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Suture Tape Augmentation ACL Repair; Stable Knee and Favorable PROMs, but a Re-rupture Rate of 11% Within Two Years

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

- **Authors' contribution**

This manuscript has been written by Dr. Heusdens who treated study patients, collected study data and who was a major contributor to the writing of the manuscript, Karen Blockhuys who was a major contributor to the writing of the manuscript, Ella Roelant who performed statistical analyses on the study data and helped editing the manuscript, Dr. Dossche who treated study patients, collected study data and helped editing the manuscript, Prof. Van Glabbeek who helped editing the manuscript and Prof. Van Dyck who interpreted MRI scans of study participants and helped editing the manuscript.

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Abstract

Purpose

The aim of this study is to investigate clinical and magnetic resonance imaging (MRI) outcomes after anterior cruciate ligament (ACL) repair using the suture tape augmentation (STA) technique.

Methods

This prospective interventional case series included 35 patients who underwent STA ACL repair and were all followed up for two years. The ACL rupture was between 4 and 12 weeks old and per-operatively confirmed repairable. The International Knee Documentation Committee (IKDC), Lysholm and Tegner scores were collected together with return to work (RTW), return to sport (RTS), re-rupture and re-intervention rate. Lachman testing was performed and ACL healing was evaluated on MRI using a grading scale based on the ACL's morphology and signal intensity with grade 1 representing good ACL healing and grade 3 representing poor ACL healing.

Results

The number of patients who returned to their pre-rupture level for IKDC, Lysholm and Tegner scores at two years of follow-up are 17/26 (65.4%), 13/25 (52.0%) and 18/27 (66.7%) patients, respectively. Median RTW and RTS periods were 5.5 weeks (range 0 to 32 weeks) and 6 months (range 2 to 22 months), respectively. The Lachman side-to-side difference decreased significantly ($P < 0.001$) to less than 3 mm after surgery and remained stable. Four patients (11.4%, 95% CI [3.2, 26.7]) suffered from a re-rupture and three other patients (8.6%, 95% CI [1.8, 23.1]) needed a re-intervention for another reason than re-rupture. MRI follow-up of 31 patients showed overall grade 1 ACL healing in 14 (45.2%) patients, grade 2 ACL healing in 11 (35.5%) patients and grade 3 ACL healing in 6 (19.4%) patients. A higher risk of re-rupture was associated with grade 3 ACL healing at 6 months postoperatively and a pre-operative Tegner score of ≥ 7 .

Conclusion

This study shows that treatment of the acute, repairable ACL with the STA technique leads to a stable knee and favorable patient-reported outcome measures (PROMs). However, the re-rupture rate of 11.4% within the 2-year follow-up is a concern.

Level of Evidence: Level IV.

Keywords

Anterior cruciate ligament · Anterior cruciate ligament rupture · Anterior cruciate ligament repair · Anterior cruciate ligament preservation · Suture tape augmentation · Suture tape reconstruction · Internal Bracing

Abbreviations

ACL	Anterior Cruciate Ligament
DIS	Dynamic Intraligamentary Stabilization
DTI	Diffusion Tensor Imaging
IKDC	International Knee Documentation Committee
MRI	Magnetic Resonance Imaging
PCL	Posterior Cruciate Ligament
PROM	Patient-reported Outcome Measure
RTS	Return to Sport
RTW	Return to Work
STA	Suture Tape Augmentation Technique
VAS	Visual Analogue Scale

Introduction

In the 1970's and 80's, repair techniques were performed to treat anterior cruciate ligament (ACL) ruptures. These open repair techniques were abandoned after disappointing five year follow-up outcomes and ACL reconstruction became the gold-standard treatment [10, 32]. The introduction of several novel ACL repair techniques in the last decade has led to renewed interest in acute primary ACL repair [15, 22, 30, 32].

Van der List et al. reported that arthroscopic ACL repair techniques were safe, with failure rates of 7 – 11%, no complications and functional outcome scores of > 85% of maximum scores [32]. Bucci et al. also reported that current literature on ACL repair reports better outcomes than in the past and subjective patient-reported outcome measures (PROMs) following ACL repair are not inferior to PROMs after ACL reconstruction [5].

One of the most published ACL repair techniques is the Dynamic Intraligamentary Stabilization (DIS) technique. The first publications by the DIS developer group confirm the healing capacity of the ACL and report excellent patient satisfaction and re-rupture rates of 2.9% and 10% [7, 15]. More recent publications from independent researchers show re-rupture rates up to 20% at two year follow-up and failure rates of 30% at five year follow-up [3, 37].

The Suture Tape Augmentation (STA) technique is a repair technique that preserves the native ACL and provides a secondary stabilizer to reinforce the repaired ACL during the healing phase [17, 42]. Preservation of the native ligament and its proprioceptors contributes to the feedback on position and dynamic stability of the knee, which improves rehabilitation after surgery [17, 24, 25, 30]. The STA technique is less invasive compared to ACL reconstruction as graft harvesting morbidity is avoided, and the 3.5 mm bone tunnels drilled for the STA technique are less than half the size of bone tunnels needed for ACL reconstruction [17, 25, 32].

Currently, literature on STA ACL repair is not extensive. Two STA ACL case series report promising results in terms of an increase in PROMs and re-rupture rates of 4.8% and 1.5%. However, both studies do not compare postoperative data with pre-rupture data and lack a clinical as well as magnetic resonance imaging (MRI) follow-up [17, 22]. A retrospective study by Ortmaier et al. on sports activity, states that short-term outcomes after STA ACL repair and ACL reconstruction are comparable, and that STA treatment enables sports activity and provides a sense of well-being similar to that of classic ACL reconstruction [36].

To the best of our knowledge, no independent prospective clinical results, longitudinal MRI follow-up or risk factors for re-rupture on STA ACL repair have been reported yet.

The purpose of this study was to investigate clinical results, re-rupture risk factors and MRI outcomes, two years after primary ACL repair with the STA technique. The hypothesis was that STA ACL repair would lead to an acceptable re-rupture rate around 6% and good clinical outcomes in terms of PROMs and knee stability.

Material & Methods

Patient recruitment

This prospective case series was approved by the institutional review board of the Antwerp University Hospital (B300201525523) and written informed consent was obtained from all study participants. Patients with a proximal or mid-substance bundle ACL rupture between 4 and 12 weeks old at the moment of surgery were recruited for treatment with the STA technique. Patients with an acute ACL rupture of less than four weeks old were recruited for treatment with DIS in a different study. Per-operative evaluation of good ACL tissue quality and sufficient contact between the stumps were vital inclusion criteria and determined whether the ACL was suitable for repair. Patients who were not active in sports and therefore could be treated with a conservative treatment, or patients who had multi-ligament injuries, excluding medial collateral ligament or anterolateral ligament lesions, or fractures that could compromise rehabilitation were not included.

