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Dynamic intraligamentary stabilization of anterior cruciate ligament repair: hardware removal has no effect on knee laxity at 2-year follow-up

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Abstract

Introduction Dynamic intraligamentary stabilization (DIS) stabilizes the knee joint during anterior cruciate ligament (ACL) healing. After 6 months, tibial hardware removal is offered to the patients if local discomfort at the implant site is present.

Aim This study compared knee laxity and functional scores 2 years after DIS between patients with and without hardware removal. It is hypothesized that it does not affect ACL healing.

Materials and methods The study retrospectively analyzed prospectively collected data from 173 patients with either hardware removal ($n=47$) or no additional intervention ($n=126$). Inverse probability of treatment weighting using the propensity score was applied to balance the groups for baseline characteristics. The primary outcome was the side-to-side difference in knee laxity measured with the rolimeter at manual maximum force (Δ-Lachman). Secondary outcomes were the pivot-shift test and subjective scores.

Results Mean age was 34 years in both groups, and female gender was 47% (hardware removal group) and 50% (control group), respectively. No significant differences were found for Δ-Lachman ($p=0.09$), pivot-shift test ($p=0.41$), and subjective scores ($p>0.10$) two years after DIS.

Conclusion Knee laxity 2 years after DIS in patients with tibial hardware removal and patients without hardware removal was not significantly different. The groups were also similar regarding all the assessed functional scores. This study confirms the hypothesis that the healing ACL resumes its stabilizing role, and the hardware can be removed beginning 6 months after surgery without adverse consequences for joint stability.

Level of evidence Case–control study, Level III.

Keywords ACL · Dynamic intraligamentary stabilization · Ligamys · Hardware removal · Knee laxity · Lachman

Introduction

Established approaches to ACL repair that rely primarily upon suture techniques have resulted in unsatisfactory clinical results and treatment failures [7, 10, 12, 34]. Insufficient primary stability might be the reason for inadequate scar tissue formation. Dynamic intraligamentary stabilization (DIS), which was introduced in 2009, overcomes this drawback [20]. The technique uses resorbable sutures to reconnect the ACL to the femoral footprint. During ACL healing, the knee joint is internally braced by a dynamic implant, which is placed into the tibial head. So far, the DIS tibial hardware has been removed in one out of three patients, on average, predominantly because of local discomfort [5, 9, 14, 16, 18, 21, 22, 30]. It has been assumed that hardware removal can be performed beginning 6 months after surgery

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with no penalty to ACL healing and subsequent joint laxity, that would decrease patient's knee stability and therewith knee function and physical performance [27]. However, joint laxity has not yet been investigated after hardware removal.

The objective of this study was to compare knee laxity and functional clinical scores of patients with and without hardware removal 2 years after ACL repair with DIS. It was hypothesized that knee laxity in the hardware removal group was not inferior to knee laxity in the control group.

Materials and methods

Study design

The study was approved by the ethics committee of the Canton of Berne, Switzerland (KEK-BE: 048/09). All patients gave informed consent for their data to be used in the study, and data extracted for study were anonymous.

The study retrospectively analyzed a prospectively and consecutively documented, single-center case series (Sonnenhof Orthopaedic Center, Berne, Switzerland) that has been described elsewhere [9, 16]. The documentation included three standardized case-report forms: form A captured patient characteristics and surgery-related information, form B recorded information regarding additional surgical interventions after the index surgery, and form C documented clinical follow-up examinations. Follow-up was carried out at 6 and 24 months postoperatively, and all forms were completed online by the treating surgeons. The data were collected using an academic, web-based documentation platform (MEMdoc), hosted at the University of Bern, Switzerland.

DIS hardware removal

Surgical technique and rehabilitation program for DIS have been previously reported in detail [6, 16]. Patient indications for DIS are similar to those for ACL reconstruction, though the surgical principle is considerably different, as it relies on healing of the injured ACL. The hardware, a 10 × 30-mm spring-screw device ("monobloc," LigamysTM, Mathys Ltd, Bettlach, Switzerland), is removed by first releasing the polyethylene braid from the clamping mechanism and then screwing the device out of the tibial head (Fig. 1). Removal of the tibial hardware results in complete release from internal bracing, because osteointegration of the chemically inert braid in the tibial bone stock is not possible.

