



# Prevalence, development, and factors associated with cyst formation after meniscal repair with the all-inside suture device

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## Abstract

**Purpose** To investigate the prevalence of cyst formation after using all-inside meniscal repair device and analysed the risk factors associated with it.

**Methods** Between August 2008 and September 2013, 51 menisci of 46 patients were included in the study, 46 menisci of which had concomitant anterior cruciate ligament (ACL) ruptures and had an ACL reconstruction. Magnetic resonance imaging (MRI) of the knee was performed at 3, 6, 12 and 24 months after meniscal surgery. The MRIs were assessed to detect the development of cysts encasing the suture anchors and to evaluate meniscal healing. Statistical analysis was performed using multiple regression analysis.

**Results** Out of the 51 menisci examined, MRI revealed cysts in 15 menisci. Cysts were detected in 3 menisci at 6 months, in 9 menisci at 12 months, and in 3 menisci at 24 months after surgery. Only 3 patients (6.5%) were symptomatic, and cystectomy was performed in 2 of these patients and arthroscopic debridement in the other. Compared with using both the suture device and an inside-out suture repair, using the suture device alone was more likely to be associated with cyst development [odds ratio (OR), 12.04]. The medial meniscus was also significantly more likely to develop a cyst compared with the lateral meniscus (OR, 12.48). There was an increased outcome for the number of device use ( $P=0.033$ ). Though it was not statistically significant, the patients with anterior knee laxity (side-to-side difference  $> 3$  mm using a knee arthrometer) were more likely to develop cysts than those without anterior knee laxity ( $P=0.06$ ). There were no significant differences between the remaining variables.

**Conclusions** The prevalence of cyst formation around the suture implant was 29%, but most cases were not symptomatic. Significant risk factors for cyst formation included the use of a suture device alone, and a location in the medial meniscus.

**Level of evidence** III.

**Keywords** Meniscus · Meniscal cyst · FasT-Fix · MRI

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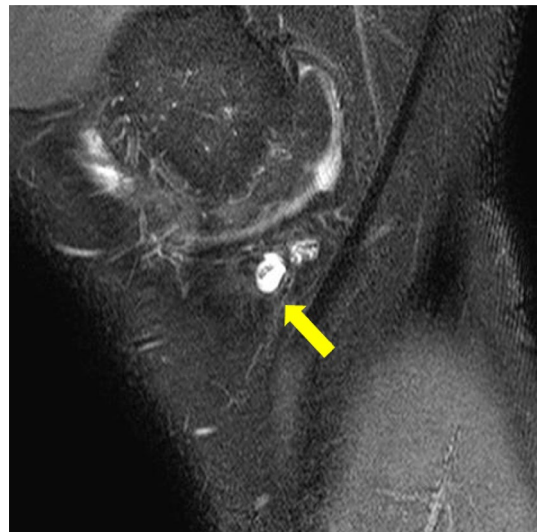
## Abbreviations

MRI	Magnetic resonance imaging
PEEK	Polyether ether ketone
DLM	Discoid lateral meniscus
ACL	Anterior cruciate ligament
AM	Anteromedial
PL	Posterolateral
IKDC	International Knee Documentation Committee
SSD	Side-to-side difference
OR	Odds ratio
CI	Confidence interval

## Introduction

Meniscal injury commonly occurs following traumatic forces applied during sports or other forms of physical exertion. The meniscus can also be torn during innocuous activities such as walking or squatting in those with a discoid lateral meniscus. Loss of meniscal function results in an increased risk of progression to osteoarthritis [1], so preservation of the meniscus is important. Arthroscopic meniscal repair is a standard treatment for meniscal injury. Since the first inside-out meniscal repair was performed in 1980 [2], inside-out meniscal repair has become the standard procedure to repair torn menisci [3]. However, the procedure carries the risk of neurovascular injury, primarily to the saphenous nerve with medial repairs [4–6] and to the peroneal nerve with lateral repairs [7, 8] and it requires additional posteromedial and posterolateral incisions. In addition, technical skill is necessary to perform an inside-out repair, so the operative time can be prolonged. Therefore, the need to develop an all-inside meniscal repair device was realized decades ago [9]. Since then, many devices have been commercialized [10–13]. Although these devices decrease operative time and make the procedure easier, there have been reports of complications due to meniscal repair devices, such as neurovascular damage [14], infection [15, 16], cartilage damage [16–19], cyst formation and synovitis [20, 21].

