 (SD = 2.31)	0.010 [a]

[a] t-test for independent samples

Radiological findings

On post-operative MRI, 20 subjects (74%) in the IB group and 22 subjects (96%) in the AI group showed an intact ACL. No significant differences were found in the post-operative MRI findings of the ACL and the medial and lateral menisci between the two surgically treated groups. The Wilcoxon matched-pairs signed-rank test revealed no significant differences between the pre-operative and post-operative MRI findings for menisci (medial and lateral) in both groups. The results are depicted in Table 6.

Table 6
Radiological findings for ACL and menisci in all-inside (AI) and Internal Brace ® (IB) patients

	IB (n = 27)	AI (n = 23)	
Intact ACL post-operatively			P = 0.090[a]
Yes	20	22	
No	3	1	
Not sure	4	0	
Intact medial meniscus post-operatively			P = 0.569[a]
Yes	16	14	
No	11	9	
Not sure	0	0	
Intact lateral meniscus post-operatively			P = 0.158[a]
Yes	24	17	
No	3	6	
Not sure	0	0	
Pre-op versus post-op results of the IB group Intact medial meniscus pre-operatively			P = 0.500[b] Z=-1.000 Effect size: r = 0.19
Yes	15		
No	12		
Not sure	0		
Intact medial meniscus post-operatively			
Yes	16		
No	11		
Not sure	0		
Pre-op versus post-op results of the AI group Intact medial meniscus pre-operatively			P = 0.156[b] Z=-1.414 Effect size: r = 0.29
Yes		11	

[a] Chi-square test

[b] Wilcoxon matched-pairs signed-rank test

	IB (n = 27)	AI (n = 23)	
No		11	
Not sure		1	
Intact medial meniscus post-operatively			
Yes		14	
No		9	
Not sure		0	
Pre-op versus post-op results of the IB group Intact lateral meniscus pre-operatively			P = 0.750[b] Z=-0.000 Effect size: r = 0.00
Yes	24		
No	3		
Not sure	0		
Intact lateral meniscus post-operatively			
Yes	24		
No	3		
Not sure	0		
Pre-op versus post-op results of the AI group Intact lateral meniscus pre-operatively			P = 0.375[b] Z=-0.816 Effect size: r = 0.17
Yes		16	
No		6	
Not sure		1	
Intact lateral meniscus post-operatively			
Yes		17	
No		6	

[a] Chi-square test

[b] Wilcoxon matched-pairs signed-rank test

	IB (n = 27)	AI (n = 23)
Not sure		0
[a] Chi-square test		
[b] Wilcoxon matched-pairs signed-rank test		

Discussion

Operative treatment of ACL injury has been established since the end of 19th century, starting with open techniques to suture the torn ACL. Since the early 1990s, open techniques have increasingly been replaced by arthroscopic procedures. Previous ACL suturing techniques resulted in poor clinical outcomes in terms of persistent knee laxity [23, 24]. In 1979 and 1982, Marshall et al., amongst others, demonstrated unsatisfactory results with high re-rupture rates [24–26]. Reasons for lack of healing of the ACL after suturing have included both mechanical and biological factors. Instability of the sutured ACL stump due to insufficient suture materials, beside the tenuous blood supply of the ACL, have been considered the main problems in ACL suturing techniques [27]. Previous repair techniques were performed via arthrotomy with transosseous sutures, followed by a post-operative rehabilitation protocol for at least 6 weeks with cast fixation, which consequently led to rigid knee joints [28, 29].

Previous attempts of primary ACL repair

Long-term follow-up studies have reported fair or poor results in nearly 30% of patients after ACL repair [30, 31]. The need for additional surgery and revision to ACL reconstruction due to persistent knee instability have also shown unacceptably high failure rates, which has been further demonstrated in long-term results [29–31], revealing a laxity of more than 5 mm based on KT-1000 assessment in 21% of patients.[32] Assuming the low healing potential of the sutured ACL, reconstruction techniques have resulted in more predictable outcomes. A randomized prospective study by Drogset and Engebregtsen et al. involving 150 patients divided into three treatment groups (primary repair, augmentation and bone-tendon-bone reconstruction with patellar tendon graft groups) revealed the limitations of repair techniques [30]. The authors concluded that at the long-term (sixteen-year) follow-up, the rate of revision after ACL surgery was ten-times higher following primary repair than that after primary repair augmented by a bone-patellar tendon-bone graft [30]. This is the reason that reconstruction is suggested for ACL ruptures and arthroscopic techniques have consistently advanced in recent years [33]. Reconstruction techniques are now considered the gold standard and have improved in recent decades [34].

