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Surgeon experience with dynamic intraligamentary stabilization does not influence risk of failure

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Abstract

Purpose Studies on dynamic intraligamentary stabilization (DIS) of acute anterior cruciate ligament (ACL) ruptures reported failure rates similar to those of conventional ACL reconstruction. This study aimed to determine whether surgeon experience with DIS is associated with revision rates or patient-reported outcomes. The hypothesis was that more experienced surgeons achieved better outcomes following DIS due to substantial learning curve.

Methods The authors prospectively enrolled 110 consecutive patients that underwent DIS and evaluated them at a minimum of 2 years. The effects of independent variables (surgeon experience, gender, age, adjuvant procedures, tear location, preinjury Tegner score, time from injury to surgery, and follow-up) on four principal outcomes (revision ACL surgery, any re-operation, IKDC and Lysholm score) were analyzed using univariable and multivariable regressions.

Results From the 110 patients enrolled, 14 patients (13%) were lost to follow-up. Of the remaining 96 patients, 11 underwent revision ACL surgery, leaving 85 patients for clinical assessment at a mean of 2.2 ± 0.4 years (range 2.0–3.8). Arthroscopic reoperations were performed in 26 (27%) patients, including 11 (11%) revision ACL surgeries. Multivariable regressions revealed: (1) no associations between the reoperation rate and the independent variables, (2) better IKDC scores for 'designer surgeons' (b=10.7; CI 4.9–16.5; p <0.001), higher preinjury Tegner scores (b=2.5, CI 0.8–4.2; p=0.005), and younger patients (b=0.3, CI 0.0–0.6; p=0.039), and (3) better Lysholm scores for 'designer surgeons' (b=7.8, CI 2.8–12.8; p=0.005) and preinjury Tegner score (b=1.9, CI 0.5–3.4; p=0.010).

Conclusion Surgeon experience with DIS was not associated with rates of revision ACL surgery or general re-operations. Future, larger-scaled studies are needed to confirm these findings. Patients operated by 'designer surgeons' had slightly better IKDC and Lysholm scores, which could be due to better patient selection and/or positively biased attitudes of both surgeons and patients.

Level of evidence Level II, prospective comparative study.

Keywords Anterior cruciate ligament \cdot Dynamic intraligamentary stabilization \cdot Ligamys \cdot Revision surgery \cdot Surgeon experience \cdot Outcomes

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Introduction

Dynamic intraligamentary stabilization (DIS) was recently introduced in the surgical treatment of acute anterior cruciate ligament (ACL) ruptures [11, 16]. The technique aims to provide knee joint stability while the ACL heals without graft harvesting. To date, ACL repair is not yet wellestablished [29]. Most clinical studies on DIS were singlecenter, published by surgeons who designed the device with a follow-up of up to 5 years [3, 8, 11, 18, 23, 26]. Articles by non-designers are currently limited to small cohorts and a follow-up of 1 year [3, 25, 27, 30]. Initial case series of patients undergoing DIS revealed high functional scores and return to previous levels of sport activity in most patients 2–5 years following surgery [8, 19, 24]. A revision ACL surgery was reported in 8 and 11% of cases after a minimum follow-up of 2 years [18, 24, 26], and similar revision rates were found in DIS and ACL reconstruction [6]. Prognostic factors such as young patient age, high baseline activity level, and central rupture location were found to increase the risks of failure after DIS [18, 26]. However, it is possible that outcomes for DIS could be related to surgeon experience with this procedure, which depends on the status of the ACL remnants and tear pattern and, therefore, may require a substantial learning curve.

The primary purpose of this study was, therefore, to determine potential associations between the rates of revision ACL surgery and surgeon experience with DIS ('designer surgeons' vs. 'non-designer surgeons'). The secondary purpose was to determine other potential prognostic factors (patient demographics and surgical characteristics) that could be associated with inferior clinical outcomes (any re-operation and patient-reported outcomes). The hypothesis was that more experienced surgeons achieved better outcomes following DIS due to substantial learning curve. To the authors' knowledge, there are no published studies that investigate surgeon experience and the success of DIS.

