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Clinical outcomes, healing rate, and presence of peri-meniscal cysts after all-inside meniscal repair in combination with anterior cruciate ligament reconstruction: a prospective comparative study with magnetic resonance imaging assessment

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Abstract

Purpose Meniscal repairs are the most common associated procedures during ACL reconstruction, but they present challenging indications and possible risks of complications or failures. The aim of the present study is to assess the clinical outcomes of all-inside meniscal repairs in the setting of ACL reconstruction.

Methods Twenty patients with ACL reconstruction and all-inside meniscal repair were compared to 20 patients with isolated ACL reconstruction. All patients were prospectively evaluated pre-operatively, at four month, and 18-month follow-up with KT-1000, Kira accelerometer for pivot-shift, KOOS, Marx score, and SF-36. Meniscal healing and presence of peri-meniscal cysts were assessed on standardized 1.5-T MRIs performed at 18 months.

Results Twenty-one meniscal repairs were performed in 20 patients (81% medial, 19% lateral). At 18 months, 48% had complete healing, 38% had incomplete healing, and 14% had no healing. Peri-meniscal cysts were present in 33% of cases. Worst pre-operative KOOS pain (p = 0.0435) and ADL (p = 0.0201) were present in patients with meniscal lesion, while no differences were present at four months and 18 months between patients with or without meniscal repair (p > 0.05). No significant differences were noted stratifying patients according to meniscal healing or cyst presence, except of a lower Qol KOOS subscale in patients with peri-meniscal cysts (p = 0.0430).

Conclusions Meniscal repairs produced good short-term results when performed in combination to ACL reconstruction. Full or partial healing at MRI was present in 86% of cases. One patient out of three developed peri-meniscal cysts.

Keywords $ACL \cdot Knee \cdot Meniscus \cdot Suture \cdot Repair \cdot Healing \cdot Cyst$

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Introduction

Menisci have an important biomechanical role as a shock absorber and secondary knee stabilizer [1]; removal of even small parts of meniscal tissue increases the risk of osteoarthritis onset [2], ACL failure [3], and increasing of stress on cartilage [4] and on ligaments [5]. For these reasons, the popularity of meniscal repair has increased during the last decades and the development of the arthroscopic all-inside devices offers nowadays the alternative to overcome the drawbacks of the inside-out repairs and to guarantee satisfactory clinical results [6].

One of the most popular and studied all-inside suture devices, characterized by self-adjusting suture-containing implants, is the FasT-Fix (Smith & Nephew, Andover, MA, USA) [7]. Despite the popularity and the overall satisfactory clinical results, such device has been questioned due to possible complications such as pullout and migration of the anchors in the intra-articular soft tissues [8], tibial surface osteolysis [9], or peri-meniscal cyst formation [10]. Differently from the formers, which represent mostly rare events, the development of peri-meniscal cysts at the level of suture anchors represents a common complication. In fact, a recent report highlighted the presence of cysts in up to 40% the cases of all-inside meniscal repair with adjustable sutures [10, 11]. Another important aspect of meniscal suture that warrants further investigation is the healing of the repair. In fact, since the success of the repair is believed to not have a strict correlation with meniscal healing, MRI assessment of meniscal repair has been generally overlooked [12], especially for the newer generation devices [13].

The aim of the present study is therefore to assess the clinical outcomes of meniscal repair performed with an all-inside device (Ultra FasT-Fix) in the setting of ACL reconstruction, and to investigate meniscal healing and the presence of peri-meniscal cysts with post-operative MRI. Furthermore, through the comparison with a control group of isolate ACL reconstruction and intact menisci, the clinical effect of meniscal repair and its correlation with MRI features were investigated. The hypothesis was that good outcomes, similar to isolate ACL reconstruction, could be obtained when meniscal lesions are repaired with an all-inside device. Moreover, high rate of healing and a low number of peri-meniscal cysts not affecting clinical results were expected after all-inside repair.

Materials and methods

Initial study protocol

The present study represents the secondary analysis of prospectively collected data from a randomized controlled study (RCT) aimed to evaluate the outcome of different techniques for ACL reconstruction. The study protocol was approved by the institutional review board and all patients signed an informed consent form before the treatment. Inclusion criteria were (1) age between 16 and 50 years, (2) traumatic and isolated ACL lesion, (3) absence prior knee surgery, (4) skeletal maturity, and (5) no risk factors for osteoarthritis or other forms of arthritis.

