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ACL suturing using dynamic intraligamentary stabilisation showing good clinical outcome but a high reoperation rate: a retrospective independent study

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Abstract

Purpose Most of the clinical outcome studies dealing with ACL repair are from the developer's perspective. It is a fact that these developer-initiated studies tend to interpret the results rather in favour than against their developed technique or product. Hence, it was the purpose of the present independent investigator-initiated study to investigate the clinical and radiological outcomes as well as failure rate of patients who underwent an ACL suture using dynamic intraligamentary stabilisation device in a specialised independent knee clinic.

Methods A retrospective study was performed on prospectively collected data of 26 patients (28 ± 9 years, range 18–50 years; male/female = 17:9) who underwent biologically augmented ACL suture using dynamic intraligamentary stabilisation. Mean time from ACL injury was 15 ± 5 days (range 4–25 days). In addition, in seven (27%) patients a medial meniscus refixation and in four (15%) patients a lateral meniscus refixation was done for associated meniscal lesions. All patients were clinically and radiologically followed up at 6 weeks, 3 and 12 months after ACL surgery using the Tegner and Lysholm score as well as IKDC score. Adverse events such as ACL failure, arthrofibrosis, pain > 3 on a visual analogue scale as well as the need and type of revision surgery were noted.

Results Four patients (15%) suffered from an ACL retear due to another adequate trauma during follow-up time. In six patients (23%), an arthrofibrosis (extension deficit of > 10° or flexion deficit > 20°) was noted. In five of those six patients, an arthroscopic arthrolysis was performed. Three patients also complained about pain VAS > 3. In nine (35%) patients, superfluous ACL scar tissue and the DIS device including the polyethylene suture and the DIS screw were removed, and in another two (8%) patients, the DIS screw only was removed. In two patients, a partial meniscectomy was performed due to a non-healed meniscal suture. The median Tegner score was 8 (range 6–10) before injury and 7 (range 3–10) at last follow-up ($p < 0.001$). The mean Lysholm score before surgery was 28 ± 14 and 94 ± 11 at last follow-up ($p < 0.001$). At last follow-up, 14 patients (66%) showed a normal total IKDC score (A) and 4 patients (19%) were nearly normal (B) and 2 patients (10%) were slightly abnormal (C) and one patient (5%) was entirely abnormal ($p < 0.001$).

Conclusion ACL suturing using the dynamic intraligamentary stabilisation device showed satisfying clinical results at 12-month follow-up. However, a retear rate of 15% and a reoperation rate of 35% due to retear or arthrofibrosis appear rather high. These results highlight the importance of adequate patient selection and the delicacy of the surgical procedure.

Level of evidence Retrospective case series, Level IV.

Keywords ACL · Anterior cruciate ligament repair · Reconstruction · Dynamic intraligamentary stabilisation · DIS · ACL healing · ACL suture

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Introduction

For the last 35 years, knee surgeons accepted the dogma that a torn anterior cruciate ligament would not heal when sutured [6]. This dogma might not be entirely true.

In the 1960s, ACL sutures were quite common after O'Donoghue [17] popularised this treatment modality. However, the results were not very convincing, as John Feagin showed in his famous paper from 1976, where almost all patients complained about knee pain and about 50% of the patients suffered from an unstable knee [6]. Those unsatisfactory results were the cornerstone for the dogma: a sutured torn ACL would not heal.

In 2009, a new system for an augmented suture technique was introduced trying to break the dogma [3]. In November 2011, the first patient was treated with this new technique as part of a multicenter study, which showed that the principle worked not only in the designing surgeons hands. In 2013, the technique was introduced into the market and made available for every surgeon interested.

In general, in the last years there has been increasing interest in ACL repair and preservation of the torn ACL [1, 2, 4, 8, 9, 11–13, 18–20]. Besides the Swiss group Martha Murray`s group in Boston can be considered as a key player for biologically augmented ACL repair [7, 15, 16, 18].