Materials and methods

The authors prospectively enrolled 110 consecutive patients that underwent DIS, as a treatment for acute primary ACL tears within 21 days from injury, between August 2013 and May 2015, at three centers. The inclusion criteria were: (i) patients aged between 18 and 50 years at the index operation, and (ii) patients who provided written informed consent to participate in this study. The exclusion criteria were: (i) patients unwilling to follow the standard rehabilitation program, (ii) patients who were pregnant at the time of diagnosis, (iii) patients with permanent corticosteroid or cytostatic medication regimen, active chronic inflammatory joint diseases or with malignancies, (iv) knees with traumatic or degenerative cartilage lesions (Outerbridge > II and/or defect > 1 cm²), (v) knees with irreparable meniscal lesion requiring resection of > 20% of the meniscus, (vi) knees in which one or more tendons had been removed.

Fifty-six (51%) of the patients were operated by two surgeons at one center who were involved in the design of the DIS device and technique, and who had performed over 200 DIS procedures prior to the start of the study ('designers'). Fifty-four (49%) of the patients were operated by four surgeons at two centers who were not involved in the design of the DIS device and technique, and who had not performed any DIS procedures prior to the start of the study ('non-designers').

Surgical technique

The surgical technique and rehabilitation protocol for DIS were described in previous published studies [8, 19]. 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 remnant ACL and, therefore, must be performed within 21 days from injury. In very rare cases where the intraoperative findings are not consistent with an acute ACL tear, surgeons consider conversion to ACL reconstruction intraoperatively. DIS intends to prevent the femur and tibia from being able to shift relative to one another during movements of the knee. The tibial remnants of the torn ACL are guided to the femoral footprint by transosseous resorbable sutures. Extensive microfracturing is performed at the femoral footprint to allow stem cells to migrate into the joint and accelerate the healing process. A debridement of the remaining ACL tissue is not performed to avoid loss of volume. The knee is then stabilized with a polyethylene cord which is brought under tension by a spring implant hosted on the antero-medial aspect of the tibia. Similar to the native ACL, the cord's tensile strength is 2000 N. The cord maintained at predetermined tension of 50-80 N (depending on patient gender and weight). Thus, the proximal tibia is maintained in a constant posterior position relative to the femur, allowing the two stumps of the ACL to remain in close proximity. The spring mechanism allows a dynamic excursion of the cord, ensuring a continuous tension over the entire range of motion. All DIS components can remain in the knee joint, as the polyethylene cord coalesces with the ligament remnants, while the ACL heals. The tibial implant is bulky, however, and may require removal, which can be done using a minimally invasive technique under local anesthesia [6, 19, 24].

Postoperative rehabilitation

For isolated ACL ruptures or those combined with a partial resection of the meniscus, the knee was kept in an extension brace for 4 days after surgery to enable adhesion of the ACL stumps. Active physiotherapy and full weight-bearing were permitted from the 5th postoperative day. After 6 weeks, unlimited training was permitted, according to the principles of progressive loading. In patients with additional meniscal sutures, brace wearing and partial-weight bearing were recommended for 4–6 additional weeks. Unlimited training was allowed only after 10 weeks and return to sport was permitted after 6–9 months.

Data collection

All patient data were collected using an academic, webbased documentation platform, comprising three standardized case report forms, completed at the time of surgery and at minimum follow-up of 2 years. The first form collected patient demographics (age, gender, and Tegner score) and surgical information (time from injury to surgery, proximal or central tear location, and any adjuvant procedures). The second form recorded details of any revision ACL surgeries or other re-operations. The third form collected patientreported outcomes using standard questionnaires for knee ligament lesions (IKDC score, Lysholm score, and Tegner score). The IKDC score (0-100 point scale) detects improvement or deterioration of knee symptoms, knee function, and sports activities. The Lysholm score (0-100 point scale) detects improvement or deterioration of knee function, particularly symptoms of instability [9]. The Tegner score (0-10 point scale) assesses sport and work activity levels [34]. The data entry procedure involved several checks of validity and completeness to avoid inappropriate or missing data.

All patients gave informed consent to participate in the study in advance. The patient data were anonymized prior to extraction from the documentation platform. The study was approved by the institutional review board and ethics committee at the study centers.