Study population

Two hundred and eighty patients who presented with a rupture of the ACL treated with DIS between July 1, 2009 and April 31, 2015, and who were followed-up for at least 2 years after surgery, were eligible for inclusion in the study. Study exclusion criteria were re-rupture of the ACL (six patients), contralateral ACL injury (two patients), additional follow-up treatment that could potentially have an effect on knee laxity [knee mobilization (8 patients), arthroscopic meniscal surgery or scar tissue debridement (25 patients)], hardware removal because of local wound infection before 6 months (1 patient), and missing knee laxity measures (65 patients). In total, 173 patients were included in the study. The hardware removal group was comprised of 47 patients with hardware removal due to local discomfort. The control group was comprised of 126 patients who had no further intervention during follow-up. The characteristics of the study population are summarized in Table 1.

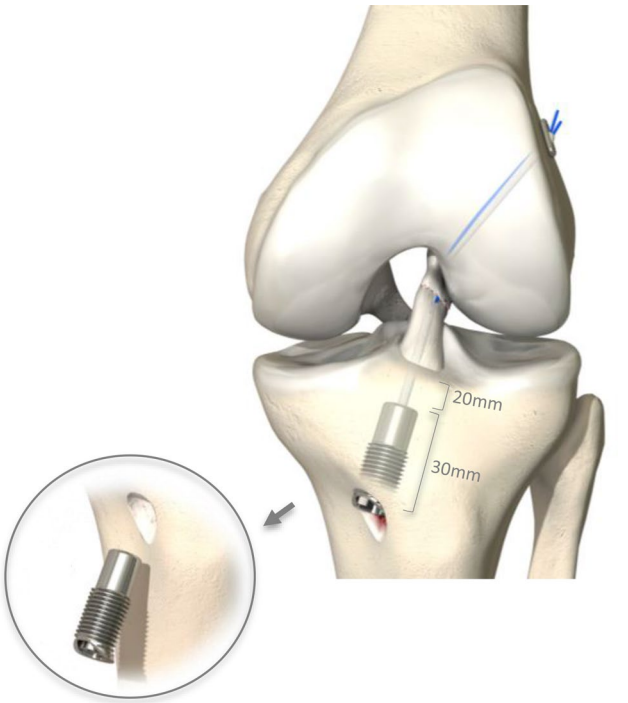

Fig. 1 Schematic illustration of DIS. The braid's tensile strength is 2′000 N. The 10 × 30-mm large spring-screw device is positioned at a distance of 50 mm from the joint line to preserve 20-mm bone stock below the tibial ACL footprint

Outcome analysis

The primary outcome was the side-to-side difference in knee laxity (Δ-Lachman) 2 years after index surgery. Knee laxity was measured in millimeters in 30° knee flexion using an arthrometer (Rolimeter, Aircast, Neubeuern, Germany) to determine the anterior translation of the tibia at manual maximum force. Secondary outcomes were the subjective International Knee Documentation Committee (IKDC) score

Table 1 Patient and treatment characteristics

	Before weighting adjustment			After weighting adjustment		
	Hardware removal ($n=47$)	Control group ($n=126$)	*P*	Hardware removal ($n=47$)	Control group ($n=126$)	*P*
Index surgery						
Age (years)	35 ± 12	34 ± 12	0.43	34 ± 15	34 ± 10	0.86
Female gender (no. (%))	29 (62%)	58 (46%)	0.07	22 (47%)	63 (50%)	0.74
BMI (kg/m^2)	23.8 ± 3.0	23.9 ± 3.3	0.78	24.0 ± 4.0	23.9 ± 2.9	0.82
Meniscus surgery (no. (%))	25 (53%)	71 (56%)	0.71	26 (56%)	71 (56%)	0.99
Six month follow-up						
Knee laxity (Δ-Lachman; mm)	0.8 ± 2.1	0.9 ± 2.0	0.98	1.0 ± 2.9	0.9 ± 1.7	0.77
Tegner (points)	4.4 ± 1.3	4.5 ± 1.5	0.89	4.6 ± 1.8	4.5 ± 1.2	0.65
Lysholm (points)	94 ± 6	97 ± 5	< 0.001	96 ± 7	96 ± 5	0.78
IKDC (points)	90 ± 7	92 ± 7	0.03	92 ± 9	91 ± 5	0.90

Mean ± SD or number and percentages within groups are shown

(0–100-point scale), and the Lysholm score (0–100-point scale), the pivot-shift test (categorically scaled according to IKDC), patients' self-reported giving-way symptoms (categorically scaled according to Lysholm), and patients' subjective knee evaluation using the Tegner activity level (0–10-point scale).