However, most of the clinical outcome studies published are still from the developer`s perspective. It is a fact that these developer-initiated studies tend to interpret the results rather in favour than against their developed technique or product. Clearly, independent studies are necessary to evaluate such developments with conflict of interest. Hence, it was the purpose of the present independent investigator-initiated study to investigate the clinical and radiological outcomes as well as failure rate of patients who underwent an ACL suture using dynamic intraligamentary stabilisation device in a specialised independent knee clinic. It was the hypothesis that ACL suturing using DIS leads to good clinical outcomes with a reasonable retear and reoperation rate.

Materials and methods

A retrospective study was performed on prospectively collected data of 26 patients (28 ± 9 years, range 18–50 years; male/female = 17:9) who underwent biologically augmented ACL suture using dynamic intraligamentary stabilisation (DIS) device (Ligamys, Mathys, Switzerland) for ACL tear in an university-affiliated specialised knee clinic. No patients had any previous ACL injury or surgery reported. Mean time from ACL injury was 15 ± 5 days (range 4–25 days).

DIS was done in agreement with the manufacturers manual and instructions by a team of three experienced knee surgeons. Biological augmentation was done by microfracturing the lateral femoral condylar wall and notch (Fig. 1).

In addition, in seven (27%) patients a medial meniscus refixation and in four (15%) patients a lateral meniscus refixation was done for associated meniscal lesions.

Mean surgery time was 87 ± 18 min (range 58–127). The patients stayed in hospital for mean 5 ± 1 days. According to Henle et al., the ACL tear was classified as type A (proximal) $n = 16$, type B (middle) $n = 8$ and type C distal $n = 2$. In $n = 8$ one ACL tear bundle, in $n = 10$ two ACL tear bundles and in $n = 8$ more than 3 ACL tear bundles were found. The synovial sheath was intact in 8 patients, > 50% intact in 10 patients and < 50% intact in 8 patients.

All patients were clinically and radiologically followed up at 6 weeks, 3 and 12 months after ACL repair by an independent observer who had not been involved in the index surgery. The minimum follow-up time was 12 months (range 12–14 months).

For clinical assessment, the Tegner and Lysholm score as well as IKDC score were used. KT-1000 or rolimeter arthrometer was used for assessment of anterior laxity for

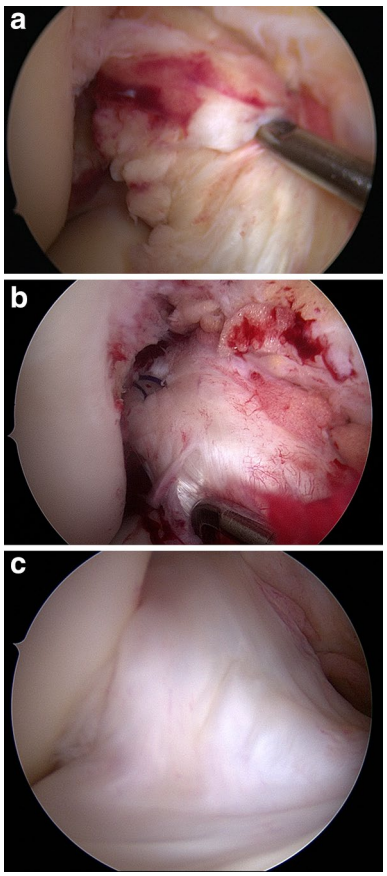

Fig. 1 **a** Intraoperative arthroscopic picture of a femoral ACL tear before treatment. **b** Intraoperative arthroscopic picture at the end of the reinsertion procedure. **c** Intraoperative second-look arthroscopic picture of a femoral ACL 1 year after initial surgery

IKDC. Categorial values of anterior laxity were noted. Radiological follow-up consisted of weight-bearing anterior–posterior and lateral radiographs.

In addition, adverse events such as ACL failure, arthrofibrosis, pain > 3 on a visual analogue scale as well as need for and type of revision surgery was noted.