The FasT-Fix (Smith & Nephew, Endoscopy Division, Andover, MA) has been widely used as a meniscal repair device around the world since it was released in 2002 [13, 22, 23]. The FasT-Fix does not require an extra skin incision and it is an easy-to-use and useful device. On the other hand, there have been several reports of cyst formation after use of the FasT-Fix [20, 21], but many of them have been case reports and no studies have analysed the factors associated with cyst formation. The purpose of this study was to investigate the prevalence of FasT-Fix-related cyst formation using magnetic resonance imaging (MRI) and to analyse the risk factors associated with their development (Fig. 1). We hypothesized that the meniscus which developed FasT-Fix-related cyst shows poor healing



**Fig. 1** Sagittal MRI image showing the “Fish-eye sign”, which encases a suture anchor in a meniscal cyst (arrow)

rate compared with the meniscus without cyst. We also hypothesized that version of device and the clinical score affect cyst formation.

## Patients and methods

Between August 2008 and September 2013, 58 consecutive patients were diagnosed with a meniscal tear and underwent meniscal repair with the FasT-Fix by an experienced surgeon (Y.H.). Five patients (5 menisci) had previously undergone meniscal repair. Of 58 patients, 12 were lost to follow-up and were excluded. In total, 46 knees from 46 patients (22 female and 24 male patients) who followed up at least 2 years were included in our study. Five patients had both the medial and lateral menisci repaired with the FasT-Fix, so we included a total of 51 menisci in the study. The indication for meniscal repair was a tear at the red–red or red–white zones of the posterior to middle portions of the medial or lateral meniscus. The FasT-Fix was used for meniscal tears less than 2 cm in length. If the tear was more than 2 cm, menisci were repaired with suture and the FasT-Fix was used for the lesion of the posterior horn. In the cases of discoid lateral meniscus, saucerization was performed first, and the meniscal repair with suture was then performed for peripheral instability. We excluded patients with tears located in other horns, those who had an inside-out meniscal suture repair alone, those with multiple ligament injuries, or those with additional trauma after surgery. Institutional Review Board approval was obtained prior to conducting this study.

## FasT-Fix

The FasT-Fix device contains two 5-mm toggle anchors made of acetal resin with a pre-loaded self-sliding knot of No. 0 nonabsorbable USP (U.S. Pharmacopoeia) braided polyester suture material. The Ultra FasT-Fix device uses the same-sized anchors made of either an absorbable poly-L-lactic acid (PLLA) or non-absorbable polyether ether ketone (PEEK) material and No. 0 suture material; however, there is only non-absorbable PEEK type available in the Japanese market. In this study, the FasT-Fix was used until December 2010 and the Ultra FasT-Fix was used after January 2011. The FasT-Fix 360 was not used in this study.