Based on the original study protocol, 60 patients were randomly assigned to receive a standard anatomic singlebundle technique, an over-the-top plus lateral plasty technique, or a non-anatomical double-bundle technique. All the reconstructions were performed with hamstrings autograft and all patients followed the same post-operative regimen. As part of the evaluation protocol, all the patients underwent pre-operative and 18-month 1.5-T MRI analysis. Furthermore, all patients underwent pre-operative, four month, and 18-month clinical evaluation with KOOS score, Marx score, SF-36 Physical Component Score (PCS) and Mental Component Score (MCS), and objective knee laxity assessment with KT1000 and Kira accelerometer for pivot-shift. Patients were contacted at a mean follow-up of three years to investigate further surgery in the involved and contralateral knee.

Study group and comparative group

Among this initial cohort, patients were retrospectively divided based on the meniscal status, independently from the surgical technique used for ACL reconstruction. Twenty patients that underwent medial or lateral meniscus all-inside suture formed the study group and, among the 27 patients with both intact menisci, 20 were selected in order to create a 1:1 matching with the study group based on age, sex, time from injury, and surgical technique, thus creating the comparative group. The last 13 patients that underwent meniscectomy were excluded because they did not reach the minimal number required by the sample size calculation for statistical significance.

Meniscal repair surgical technique

Indications for meniscal repair were unstable lesions larger than 5 mm in the red-red or red-white zone. Repair was performed in all cases with an all-inside device (Ultra FasT-Fix, Smith & Nephew, Andover, MA, USA) through the standard arthroscopic portals. Vertical or horizontal stitches were placed based on the lesion pattern. A stitch was placed every 5 mm, until a stable construct was obtained under probing. In the case of meniscal repair, an extension brace for four weeks was used with partial weight-bearing, while passive range of motion exercises were initiated after ten days.

MRI evaluation

Healing of the meniscal repairs was assessed on 18-month MRI; these were performed at the same institution, using the same protocol, with the patients in a supine position and the knee maintained extended. The orientation of sagittal, coronal, and axial planes was defined after the acquisition of two-dimensional scout images. Two investigators evaluated all MRI using the DICOM viewer Osirix Lite 7.0.3 (Pixmeo, Switzerland) according to a pre-refined protocol. In the case of controversy, a third investigator was involved to reach consensus. Meniscal signal was assessed in pre-operative and 18-month MRI according to Mink classification [14]. Grade 0 was defined as normal meniscus with

a homogeneous hypointensity, grade I as the presence of irregularly marginated intra-meniscal sign without communication with an articular margin, grade II as a linear signal that did not communicate with an articular margin, grade IIIa linear signal intensity that communicated with articular margin, and grade IIIb as globular or irregular signal that communicated with articular margin [14, 15]. Meniscal healing was classified according to Henning's criteria [16, 17] on the 18-month MRI as "Full Healing" in the case of it was healed over the full thickness of the tear, "Incomplete Healing" in the case of healing over at least 50% of the tear, and "No Healing" in the case of fluid-equivalent signal in the tear zone in more than 50% of tear size [17]. The presence of peri-meniscal cysts was defined as the presence of a round formation with high-intensity signal on T2 MRI sequences surrounding the suture anchors, with a diameter of at least 5 mm and co-localized with the position where the FasT-Fix was used [11]. This aspect has been previously defined as "fish-eye sign." Based on radiological features (Kellgren-Lawrence grading, zone of tear, pattern of tear) and patient characteristics (age, chronicity), the Ortho One PROMT score [18] was calculated retrospectively. The latter score has been developed to predict the reparability of traumatic meniscal tears, suggesting meniscal removal in the case of lesions with score ≥ 7 and repair in the case of lesions with score ≤ 6 .

The inter-rater agreement (kappa) between the two investigators was calculated on all MRI regarding all the radiological outcomes: meniscal signal, healing of the repair, and presence of peri-meniscal cysts.