Ethical approval was obtained from the Ethikkommission Nordwest- und Zentralschweiz (2014/167, EKNZ, Basel). All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Statistical analysis

A post hoc power analysis was performed and showed a sufficient sample size for this retrospective study. Data were analysed using IBM SPSS Statistics for Windows 22.0 (Armonk, NY: IBM Corp.). Continuous variables were described using mean and standard deviation or median and range. Categorical variables were tabulated as absolute and relative frequencies. A two-tailed Pearson's correlation was used to compute associations between patient related, clinical and radiological outcome variables. For all analyses, $p < 0.05$ was considered statistically significant.

Results

Four patients (15%) suffered from an ACL retear due to another adequate trauma during follow-up time. In six patients (23%), arthrofibrosis was present. Arthrofibrosis was defined as extension deficit of > 10° or flexion deficit > 20°. In five of those six patients, an arthroscopic arthrolysis was performed, which led to improved but not normal range of motion. At one-year follow-up, two patients had a persistent extension deficit of 6°–10° and two patients > 10° (Fig. 2). Flexion deficit was 6°–15° in one and 3°–5° in one patient. Three patients also complained about pain VAS > 3.

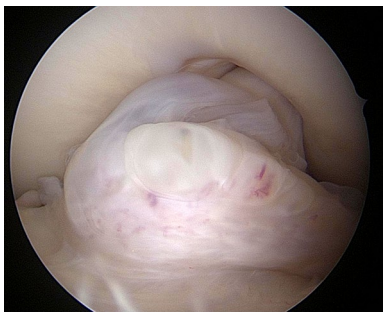

Fig. 2 Cyclops lesion anterior to the reinserted ACL 12 months postoperatively preventing full extension

In nine (35%) patients, the DIS device including the polyethylene suture and ACL scar tissue was removed, and in another two (8%) patients, the DIS screw was removed. In two patients, a partial meniscectomy was performed due to a not healed meniscal lesion. Reoperation was done 4 ± 4 months after DIS.

The median Tegner score was 8 (range 6–10) before injury and 7 (range 3–10) at last follow-up ($p < 0.001$). In 45% of patients the Tegner score decreased when compared to preinjury level. The mean Lysholm score before surgery was 28 ± 14 and 94 ± 11 at last follow-up ($p < 0.001$).

Preoperatively, the IKDC score was nearly normal in 5 (22%) and slightly abnormal (C) in 18 (78%) patients. At last follow-up, 14 patients (66%) showed a normal total IKDC score (A) and 4 patients (19%) were nearly normal (B) and 2 patients (10%) were slightly abnormal (C) and one patient (5%) was entirely abnormal ($p < 0.001$). The categorised anterior laxity values preoperatively and at one-year follow-up are shown in Table 1.

On radiographs, no adverse events such as displacement of DIS device or tunnel widening were observed.

Discussion

The most important findings of the present study were threefold. Firstly, clinical outcomes in terms of Tegner score, Lysholm score and IKDC were comparable to patients undergoing ACL reconstruction. However, the retear rate of 15% at one-year follow-up is markedly higher. In addition,

Table 1 Categorised anterior laxity in comparison with contralateral side (in mm)

	Before surgery	12 months after ACL repair
Lachman test (25° flexion, 134 N)	–2 mm: –	–2 mm: 18
	3–5 mm: –	3–5 mm: 1
	6–10 mm: 11	6–10 mm: 2
	>10 mm: 15	>10 mm: 5
Lachman test (25° flexion, maximum)	–2 mm: –	–2 mm: 18
	3–5 mm: –	3–5 mm: 1
	6–10 mm: 11	6–10 mm: 2
	>10 mm: 15	>10 mm: 5
Total AP translation (25° flexion)	–2 mm: –	–2 mm: 18
	3–5 mm: –	3–5 mm: 1
	6–10 mm: 11	6–10 mm: 2
	>10 mm: 15	>10 mm: 5
Total AP translation (70° flexion)	–2 mm: –	–2 mm: 18
	3–5 mm: –	3–5 mm: 1
	6–10 mm: 11	6–10 mm: 2
	>10 mm: 15	>10 mm: 5

a high reoperation rate of 35% due to retear or arthrofibrosis was observed.