Anatomical examination of the blood supply of the ACL has shown that the ACL has the potential to heal [35]. Steadman and colleagues showed that proximal ruptures of the ACL can heal when the insertion zone is perforated to induce bleeding prior to repair [36].

Murray et al. described the factors that affect healing, and showed that a platelet-enriched collagen sponge combined with stable fixation, younger age and early intervention can lead to stable histological and biomechanical healing [37, 38]. Therefore, an injured ACL can evidently result in a stable scar under certain circumstances [39–43]. Factors that hinder healing include the synovial fluid environment [44, 45], alterations of the weak blood supply [46, 47] and post-injury instability, which obstructs the development of a sufficient scar [2, 39, 48]. ACL repair should be performed within the first 3–6 weeks after injury, which is normally the phase at which MRI is used to confirm the clinical diagnosis and the decision regarding whether to operate is determined. Additionally, some argue that surgery should be performed at least 6 weeks after the injury or after guided proprioceptive training. Others argue that ACL reconstruction is only required in cases of persistent instability after conservative treatment attempts have failed. The next problems in this phase are logistical in nature and are related to the potentially limited availability of time in the operating room. One of the most important arguments for performing surgery immediately after injury is the opportunity to possibly repair concomitant lesions, especially meniscal and chondral lesions, which have the greatest potential to heal if treated in the early phase.

Anterior knee translation

Except for the manual maximum test, no significant differences were observed in anterior knee translation of the surgically treated knee between the IB and AI groups. However, subjects in the IB group generally presented higher values of anterior translation, and five subjects in the IB group exceeded the pathologic laxity threshold of 13.5 mm. The mechanism inducing knee laxity in this group of surgically treated patients requires further investigation. Additionally, patients with physical finding of grade 3 pivot shift phenomenon do generally reflect a non-functional or failed surgery and require closer follow-up. However, none of the studied patients required revision surgery after ACL repair one and a half years post-operatively and showed acceptable clinical and functional scores in general.

Measurements of anterior translation after surgery are considered a surrogate parameter for knee joint stability, and their correlation with patient satisfaction scores are reported to be poor. [49] In contrast, proprioception is of utmost importance in measuring the overall outcome of ACL reconstruction. The preservation of hamstring tendons, with their proposed protective effect for anterior translation is considered to be a positive factor for stability.

Radiological findings

Whether MRI of the ACL can be used to assess healing after repair and reconstruction is debatable.[50] Directed scarring or remodeling was visible in most patients; however, stability could only be indirectly assessed based on signs of instability, such as bone marrow edema or secondary meniscal lesions. The direction of MRI was tilted in line with the ACL, as this was the main region of interest in this study. No apparent correlation was found between the MRI findings and clinical outcome measures.

Altered signal intensity was not a useful tool for evaluating the integrity of ACL reconstruction, because the post-operative scans were performed early (12–18 months), and all IB-repaired knees still showed higher signal intensity, suggestive of scar tissue or healing progression in the PDw images. Full ligamentization in IB-repaired knees could not be determined by MRI, and none of the IB-reconstructed ligaments showed original signals after this period.

Secondary signs of ACL instability eliciting suspicion of re-rupture of the ACL included bone marrow edema around the tibial or femoral drill holes, anterior tibial translation, a hyperbuckled PCL and uncovering of the posterior horn of the lateral meniscus or secondary atraumatic meniscal tears. To address whether full resolution had occurred, re-arthroscopies with manual testing of the insertion zone or histological evaluation would be required.

Limitations and further research

Certain limitations and weaknesses must be considered, including natural variability in knee kinematics when comparing the operated knee joint with the contralateral knee. The small sample size in our study resulted from the strict criteria used for patient selection, especially in the IB group. A follow-up MRI after a prolonged time period, and a second-look arthroscopy would provide a better knowledge of ACL healing. We performed MRI 12–18 months after surgery and were able to compare pre-operative MRI scans to follow-up MRI scans in all study subjects. Longer follow-up intervals are required to assess when, and the extent to which the ligamentization process of the ACL is completed. Future comparative studies are needed to verify the safety, and long-term results of surgical procedures for ACL primary repair. Whether these new techniques result in satisfactory long-term outcomes or can prevent post-traumatic OA could not be fully determined.