## Surgical technique

General anaesthesia was administered in all patients. After diagnostic arthroscopy was performed using a 30° oblique arthroscope in the anterolateral portal and a probe in the anteromedial portal, the intraoperative morphology of the meniscus tear was determined. The tear length and the rim width were recorded at the time of surgery. In cases of a discoid lateral meniscus (DLM), saucerization was performed first, which consisted of centrifugal resection until a residual peripheral rim of 6 to 8 mm at the meniscal mid-body was confirmed using a probe with a gauge. After confirmation of meniscal instability, defined as a longitudinal tear in the vascular area of the meniscus [24], the torn edge was debrided with a meniscus rasp and shaver to stimulate a healing response. If the tear was smaller than 2 cm, it was repaired with the FasT-Fix alone. If the tear was larger than 2 cm, it was repaired with No. 2–0 braided polyester suture (Stryker Japan KK, Tokyo, Japan), and the FasT-Fix was used for repair of the posterior horn of the medial or lateral meniscus. All cases of instability at the posterior portion of the longitudinal meniscal tear were treated with an inside-out arthroscopic repair technique with stitches placed at 3-mm intervals. The FasT-Fix was used with vertical mattress suture, namely the delivery needle was introduced below the tear and then above the tear (the meniscus was perpendicularly pierced), so that the repair was completed. All patients with an anterior cruciate ligament (ACL) injury also underwent double-bundle ACL reconstruction (ACLR) with a transportal technique.

## Rehabilitation protocol

The rehabilitation protocol was different in meniscal repair alone versus meniscal repair with ACLR. After surgery, a knee brace with 10° flexion was used for a week and then knee range of motion exercises was started using a continuous passive motion device for both operations (0–90° for 3 weeks and 0–120° for 5 weeks). Partial weight-bearing

started 3 weeks after surgery and full weight-bearing was allowed 6 weeks after surgery in meniscal repair alone. In meniscal repair combined with ACLR, we waited 2 weeks to allow partial weight bearing and 5 weeks to allow full weight-bearing, because we think bone marrow from the bone tunnel stimulates the meniscal healing. Full squatting beyond 120° and bicycling were allowed after 12 weeks. Jogging began after 3 months in the group with meniscal repair alone and at 5–6 months in the group with meniscal repair combined with ACLR. Return to sports was allowed after 6 months in those with a meniscal repair alone, and after 8 months in those with a meniscal repair combined with ACLR.

## Radiographic assessment

MRI examinations were performed preoperatively and a follow-up MRI was performed at 3, 6, 12 and 24 months after surgery using a 3.0-Tesla scanner (Philips: Achieva 3.0T TX). Sequences that were utilized for the image interpretation were coronal, sagittal and axial proton density with standard settings (TR/TE: 2117/10 ms, FOV: 16 cm, matrix: 256 9 256-192, slice thickness: 3.3 mm) and fat saturation (TR/TE: 3460/80 ms, FOV: 16 cm, matrix: 256 9 256-192, slice thickness: 3.3 mm). Two orthopaedic specialists (Y.H, S.T) analysed the MRIs to identify parameniscal cysts at least 5 mm in size (Fish-eye sign) surrounding the suture anchors, and if they were co-localized with the position where the FasT-Fix was used, they were deemed to be FasT-Fix-related cysts. Each torn meniscus was evaluated using the Mink classification [25] on pre-operative and 2-year post-operative MRIs to assess the healing rate of the meniscus.

## Clinical assessment

The Lysholm score, International Knee Documentation Committee (IKDC) score and Tegner activity scale were used to assess subjective and objective clinical parameters. Side-to-side difference (SSD) was calculated using the KT-2000 knee arthrometer (MEDmetric Corporation, San Diego, CA) in those who underwent ACLR, and SSD > 3 mm indicated the existence of anterior knee laxity. If cysts were discovered, related symptoms were investigated. The data were collected preoperatively and postoperatively (at 6, 12 and 24 months).

## Statistical analysis

The Kaplan–Meier method was used to perform survival analysis using the Log-rank test. Time to failure was defined as the time to formation of the cysts after using FasT-Fix. We performed statistical analyses [Chi-square test or the

Fisher exact (2-tailed) test] to identify the effect of 10 factors (age, sex, FasT-Fix use alone vs combined inside-out and FasT-Fix use, medial menisci vs lateral menisci, ACLR and meniscal repair vs meniscal repair alone, number of devices use, type of devices used, clinical scores, anterior knee laxity, radiographic evaluation). Conditional logistic regression analyses were used to estimate odds ratios (OR) of FasT-Fix use and the 95% confidence interval (CI) for cyst generation among all subjects. Multivariable analysis was performed to remove bias among factors that predispose to FasT-Fix-related cyst formation. SAS software (version 9.3 2; SAS Institute Inc., Cary, NC, USA) was used for all analyses. Chi-square tests were used to compare clinical outcomes. The significance level was set at  $P < 0.05$ . All hypotheses were tested assuming a 0.05 significance level and a two-sided alternative hypothesis.