Statistical analysis

Normality of distributions was tested using the Shapiro-Wilk test. For continuous variables (IKDC score and Lysholm score) with non-parametric distribution, group differences were evaluated using Wilcoxon rank sum tests (Mann Whitney U test). Categorical data (revision ACL surgery and any re-operation) were analyzed using Pearson Chi-squared tests. The effects of independent variables on four principal outcomes were analyzed using univariable and multivariable logistic (revision ACL surgery and any re-operation) and linear (IKDC score and Lysholm score, both on scales from 0 to 100) regression models. The independent variables included surgeon experience ('designer surgeons' vs. 'non-designer surgeons'), patient gender (female vs. male), patient age (years), adjuvant procedures (yes vs. no), tear location (proximal vs. central), preinjury Tegner score (scale from 0 to 10), time from injury to surgery (days), and follow-up (days). The Tegner score, a likerttype scale, was treated as interval data [33]. A power analysis was performed to determine the sample size required for two outcomes: ACL revision rate (primary) and IKDC score (secondary). Assuming ACL revision rates of 10% for the designer group and 15% for the non-designer group, a sample of 686 patients was required to determine statistical significance with a power of 0.8, which was not feasible considering the novelty of DIS. Assuming IKDC scores of 95 points for the designer group and 85 points for nondesigner group, with equal standard deviations of 10 points, a sample size of 34 patients was required to determine statistical significance with a power of 0.8. Statistical analyses were performed using R version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria) with the level of significance defined at 0.05.

Results

From the 110 patients enrolled, 14 patients (13%) were lost to follow-up. Of the remaining 96 patients, 11 underwent revision ACL surgery, leaving 85 patients for clinical assessment at a follow-up of 2.2 ± 0.4 years (range 2.0-3.8) (Fig. 1). Of the remaining 96 patients, 53 (55%) had been operated by 'designer surgeons', while 43 (45%) had been operated by 'non-designer surgeons'. The two groups were similar in terms of patient demographics and surgical characteristics, but the former had fewer patients lost to followup (3 vs. 11, p=0.018), as well as lower preoperative Tegner scores (p=0.016) and more adjuvant procedures (p=0.014) (Table 1).

Any re-operation

Arthroscopic re-operations were performed in 26 (27%) (Table 2) of the 96 patients included, of which 11 revision ACL surgeries, 6 debridements for stiffness, 4 repairs of new meniscal tears, 2 hardware removals, 1 lavage for hematoma; 1 for medial condyle chondromalacia associated with medial patellar plica; and 1 for unspecified reason. Univariable and multivariable regressions revealed no significant associations with re-operations (Table 3).

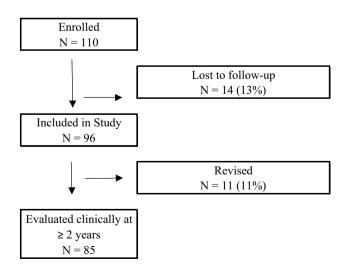




Table 1 Patient demographics

	Total $(n=96)$	Designer surgeons $(n=53)$	Non-designer surgeons $(n=43)$	p value
Age (years)	31.5 ± 9.8	31.7 ± 10.2	31.2 ± 9.3	n.s
Tegner score (0-10)	5 ± 2	5 ± 1	6 ± 2	0.016
Injury to surgery (days)	14±4.6	14 ± 4.4	13 ± 4.9	n.s
Male gender	51 (53%)	24 (45%)	27 (63%)	n.s
Proximal tears	79 (82%)	43 (81%)	36 (84%)	n.s
Adjuvant procedures ^a	40 (42%)	28 (53%)	12 (28%)	0.014
Meniscus sutures ^b	33	24	9	0.013
Menisectomies ^b	12	7	5	n.s
Others ^b	6	4	2	-

Data presented as mean \pm standard deviation, or number (percentage)

^aPatients that had one or more adjuvant procedures in addition to DIS

^bNote that some patients had two or three concomitant adjuvant procedures in addition to DIS

	Total $(n=96)$	Designer surgeons $(n=53)$	Non-designer surgeons $(n=43)$	p value
Revision ACL surgery	11 (11%)	7 (13%)	4 (10%)	n.s
Any re-operation	26 (27%)	17 (31%)	9 (22%)	n.s

Data presented as number (percentage)

Table 3 Uni- and multi-variableregression analysis of factorsassociated with any re-operation