Statistical analysis

The sample-size calculation was centered on the hypothesis of non-inferiority of postoperative knee laxity between the hardware removal group and the control group. The mean postoperative Δ-Lachman was anticipated to be 2.0 mm with standard deviation of 1.5 mm [16]. A low ($r=0.05$) correlation of knee laxity between the matched pair was assumed. The non-inferiority margin was set at the minimum quantifiable measured value of 1.0 mm [31]. A one-sided paired test with 80% power resulted in a sample size of 28 patients per group.

To adjust for case mix, inverse probability of treatment weighting (IPTW) using the propensity score was applied to balance the two patient groups for patient and treatment characteristics [2]. The propensity score was estimated without regard to outcome variables using multiple logistic regression. Meniscus surgery during index surgery and the patient characteristics of age, sex, and BMI at baseline, and Δ-Lachman, Tegner activity level, and Lysholm and IKDC score values at 6-month follow-up were included in the propensity score. Bivariate comparison of patient and treatment characteristics in the patient groups before and after weighting adjustment was performed using the Wilcoxon signed-rank test, the Chi-square test, or the Student's *t* test as appropriate. Comparisons of the outcome measures were performed using the paired Student's *t* test or the Chi-square test. The effect size was measured using mean differences and relative risk ratios with 95% confidence limits (CL). Unless otherwise stated, mean ± standard deviation (SD) is shown. To analyze the effect of the timing of hardware removal on knee laxity as a potential source of bias, a binary correlation analysis using the Spearman's rank correlation coefficient was applied.

All statistical analyses were conducted in SAS 9.4 (SAS Institute Inc., Cary, NC, USA) with the level of significance set at 0.05.

Results

The hardware was removed in 47 patients in the study population of 178 DIS patients (27%). Removal was performed on average 12 ± 5 months after DIS. Patient and treatment characteristics before and after IPTW adjustment are summarized in Table 1. Before IPTW adjustment, patient groups differed significantly in Lysholm (94 points in cases versus 97 points in controls, $p<0.001$) and IKDC scores (90 points in cases versus 92 points in controls, $p=0.013$) at 6-month follow-up and the proportion of women was higher in the hardware removal group (62% vs. 46%, $p=0.07$). Propensity score-based weights were calculated and the groups were balanced for all characteristics.

The outcome analysis is summarized in Table 2. The follow-up evaluation took place on average 24 ± 2 months after DIS in both groups. No significant differences were found between the groups for primary as well as for secondary outcomes. From 6 to 24 months postoperatively, the side-to-side difference in knee laxity increased 0.5 ± 2.9 mm in the hardware removal group, and 1.0 ± 1.9 mm in the control group ($p=0.09$). Most patients had a negative pivot-shift test (70% in cases; 61% in controls) and reported no giving-way episodes (99% in cases; 94% in controls). Both groups

Table 2 Weighted outcome measures after 2 years of follow-up. Mean ± SD or number and percentages within groups are shown

		Hardware Removal (n = 47)	Control Group (n = 126)	Effect size (95% CL)	Comparison (p-value)
Objective outcome measures					
Knee laxity (Δ-Lachman; mm)		1.5 ± 2.2	2.0 ± 1.7	0.5 (0.0 - 1.0)	0.09
Pivot Shift (no. (%))	negative	33 (70%)	77 (61%)	0.8 (0.5 - 1.2)	0.41
	+ positive (glide)	9 (20%)	35 (28%)		
	++ positive (clunk)	5 (10%)	14 (11%)		
	+++ positive (gross)	0	0		
Subjective outcome measures					
Tegner (points)		5.2 ± 2.2	4.8 ± 1.2	-0.4 (-0.9 - 0.0)	0.10
IKDC (points)		97 ± 8	97 ± 4	-0.5 (-1 .0 - 2.0)	0.53
Lysholm overall (points)		99 ± 4	98 ± 3	-0.5 (-1 .4 - 0.5)	0.36
Lysholm giving-way symptoms (no. (%))	Never	46 (99%)	119 (94%)	0.2 (0.01 - 1.7)	0.37
	Rarely during severe exertion	1 (1%)	5 (4%)		
	Frequently during severe exertion	0	1 (1%)		
	Occasionally in daily activities	0	1 (1%)		
	Often in daily activities	0	0		
	Every step	0	0		

Effect size was calculated using mean differences or relative risk ratios (dichotomized between negative/never and other values)

CL confidence limit

P value was calculated using paired t tests or Chi-square tests

reported an average Tegner activity level of 5, representing activities, such as frequent jogging, hiking, biking, or strenuous physical work. Overall, high Lysholm (≥ 98 points) and IKDC scores (≥ 97 points) were observed in both groups.