Seventy-two patients presented at the Antwerp University Hospital between 2015 and 2017 with an acute ruptured ACL of less than 12 weeks old. Thirteen patients were pre-operatively excluded for not meeting in- and exclusion criteria. Fifteen patients were treated within 4 weeks with DIS and 44 patients were allocated to be treated with the STA technique. Seven of these 44 patients were per-operatively excluded due to a non-repairable ACL rupture and two patients refused to be followed up. This prospective case series thus includes the first 35 consecutive patients treated with the STA technique at the Antwerp University Hospital who were all followed up for two years. (Figure 1)

The mean age (SD) of the study population was 32.8 (9.7) years old and ranged from 18 to 54 years, 18 (51.4%) patients were female.

Study design

Pre-rupture and postoperative PROMs after 6, 12 and 24 months were collected via questionnaires completed during consultation. The International Knee Documentation Committee (IKDC), Lysholm, Tegner and Visual Analogue Scale (VAS) satisfaction scores were collected [13, 41]. Time between the surgery and return to work (RTW), time between the surgery and return to sport (RTS), re-intervention and re-rupture data were collected as well. Patients who suffered from re-rupture were subsequently treated with ACL reconstruction and further excluded from analysis of study results. Lachman testing was performed using a Rolimeter (Aircast, Neubeuern, Germany) to measure the anterior-posterior knee laxity difference between the injured and contralateral knee [19]. Clinical failure was defined as Lachman test of >3 mm difference between the injured and contralateral knee in combination with a subjective feeling of instability. All patients were asked to undergo MRI follow-up at 6, 12 and 24 months postoperatively. Imaging was performed on a commercially available, clinical whole-body 3T MRI system (Magnetom Prisma Fit, Siemens Healthcare, Erlangen, Germany). A dedicated phased-array knee-coil with 15 receiver channels and 1 transmission channel (Quality Electrodynamics, Mayfield Village, OH, USA) was used. A radiologist with 20 years of experience in musculoskeletal radiology interpreted all images, blinded to the patient's clinical information. ACL healing on MRI was evaluated and categorized based on the ACL's morphology and signal intensity, as follows: grade 1: well-defined, straight, continuous, normal-sized ACL with signal intensity similar to or only slightly higher than that of the posterior cruciate ligament (PCL); grade 2: normal sized (or slightly thickened) continuous, straight ACL demonstrating a high signal compared to that of the PCL;

and grade 3: an ill-defined, irregular ACL that is thinned or not discernible [23, 40]. The ACL healing grade was defined per time point and an overall healing grade was determined for each patient with two or three postoperative MRI images based on the evolution of the ACL's healing process over time during follow-up. For the test-retest reliability we calculated a weighted kappa and found a very good reliability of 0.85 (95% CI [0.71, 0.98]) [29].

Surgical technique

The surgical technique has previously been described by Heusdens et al. [17]. Proximal and mid-bundle ACL ruptures were repaired using the STA technique (InternalBrace™ Ligament Augmentation Repair, Arthrex Inc., Naples, FL). After inspection of the ACL stump, a 3.5 mm tibial tunnel was drilled, ending at the center of the ACL footprint. A looped suture (FiberLink®, Arthrex Inc., Naples, FL) was placed through the distal ACL stump. At the femoral attachment, two to four microfracturing holes were made to enhance healing of the ACL. The femoral tunnel was drilled from the center of the femoral footprint inside out, with the knee fully flexed. A suture shuttle and the looped suture were passed through the femoral tunnel. A femoral button, loaded with a high-strength tape (FiberTape®, Arthrex Inc., Naples, FL), was flipped on the femoral cortex and the high-strength tape was advanced in the femoral tunnel. The high-strength tape was fixed in extension in the tibia with a bone anchor (SwiveLock®, Arthrex Inc., Naples, FL). The ruptured ACL fibers were gently tensioned with the looped suture to approximate the distal stump to the femoral footprint with the knee in 90° of flexion. The looped suture was tied on the femoral button with appropriate tension on the ACL.

Postoperative rehabilitation

The postoperative rehabilitation protocol could be compared to an accelerated ACL reconstruction protocol. Patients were allowed full weight-bearing with crutches as required during the first weeks. Physical therapy focused on early range of motion, muscle control and restoration of function. This was facilitated by the limited pain and swelling, allowing accelerated early-phase rehabilitation. Patients were allowed to perform pivoting sports if the knee had a full range of motion, no effusion, upper leg muscular circumference > 90% and a single leg hop test > 90% [17].

Statistical analyses

A post-hoc sample size calculation was performed, indicating that to obtain a 95% confidence interval of width 16% around the acceptable re-rupture rate of 6%, a total of 34 patients was needed. The goal of this study was to recruit all possible patients during a two-year period and explore the findings. IKDC, Lysholm, VAS satisfaction scores and the Lachman difference were presented as mean with standard deviation (SD) and Tegner score as median with range at the different time points. A linear mixed model including time (categorical variable) as a fixed effect and individual as a random intercept was fitted for each of the outcomes. In case of a significant time effect, post-hoc testing was done comparing each of the considered time points to the pre-rupture (preoperative) values on the one hand, and the consecutive time points on the other. Raw and corrected P values using the Bonferroni-Holm correction for multiple testing were reported. The mixed model was corrected for age and gender by adding these factors, one by one, to the model. Return to pre-rupture level was defined respectively for the IKDC, Lysholm and Tegner scores. A return to pre-rupture level was considered for the IKDC score if the current score was higher than or equal to the IKDC score pre-rupture minus 10 points [20]. A return to pre-rupture level was considered for the Lysholm score if the current score lay within the same range or a higher range as the pre-

rupture score, assuming the following ranges: < 65 poor, 65 – 83 fair, 84 – 90 good, > 90 excellent [33, 41]. For the Tegner score, a return to pre-rupture level was considered when the current score was the same as or higher than the pre-rupture score [20, 41]. Median times to reach the pre-rupture level were calculated for each of these scores with 95% confidence intervals. For RTW and RTS, Kaplan-Meier curves were produced and median RTW and RTS with 95% confidence intervals were reported. For each time point during follow-up, the proportion of patients with different grades of ACL healing on MRI were reported. The ACL re-rupture rate was expressed as a proportion with 95% confidence interval (using exact Clopper-Pearson method). The association between the occurrence of re-rupture and the type of rupture, grade of ACL healing on MRI 6 months postoperative, preoperative Tegner score (< 7 versus \geq 7) and age (< 25 versus \geq 25) on re-rupture was evaluated using a Fisher's exact test. Results were considered significant if $P < 0.05$. All analyses were performed with SPSS statistics (IBM, version 21) and R 3.5.2 (R core team, 2018) except the mixed model, which was done in SAS 9.4 (SAS Institute, Cary NC).