## Results

### Demographic data

The mean age at surgery was 24 years (range 12–48). Of the 51 menisci, 32 menisci were repaired with FasT-Fix alone

and in 19 menisci, FasT-Fix was combined with suture repair. The medial meniscus was affected in 34 knees and the lateral meniscus was affected in 17 knees. ACLR was performed in 41 knees (46 menisci). All 5 patients who had meniscal repair surgery alone (5 menisci, 5 knees) had a DLM. Among the 5 knees with a DLM, the FasT-Fix was used after saucerization in 3 menisci (3 knees), and in the other 2 menisci (2 knees) both the FasT-Fix and an inside-out suture technique were used. The FasT-Fix was used with 14 menisci and the Ultra FasT-Fix was used with 37 menisci. Significantly increased outcome was identified for the number of device use (Table 1).

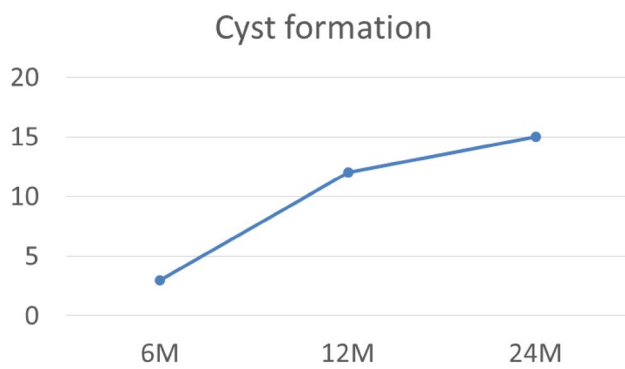
### Cyst formation

The mean follow-up in this study was 3.78 years (range 2–7 years). Out of the 51 menisci examined, MRI revealed cyst formation in 15 menisci (29.4%) (Fig. 3a). Cyst formation was detected in 3 menisci at 6 months, in 9 menisci at 12 months, and in 3 menisci at 24 months after surgery (Fig. 2). Within 46 patients, forty-three patients (93.5%) had asymptomatic menisci, while 3 patients (6.5%) were symptomatic. One patient developed a symptomatic cyst 4 years after surgery with slight tenderness, one felt pain

**Table 1** Characteristics of menisci with cysts and without cysts

Characteristics	Menisci with cyst formation ( $N=15$ )	Menisci without cyst formation ( $N=36$ )	$P$ value
Age (years)	20.7	25.4	
Mean $\pm$ SD	7.6	10.7	0.31
Range	12–38	14–48	
Sex			
Male	6	20	0.43
Female	9	16	
Suture procedure			
FasT-Fix alone	13	19	0.034
FasT-Fix with suture	2	17	
Menisci			
Medial	13	21	0.088
Lateral	2	15	
Surgery			
ACLR and meniscal repair	15	31	0.13
Saucerization with repair	0	5	
Device			
FasT-Fix	3	11	0.44
Ultra FasT-Fix	12	25	
Usage of FasT-Fix			
1	1	16	0.033
2	6	9	
3	2	6	
4<	6	5	

ACLR anterior cruciate ligament reconstruction



**Fig. 2** MRI was used to detect cyst formation. Cyst formation was observed in 3 menisci at 6 months after surgery, in 9 menisci at 12 months after surgery, and in 3 menisci at 24 months after surgery