Timing of hardware removal and knee laxity showed no correlation ($r = 0.004$).

Discussion

The main finding of this study was that knee laxity in patients with tibial hardware removal and in those without hardware removal did not differ 2 years after ACL repair with DIS.

DIS uses a dynamic implant system to internally brace the knee joint to enable ACL healing [8, 19, 20]. Recent studies have shown that the tibial hardware of this system, a spring-screw device, was removed in one out of three patients on average. The removal was performed mainly due to local discomfort or a non-symptom related patient preference [9, 14, 16, 18]. In this study, lower Lysholm and IKDC scores were found in the hardware removal group before IPTW adjustment. Lower subjective knee rating is likely associated with local discomfort from the implant. In addition, slightly more female than male patients (62% vs. 46%) were treated with hardware removal. Female patients have on average a smaller tibia in comparison to male patients. Because of this gender difference in tibia morphology, the hardware is positioned closer to the pes anserinus in females and may, therefore, cause irritation.

To date, only a few studies have analyzed the outcomes of DIS hardware removal. Two independent studies reported no increase health care costs after DIS when compared with ACL reconstruction despite the additional expense of hardware removal [4, 5]. Another study did not observe any association between hardware removal and revision surgery [15]. Joint laxity has not yet been investigated after hardware removal. It has been assumed that hardware removal can be performed beginning 6 months after DIS surgery without jeopardizing ACL healing [21]. Thus, in this study, we focused on side-to-side differences in joint laxity with or without hardware removal. The Lachman test is the most widely used clinical test for the assessment of knee laxity [11, 15, 23, 28]. No differences in knee laxity between patients with hardware removal and patients without hardware removal were found. However, knee stability is multifactorial and the Lachman test can only provide information about anterior–posterior translation [25]. Therefore, the pivot-shift test and patient-reported outcomes on activity levels and knee function were included as secondary outcomes. Likewise, none of these outcomes differed in the hardware removal and control groups 2 years after DIS. This confirms the hypothesis of this study and suggests that DIS hardware can be removed without adverse consequences for knee laxity beginning 6 months after surgery.

The postoperative interval to hardware removal (range: 6–24 months after DIS) was not associated with knee laxity. Remodeling of a torn ligament starts approximately 3 weeks after repair. Collagen fibers realign along the lines of stress, the ligament gradually becomes stronger, and unrestricted load

enhancement is possible before 6 months of rehabilitation have elapsed [6]. Considering the ligament healing phases, it can be assumed that collagen fibers have been remodeled to viable tissue at the time hardware removal was performed.

Unlike with DIS, in ACL reconstruction, the remaining ACL tissue is removed and is being replaced by graft tissue. It has been found that surgical parameters such as positioning techniques (e.g., anatomic tunnel positioning for the graft) [1, 3, 17] as well as patient-related factors (e.g., work intensity) [13] are critical parameters to improve clinical outcomes in this procedure. In addition, it is well known that the grafts have to undergo several phases of healing that changes their biological and mechanical properties [35]. Characteristic differences in the structural properties (e.g., failure load and stiffness) remain between the graft and a normal ACL and a graft does not reach the initial mechanical strength of the intact ACL [29, 35]. However, it has been shown that ACL reconstruction can restore the anterior tibial translation similar to the intact state [26, 33].

A limitation of this study derives from the fact that the ACL is not the sole structure restricting knee laxity. The posteromedial meniscus acts as a second line of defense in case of ACL insufficiency and may affect outcome measures [24, 32]. However, meniscus repair was included in the propensity score. In rare cases, hardware removal may be required less than 6 months after DIS due to medical reasons like superficial surgical site infection or a range of motion deficit [14]. These patients were excluded from the study population and no statement regarding the effect of earlier hardware removal can be made.

Conclusion

Two years after DIS, knee laxity of patients in whom tibial hardware was removed was not significantly different from that of patients in whom DIS hardware was retained. The groups were also similar with respect to all the assessed functional scores. These results confirm the hypothesis that the DIS hardware can be removed beginning 6 months after surgery without negative consequences on joint stability.

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Compliance with ethical standards

Conflict of interest All authors have received reimbursements or funding from Mathys AG Bettlach, Switzerland, in the past 5 years. The authors are not compensated for this work.

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