Statistical analysis

The statistical analysis was performed using the statistical software MedCalc. The sample size calculation identified a number of 18 patients per group to detect a 8 ± 8 point difference in KOOS subscales between study and control groups, which corresponds to the minimally clinical important

difference (MCID), with a power of 90% and an alpha significance of 0.05 [19].

Continuous variables were reported as mean \pm standard deviation, while categorical variables were performed as raw number and percentage of the total. Differences between the two groups, and between different follow-ups were analyzed with the paired sample *t*-test. Regarding the KOOS score, the Patient Acceptable Symptom State (PASS) threshold value [20] was used to dichotomize the KOOS subscales. When more than two groups were compared, ANOVA test was used. Categorical variables were compared using the chi-squared test or the Fisher exact test based on the number of variables considered. The inter-rater agreement (kappa) of MRI parameters was calculated between the two investigators, with its 95% confidence interval (95%CI). Kappa was rated as "very good" (0.81-1.00), "good" (0.61-0.80), "moderate" (0.41-0.60), "fair" (0.21-0.40), or "poor" (0.00–0.20). Values were considered statistically significant with p < 0.05.

Results

Patients' characteristics

Pre-operative demographic characteristics were similar between the 20 patients with isolate ACL reconstruction and the 20 patients with combined ACL reconstruction and meniscal repair. Moreover, also the different ACL reconstruction techniques were equally distributed within the two groups (Table 1). Overall, 21 menisci were repaired (17 medial and 4 lateral) in the 20 patients of the ACL reconstruction and suture group; 39% of meniscal lesions were localized in the posterior horn, 62% in the mid-body. Lesions involved the red-red zone in 57% of cases and the white-red zone in the remaining 43%. One suture was used in ten tears (47.5%), two sutures in other ten tears (47.5%), and three sutures in only one tear (5%) (Table 2). According

Table 1 Demographics and surgical characteristics of the patients included in the two groups (M, male; F, female; R, right, L, left)

	ACL $(n=20)$	ACL + suture $(n=20)$	p value
Demographics			
Age (years)	25.9 ± 8.1	25.8 ± 8.5	=0.9698
Sex (M/F)	17 (85%)/3 (15%)	18 (90%)/2 (10%)	=1.0000
Side (R/L)	11 (55%)/9 (45%)	13 (65%)/7 (35%)	=0.7469
Time from injury to surgery (months)	6.0 ± 5.0	4.9 ± 5.2	=0.4994
Surgical technique			=0.5624
Single-bundle	6 (30%)	4 (20%)	
Single-bundle + lateral plasty	9 (45%)	8 (40%)	
Double-bundle	5 (25%)	8 (40%)	

Table 2	MRI charact	eristics of the	e included	meniscal	lesions
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	Total repair $(n=2)$	21)
Meniscus involved (medial/lat- eral)		
Medial	17 (81%)	
Lateral	4 (9%)	
Tear location		
Anterior horn	0 (0%)	
Mid-body	13 (62%)	
Posterior horn	8 (38%)	
Tear zone		
Red-red	12 (57%)	
White-red	9 (43%)	
White-white	0 (0%)	
Number of stitches		
1 stitch	10 (47.5)	
2 stitches	10 (47.5)	
3 stitches	1 (5%)	
Mink classification	Pre-operative	18 months
Grade I	0 (0%)	10 (48%)
Grade II	1 (5%)	8 (38%)
Grade IIIa	17 (81%)	0 (0%)
Grade IIIb	3 (14%)	3 (14%)
Repair healing		
Complete healing	10 (48%)	
Incomplete healing	8 (38%)	
No healing	3 (14%)	
Peri-meniscal cysts		
No	14 (67%)	

to the Ortho One PROMT, all tears except one (95%) were considered repairable (score ≤ 6).

MRI assessment of the repair

Overall, ten lesions (48%) were classified as "Complete Healing" (Figs. 1 and 2), eight lesions (38%) as "Incomplete Healing", while only three lesions (14%) were classified as "No Healing" (Fig. 3) at the 18-month MRI assessment (Table 2). Peri-meniscal cysts with a diameter > 5 mm were present in seven cases (33%), either in the case of complete healing (3 cases) (Fig. 2), incomplete healing (2 cases), and no healing (2 cases) (Fig. 3). The inter-rater agreement (kappa) for meniscal signal, healing, and presence of cysts was 0.849 (95%CI 0.653–1.000), 0.847 (95%CI 0.648–1.000), and 0.889 (95%CI 0.678–1.000), respectively. Thus, the agreement was considered "very good" for all the three parameters.