Conclusion

Preserving the native ACL with the Internal Brace® primary repair technique can aid in achieving patient satisfaction in the short-term. Proximal rupture and good tissue quality are required for repair in select patients. Further prospective investigations with longer follow-up and a higher number of patients are required to gain better knowledge on factors associated with better or equal outcomes of IB compared to AI or other so-called gold-standard reconstructive techniques. Although statistically not significant, clinically relevant limitations such as more pathologic laxity with patients more prone to pivot shift phenomenon are obvious in the short-term follow up.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee of the Austrian social insurance for occupational risks group (AUVA). The study was performed according to the protocol, and all subjects provided written informed consent authorizing the evaluations, radiological examinations, return-to-sport testing, and data publication.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request and with permission of the Ethics Committee of the Austrian social insurance for occupational risks group.

Competing interests

The authors declare no competing interests.

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Authors' contributions

GM was responsible for acquisition of the data, examination of the patients, analysis and interpretation of the data and drafting of the manuscript. IL was involved in return-to-sport testing, analysis and interpretation of the data, and correction of the manuscript. HK was responsible for the statistical analysis and revision of the manuscript. RO critically revised the manuscript and improved the Discussion section. JB operated on the patients and revised the manuscript. IV reviewed the pre-operative and post-operative MRI scans. STK critically revised the manuscript for important intellectual content. KK applied for the grant and was responsible for study logistics. All authors have read and approved the final version of the manuscript.

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List Of Abbreviations

IB	Internal Brace® method
AI	All-inside reconstructive surgery
ACL	anterior cruciate ligament
PCL	posterior cruciate ligament
MCL	medial collateral ligament
LCL	lateral collateral ligament
MRI	magnetic resonance imaging