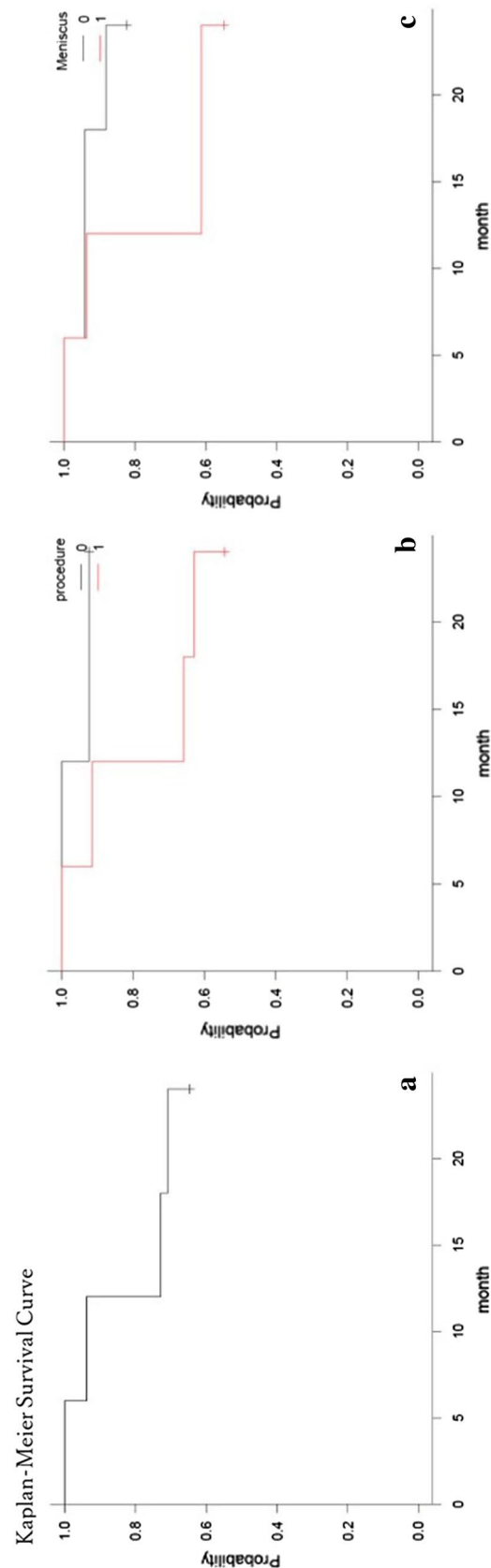
with movement 1 year after surgery and was found to have developed a cyst, and another experienced pain with deep flexion 2 years after surgery. Two cases underwent cystectomy and one had the cyst removed with an arthroscopic shaver, and all became asymptomatic after surgery. There was one failure which was revealed during the second look arthroscopy and was performed partial meniscectomy.

### Univariate and multivariate analysis

Compared with the subjects with combined use of the inside-out suture and FasT-Fix, the subjects with FasT-Fix alone had an increased risk of cyst formation (Fig. 3b). The crude OR of the subjects with FasT-Fix alone was 5.81 and this was increased after adjustment for all other confounders (OR 12.05, 95% CI, 1.81 to 83.33,  $P=0.010$ ). On the other hand, although the crude OR for the number of FasT-Fix used was 11.20, the adjusted OR was 0.71 and the significance of cyst formation disappeared. We were unable to calculate values for the subjects undergoing ACLR and meniscal repair versus meniscus repair alone. Surgery on the medial meniscus tended to increase the rate of cyst formation using the Chi square test ( $P=0.088$ ), but after multivariate analysis, the adjusted OR increased to 12.48 (95% CI 1.59–97.99) and the  $P$  value was 0.016, making medial meniscus involvement a significant risk factor (Fig. 3c). There were no statistical differences observed with the remaining factors (Table 2).

