1 Surgeon experience with dynamic intraligamentary stabilization does not

2 influence risk of failure

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25 COMPLIANCE WITH ETHICAL STANDARDS

26 **Conflict of interest**

- 27 All authors have received reimbursements or funding from Mathys AG Bettlach, Switzerland, in the
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- 29

30 Ethical approval

- 31 All procedures performed in studies involving human participants were in accordance with the
- 32 ethical standards of the institutional and national research committee and with the 1964 Helsinki
- 33 declaration and its later amendments or comparable ethical standards.
- 34

35 Informed consent

36 Informed consent was obtained from all individual participants included in this study.

38 7 Tables and 1 Figures

- 39 **Table 1:** Patient demographics
- 40 Table 2: Incidence of revision ACL surgery and of any re-operation
- 41 **Table 3:** Uni- and multi-variable regression analysis of factors associated with any re-operation.
- 42 **Table 4**: Uni- and multi-variable regression analysis of factors associated with revision ACL surgery
- 43 Table 5: Postoperative IKDC, Lysholm and Tegner scores
- 44 **Table 6**: Uni- and multi-variable regression analysis of factors associated with postoperative IKDC
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- 46 **Table 7**: Uni- and multi-variable regression analysis of factors associated with postoperative Lysholm
- 47 Score
- 48 **Figure 1:** Flow chart.

50 ABSTRACT

51 Purpose

52 Studies on dynamic intraligamentary stabilization (DIS) of acute anterior cruciate ligament (ACL)

53 ruptures reported failure rates similar to those of conventional ACL reconstruction. This study aimed

54 to determine whether surgeon experience with DIS is associated with revision rates or patient-

55 reported outcomes. The hypothesis was that more experienced surgeons achieved better outcomes

56 following DIS due to substantial learning curve.

57

58 <u>Methods</u>

59 The authors prospectively enrolled 110 consecutive patients that underwent DIS and evaluated

60 them at a minimum of 2 years. The effects of independent variables (surgeon experience, gender,

61 age, adjuvant procedures, tear location, preinjury Tegner score, time from injury to surgery, and

62 follow-up) on four principal outcomes (revision ACL surgery, any re-operation, IKDC and Lysholm

63 score) were analyzed using univariable and multivariable regressions.

64

65 <u>Results</u>

66 From the 110 patients enrolled, 14 patients (13%) were lost to follow-up. Of the remaining 96 67 patients, 11 underwent revision ACL surgery, leaving 85 patients for clinical assessment at a mean of 68 2.2 ± 0.4 years (range 2.0–3.8). Arthroscopic reoperations were performed in 26 (27%) patients, 69 including 11 (11%) revision ACL surgeries. Multivariable regressions revealed: (1) no associations 70 between the reoperation rate and the independent variables, (2) better IKDC scores for 'designer 71 surgeons' (b = 10.7; Cl 4.9–16.5; p < 0.001), higher preinjury Tegner scores (b = 2.5, Cl 0.8–4.2; p = 72 (0.005), and younger patients (b = 0.3, Cl 0.0–0.6; p = 0.039), and (3) better Lysholm scores for 73 'designer surgeons' (b = 7.8, Cl 2.8-12.8; p = 0.005) and preinjury Tegner score (b = 1.9, Cl 0.5-3.4; p 74 = 0.010).

76 <u>Conclusion</u>

- 77 Surgeon experience with DIS was not associated with rates of revision ACL surgery or general re-
- 78 operations. Future, larger-scaled studies are needed to confirm these findings. Patients operated by
- 79 'designer surgeons' had slightly better IKDC and Lysholm scores, which could be due to better
- 80 patient selection and/or positively biased attitudes of both surgeons and patients.
- 81
- 82 <u>Level of evidence</u>
- 83 Level II, prospective comparative study.
- 84