Results

Patient and surgical characteristics

The patient population of this study consists of non-elite athletes from various sport levels, with pre-rupture Tegner scores ranging from 1 to 9, and a median Tegner score of 6. Pre-rupture, 9/33 (27.3%) patients were performing heavy physical work, 10/33 (30.3%) patients light physical work and 14/33 (42.4%) patients sedentary work, the working category of the two remaining patients is unknown.

Twenty-two (62.9%) patients had one or more additional procedures together with the STA surgery. (Table 1) The overall mean (SD) surgery time was 91 (21) minutes. The mean (SD) surgery time of the patient group ($n = 22$) that underwent additional procedures during primary intervention was 102 (18) minutes and of the patient group ($n = 13$) without additional procedures was 73 (11) minutes.

Clinical outcomes during 2-year follow-up

Mean scores (SD) of IKDC, Lysholm and VAS satisfaction at different time points during follow-up are reported in Table 2 together with the mean (SD) Lachman side-to-side difference in millimeters and median Tegner (range). The Lachman side-to-side difference remained < 3 mm postoperatively for all patients and no clinical failure was observed, except for those suffering from re-rupture. A linear mixed model with time as fixed effect showed significant effects over time for all these measurements ($P < 0.001$), except for VAS satisfaction (n.s.) which can be expected since there are no preoperative data available about patient satisfaction. Comparing the two-sided 95% CI for the difference between IKDC score at 24 months postoperatively and pre-rupture [15.1, -4.7] to a non-inferiority margin of 10 IKDC points, showed no non-inferiority after 24 months compared to the pre-rupture level. When correcting the linear mixed model for age and gender we found a significant effect of these variables on the reported Tegner scores ($P = 0.012$ and $P = 0.041$, respectively). On average there is a decrease in Tegner score of 1 point per 10 years (95% CI [-1, -0.2]) and on average this score is 1 point (95% CI [-2, -0.04]) lower for women compared to men (time estimates were similar in the unadjusted and adjusted models). (Supplementary table 1)

The proportions of patients who returned to their pre-rupture level for IKDC, Lysholm and Tegner scores at different time points during follow-up are reported in Table 3. The median times to return to the pre-rupture level were 24 months (95% CI [17.8, 30.2]), 6 months (95% CI [3.2, 8.8]) and 12 months (95% CI [5.6, 18.4]) for the IKDC, Lysholm and Tegner score, respectively. The median RTW period was 5.5 weeks (95% CI [4.4, 6.6]), ranging from 0 to 32 weeks, and is represented in Figure 2. The median RTS period was 6 months (95% CI [4.6, 7.4]), ranging from 2 to 22 months, and is represented in Figure 3.

MRI, re-intervention and re-rupture

The proportion of patients for the different grades of ACL healing per time point are presented in Table 4. Crosstabulation of the ACL healing grades showed that ACL healing grade did not change between one and two years of follow-up for the 20 patients who fully completed their MRI follow-up.

Three (8.6%) patients had a second surgery. One patient was treated for a medial meniscus rupture in combination with arthrofibrosis. The second patient suffered from arthrofibrosis and a cyclops lesion. The third patient was treated for an extension deficit that was caused by an overly tight FiberTape® (Arthrex, Inc., Naples, FL). These problems were solved after the re-intervention.

Four other patients (11.4%) suffered from re-rupture. One patient had a motorcycle accident 7 months postoperatively which resulted in an ACL re-rupture. Two patients experienced the re-rupture while playing soccer at 9 and 13 months postoperatively and one patient while dancing 22 months postoperatively. These patients were subsequently treated with an ACL reconstruction and further excluded from analysis of study results. Significance between type of rupture (proximal or mid-bundle), age, pre-operative Tegner score, and grade of ACL healing on MRI six months postoperatively and re-rupture are reported in Table 5.

Discussion

The most important findings of this study are that treatment with the STA ACL repair technique leads to a stable knee and favorable PROMs. However, four (11.4%) patients of our study cohort experienced a re-rupture within the two year follow-up. Analysis of risk factors for re-rupture showed that patients with a pre-operative Tegner score of ≥ 7 and with grade 3 ACL healing on MRI 6 months postoperatively have a higher chance of re-rupture.

Longitudinal MRI follow-up shows healing of the ACL between 6 and 12 months. The healing status remained unchanged between 12 and 24 months postoperatively in our study, suggesting that the repaired ACL does not further heal after one year postoperatively. Similar findings have been described in a study after ACL repair with DIS [16]. However, in a non-longitudinal MRI study, van der List et al. describe different results after ACL repair with a hyper intense repaired ligament within one year, and a signal similar to that of the intact PCL only after two years [31]. Van Dyck et al. performed a Diffusion Tensor MRI (DTI) study on 14 patients treated with the STA technique. DTI results are different from conventional MRI, as DTI provides information about tissue microstructure and its degree of organization by quantifying water diffusion. Their findings suggest that healing of the ACL is incomplete at 24 months postoperatively [6]. We observed overall poor ACL healing on MRI in six (19.4%) of our study patients during the two year follow-up. Mid- to long-term MRI follow-up could contribute in determining the ACL repair healing time and potential clinical consequences. In addition, we observed a significant association between grade 3 ACL healing at six months postoperatively on MRI and re-rupture ($P =$

0.006). Postoperative MRI grading as a possible predictor for re-rupture after ACL repair has not been described before and needs to be further investigated.

Only two other STA ACL repair case series on adults, from the developer of the STA technique, have been published. They reported re-rupture rates of 1.5% and 4.5% [17, 22]. The re-rupture rate of 11.4% in this case series is rather high. The learning curve that comes with new techniques could be a possible explanation for this re-rupture rate. Also, patient selection could have influenced the re-rupture rate as patients with proximal and mid-bundle ruptures were included while recent literature on other ACL repair techniques states that mid-substance ruptures are less suitable for repair and have a higher complication rate [8, 9, 34, 39]. Achtnich et al. and Jonkergouw et al. found similar results regarding failure after ACL repair using suture anchors with failure rates of 15% and 10.7%, respectively [1, 24]. Ahmad et al. conclude that there is evidence for the potential space of ACL repair in the decision tree for individualized treatment, and the best outcome will be in hands of the best patient selectors [2].