### Clinical and radiographic outcomes

There was no significant difference in characteristics between the cohort with cyst formation and those without cyst formation. However, though not statistically significant, patients with anterior knee laxity ( $SSD > 3$  mm) were observed only in the cohort with cyst formation ( $P=0.06$ ). The healing rate of the menisci was measured using the



**Fig. 3** Kaplan–Meier survival curve for meniscal cysts. **a** Total meniscus. **b** Isolated FasT-Fix (1) and combined meniscal repair (0) **c** Medial (1) and lateral meniscus (0)

**Table 2** Outcomes of uni- and multivariate analysis for cyst formation

Variable	Univariate analysis		Multivariate analysis	
	Odds ratio (95% CI)	<i>P</i> value	Odds ratio (95% CI)	<i>P</i> value
FasT-Fix alone vs FasT-Fix with suture	5.81 (1.14–29.4)	0.034	12.05 (1.81–83.33)	0.01
ACLR and meniscal repair vs Meniscal repair	Not calculable			
Female vs Male	1.81 (0.61–6.81)	0.24	1.21 (0.25–5.90)	0.81
Medial meniscus vs Lateral meniscus	4.13 (0.81–21.3)	0.088	12.48 (1.59–97.99)	0.016
More than 2 FasT-Fix vs 1 FasT-Fix	11.20 (1.33–94.47)	0.026	0.71 (0.07–6.78)	0.76
FasT-Fix vs Ultra FasT-Fix	1.76 (0.41–7.51)	0.44	0.70 (0.13–3.66)	0.67

ACLR anterior cruciate ligament reconstruction, CI confidence interval

Mink classification, but no significant differences were found between the two groups (Table 3).

## Discussion

The most important finding of this study was that we have revealed the prevalence of cyst formation after using the meniscal repair device “FasT-Fix” and its risk factors. The meniscal repair device “FasT-Fix” has the potential to lead to cyst formation and in some cases require extra surgery to remove the implants [26]. In this study, we found that cyst formation occurred in 29% of those in which the FasT-Fix was used, but in case of symptomatic the percentage decrease to 6.5% among 46 patients. Only 2 previous studies have reported the prevalence of cyst formation [20, 21]. Choi et al. found an overall 8% incidence of cyst generation, and Hoffelner et al. found an overall 11.1% incidence in their

study [20, 21]. There was small difference among our study and previous 2 studies.

Our results indicated that menisci repaired with FasT-Fix had cyst formation, with an average of  $12.4 \pm 5.3$  months after surgery. Twelve menisci out of 15 (75.0%) developed cysts within 1 year. The risk factors for cyst formation were investigated using both univariate and multivariate analyses. In this study, the risk factors on multivariate analyses were the use of FasT-Fix alone, and surgery involving the medial meniscus. One of the possibilities that using FasT-Fix alone is a risk factor for cyst formation may be that the load to failure of FasT-Fix is lower than that of suture repair [27]. Another reason may be that in more than 90% of menisci, the FasT-Fix was used at the posterior horn of the meniscus, and bearing stress was converted into shear stress, leading to cyst development behind the posterior horn of the meniscus. Surgery to the medial meniscus was also a risk factor for cyst formation. Dold et al. reported in their anatomical research

**Table 3** Outcomes at pre-op and final follow-up examination

Variable	Pre-op			Post-op 2Y		
	Cohort with cyst formation	Cohort without cyst formation	<i>P</i> value	Cohort with cyst formation	Cohort without cyst formation	<i>P</i> value
Lysholm score	63.2 ± 18.2	60 ± 18.5	0.70	95.3 ± 3.1	94 ± 6.3	0.24
IKDC score	54.5 ± 12.6	57.8 ± 14.3	0.78	82.6 ± 4.9	79.6 ± 7.7	0.53
Tegner scale	2.9 ± 0.9	2.8 ± 0.8	0.66	6.2 ± 1.3	6.0 ± 1.2	0.70
SSD ≤ 3mm				13	25	0.06
SSD > 3mm				2	0	
MRI						
Mink 0	0	0		4	11	
Mink 1	1	2		3	4	
Mink 2	0	1		2	3	
Mink 3A	3	5		4	5	
Mink 3B	11	28		2	13	
Mink improved				10	24	1
Mink not improved				5	12	