There were no significant differences in patients' characteristics and lesion pattern based on the outcome of meniscal repair healing. Differently, patients with peri-meniscal cysts were significantly older (p=0.0211) with respect to those without cysts at the 18-month MRI evaluation (Table 3). Moreover, they had a higher median value of the pre-operative Ortho One PROMT score (p=0.0171) and a higher percentage of patients with a score > 4 (p=0.0263) as well.

Clinical outcomes

All clinical scores improved from pre-operative status to the four month evaluation in the two groups, except of Marx score, MCS, and KOOS Symptoms subscale (Fig. 4). However, the KOOS Symptoms subscale was significantly improved from the pre-operative status to the final 18-month follow-up only in patients with concomitant ACL and meniscal repair (p = 0.0252), but not in those with isolate ACL reconstruction (p = 0.1674).

At the pre-operative status, despite the similar mean values of all KOOS subscales, the group of ACL and meniscus lesion had a lower percentage of patients with KOOS values reaching the PASS threshold, with respect to those with

PRE-OP 18-MONTH

Fig. 1 The horizontal tear of the medial meniscus posterior horn at the pre-operative status (red arrow) is completely healed at 18-month MRI evaluation (white arrow) without the development of peri-meniscal cysts

Fig. 2 The vertical tear of the medial meniscus posterior horn and mid-body at the preoperative status (red arrow) is completely healed at 18-month MRI evaluation (white arrow), but developing a peri-meniscal cyst (yellow arrowheads) (**a**). Another medial meniscus posterior horn tear (red arrow) is completely healed after 18 months (white arrow) but with the development of two different cysts (yellow arrowheads) (**b**)

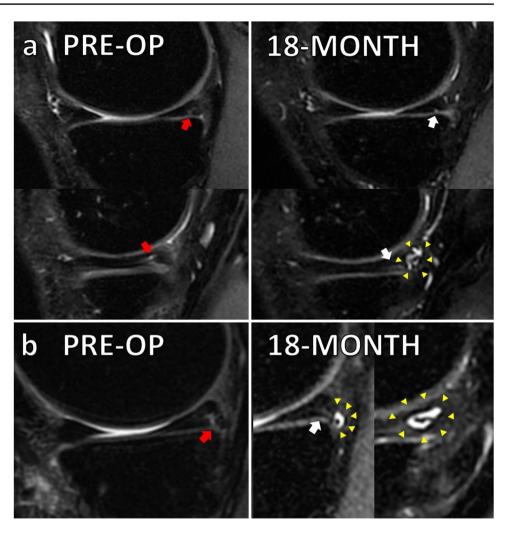
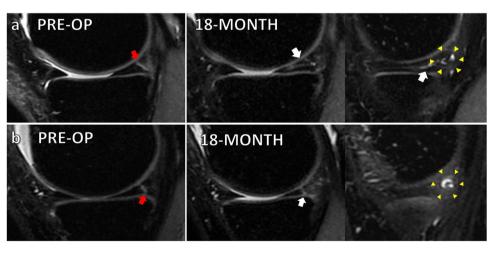


Fig. 3 The oblique tear of the medial meniscus posterior horn and mid-body at the pre-operative status (red arrow) is not completely healed at 18-month MRI evaluation (white arrow) and a cyst is present (yellow arrowheads) (**a**). Another medial meniscus posterior horn tear (red arrow) is not healed after 18 months, where a hyperintense intrameniscal signal is still present (white arrow) together with a peri-meniscal cyst (yellow arrowheads) (**b**)



intact menisci, both for the Pain (5% vs 35%, p=0.0435) and ADL (0% vs 30%, p=0.0201) subscales (Fig. 5). Differently, no difference between the two groups in the percentage of patients reaching the PASS was found at the four month and 18-month follow-up (Appendix 1).