85 INTRODUCTION

86 Dynamic intraligamentary stabilization (DIS) was recently introduced in the surgical treatment of 87 acute anterior cruciate ligament (ACL) ruptures [11, 16]. The technique aims to provide knee joint 88 stability while the ACL heals without graft harvesting. To date, ACL repair is not yet well-established 89 [29]. Most clinical studies on DIS were single-center, published by surgeons who designed the device 90 with a follow-up of up to 5 years [3, 8, 11, 18, 23, 26]. Articles by non-designers are currently limited 91 to small cohorts and a follow-up of 1 year [3, 25, 27, 30]. 92 Initial case series of patients undergoing DIS revealed high functional scores and return to previous 93 levels of sport activity in most patients 2–5 years following surgery [8, 19, 24]. A revision ACL surgery 94 was reported in 8 and 11% of cases after a minimum follow-up of 2 years [18, 24, 26], and similar 95 revision rates were found in DIS and ACL reconstruction [6]. Prognostic factors such as young patient 96 age, high baseline activity level, and central rupture location were found to increase the risks of 97 failure after DIS [18, 26]. However, it is possible that outcomes for DIS could be related to surgeon 98 experience with this procedure, which depends on the status of the ACL remnants and tear pattern 99 and, therefore, may require a substantial learning curve. 100 The primary purpose of this study was, therefore, to determine potential associations between the 101 rates of revision ACL surgery and surgeon experience with DIS ('designer surgeons' vs. 'non-designer 102 surgeons'). The secondary purpose was to determine other potential prognostic factors (patient 103 demographics and surgical characteristics) that could be associated with inferior clinical outcomes 104 (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

107 DIS.

108

110 MATERIALS AND METHODS

111 The authors prospectively enrolled 110 consecutive patients that underwent DIS, as a treatment for 112 acute primary ACL tears within 21 days from injury, between August 2013 and May 2015, at three 113 centers. The inclusion criteria were: (i) patients aged between 18 and 50 years at the index 114 operation, and (ii) patients who provided written informed consent to participate in this study. The 115 exclusion criteria were: (i) patients unwilling to follow the standard rehabilitation program, (ii) 116 patients who were pregnant at the time of diagnosis, (iii) patients with permanent corticosteroid or 117 cytostatic medication regimen, active chronic inflammatory joint diseases or with malignancies, (iv) 118 knees with traumatic or degenerative cartilage lesions (Outerbridge > II and/or defect > 1 cm²), (v) 119 knees with irreparable meniscal lesion requiring resection of > 20% of the meniscus, (vi) knees in 120 which one or more tendons had been removed. 121 Fifty-six (51%) of the patients were operated by two surgeons at one center who were involved in 122 the design of the DIS device and technique, and who had performed over 200 DIS procedures prior 123 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 124 125 who had not performed any DIS procedures prior to the start of the study ('non-designers').

126

127 Surgical technique

128 The surgical technique and rehabilitation protocol for DIS were described in previous published 129 studies [8, 19]. Patient indications for DIS are similar to those for ACL reconstruction, though the 130 surgical principle is considerably different, as it relies on healing of the remnant ACL and, therefore, 131 must be performed within 21 days from injury. In very rare cases where the intraoperative findings 132 are not consistent with an acute ACL tear, surgeons consider conversion to ACL reconstruction 133 intraoperatively. DIS intends to prevent the femur and tibia from being able to shift relative to one 134 another during movements of the knee. The tibial remnants of the torn ACL are guided to the 135 femoral footprint by transosseous resorbable sutures. Extensive microfracturing is performed at the 136 femoral footprint to allow stem cells to migrate into the joint and accelerate the healing process. A 137 debridement of the remaining ACL tissue is not performed to avoid loss of volume. The knee is then 138 stabilized with a polyethylene cord which is brought under tension by a spring implant hosted on the 139 antero-medial aspect of the tibia. Similar to the native ACL, the cord's tensile strength is 2000 N. The 140 cord maintained at predetermined tension of 50-80 N (depending on patient gender and weight). 141 Thus, the proximal tibia is maintained in a constant posterior position relative to the femur, allowing 142 the two stumps of the ACL to remain in close proximity. The spring mechanism allows a dynamic 143 excursion of the cord, ensuring a continuous tension over the entire range of motion. All DIS 144 components can remain in the knee joint, as the polyethylene cord coalesces with the ligament 145 remnants, while the ACL heals. The tibial implant is bulky, however, and may require removal, which 146 can be done using a minimally invasive technique under local anesthesia [6, 19, 24]. 147 148 Postoperative rehabilitation 149 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 150 151 physiotherapy and full weight-bearing were permitted from the 5th postoperative day. After 6

152 weeks, unlimited training was permitted, according to the principleS of progressive loading. In

153 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.