IKDC International Knee Documentation Committee

WOMAC Western Ontario and McMaster Universities Arthritis Index

SF-36 short form 36

KOOS Knee Osteoarthritis Outcome Score

OA osteoarthritis

BMI body mass index

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Figures

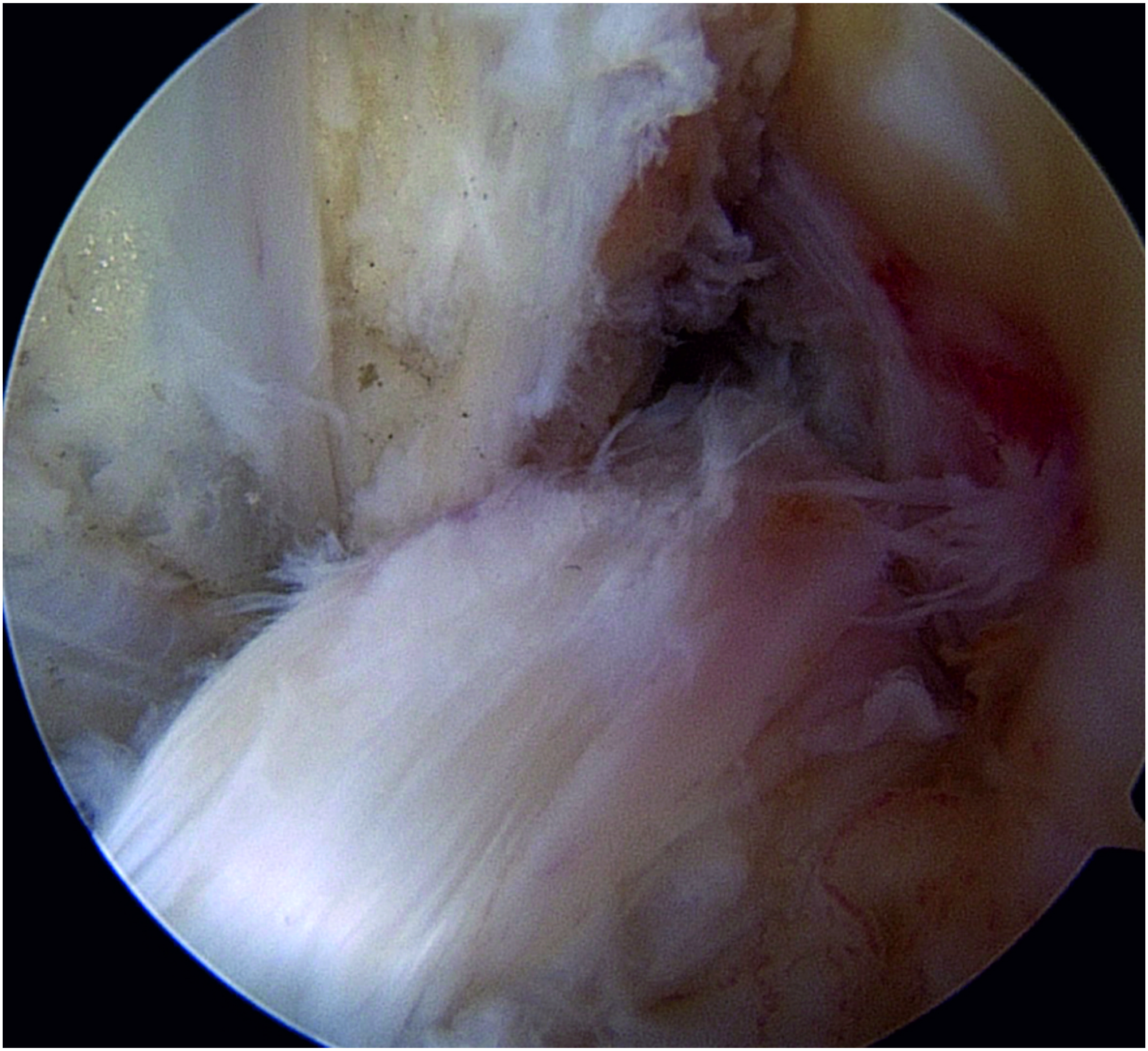

Figure 1

Proximal rupture of the anterior cruciate ligament.

