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Patient and surgical characteristics that affect revision risk in dynamic intraligamentary stabilization of the anterior cruciate ligament

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Author's contribution

PH was one of the treating surgeons, conceived the study, interpreted the data and helped drafting the manuscript. KSB participated in the design of the study, conducted statistical analyses, interpreted the data and drafted the manuscript. EA participated in the design of the study, helped to interpret the data, to perform the statistical analysis, and supervised the drafting of the manuscript. JH participated in the design of the study, helped to interpret the data and revised the manuscript. JB participated in the design of the study, supervised the statistical analyses and revised the manuscript. MB helped in data acquisition and revised the manuscript. MK helped in data acquisition and revised the manuscript. SE was one of the treating surgeons, supervised the complete study and revised the manuscript. All authors have read and approved the final manuscript.

Conflict of interest

PH and SE act as clinical advisers for Mathys AG Bettlach, Switzerland. The PhD project of KSB is partially funded by Mathys AG Bettlach, Switzerland. JB is employed by Mathys AG Bettlach, Switzerland.

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Ethical approval

All procedures performed in studies 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 all individual participants included in the study.

Keywords

Anterior cruciate ligament, Dynamic intraligamentary stabilization, ACL repair, Failure,·Revision surgery, Risk factors, Outcomes, ACL suture,·Ligamys

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ABSTRACT

Purpose

Failure of dynamic intraligamentary stabilization (DIS) that requires revision surgery of the anterior cruciate ligament (ACL) has not been studied. The aim of this study was to investigate the incidence of revision ACL surgery, and the patient characteristics and surgery-related factors that are associated with an increased risk of ACL revision after DIS.

Methods

This study analysed a prospective, consecutively documented single-centre case series using standardized case report forms over a 2.5-year follow-up period. The primary endpoint was revision ACL surgery. We used Kaplan–Meier analysis to examine the revision-free survival time, and a multiple logistic regression model of potential risk factors including age, sex, BMI, smoking status, previous contralateral ACL injury, Tegner activity score, interval to surgery, rupture pattern, hardware removal, and postoperative side-to-side difference in knee laxity. Relative risk was calculated for subgroups of significant risk factors.

Results

In total, 381 patients (195 male) with a mean age of 33 ± 12 years were included in the analysis. The incidence of revision ACL surgery was 30/381 (7.9%). Younger age ($p = 0.001$), higher Tegner activity score ($p = 0.003$), and increased knee laxity ($p = 0.015$) were significantly associated with revision ACL surgery. The increased relative risk for patients who were less than 24 years old, participated in activities at a Tegner level >5 points, or had >2 mm of side-to-side difference in knee laxity was 1.6, 3.7, and 2.3, respectively.

Conclusion

Young age, high level of sport activity, and high knee laxity observed in follow-up examinations increased the likelihood for revision surgery after DIS. Patients undergoing DIS should be informed of their potentially increased risk for therapy failure and carefully monitored during recovery.

Level of evidence

Case series, Level IV.

INTRODUCTION

Dynamic intraligamentary stabilization (DIS) was recently introduced in the surgical treatment of acute anterior cruciate ligament (ACL) ruptures [11]. The technique aims to provide knee joint stability while the ACL heals, and graft harvesting is not required. Initial case series of patients undergoing DIS have reported high functional scores and a return to previous levels of sport activity in the majority of patients up to 5 years following surgery [7, 16, 19]. However, treatment failure has not yet been investigated for this innovative approach.

Failure of surgical reconstruction of the ACL is in general defined by revision surgery. The incidence of revision ACL surgeries varies, but revision rates 2–5 years postoperatively have been reported up to 25% [3, 14, 25]. A high level of activity is known to increase the risk of treatment failure, but the extent to which other factors such as age or surgical technique may increase the risk is still a subject of debate [23]. A better understanding of the incidence of revision ACL surgery after DIS and associated risk factors could revise indications for DIS, improve individual risk assessments, and benefit patients if the need for revision surgeries, which are associated with an elevated risk of poor long-term knee function [2, 15, 22], could be reduced.

The twofold purpose of this study was therefore to determine the incidence of revision ACL surgery over 2.5 years following DIS and to assess which patient characteristics and surgery-related factors are associated with an increased risk of ACL revision after DIS.