Table 2Incidence of revisionACL surgery and of any

re-operation

Variable	Univariable			Multivariable $(n=96)$		
	OR	95% CI	p value	OR	95% CI	p value
Categoric						
Designer surgeons	1.78	(4.70–0.71)	n.s	1.76	(0.64–5.15)	n.s
Male gender	1.04	(0.42 - 2.60)	n.s	0.97	(0.33-2.79)	n.s
Proximal tear	0.59	(0.20–1.91)	n.s	0.69	(0.20 - 2.50)	n.s
Adjuvant procedure	1.59	(0.64–3.98)	n.s	1.36	(0.51-3.65)	n.s
Continuous						
Age (years)	0.98	(0.93–1.03)	n.s	0.99	(0.94 - 1.05)	n.s
Tegner score (0-10)	1.09	(0.83–1.43)	n.s	1.09	(0.79–1.53)	n.s
Injury to surgery (days)	0.98	(0.89 - 1.08)	n.s	0.96	(0.87 - 1.07)	n.s

Revision ACL surgery

Revision ACL surgery was performed on 11 (11%) (Table 2) of the 96 patients included, of which 7 had traumatic reruptures and 4 suffered from chronic instability. Univariable regression revealed revision ACL surgery to be significantly associated with preinjury Tegner score (OR = 1.55; CI 1.05–2.38; p = 0.032) and patient age (OR = 0.88; CI 0.78–0.97; p = 0.020), but multivariable regression revealed no significant associations (Table 4).

IKDC score

The IKDC score for the 85 patients evaluated clinically was 91 ± 12 (range 44–100) (Table 5). Univariable regression revealed significantly better IKDC scores for patients operated by 'designer surgeons' (b=7.3; CI 2.4–12.1; p=0.004), and multivariable regression confirmed this association (b=10.7; CI 4.9–16.5; p<0.001), in addition to preinjury Tegner score (b=2.5, CI 0.8–4.2; p=0.005) and patient age (b=0.3, CI 0.0–0.6; p=0.039) (Table 6).

Table 4Uni- and multi-variableregression analysis of factorsassociated with revision ACLsurgery

Variable	Univar	Univariable			Multivariable $(n = 96)$		
	OR	95% CI	p value	OR	95% CI	p value	
Categoric							
Designer surgeons	1.48	(0.42-6.01)	n.s	2.25	(0.45–14.25)	n.s	
Male gender	2.60	(0.70-12.51)	n.s	2.24	(0.40–16.01)	n.s	
Proximal tear	0.27	(0.07 - 1.18)	n.s	0.29	(0.05 - 1.69)	n.s	
Adjuvant procedure	1.19	(0.32-4.25)	n.s	1.23	(0.24–6.01)	n.s	
Continuous							
Age (years)	0.88	(0.78–0.97)	n.s	0.92	(0.80 - 1.02)	n.s	
Tegner score (0–10)	1.55	(1.05-2.38)	n.s	1.45	(0.87-2.62)	n.s	
Injury to surgery (days)	0.97	(0.84–1.11)	n.s	2.25	(0.85-1.18)	n.s	

 Table 5
 Postoperative IKDC, Lysholm and Tegner scores

	Total $(n=85)$	Designer surgeons (n=46)	Non-designer surgeons (n=39)	p value
IKDC score	91±12	94±8	87 ± 14	0.002
Lysholm score	93±10	96±6	90 ± 12	< 0.001
Tegner score	5±2	5 ± 2	5 ± 2	n.s

Data presented as mean ± standard deviation

Lysholm score

The Lysholm score for the 85 patients evaluated clinically was 93 ± 10 (range 43–100) (Table 5). Univariable regression revealed significantly better Lysholm scores for patients operated by 'designer surgeons' (b=6.3; CI 2.2–10.4; p=0.003), and multivariable regression confirmed this association (b=7.8, CI 2.8–12.8; p=0.005), in addition to preinjury Tegner score (b=1.9, CI 0.5–3.4; p=0.010) (Table 7).

Discussion

The most important finding of the study was that, surgeon experience with DIS was associated with better patientreported outcomes, but not with rates of revision ACL surgery or general re-operations. Multivariable analysis revealed that patients operated by 'designer surgeons' had significantly better IKDC and Lysholm scores, but no significant difference in rates of revisions and re-operations, which is likely due to the small sample size.