No differences were noted at the 18 months between the control group of isolate ACL and the group of patients with "Complete Healing" or "Incomplete\No Healing" of meniscal repairs (Appendix 2). Differently, significantly lower values of the Qol KOOS subscale (p = 0.0430) were

	Repair healing assessment	ent		Peri-meniscal cyst assessment	sessment	
	Complete $(n = 10)$	Incomplete\No $(n = 11)$	<i>p</i> value	No cysts $(n = 14)$	Cysts $(n=7)$	<i>p</i> value
Demographics						
Age (years)	25.2 ± 7.2	26.4 ± 10.1	= 0.7596	23.4 ± 7.7	32.4 ± 7.8	$= 0.0211^{*}$
Sex (M/F)	9 (90%)/1 (10%)	10 (91%)/1(9%)	= 1.0000	12 (86%)/2(14%)	7 (100%)/0(0%)	= 1.0000
Side (R/L)	6 (60%)/4(40%)	8 (72%)/3(28%)	= 0.8772	8 (57%)/6(43%)	6 (86%)/1 (14%)	= 0.3771
Time from injury to surgery (months)	4.7 ± 4.3	5.0 ± 6.2	= 0.8999	3.4 ± 1.9	7.3 ± 8.2	= 0.0988
Surgical technique			= 1.0000			= 1.0000
Single-bundle	2 (20%)	2 (19%)		3 (21%)	1 (14%)	
Single-bundle + lateral plasty	4(40%)	5 (45%)		6(43%)	3 (43%)	
Double-bundle	4(40%)	4(36%)		5 (46%)	3 (43%)	
Meniscus involved			= 0.3107			=0.2549
Medial	7 (70%)	10(91%)		10 (71%)	7 (100%)	
Lateral	3 (30%)	1(9%)		4 (29%)	(%0) (0%)	
Tear location			=0.5250			= 0.1684
Anterior horn	1 (10%)	0 (0%)		1 (7%)	(%0) (0%)	
Mid-body	5 (50%)	7 (64%)		6 (43%)	6(86%)	
Posterior horn	4 (40%)	4(36%)		7 (50%)	1 (14%)	
Tear zone			=0.8499			= 0.6400
Red-Red	5 (50%)	7 (64%)		9 (64%)	3 (43%)	
White-Red	5 (50%)	4(36%)		5 (36%)	4 (57%)	
White-White	(%0)	0 (0%)		0 (0%)	(%0) (0%)	
Number of stitches			=0.4155			=0.6873
1 stitch	4 (40%)	6 (55%)		7 (50%)	3 (43%)	
2 stitches	6 (60%)	4(36%)		6 (43%)	4 (57%)	
3 stitches	(%0)	1 (9%)		1 (7%)	(%0) (0%)	
Mink classification			=0.5098			=0.3669
Grade I	(%0) (0%)	0%(0%)		0 (0%)	(%0) (0%)	
Grade II	(%0)	1 (9%)		1 (7%)	(%0) (0%)	
Grade IIIa	6 (%) (%) (%)	8 (73%)		12 (86%)	5 (71%)	
Grade IIIb	1 (10%)	2 (18%)		1 (7%)	2 (29%)	
Ortho One PROMT score						
Median (IQR)	3 (2-4)	4 (24)	=0.5202	2 (1–4)	4 (3–5)	$=0.0171^{*}$
>4 points	1(10%)	2 (18%)	= 1.0000	(%0) (0%)	3 (43%)	$= 0.0263^{*}$

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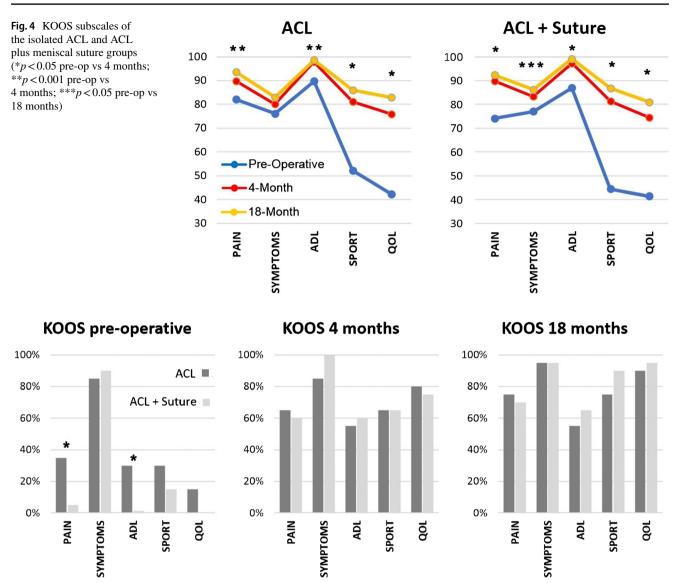