MATERIALS AND METHODS

This study analysed a prospective, consecutively documented single-centre case series (Bern, Switzerland) that has been described elsewhere [11, 16]. Three case report forms were used: form A captured patient characteristics, and injury and surgery-related information; form B recorded information regarding adverse events and surgical interventions during follow-up that included revision ACL surgeries; and form C reported on the clinical follow-up examinations at 6, 12, and 24 months. The forms were completed online at the time of surgery, and upon follow-up and reintervention. The treating surgeons completed forms A and B. The objective evaluation of the two-part follow-up form C was completed by the surgeons and the subjective scores by their patients. The data are hosted at an academic web-based documentation platform (MEMdoc) at the University of Bern, Switzerland. All data were extracted anonymously.

Indications for DIS surgery were acute ACL injury, closed growth plates, performance of high-risk activities (e.g., pivoting sports), or competitive sport activity level, and patient not eligible for or not accepting conservative treatment. Conservative treatment was recommended if all of the following criteria were fulfilled: no more than a 3 mm difference in AP translation when compared with the uninjured contralateral side, no high-risk activities, and no meniscal lesions.

The surgical technique and corresponding rehabilitation programme for DIS have been reported in detail [7, 16]. In brief, a hollow screw with an integrated spring system (Ligamys ™, Mathys Ltd, Bettlach, Switzerland) is fixed into the tibia, and an integrated polyethylene cord is secured in the femur. This is intended to prevent the femur and tibia from being able to shift relative to one another during movements of the knee. The two cruciate ligament stumps are not sutured together, but rather held in close proximity to each other using the cord. The ruptured ends make loose contact and can grow together free from tensile load. After surgery, the knee is kept in extension in a brace for 4 days to enable adhesion of the ACL stumps. For isolated ACL ruptures or those combined with a partial resection of the meniscus, active physiotherapy and full weight bearing are permitted starting on the fifth postoperative day. After 6 weeks, training with progressive load enhancement is permitted. In patients with sutured meniscal lesions, further brace wearing and partial weight bearing for 4 to 6 weeks after surgery are recommended. Unlimited training is allowed only after 10 weeks. Patients are generally not permitted to resume sports for at least 6 months and then only after all steps of the rehabilitation have been completed.

Inclusion criteria and study population

The study's inclusion flow chart is shown in Fig. 1. The study's follow-up period was 2.5 years. Patients who presented with a rupture of the ACL that was treated with DIS between 2009 and 2014 were eligible for inclusion in the study. Patients treated within 60 days after injury were included in the study. DIS surgery is recommended within the first 21 days after injury because ACL healing depends upon the biologic activity of the injured tissue [16]. Thus, patients presenting with an ACL rupture between 21 and 60 days after injury were considered for DIS by the surgeon only if biologic activity of the injured tissue could be confirmed intraoperatively. Study exclusion criteria were no acute rupture of the ACL (DIS treatment later than 60 days after injury), contralateral injury during follow-up or no follow-up data due to loss to follow-up. The characteristics of the study population are summarized in Table 1.

Outcome measure

The primary endpoint in this study was revision ACL surgery, defined as an ACL reconstruction. Patient and surgical characteristics were considered a priori as potential risk factors for ACL revision surgery. Patient characteristics included in the study were age, sex, BMI, smoking status, previous contralateral ACL injury, baseline activity level, and postoperative side-to-side difference in knee laxity. Activity level was determined using the self-reported Tegner score that relies on a 0–10 numerical rating scale to assess sport and work activity levels [31]. Scores of up to 5 include activities such as jogging *(≥twice weekly) or strenuous physical work, but not regular participation in game sports. Scores of 6 and above include game sports and downhill skiing. The side-to-side difference in

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knee laxity was the absolute difference (Δ) in anterior–posterior (AP) translations of both knees measured as the knee translation of each knee at 30 degrees of flexion using an arthrometer (Rolimeter, Aircast, Neubeuern, Germany). The value used was that from the last available follow-up. DIS surgery characteristics included interval to surgery, hardware removal, and rupture pattern. The rupture pattern was defined by three different ACL rupture classifications described by Henle et al. [16]: (1) rupture location (proximal, midsubstance, or distal tear), (2) rupture type (1 bundle versus ≥2 bundles), and (3) integrity of the synovial sheath (completely intact versus partially or totally damaged). The rupture classification took place intraoperatively.