The literature reports failures of ACL reconstruction in 1–27% of cases [4, 5, 7], whereas large registry studies indicate failures in 2–4% at a minimum follow-up of 2 years [1, 21, 35]. Failure of ACL repair in this study was observed in 11%, which is higher than typical rates following ACL reconstruction. The latter could be due to three reasons; First, the activity level—a well-known risk factor for ACL injury and failure [28]—is probably higher for patients undergoing DIS than those undergoing ACL reconstruction. Second, the odds of undetected failures are greater in registry studies than in prospective cohort studies. Third, while DIS has the benefit of being less invasive than ACL reconstruction, it relies on

Table 6Uni- and multi-variableregression analysis of factorsassociated with postoperativeIKDC Score

Variable	Univariable			Multivariable $(n=85)$		
	Regression coefficient	95% CI	p value	Regression coefficient	95% C.I.	p value
Categoric						
Designer surgeons	7.25	(2.37 to 12.13)	0.004	10.67	(4.88 to 16.46)	< 0.001
Male gender	- 0.99	(- 6.09 to 4.11)	n.s	- 1.08	(- 6.47 to 4.30)	n.s
Proximal tear	- 1.46	(- 8.37 to 5.45)	n.s	- 0.55	(- 7.59 to 6.49)	n.s
Adjuvant procedure	2.36	(- 2.81 to 7.53)	n.s	0.43	(- 4.63 to 5.50)	n.s
Continuous						
Age (years)	0.11	(- 0.15 to 0.37)	n.s	0.30	(0.02 to 0.58)	0.039
Tegner score (0-10)	1.02	(- 0.52 to 2.57)	n.s	2.48	(0.79 to 4.16)	0.005
Injury to surgery (days)	0.32	(- 0.24 to 0.89)	n.s	0.36	(- 0.17 to 0.89)	n.s
Last FU (days)	0.00	(-0.02 to 0.30)	n.s	0.02	(- 0.01 to 0.04)	n.s

Table 7Uni- and multi-variableregression analysis of factorsassociated with postoperativeLysholm Score

Variable	Univariable			Multivariable (n=85)		
	Regression coefficient	95% CI	p value	Regression coefficient	95% CI	p value
Categoric						
Designer surgeons	6.32	(2.22 to 10.41)	0.003	7.84	(2.84 to 12.84)	0.003
Male gender	- 2.63	(- 6.89 to 1.63)	n.s	- 2.37	(- 7.02 to 2.29)	n.s
Proximal tear	- 1.95	(- 7.78 to 3.88)	n.s	- 0.57	(- 6.63 to 5.48)	n.s
Adjuvant procedure	0.82	(- 3.54 to 5.18)	n.s	- 0.63	(- 4.93 to 3.66)	n.s
Continuous						
Age (years)	0.07	(- 0.15 to 0.37)	n.s	0.19	(-0.05 to 0.43)	n.s
Tegner score (0–10)	0.71	(- 0.59 to 2.02)	n.s	1.93	(0.48 to 3.39)	0.010
Injury to surgery (days)	0.22	(- 0.25 to 0.69)	n.s	0.22	(- 0.24 to 0.67)	n.s
Last FU (days)	- 0.01	(- 0.02 to 0.00)	n.s	0.00	(- 0.01 to 0.02)	n.s

the healing capacity of torn ligament remnants, which is less guaranteed than the integrity of a full ACL graft. The failure rate in our study is comparable to rates reported in other studies on DIS: In a series of 50 patients evaluated at a minimum of 2 years, Kohl et al. [24] reported revisions in 10%; In another series of 264 patients also evaluated at a minimum of 2 years, Krismer et al. [26] reported revisions in 10%; A case series of 381 patients evaluated at 2.5 years, published by Henle et al. [18], reported revisions in 8%; The most recent study of 26 patients, published by Meister et al. [27], reported revisions in 15% at 1 year. In agreement with the aforementioned studies [18, 26], univariable (but not multivariable) analysis found ACL revisions to be significantly associated with young age, higher activity levels (preinjury Tegner score), and central tear locations. First, a higher activity level increases the risk for treatment failure [28]. Even if our study only recorded preinjury activity levels, it is likely that most patients attempted to resume sports at similar levels, which could explain our findings. Second, young age is also known to increase risks of revision following ACL reconstruction [31, 38]. It is important to note that age is often inversely correlated with activity [32] and could be a confounding variable. Finally, tear location was reported to influence outcomes of DIS (odds ratio > 2.4) [18, 26]. From a clinical point of view, this might be because the vascularity of the central region is poorer than that of the proximal region. A lack of blood supply might limit the biological healing process [36]. However, the results remain inconclusive. First, cases with central tears are less frequent than proximal tears. Second, the blood supply of the ACL remnants was assumed to be sufficient for healing in all cases at index surgery, which took place within 21 days from injury.