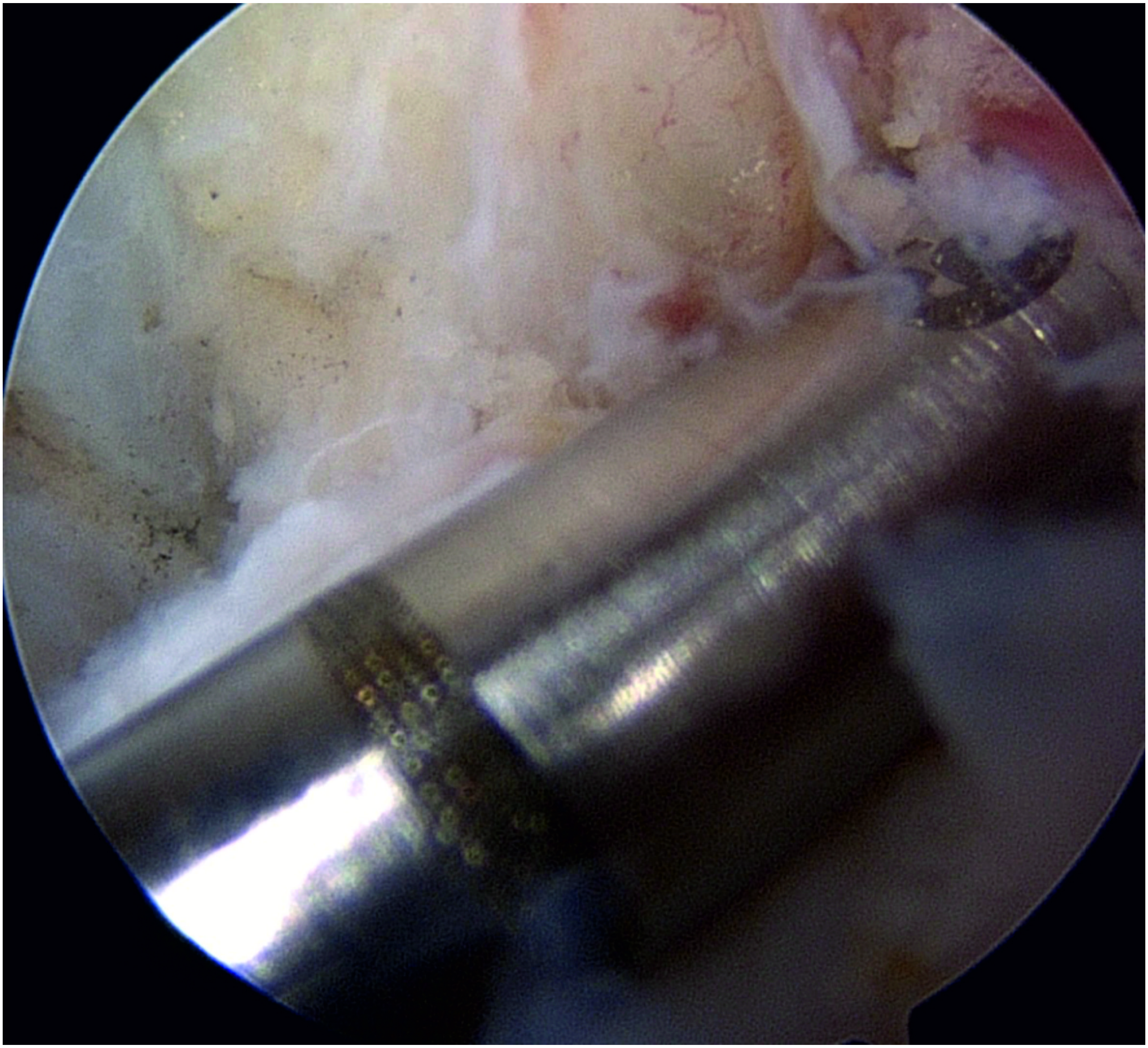

Figure 2

A 4-mm tunnel is being drilled through the femoral insertion zone.