Fig. 5 Percentage of patients achieving the Patient Acceptable Symptom State (PASS) for the KOOS subscales⁴¹ at the different time points, for both isolate ACL (dark gray) and ACL plus suture (pale gray) groups (*p < 0.05)

found in patients presenting peri-meniscal cysts after allinside repair (67.0 ± 30.4) in comparison with patients without cysts (89.1 ± 10.4) and with intact menisci (82.9 ± 15.8) (Appendix 3).

Complications and re-operations

One patient (5%) in the ACL and meniscal repair group experienced a traumatic ACL re-rupture due to a knee sprain during a motocross race 22 months after surgery, while no patients (0%) with isolate ACL reconstruction experienced a re-rupture. The overall failure rate was therefore 0% at 18-month follow-up and 2.5% at three year follow-up. One other patient (5%) that underwent meniscal repair and with "No Healing" of the repair at 18-month MRI underwent partial medial meniscectomy due to increasing pain 42 months after initial surgery. Both surgical procedures were performed after the completion of the study, after the 18-month follow-up.

Five patients (13%; 2 in isolate ACL and 3 in ACL with repair) experienced contralateral ACL injury and underwent ACL reconstruction within the study follow-up period (before 18 months) in one case and after the study completion in four cases.

Discussion

The most important findings of the present study were that good short-term clinical results could be obtained after all-inside meniscal repair in combination with ACL reconstruction; such outcomes were in fact comparable to isolate ACL reconstruction with intact menisci. Moreover, some extent of repair healing was detected with MRI in 86% of cases. On the other hand, one out of three patients developed peri-meniscal cysts, which however did not affect the outcomes except the KOOS Qol subscale.

The results of the present study represent an important insight for understanding the performance of meniscal repair, using last-generation all-inside devices. This is in fact the first study to assess meniscal healing and the development of meniscal cysts with MRI using the all-inside Ultra FasT-Fix and compare its outcomes to a control group of patients with intact menisci.

Since at the pre-operative status patients with meniscal lesion amenable for repair had significantly worst pain and performances in daily life activities according to the PASS thresholds, it could be affirmed that meniscal repair was able to minimize the clinical consequences of meniscal injury in the setting of ACL reconstruction. This was confirmed by the presence of a significant improvement of KOOS Symptoms subscale at 18-month follow-up, which was not instead detected after isolated ACL reconstruction.

Another important aspect emerged from the current data is the healing rate of meniscal repair with the all-inside Ultra FasT-Fix device; in fact, the rates of complete (48%), incomplete (38%), or no healing (14%) were similar to the distribution reported by Willinger et al. [17] (56%, 35%, and 9%, respectively). However, the authors performed meniscal repair with both all-inside FasT-Fix device and inside-out sutures, included patients either with or without concomitant ACL reconstruction, and limited the evaluation to the first 6 months after surgery. Choi et al. [21] reported a similar healing rate in 25 cases with 1.5-T MRI (60%, 28%, and 12%, furthermore comparable to suture knots), and Pujol et al. [22] in 53 cases using the arthro-CT (58%, 24%, 18%). Considering this background, the data of the present study further confirm the healing capacity of meniscal repair using the all-inside Ultra FasT-Fix, which incur in a complete lack of MRI healing only in nearly 10-15% of cases. Interestingly, comparing the clinical scores stratified for MRI healing did not produce significant findings, suggesting that the main method to assess the success of meniscal repair remains the clinical evaluation, with MRI reserved mostly for possible complications. However, it should be acknowledged that, due to the small sample size and an exiguous number of not-healed repair (3 cases), it was possible the comparison only between patients with complete healing and patients with incomplete or no healing, thus possibly missing the real clinical effect of complete lack of healing. It should be acknowledged that all the patients in the present study underwent concomitant ACL reconstructionwhich is known as a positive prognostic factor for meniscal repair—all except two repairs were performed less than 12 months after trauma, and that there were no complex or bucket handle tears. All those reasons could be responsible of the enthusiastic results obtained in terms of re-operations.