A quick rehabilitation was observed in this case series with a median RTW of 5.5 weeks (range 0 to 32 weeks) and median RTS of 6 months (range 2 to 22 months). Patients were only allowed to return to their pivoting sports if the knee had a full range of motion, no effusion, upper leg muscular circumference > 90% and a single leg hop test > 90% [17]. Groot et al. describe a general RTW of 11 weeks after ACL reconstruction [12]. Lai et al. report that most elite athletes RTS between 6 and 13 months after ACL reconstruction, which is less time than reported for non-elite athletes [28]. The healing phases of the repaired ACL differs from the ACL reconstruction ligamentization phases and therefore the rehabilitation period could be different as well [40]. The quick rehabilitation in our study could be explained by the less-invasive STA technique and the preservation of the native ACL with its proprioceptors. ACL reconstruction does not preserve the native ligament with its proprioceptors which could lead to overloading of the ACL graft or loss of confidence in the knee [4, 11, 22, 25]. Kiapour et al. state that preservation of the native ACL with its proprioceptors may lead to more normal joint mechanics and a decreased risk for post-traumatic osteoarthritis [25].

The proportion of study patients who returned to their pre-rupture level for IKDC, Lysholm and Tegner score increased over time to 65.4%, 52.0% and 66.7%, respectively, but it needs to be noted that some patients who reached their pre-rupture level within one year lost this level again at two years. This is also observed after ACL reconstruction [20]. Ardern et al. report that less than 50% of patients RTS at their pre-rupture level after ACL reconstruction [4]. Ohsawa et al. on the other hand report that 64.6% of patients return to their pre-rupture level of Tegner score after ACL reconstruction, which is similar to the proportion observed in this study [35].

Risk factors for a re-rupture with the STA technique have not previously been described for adults. For DIS repair, young age and a high level of sport activity have been found to influence the risk of failure [2, 3, 14, 26, 27]. This case series with four patients who experienced a re-rupture, suggests a higher risk on re-rupture for patients with a pre-operative Tegner ≥ 7 ($P = 0.035$) and for patients with grade 3 ACL healing on MRI at 6 months postoperatively ($P = 0.006$). In this study, the risk on a re-rupture for patients younger than 25 years did not reach significance ($P = 0.061$). As patient selection is emphasized for ACL repair further investigation is needed [2].

The re-intervention rate of 20% in this STA ACL repair cohort study is similar to the re-intervention rate reported in other studies. Rousseau et al. observed a surgical re-intervention rate of 28% in their cohort of 958 ACL

reconstruction patients [38]. Two randomized controlled trials comparing ACL DIS repair versus ACL reconstruction, report an overall re-intervention rate of 25.6% and 29.5% in the ACL DIS repair groups versus 22.5% and 33.3% in the ACL reconstruction groups [20, 26].

This study has several limitations. First, the sample size is relatively small, as the goal of this study was to recruit all possible patients during a two-year period and explore the findings. We realize that a sample of 35 patients is not adequate to prove non-inferiority of 24 months to pre-rupture or the estimate percentage returned to pre-rupture level in a very precise way due to lack of power. Also the results on the effect of patient characteristics on the clinical outcomes or the analysis of the risk factors for re-ruptures are only explorative in this relative small sample and need further investigation. However results in this study can serve as a pilot to guide future sample size calculations. Secondly, as this study is a case series, no direct comparison can be made between the STA technique and reconstruction surgery or other repair techniques. Hence, high-quality large randomized clinical trials with longer follow-up comparing ACL repair techniques and ACL reconstruction are needed [18, 21]. Third, patients were recruited at one center, which could bias the representativeness of our study population. Fourth, a learning curve could have influenced the results as patients included in this case series are the first patients who have been treated with the STA technique by two surgeons.

To the best of our knowledge, this is the first case series which presents independent prospective clinical results, longitudinal MRI follow-up and risk factors for re-rupture on STA ACL repair. Patients with Tegner ≥ 7 have a higher chance on re-rupture. A strict patient selection could contribute in decreasing the re-rupture rate. Further studies with a long-term follow-up will have to show if modern ACL repair can be a “game changer” or if history will repeat itself [10].

Conclusion

This study shows that treatment of the acute, repairable ACL with the STA technique leads to a stable knee and favorable patient-reported outcome measures (PROMs). However, the re-rupture rate of 11.4% within the two-year follow-up is a concern.

Tables

Table 1

TABLE 1 Additional Procedures During Primary Surgery

Additional Procedure	Number of Patients
Medial Meniscus Suture	9
Lateral Meniscus Suture	7
Partial Medial Meniscus Resection	5
Partial Lateral Meniscus Resection	2
Medial Collateral Ligament Repair	4
Anterolateral Ligament Repair	1

Table 2

TABLE 2 Outcome Measures at Different Time Points During Follow-up ^a

Scale	Pre-rupture ^d	Pre-operative	6 months	12 months	24 months
Lachman difference (mm) ^b		3.7 (2.1)	0.7 (1.7)	0.7 (1.1)	1.0 (1.2)
IKDC ^c	94.8 (9.2)		75.0 (13.8)	81.6 (12.1)	85.3 (13.2)
Lysholm	93 (14)		85 (12)	85 (11)	86 (10)
Tegner	6 (1 - 9)		4.5 (2 - 8)	5 (1 - 8)	6 (1 - 9)
VAS Satisfaction	-	-	8 (1)	8 (2)	9 (1)

^a Lachman difference, IKDC score, Lysholm score and VAS satisfaction score are reported as mean (SD). Tegner score is reported as median (range).

^b Lachman testing was performed using a Rolimeter. Measured side-to-side differences are reported in mm.

^c IKDC; International Knee Documentation Committee Score.

^d Pre-rupture data were collected via questionnaires during preoperative consultation.

Table 3

TABLE 3 Proportion of Patients Who Returned to Their Pre-rupture Level at Different Time Points During Follow up

Outcome	6 months	12 months	24 months
IKDC^a	6/31 (19.4%)	11/25 (44.0%)	17/26 (65.4%)
Lysholm	13/27 (48.1%)	13/26 (50.0%)	13/25 (52.0%)
Tegner	11/32 (34.4%)	11/27 (40.7%)	18/27 (66.7%)

^a IKDC; International Knee Documentation Committee Score.