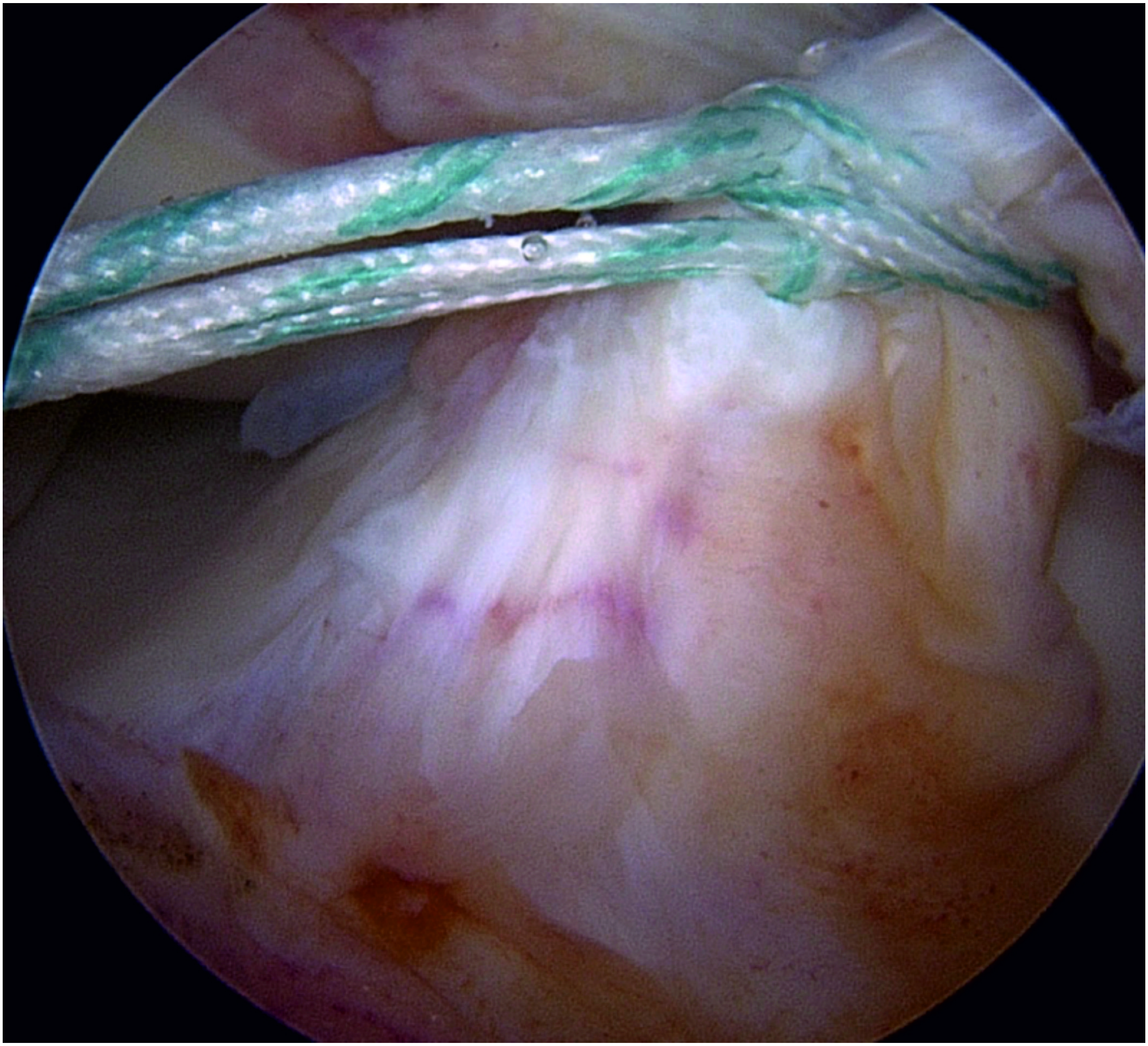

Figure 3

Two non-absorbable sutures were passed through the proximal ACL stump.

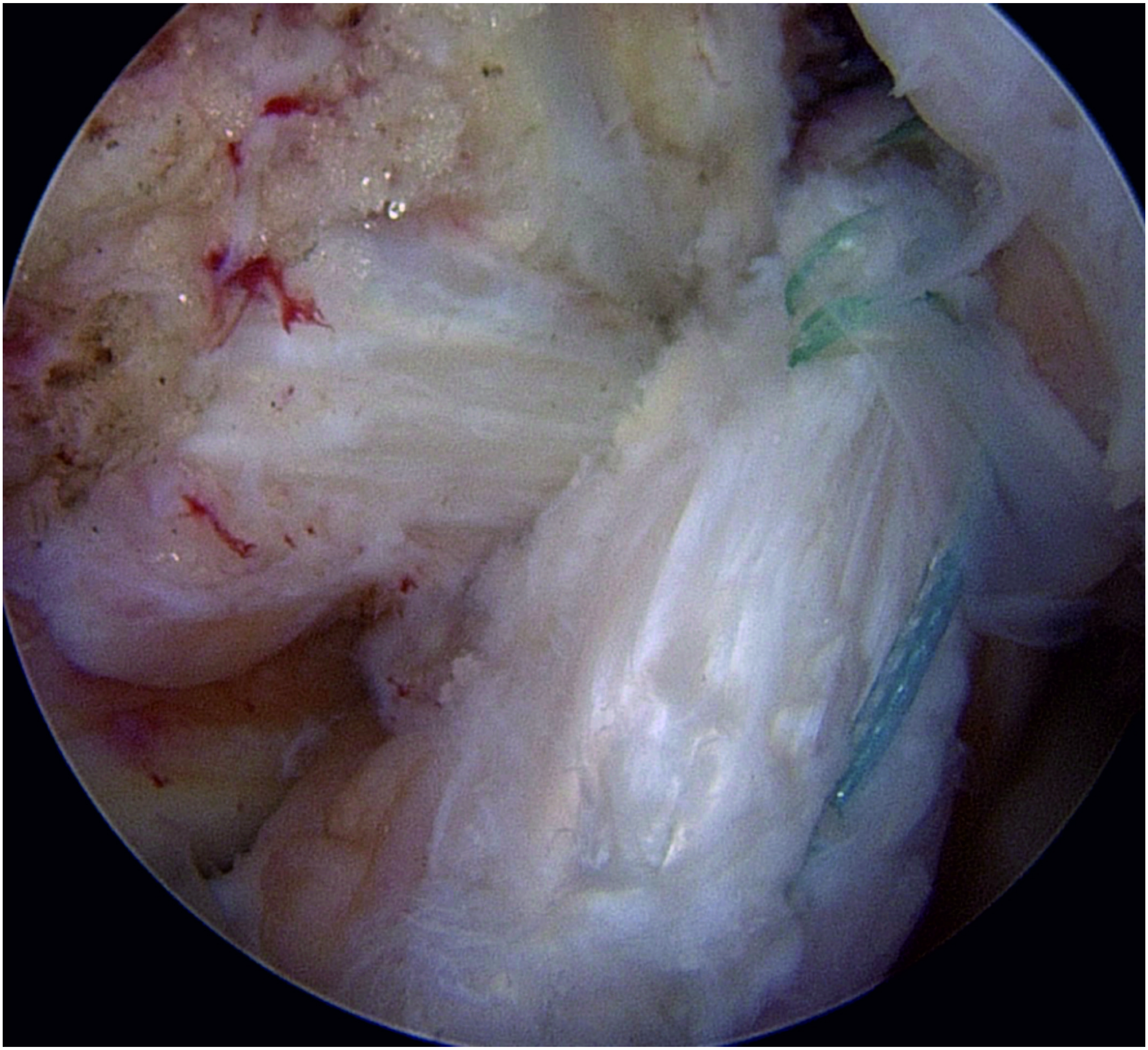

Figure 4

After a 4-mm tunnel was drilled through the tibial footprint using a target device, a FiberTape was pulled through the tibial and femoral tunnels.