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

Statistical methods

All data were normally distributed and tested using the Shapiro–Wilk test. For descriptive statistics, mean ± standard deviation (SD) is given. The Tegner score, a Likert-type scale, was treated as interval data [30]. To determine the incidence of revision ACL surgery after DIS, Kaplan–Meier analysis was applied to examine the revision-free survival time. To determine the risk factors for revision ACL surgery, a multiple logistic regression model was built including the exposure variables age, sex, BMI, smoking status, previous contralateral ACL injury, Tegner score, ΔAP translations, interval to surgery, rupture pattern, and hardware removal. For patients lost to follow-up (11%), a worst-case scenario for the multiple logistic regression model (including all patients in the revision group or in the control group, respectively) was additionally performed. This did not change the significance of the results. After identification of the significant risk factors for revision surgery, a ROC analysis was performed for continuous risk factors to identify optimal cut-off values discriminating between revision patients and controls. Finally, relative risks were calculated for high- and low-risk subgroups. All statistical analyses were conducted in SAS 9.4 (SAS Institute Inc., Cary, NC) with the level of significance set at 0.05.

RESULTS

Incidence of ACL revision surgery

Over the study's 2.5 years of follow-up, 30 of the 381 patients (7.9%) underwent a revision ACL surgery. All revised patients were treated with an ACL reconstruction using patellar (n = 19), quadriceps (n = 8), or hamstring tendon (n = 5) autografts. Bone grafting of the implant socket was never necessary. In 22 of the revised patients (73%), the reason for revision surgery was a traumatic reinjury after resumption of sports. Five patients (17%) reported unbearable giving-way symptoms (chronic knee instability) without a new traumatic event. For three patients (10%), the reason for revision was not specified. Revision surgery was performed on average 18 ± 6 (10–30) months after the index procedure; 16 revision surgeries occurred between 1 and 2 years after the index procedure. Figure 2 shows the revision-free survival up to 2.5 years of follow-up after DIS index surgery. Cumulative survivorship (S) was 0.92 [95% confidence interval (CI) 0.89–0.94]. The respective 1- and 2-year postoperative incidences of revision were 2.0% (8 patients; S 0.98, 95% CI 0.96–0.99) and 6.3% (24 patients; S 0.94, 95% CI 0.91–0.96).

Exposure variables and risk for revision ACL surgery

Table 2 summarizes the exposure variables by which ACL revision patients and controls were compared. The multivariate analysis showed significantly different odds ratios for age, Tegner score at baseline, and postoperative ΔAP translation. ACL revision patients were on average 12 years younger than patients with no revision (OR 0.90, 95% CI 0.84–0.95; p = 0.001), had a mean Tegner score of 6 compared with 5 (OR 1.66, 95% CI 1.19–2.32; p = 0.003), and 1.5 mm increased ΔAP translation (OR 1.34, 95% CI 1.06–1.7; p = 0.015) at the last available follow-up (days after index surgery; control group, 714 ± 107; ACL revision group, 318 ± 148). No significant differences were observed between the groups with respect to other exposures.

After identification of three continuous factors significantly associated with revision surgery (Table 1), the ROC analysis identified the most distinctive cut-off between the revision group and the controls for each of the factors. Cutoff values of 23.7 years of age, 2.0 mm of ΔAP translation, and a Tegner score of 5 points were found with sensitivity/specificity of 79/80% [area under the curve (AUC 0.80)], 73/64% (AUC 0.70), and 65/67% (AUC 0.70), respectively. The relative risk analysis for revision ACL surgery in the respective subgroups is shown in Table 3.

DISCUSSION

The study observed an incidence of revision ACL surgery after DIS of 7.9% over 2.5 years of follow-up and found that young age, high baseline activity level, and postoperative knee laxity were significantly associated with an increased risk of ACL revision after DIS.

Incidence if revision ACL surgery

To our knowledge, there are no published studies to have estimated the incidence of revision surgery after DIS to which our results could be compared. After ACL reconstruction, treatment failure rates vary widely and up to 25%. [4–6]. Large cohort studies and registries have shown a slightly lower incidence of failure 2 years postoperatively (1.8–4.4%) [1, 18, 32]. However, varying follow-up intervals, different definitions of treatment failure, and limited descriptions of study populations (e.g., lack of information on activity levels) make comparisons with our study difficult.

Exposure variables and risk for revision ACL surgery

The risk analysis of patient characteristics showed an increased risk for revision ACL surgeries for younger patients. The ROC analysis identified the age of 24 years as the optimal cut-off separating the study's high- and low-risk groups. The risk increased by a factor of 3.7 below this cut-off. Other studies analysing ACL reconstruction have reported similar results [27, 33]. However, young age is correlated with high activity level [29]. In our study, the Tegner score may be not precise enough to separate this interaction. Even with scores equal to older patients, younger patients may experience a higher risk for rerupture because their physical activity occurs more often and at a higher intensity.