Table 4

TABLE 4 Number of Patients with Different Grades of ACL Healing on MRI at Different Time Points During Follow-up ^a

	6 months	12 months	24 months	Overall
Patients	35	28	23	31
Grade 1	0 (0.0%)	11 (39.3%)	13 (56.5%)	14 (45.2%)
Grade 2	30 (85.7%)	11 (39.3%)	7 (30.4%)	11 (35.5%)
Grade 3	5 (14.3%)	6 (21.4%)	3 (13.0%)	6 (19.4%)

^a Data are reported as number (percentage)

Table 5

TABLE 5 Association Between Type of Rupture, ACL Healing on MRI 6 Months Postoperatively, Age, Pre-operative Tegner Score and Occurrence of Re-rupture

	No Re-rupture	Re-rupture	% Re-rupture Within Group	P Value Fisher's Exact Test
Proximal rupture	26	3	10.3	(n.s.)
Mid-bundle rupture	5	1	16.7	
Grade 1 healing	0	0	0.0	0.006 ^a
Grade 2 healing	29	1	3.3	
Grade 3 healing	2	3	60.0	
Age < 25	7	3	30.0	(n.s.)
Age ≥ 25	24	1	4.0	
Tegner pre-op < 7	19	0	0.0	0.035 ^a
Tegner pre-op ≥ 7	12	4	25.0	

^a P < 0.05.

Figure legends

Figure 1

Figure 1. CONSORT flow diagram.

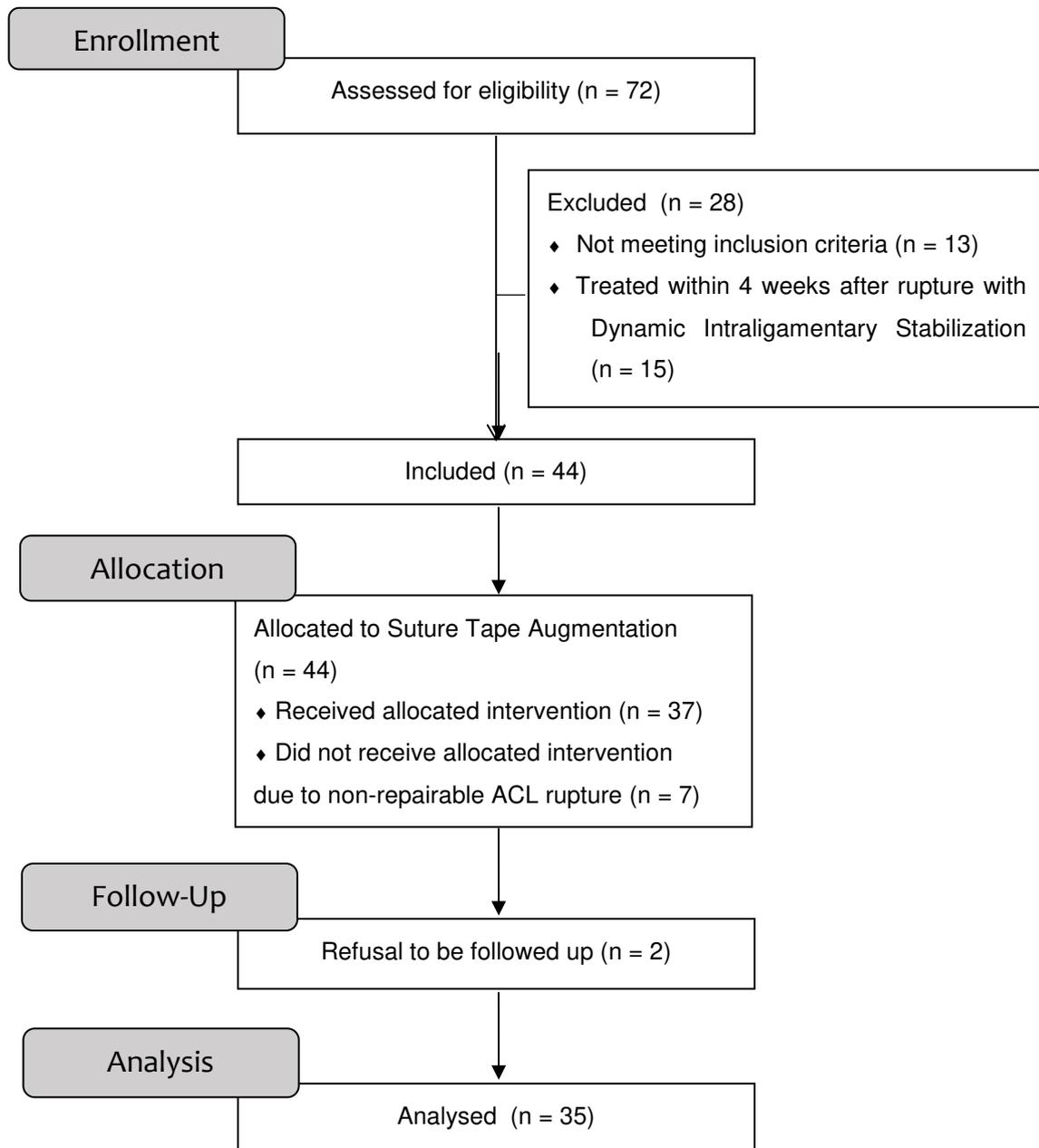


Figure 2

Figure 2. Kaplan-Meier curve of the time to event with the return to work as event and time of surgery as time 0. Nr at risk below the figure is the number of patients not at work at the given time points.