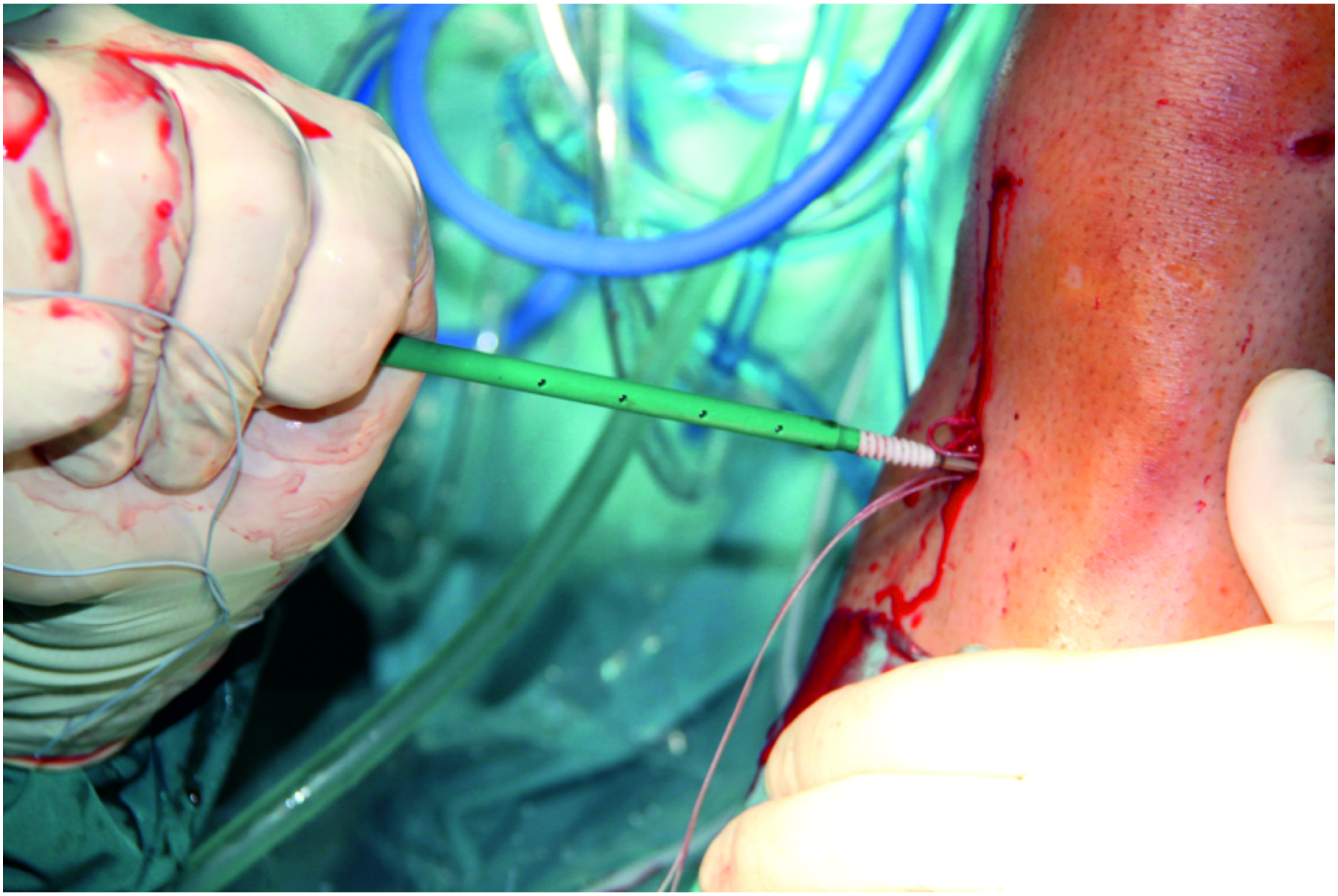

Figure 5

The braid was fixed via Swivelock or alternatively with a tibial suture button.