The last important finding that emerged from MRI assessment of all-inside meniscal repair with the Ultra FasT-Fix was the presence of peri-meniscal cysts in 33% of cases. This value is similar to the 29% reported by Terai et al. [11] and the 36% reported by Nishino et al. [10], thus indicating that such event could be more common than generally reported [23], especially if a targeted search through MRI is carried out. However, the clinical relevance of the cyst's presence could be questioned, since no meaningful differences between patients with or without cysts were found, except the KOOS Qol subscale.

The most widely held theory behind the aetiology of perimeniscal cyst formation is that they could result from the absorption of synovial fluid through a tear in the meniscus surface, which is formed where the device needle creates a micro-trauma; therefore, migration of synovial cells can occur through the meniscal suture hole [24]. Moreover, also the interference between anchors could play a role [25]. Risk factors for cyst formation have been studied and, apart from the use of all-inside devices, were identified also in medial meniscus involvement [8, 10] and concomitant ACL reconstruction [10]. These variables were not assessed in our study since all repairs were performed with all-inside devices, always in combination with ACL reconstruction, and mostly in medial menisci (81%). Differently, an older age was found in patients with peri-meniscal cysts respect to those without cysts. This could indicate that the quality of meniscal tissue could play a role in the mechanism of cysts development, and that the effect of aging could be relevant.

The present study has several limitations. First, the sample size was small; thus, some of the statistical analysis could be underpowered. However, the extreme homogeneity in patient characteristics, repair technique, and concomitant ACL reconstruction—characteristics that are hardly found in the current literature [11, 17]—limited the role of confounders needing statistical investigation. Another limitation was the absence of complex lesions such as bucket handle tears and RAMP lesions, thus making unpredictable the results of all-inside repair in relation to these more challenging situations.

One more limitation of this study is the lack of a third group of patients undergoing ACLR and partial meniscectomy; these patients were excluded because they did not reach the minimal number required by the sample size calculation. Therefore, it is not possible to draw conclusions about the clinical benefits of meniscal suture in comparison to meniscectomy.

Finally, the fixed time point of MRI at 18 months does not allow to investigate the stepwise short-term healing course nor the long-term clinical effect and MRI signal evolution of meniscal repair. Also, MRI assessment implies the personal judgment of the operators, which was however limited because of the high reliability of the parameter used.

Conclusions

Meniscal repair with the all-inside Ultra FasT-Fix device was able to produce good short-term results when performed in combination with ACL reconstruction, similar isolate ACL reconstruction with intact menisci. Full or partial healing at MRI was present in 86% of cases, and re-rear requiring partial meniscectomy was required in only 5% of cases. However, 1 patient out of 3 developed peri-meniscal cysts, which compromised clinical outcomes only marginally.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00264-022-05426-w.

Author contribution All authors have contributed to the execution of the work. Stefano Zaffagnini, Giuseppe Filardo, and Nicola Lopomo were involved during the conception and design of the study. Luca Macchiarola, Giacomo Dal Fabbro, Gian Andrea Lucidi, and Ilaria Cucurnia took care of data acquisition, while Alberto Grassi performed analysis and took care of the writing of the manuscript. Stefano Zaffagnini dealt with surgery. Lastly, Alberto Grassi dealt with the critical revising of the article.

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Data availability Data for this study are not made available.

Declarations

Ethical approval This study was performed in line with the principles of the Declaration of Helsinki. The study protocol was approved by the institutional review board (Prot.Gen. 0013202, April 19, 2013).

Consent to participate Written informed consent to participate was obtained from all the patients involved in this study.

Consent to publish Written informed consent for material publication was obtained from all the patients involved in this study.

Competing interests The authors declare no competing interests.

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