The results of the present independent study are also inferior to the previously published results from the developer's group. Henle et al. described a revision rate of 7.9% over 2.5 years of follow-up after DIS [9]. This might be at least partly due to the very wide indication spectrum [9]. In terms of timing of ACL repair, the members of the DIS-study group agreed on an arbitrarily chosen timeframe of 3 weeks between injury and the operation. A as short as possible period is considered favourable since after more than 4 weeks the injured knees usually have calmed down, the ACL stumps get rounded and tend to get at least partially resorbed. The healing potential of a torn ACL is expected to reduce over time [10].

In terms of indication for ACL repair at time of introduction of primary ACL repair using DIS, there were no clear indications defined yet. However, a recent paper has outlined possible indications for primary ACL repair using DIS [9]. Henle et al. found an increased risk of ACL revision surgery for younger patients < 24 years. The risk of revision was increased 3.7-fold in the younger age group. High sport activity as well as increased laxity after DIS was also found to be a significant risk factor for failure. The authors then concluded that younger patients, patients participating in activities at a Tegner score level greater than 5, and patients with increased knee laxity should be informed of their potentially increased risk of retear after DIS.

In another study by the developing group Krismer et al. found retear rate of 9.5%, a persistent instability in 4.1% and fixed flexion deficit > 10° in 1.5% [14]. Competitive sport activity (Tegner preinjury score > 7), age as well as a mid-substance ACL tear were identified as risk factors for post-operative problems. In this study, the follow-up was comparable to the one presented.

In the present study, the younger patients were more prone to retear, whereas the older ones were more prone for arthrofibrosis. Arthrofibrosis appears to be a relevant problem after ACL repair or ACL reconstruction [5]. In fact, to date the scar formation of the torn ACL is not controlled. A local arthrofibrosis is needed, but an excessive scarring such as in the case of a general arthrofibrosis results in extension and or flexion deficit. Interestingly, using another ACL suturing technique such a problem with limited range of motion and arthrofibrosis was not reported [21]. In contrast van der List et al. [21] showed that ACL repair patients had a better range of motion than ACL reconstructed ones.

The general message of this paper is that DIS works, but the indication should be set with all due care. The patients need to be informed about higher failure rates in young patients, patients performing highly competitive sports as well as patients with mid-substance tears. The ideal candidate for primary ACL repair appears to be a middle-aged patient with a proximal femoral ACL tear performing recreational sports. However, then the question also arises, if such a patient needs to undergo ACL surgery at all, should be treated with physiotherapy for a certain period and then reassessed. This question is still unanswered.

A considerable number of limitations have to be considered. This is a retrospective independent investigator-initiated study with a rather small sample size. However, sample is large enough to sufficiently answer the study questions. As the patients represent the first patients treated with such a device a learning curve of the procedure needs to be considered. However, a team of experienced knee surgeons did all surgeries minimising such effect. Another limitation might be that three knee surgeons operated on the sample presented here. However, it was a team of three experienced knee surgeons working together.

Most of the clinical outcome studies dealing with ACL repair are from the developer`s perspective. It is a fact that these developer-initiated studies tend to interpret the results rather in favour than against their developed technique or product. In this independent investigator-initiated study, ACL suturing using the dynamic intraligamentary stabilisation device showed satisfying clinical results at 12-month follow-up. However, a retear rate of 15% and a reoperation rate of 35% due to retear or arthrofibrosis appear rather high. These results highlight the importance of adequate patient selection and the delicacy of the surgical procedure.

Conclusion

ACL suturing using the dynamic intraligamentary stabilisation device DIS showed satisfying clinical and radiological outcomes at 12-month follow-up. The dogma a torn ACL does not heal needs to be revised since 70% of ACLs healed using ACL suturing. However, a retear rate of 15% and a reoperation rate of 35% due to retear or arthrofibrosis appear rather high and highlight the importance of adequate patient selection plus learning curve.

Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

Funding There was no financial conflict of interest with regards to this study.

Ethical approval Ethical approval was obtained from the Ethikkommission Nordwest- und Zentralschweiz (2014/167, EKNZ, Basel). All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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