IKDC International knee documentation committee score, SSD side-to-side difference in KT-2000 measurements, MRI magnetic resonance imaging



that the medial meniscus that has a tear at the posterior horn has increased instability because the meniscotibial portion of the deep medial collateral ligament is an essential stabilizer with the so-called brake-stop function to resist anterior tibial translation [28]. In addition, screw-home movement of the tibiofemoral joint which denotes the cartilage of medial condyle is likely to receive more damage than lateral condyle in terminal knee extension [29, 30] and it is well known that medial meniscus has poorer mobility than lateral meniscus during knee flexion due to the peripheral attachment [31]. Therefore, it seems reasonable to conjecture that cysts tend to occur at the medial meniscus. The number of device use significantly increased in the menisci with cyst formation and Hupperich's report does not conflict with our result [32]. Anterior knee laxity was observed only in the cohort with cyst formation even though the difference was not significant on Chi-square tests. There was a trend, however, since this result was consistent with the interpretation of the results of the multivariate analyses. On the other hand, contrary to our prediction, the type of device used, the clinical scores, and the healing rates of menisci were not significant risk factors for cyst formation. The implants of FasT-Fix consist of acetal resin and that of Ultra FasT-Fix consist of PEEK material. In this study, there was no significant difference between the two materials. The both implants were non-absorbable; therefore, it might be possible to say that the Ultra FasT-Fix with absorbable PLLA anchors, which is not available in Japanese market, could result in different outcome. Clinical outcomes such as the Lysholm score, IKDC score and Tegner activity scale were not related to cyst formation. This indicates that the intensity of activity may not affect cyst formation, but knee instability may potentially lead to cysts. Meniscal healing rate was not associated with cyst formation, even though we speculated meniscal poor healing facilitate cyst formation. According to Kijowski's report, the signal change on MRI did not reflect true meniscal healing [33]. If healing rate of repaired meniscus was evaluated by arthroscopy, the result could be different.

The cause of cyst formation was considered by Kimura et al. to be the pumping action from joint motion, while Kang et al. suggested that it was due to irritation from repetitive trauma from the suture threads [34, 35]. Lombardo et al. suggested that sutures should be placed at least 4 to 5 mm apart, and that it was advantageous to minimize the size and number of sutures [36]. In addition, we believe that the hole created by the needle promotes cyst formation. The FasT-Fix should be used in combination with an inside-out procedure, and its anchors should be shot in such a way that they do not interfere with each other.

Our study had several limitations. First, it was a retrospective cohort study and vulnerable to bias associated with patients' backgrounds. Second, we did not assess meniscal healing using arthroscopy, but rather with MRI. If meniscal

healing had been assessed by arthroscopy, the relationship between healing rate and meniscal cysts could be detected. However, it is difficult to use second-look arthroscopy in all patients due to cost. Third, the number of samples was not large, and the follow-up period may have been inadequate to fully evaluate the factors associated with cyst formation. Fourth, the location of the cysts was not considered in this study, though almost all the cysts occurred in the posterior segment. Fifth, the follow-up rate is slightly high because of the young average age. Sixth, there are two different types of anchor in this study and may influence the results; however, there was no significant difference between anchors for developing cysts.

## Conclusion

In this study, the prevalence of cyst formation on MRI after meniscal repair using FasT-Fix was 29.4%. Use of the FasT-Fix alone and surgery to the medial meniscus were considered risk factors for the development of meniscal cysts.

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## Compliance with ethical standards

**Conflict of interest** No authors declare any conflicts of interest relating to the submitted paper.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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