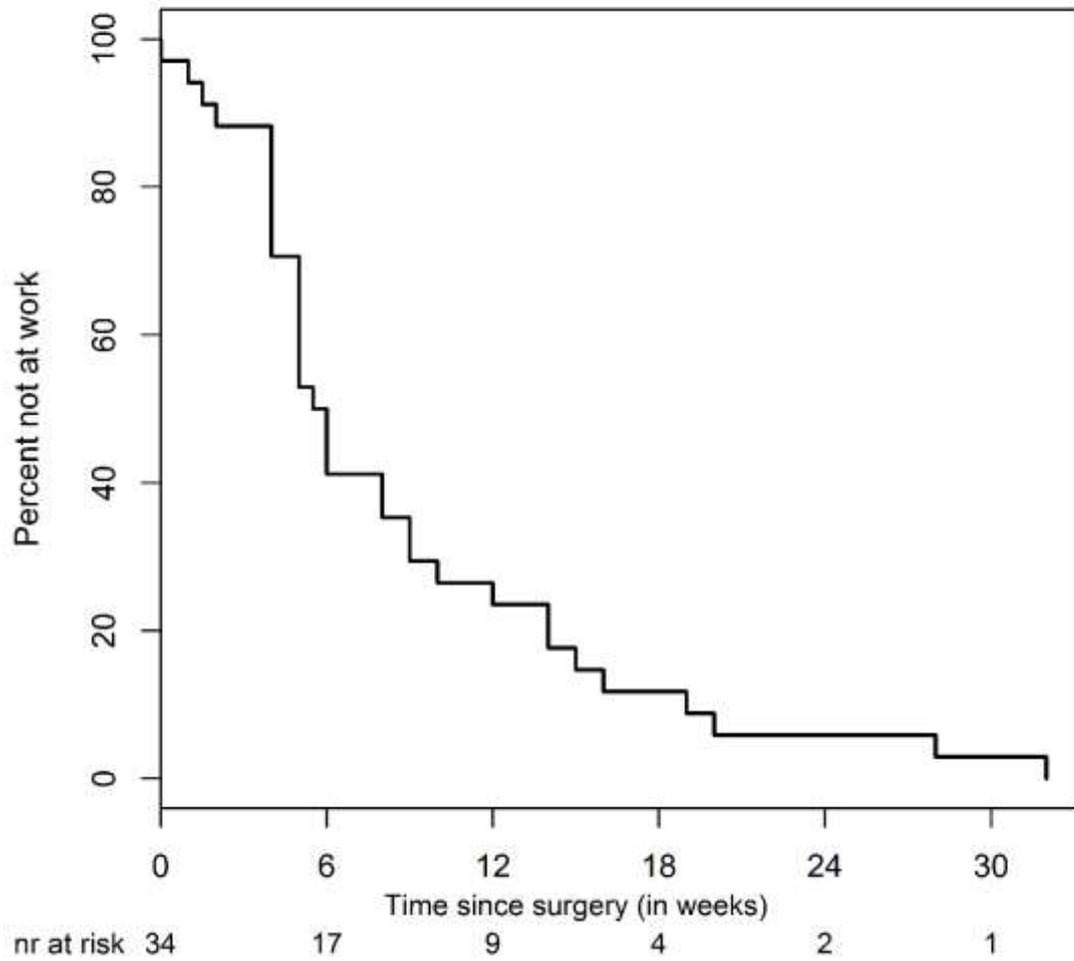
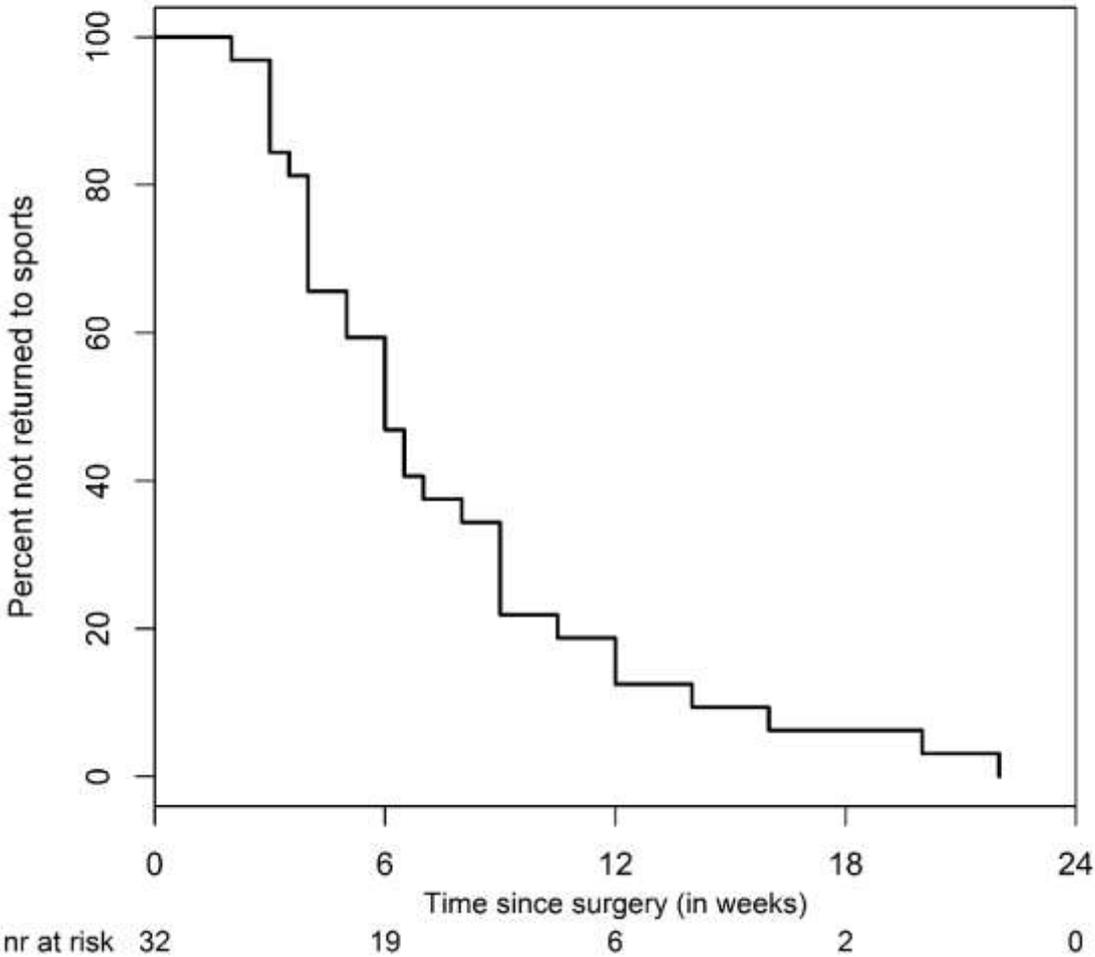


Figure 3

Figure 3. Kaplan-Meier curve of the time to event with the return to sports as event and time of surgery as time 0. Nr at risk below the figure is the number of patients not returned to sports at the given time points.