For patients regularly participating in game sports with abrupt start/stop activity or downhill skiing (Tegner score >5), the risk for revision ACL surgery was 1.6 times higher compared with less demanding activities (Tegner score ≤5). Several other studies report significantly more graft failures among patients with higher activity scores [4, 18] and increased competitive levels [20], and in soccer players compared with other sports [1, 20]. Return to high-demand activity levels is recognized as an independent risk factor for traumatic reinjury and subsequent revision surgery [4, 6, 20, 26, 29, 34]. This sustains the assumption that a return to the preinjury activity levels is the reason why young age and high baseline activity are associated with revision risk.

Side-to-side difference in AP knee joint laxity is widely used to measure the success of the reconstructed ACL graft [21]. In general, a side-to-side difference of >2 mm is defined as failure [3, 5, 8, 9]. In the present study, an increased postoperative side-to-side difference was associated with revision ACL surgery. The ROC analysis resulted in a cut-off of 2 mm with a doubled risk of a revision surgery for patients with higher knee laxity. Other studies have reported similar findings [12, 24]. However, increased postoperative knee laxity measured as AP translation was not correlated with subjective symptoms and function after ACL reconstruction. Factors that predict increased postoperative AP translation have not yet been identified. It is assumed that a biomechanical deficit may exist in these patients despite a high level of functional performance and return to sports activities [17, 28].

Other patient characteristics of the two groups including sex, BMI, and smoking did not differ. These results agree with current research findings for ACL reconstruction [10, 27].

The analysis of DIS surgery characteristics was performed for surgical timing, hardware removal, and rupture pattern. It is not yet well understood whether ACL healing is affected by some of these factors. For surgical timing, the effect size of the adjusted analysis on revision ACL surgery was marginal with an odds ratio of 1.02 per extended interval day (p = n.s.). The intervals from injury to DIS ranged from 3 to 60 days, and 55 patients underwent DIS after the 21-day limit, after the surgeon having recognized the healing potential of the ruptured ACL intraoperatively. The biologic activity of the injured tissue may be maintained longer than previously assumed. Further, no association of hardware removal with revision ACL surgery was found. The bulky DIS hardware mechanically stabilizes the injured knee, functioning only temporarily during ACL healing. Previous studies reported that hardware is removed in approximately half of DIS patients due to local discomfort. No evidence of an effect of removal on recovery has been shown [7, 16, 19]. In our study, twice as many hardware removals were reported in patients without revision surgery (40 vs. 20%, Table 2). This might have occurred because patients experience discomfort and thus are less active in sports before the hardware is removed. Finally, the rupture pattern was also not significantly associated with revision ACL surgery. However, a revision incidence of 11% for midsubstance tears (6 out of 56) compared with 6% for proximal tears (17 out of 285) was found. A previous study specifically of midsubstance ACL ruptures documented rerupture in 13 of 96 patients (14%) at 2-year follow-up, but no control group was included [13]. Since the majority of ACL ruptures described in previous reports were proximal [16, 19], and the number of cases with midsubstance tears was small in this study, the results remain inconclusive from a clinical point of view.

Limitations

Revision ACL surgery, the study's primary endpoint, serves as a proxy for therapy failure that could also be defined by measurement of increased laxity or patient-reported unsatisfactory outcome. The possibility therefore exists for the study to have missed patients with clinically relevant concerns or problems such as recurrent instability who, for one reason or another, did not have a revision within 2.5 years. With this limitation in mind, the 7.9% incidence of revision surgery we observed might be regarded as a reasonable estimate of the minimum rate of DIS treatment failure. An additional factor that could have affected this revision rate is that 11% of the study population was lost to follow-up. Another limitation might involve the study's exposure variables, which were limited to the set captured by the documentation platform. Among those that were included, as noted above the Tegner score has its own limitations. Postoperative activities may certainly affect the need for revision. However, return to sport, no matter how it takes place, and with it exposure to risk of injury is difficult to assess. Finally, this study relied upon data from only one centre. For other reasons as well, further examination of treatment failure after midsubstance ACL ruptures and factors affecting postoperative knee laxity are needed.

CONCLUSION

Younger patients, patients participating in activities at a Tegner score level greater than 5, and patients with increased knee laxity observed in follow-up examinations should be informed of their potentially increased risk for therapy failure after DIS and carefully monitored during recovery.