The literature also reports on re-operations without graft revision following ACL reconstruction, often to repair or remove meniscal tears (7-15%) [10, 13, 14, 22]. Non-revision re-operations in this study were reported in 16%,

which is comparable to rates reported in other studies on DIS: In a study with two matched cohorts of DIS and ACL reconstruction, each with 53 patients, Bieri et al. [8] reported non-revision re-operations in 17 and 19% respectively, at a minimum of 2 years; In a series of 26 patients evaluated at 1 year, Meister et al. [27] documented non-revision re-operations in 20%. In another case series of 446 patients, Haeberli et al. [17] reported non-revision re-operations in 12%, also at a minimum of 2 years. As with Haeberli et al. [17], we reported re-operations due to new meniscal lesions in only 4%, which is lower than previously described for ACL reconstruction, and could be a benefit of early intervention with DIS [6, 12].

There are considerable variations in patient-reported outcomes following ACL reconstruction, with average IKDC scores between 83 and 100, and average Lysholm scores between 88 and 96 [2, 20]. In this study, mean IKDC and Lysholm scores of 91 and 93, respectively, at a mean follow-up of 2.2 years, were observed. High patient-reported scores were consistently reported after DIS: In a case series of 50 patients, Kohl et al. [24] found median IKDC and Lysholm scores of 98 and 100, respectively, at a minimum of 2 years; In another case series of 62 patients also evaluated at a minimum of 2 years, Henle et al. [19] reported mean IKDC and Lysholm scores of 95 and 97, respectively; Most recently, a randomized study of DIS and ACL reconstruction, each with 30 patients, Schliemann et al. [30] reported mean IKDC scores of 86 and 85 for DIS and ACL reconstruction, respectively, and mean Lysholm scores of 90 for both groups, at 1 year. Our multivariable regression revealed significantly better IKDC scores for patients operated by 'designer surgeons' (p < 0.001), in addition to associations with preinjury Tegner score (p=0.005)and patient age (p=0.039). Multivariable regression also revealed significantly better Lysholm scores for patients operated by 'designer surgeons' (p=0.005), in addition to an association with preinjury Tegner score (p = 0.010). The higher scores for patients operated by 'designer surgeons' could be due to positively biased attitudes of both the surgeons and the patients towards DIS. The average differences were 7 points for the IKDC score and 6 points for the Lysholm score, which do not exceed the minimum clinically important difference (MCID). The minimal detectable change for the IKDC score was reported between 8.8 and 15.6, and the MCID is between 10 and 20. The minimal detectable change for the Lysholm score was reported between 8.9 and 10.1 (the MCID was not reported) [9]. The slight effects of preinjury Tegner score and patient age on patient-reported outcomes could be attributed to various factors that this study did not account for, including different rehabilitation programs or tissue healing capabilities in younger and more active patients [15, 37].

The principal limitation of the present study is its small sample size, with relatively few events, which could invalidate our inferences. While the study is sufficiently powered to compare differences in IKDC scores, the present sample size does not allow statistical implications for ACL revision rates. It is important to note, however, the difficulty of obtaining sufficiently large samples in the first decade following the launch of a novel medical device. Moreover, greater losses to follow-up were documented for 'non-designers' and hence some revisions or re-operations may be unrecorded. Another limitation is the relatively short follow-up, by virtue of the novelty of DIS, which leave uncertainties regarding long-term outcomes. Finally, the study did not consider all intrinsic (biologic) and extrinsic (rehabilitation) factors that could influence outcomes and survival. The main strengths of the study are, however, its prospective and multi-centric design, and its original distinction between patients by 'designer surgeons' versus 'non-designer surgeons'.

Conclusion

Surgeon experience with DIS was not associated with rates of revision ACL surgery or general re-operations. Future, largerscaled studies are needed to confirm these findings. Patients operated by 'designer surgeons' had slightly better IKDC and Lysholm scores, which could be due to better patient selection and/or positively biased attitudes of both surgeons and patients.

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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. **Ethical approval** All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from the participants included in this study.

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