Supplementary Material

Supplementary table 1

SUPPLEMENTARY TABLE 1 Post-hoc Comparisons of the Different Time Points Using the Linear Mixed Model

Comparison	Estimate	Lower	Upper	Raw P Value	Corrected P Value
Lachman					
6m-Preop	-3.0	-3.5	-2.4	< 0.001 ^b	< 0.001 ^b
12m-Preop	-2.9	-3.5	-2.3	< 0.001 ^b	< 0.001 ^b
24m-Preop	-2.7	-3.4	-2.1	< 0.001 ^b	< 0.001 ^b
12m - 6m	0.03	-0.6	0.7	(n.s.)	(n.s.)
24m - 12m	0.2	-0.5	0.9	(n.s.)	(n.s.)
IKDC^a					
6m-Prerupture	-20.6	-25.5	-15.7	< 0.001 ^b	< 0.001 ^b
12m-Prerupture	-12.6	-17.9	-7.3	< 0.001 ^b	< 0.001 ^b
24m-Prerupture	-9.9	-15.1	-4.7	< 0.001 ^b	0.001 ^b
12m - 6m	8.0	2.6	13.4	0.004 ^b	0.008 ^b
24m - 12m	2.6	-2.9	8.2	(n.s.)	(n.s.)
Lysholm					
6m-Prerupture	-9	-14.6	-3.7	0.001 ^b	0.007 ^b
12m-Prerupture	-7	-12.5	-1.4	0.014 ^b	(n.s.)
24m-Prerupture	-7	-12.5	-1.3	0.016 ^b	(n.s.)
12m - 6m	2	-3.5	7.9	(n.s.)	(n.s.)
24m - 12m	0.1	-5.8	5.9	(n.s.)	(n.s.)
Tegner					
6m-Prerupture	-1	-1.9	-0.7	< 0.001 ^b	< 0.001 ^b
12m-Prerupture	-1	-1.7	-0.4	0.002 ^b	0.010 ^b
24m-Prerupture	-0.3	-1.0	0.3	(n.s.)	(n.s.)
12m - 6m	0.3	-0.4	1.0	(n.s.)	(n.s.)
24m - 12m	0.7	0.0	1.4	0.045 ^b	(n.s.)

a IKDC; International Knee Documentation Committee Score.

b P < 0.05.

References

1. Achtnich A, Herbst E, Forkel P, Metzclaff S, Sprenger F, Imhoff AB, Petersen W (2016) Acute Proximal Anterior Cruciate Ligament Tears: Outcomes After Arthroscopic Suture Anchor Repair Versus Anatomic Single-Bundle Reconstruction. *Arthroscopy* 32:2562-2569
2. Ahmad SS, Schreiner AJ, Hirschmann MT, Schröter S, Döbele S, Ahrend MD, Stöckle U, Ateschrang A (2019) Dynamic intraligamentary stabilization for ACL repair: a systematic review. *Knee Surg Sports Traumatol Arthrosc* 27:13-203.
3. Ahmad SS, Schürholz K, Liechti EF, Hirschmann MT, Kohl S, Klenke FM (2020) Seventy percent long-term survival of the repaired ACL after dynamic intraligamentary stabilization. *Knee Surg Sports Traumatol Arthrosc*;10.1007/s00167-019-05749-z
4. Ardern CL, Taylor NF, Feller JA, Webster KE (2012) Return-to-sport outcomes at 2 to 7 years after anterior cruciate ligament reconstruction surgery. *Am J Sports Med* 40:41-48
5. Bucci G, Begg M, Pillifant K, Singleton SB (2018) Primary ACL Repair vs Reconstruction: Investigating the Current Conventional Wisdom. *Orthop J Sports Med.* 2018 Jun 28;6(6 suppl3):2325967118S00049. doi: 10.1177/2325967118S00049. eCollection 2018 Jun.
6. Van Dyck P, Froeling M, Heusdens CHW, Sijbers J, Ribbens A, Billiet T (2020) Diffusion tensor imaging of the anterior cruciate ligament following primary repair with internal bracing: A longitudinal study. *J Orthop Res*;10.1002/jor.24684
7. Egli S, Kohlhof H, Zumstein M, Henle P, Hartel M, Evangelopoulos DS, Bonel H, Kohl S (2015) Dynamic intraligamentary stabilization: novel technique for preserving the ruptured ACL. *Knee Surg Sports Traumatol Arthrosc* 23:1215-1221
8. Engebretsen L, Svenningsen S, Benum P (1988) Poor results of anterior cruciate ligament repair in adolescence. *Acta Orthop Scand* 59:684-686
9. Evangelopoulos DS, Kohl S, Schwienbacher S, Gantenbein B, Exadaktylos A, Ahmad SS (2017) Collagen application reduces complication rates of mid-substance ACL tears treated with dynamic intraligamentary stabilization. *Knee Surg Sports Traumatol Arthrosc* 25:2414-2419
10. Feagin JA, Curl WW (1976) Isolated tear of the anterior cruciate ligament: 5-year follow-up study. *Am J Sports Med* 4:95-100
11. Fridén T, Roberts D, Ageberg E, Waldén M, Zätterström R (2001) Review of knee proprioception and the relation to extremity function after an anterior cruciate ligament rupture. *J Orthop Sports Phys Ther* 31:567-576
12. Groot JAM, Jonkers FJ, Kievit AJ, Kuijer PPFM, Hoozemans MJM (2017) Beneficial and limiting factors for return to work following anterior cruciate ligament reconstruction: a retrospective cohort study. *Arch Orthop Trauma Surg* 137:155-166