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TABLES

Table 1: Characteristics of the study population

a Activities such as jogging (≥twice weekly) or strenuous physical work, but no game sports

b Game sports on a recreational level as well as downhill skiing

c The lesion was conservatively treated

	Characteristics of the study population ($n = 381$)
Demographics	
Patient age (years)	33 ± 12
Male sex	19 (63%)
History of a contralateral ACL injury	46 (12%)
Sport activity level	
Tegner score 5[a]	99 (26%)
Tegner score 6[b]	96 (25%)
Principal sport discipline	
Game sports	112 (30%)
Downhill skiing	80 (21%)
Category of work	
Sedentary	163 (43%)
Moderate	155 (41%)
Strenuous	63 (16%)
Surgery characteristics	
Lesion medial collateral ligament[c]	29 (8%)
Menisci fixation	126 (33%)
Menisci partial resection	40 (11%)

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Table 2: Exposures associated with revision ACL surgery

	Revision group ($n = 30$)	Controls ($n = 351$)	p value	Odds ratios (95% CI)
Patient characteristics				
Patient age (years)	22 ± 7	34 ± 12	0.001	0.90 (0.84–0.95)
Sex				
Male	19 (63%)	176 (50%)		
Female	11 (37%)	175 (50%)	n.s.	0.83 (0.31–2.20)
BMI (points)	24 ± 3	24 ± 3	n.s.	1.06 (0.91–1.24)
Smoking				
No	24 (80%)	291 (83%)		
Yes	6 (20%)	60 (17%)	n.s.	0.45 (0.14–1.45)
Tegner score at baseline (points)	6 ± 2	5 ± 1	0.003	1.66 (1.19–2.32)
History of a contralateral ACL injury	2 (7%)	44 (13%)	n.s.	1.89 (0.31–11.61)
Postoperative ΔAP translation	3.2 ± 2.0	1.7 ± 1.9	0.015	1.34 (1.06–1.70)
DIS surgery characteristics				
Rupture location				
Distal	0	0		
Proximal	17 (57%)	268 (76%)		
Midsubstance	13 (43%)	83 (24%)	n.s.	2.39 (0.90–6.38)
Synovial sheath				
Intact	12 (40%)	91 (26%)		
Damaged	18 (60%)	260 (74%)	n.s.	2.08 (0.80–5.40)
Rupture status				
One bundle	12 (40%)	133 (38%)		
≥Two bundles	18 (60%)	218 (62%)	n.s.	1.69 (0.60–4.76)
Interval to surgery (days)	18 ± 9	16 ± 7	n.s.	1.02 (0.97–1.08)
Hardware removal	6 (20%)	139 (40%)	n.s.	2.23 (0.77–6.49)

Table 3: Relative risk of revision ACL surgery in age, Δ AP translation, and Tegner score subgroups.

	No. of patients with a revision ACL surgery/total	Incidence (%)	Relative risk (95% CI)
Overall	30/381	7.9	
Age			
>24 years	6/281	2.1	
≤24 years	24/100	24.0	3.7 (2.8–4.8)
ΔAP translation			
≤2.0 mm	11/267	7.3	
>2.0 mm	19/114	16.7	2.3 (1.7–3.2)
Tegner score			
≤Score 5	13/242	5.4	
>Score 5	17/139	12.2	1.6 (1.2–2.3)

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FIGURES

Figure 1: Study flow chart.

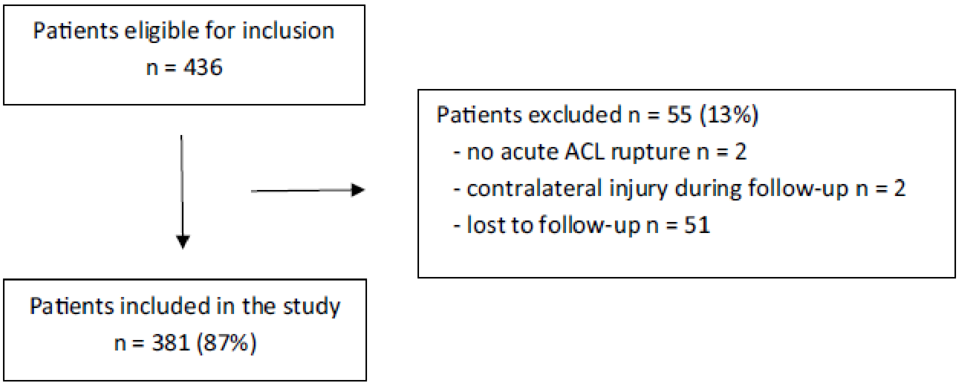

Figure 2: The revision-free survival during 2.5 years of follow-up.

The interval shown is days after DIS surgery