13. Haverkamp D, Sierevelt IN, Breugem SJM, Lohuis K, Blankevoort L, Van Dijk CN (2006) Translation and validation of the Dutch version of the International Knee Documentation Committee Subjective Knee Form. *Am J Sports Med* 34:1680-1684
14. Henle P, Bieri KS, Brand M, Aghayev E, Bettfuehr J, Haeberli J, Kess M, Egli S (2018) Patient and surgical characteristics that affect revision risk in dynamic intraligamentary stabilization of the anterior cruciate ligament. *Knee Surg Sports Traumatol Arthrosc* 26:1182-1189
15. Henle P, Röder C, Perler G, Heitkemper S, Egli S (2015) Dynamic Intraligamentary Stabilization (DIS) for treatment of acute anterior cruciate ligament ruptures: Case series experience of the first three years. *BMC Musculoskelet Disord* 16:27
16. Heusdens CH, Dossche L, Zazulia K, Michielsen J, Van Dyck P (2019) Tips and Tricks to Optimize Surgical Outcomes After ACL Repair Using Dynamic Intraligamentary Stabilization. *Surg Technol Int* 36:
17. Heusdens CHW, Hopper GP, Dossche L, Roelant E, Mackay GM (2019) Anterior cruciate ligament repair with Independent Suture Tape Reinforcement: a case series with 2-year follow-up. *Knee Surg Sports Traumatol Arthrosc* 27:60-67
18. Heusdens CHW, Zazulia K, Roelant E, Dossche L, Van Tiggelen D, Roeykens J, Smits E, Vanlauwe J, Van Dyck P (2019) Study protocol: A single-blind, multi-center, randomized controlled trial comparing dynamic intraligamentary stabilization, internal brace ligament augmentation and reconstruction in individuals with an acute anterior cruciate ligament rupture: LIBRE study. *BMC Musculoskelet Disord* 20:547
19. Höher J, Akoto R, Helm P, Shafizadeh S, Bouillon B, Balke M (2015) Rolimeter measurements are suitable as substitutes to stress radiographs in the evaluation of posterior knee laxity. *Knee Surg Sports Traumatol Arthrosc* 23:1107-1112
20. Hoogeslag RAG, Brouwer RW, Boer BC, de Vries AJ, Huis in 't Veld R (2019) Acute Anterior Cruciate Ligament Rupture: Repair or Reconstruction? Two-Year Results of a Randomized Controlled Clinical Trial. *Am J Sports Med* 47:567-577
21. Hoogeslag RAG, Brouwer RW, de Vries AJ, Boer BC, Huis in 't Veld R (2020) Efficacy of Nonaugmented, Static Augmented, and Dynamic Augmented Suture Repair of the Ruptured Anterior Cruciate Ligament: A Systematic Review of the Literature. *Am J Sports Med*;10.1177/0363546520904690363546520904690
22. Iain C Anthony GM (2015) Anterior Cruciate Ligament Repair Revisited. Preliminary Results of Primary Repair with Internal Brace Ligament Augmentation: A Case Series. *Orthopedic & Muscular System: Current Research* 4:
23. Ihara H, Miwa M, Deya K, Torisu K (1996) MRI of anterior cruciate ligament healing. *J Comput Assist Tomogr* 20:317-321

24. Jonkergouw A, van der List JP, DiFelice GS (2019) Arthroscopic primary repair of proximal anterior cruciate ligament tears: outcomes of the first 56 consecutive patients and the role of additional internal bracing. *Knee Surg Sports Traumatol Arthrosc* 27:21-28
25. Kiapour AM, Murray MM (2014) Basic science of anterior cruciate ligament injury and repair. *Bone Joint Res* 3:20-31
26. Kösters C, Glasbrenner J, Spickermann L, Kittl C, Domnick C, Herbort M, Raschke MJ, Schliemann B (2020) Repair With Dynamic Intraligamentary Stabilization Versus Primary Reconstruction of Acute Anterior Cruciate Ligament Tears: 2-Year Results From a Prospective Randomized Study. *Am J Sports Med* 48:1108-1116
27. Krismer AM, Gousopoulos L, Kohl S, Ateschrang A, Kohlhof H, Ahmad SS (2017) Factors influencing the success of anterior cruciate ligament repair with dynamic intraligamentary stabilisation. *Knee Surg Sports Traumatol Arthrosc* 25:3923-3928
28. Lai CCH, Ardern CL, Feller JA, Webster KE (2018) Eighty-three per cent of elite athletes return to preinjury sport after anterior cruciate ligament reconstruction: A systematic review with meta-analysis of return to sport rates, graft rupture rates and performance outcomes. *Br J Sports Med* 52:128-138
29. Landis JR, Koch GG (1977) The Measurement of Observer Agreement for Categorical Data. *Biometrics*. 33:159-74
30. van der List JP, DiFelice GS (2017) Primary repair of the anterior cruciate ligament: A paradigm shift. *Surgeon* 15:161-168
31. Van Der List JP, Mintz DN, DiFelice GS (2019) Postoperative Magnetic Resonance Imaging following Arthroscopic Primary Anterior Cruciate Ligament Repair. *Adv Orthop* 2019:5940195
32. van der List JP, Vermeijden HD, Sierveelt IN, DiFelice GS, van Noort A, Kerkhoffs GMMJ (2019) Arthroscopic primary repair of proximal anterior cruciate ligament tears seems safe but higher level of evidence is needed: a systematic review and meta-analysis of recent literature. *Knee Surg Sports Traumatol Arthrosc*;10.1007/s00167-019-05697-8
33. Lysholm J, Gillquist J (1982) Evaluation of knee ligament surgery results with special emphasis on use of a scoring scale. *Am J Sports Med* 10:150-154
34. Mahapatra P, Horriat S, Anand BS (2018) Anterior cruciate ligament repair – past, present and future. *J Exp Orthop* 5:20
35. Ohsawa T, Kimura M, Chikuda H (2020) Patient-reported evaluation on giving way is important for return to preinjury activity level after Anterior Cruciate Ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc*;10.1007/s00167-020-06111-4
36. Ortmaier R, Fink C, Schobersberger W, Kindermann H, Leister I, Runer A, Hepperger C, Blank C, Mattiassich G (2020) Return to Sports after Anterior Cruciate Ligament Injury: a Matched-Pair Analysis of Repair with Internal Brace and Reconstruction Using Hamstring or Quadriceps Tendons. *Sportverletz*

Sportschaden;10.1055/a-1019-0949

37. Osti M, El Attal R, Doskar W, Höck P, Smekal V (2019) High complication rate following dynamic intraligamentary stabilization for primary repair of the anterior cruciate ligament. *Knee Surg Sports Traumatol Arthrosc* 27:29-36
38. Rousseau R, Labruyere C, Kajetanek C, Deschamps O, Makridis KG, Djian P (2019) Complications After Anterior Cruciate Ligament Reconstruction and Their Relation to the Type of Graft: A Prospective Study of 958 Cases. *Am J Sports Med* 47:2543-2549
39. Sherman MF, Lieber L, Bonamo JR, Podesta L, Reiter I (1991) The long-term followup of primary anterior cruciate ligament repair: Defining a rationale for augmentation. *Am J Sports Med* 19:243-255
40. De Smet E, Heusdens CHW, Parizel PM, Van Dyck P (2019) MRI following primary repair of the anterior cruciate ligament. *Clin Radiol* 74:649 e641-649 e610
41. Tegner Y, Lysholm J (1985) Rating systems in the evaluation of knee ligament injuries. *Clin Orthop Relat Res* 43-49
42. Wilson WT, Hopper GP, Byrne PA, MacKay GM (2016) Anterior Cruciate Ligament Repair with Internal Brace Ligament Augmentation. *Surg Technol Int* 29:273-278