156

157 Data collection

All patient data were collected using an academic, web-based 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 162 procedures). The second form recorded details of any revision ACL surgeries or other re-operations. 163 The third form collected patient-reported outcomes using standard questionnaires for knee ligament 164 lesions (IKDC score, Lysholm score, and Tegner score). The IKDC score (0–100 point scale) detects 165 improvement or deterioration of knee symptoms, knee function, and sports activities. The Lysholm 166 score (0–100 point scale) detects improvement or deterioration of knee function, particularly 167 symptoms of instability [9]. The Tegner score (0–10 point scale) assesses sport and work activity 168 levels [34]. The data entry procedure involved several checks of validity and completeness to avoid 169 inappropriate or missing data. 170 All patients gave informed consent to participate in the study in advance. The patient data were 171 anonymized prior to extraction from the documentation platform. The study was approved by the 172 institutional review board and ethics committee at the study centers. 173

174 Statistical analysis

175 Normality of distributions was tested using the Shapiro–Wilk test. For continuous variables (IKDC 176 score and Lysholm score) with non-parametric distribution, group differences were evaluated using 177 Wilcoxon rank sum tests (Mann Whitney U test). Categorical data (revision ACL surgery and any re-178 operation) were analyzed using Pearson Chi-squared tests. The effects of independent variables on 179 four principal outcomes were analyzed using univariable and multivariable logistic (revision ACL 180 surgery and any re-operation) and linear (IKDC score and Lysholm score, both on scales from 0 to 181 100) regression models. The independent variables included surgeon experience ('designer 182 surgeons' vs. 'non-designer surgeons'), patient gender (female vs. male), patient age (years), 183 adjuvant procedures (yes vs. no), tear location (proximal vs. central), preinjury Tegner score (scale 184 from 0 to 10), time from injury to surgery (days), and follow-up (days). The Tegner score, a likert-185 type scale, was treated as interval data [33]. A power analysis was performed to determine the 186 sample size required for two outcomes: ACL revision rate (primary) and IKDC score (secondary). 187 Assuming ACL revision rates of 10% for the designer group and 15% for the non-designer group, a

188 sample of 686 patients was required to determine statistical significance with a power of 0.8, which 189 was not feasible considering the novelty of DIS. Assuming IKDC scores of 95 points for the designer 190 group and 85 points for non-designer group, with equal standard deviations of 10 points, a sample 191 size of 34 patients was required to determine statistical significance with a power of 0.8. Statistical 192 analyses were performed using R version 3.2.2 (R Foundation for Statistical Computing, Vienna, 193 Austria) with the level of significance defined at 0.05. 194 195 RESULTS 196 From the 110 patients enrolled, 14 patients (13%) were lost to follow-up. Of the remaining 96 197 patients, 11 underwent revision ACL surgery, leaving 85 patients for clinical assessment at a follow-198 up of 2.2 ± 0.4 years (range 2.0-3.8) (Fig. 1). Of the remaining 96 patients, 53 (55%) had been 199 operated by 'designer surgeons', while 43 (45%) had been operated by 'non-designer surgeons'. The 200 two groups were similar in terms of patient demographics and surgical characteristics, but the 201 former had fewer patients lost to follow-up (3 vs. 11, p = 0.018), as well as lower preoperative 202 Tegner scores (p = 0.016) and more adjuvant procedures (p = 0.014) (Table 1). 203 204 Any re-operation 205 Arthroscopic re-operations were performed in 26 (27%) (Table 2) of the 96 patients included, of 206 which 11 revision ACL surgeries, 6 debridements for stiffness, 4 repairs of new meniscal tears, 2 207 hardware removals, 1 lavage for hematoma; 1 for medial condyle chondromalacia associated with 208 medial patellar plica; and 1 for unspecified reason. Univariable and multivariable regressions 209 revealed no significant associations with re-operations (Table 3). 210

211 Revision ACL surgery

Revision ACL surgery was performed on 11 (11%) (Table 2) of the 96 patients included, of which 7
had traumatic re-ruptures and 4 suffered from chronic instability. Univariable regression revealed

revision ACL surgery to be significantly associated with preinjury Tegner score (OR = 1.55; Cl 1.05–

215 2.38; p = 0.032) and patient age (OR = 0.88; Cl 0.78–0.97; p = 0.020), but multivariable regression

- 216 revealed no significant associations (Table 4).
- 217

218 IKDC score

- The IKDC score for the 85 patients evaluated clinically was 91 ± 12 (range 44–100) (Table 5).
- 220 Univariable regression revealed significantly better IKDC scores for patients operated by 'designer
- surgeons' (b = 7.3; Cl 2.4–12.1; p = 0.004), and multivariable regression confirmed this association (b
- 222 = 10.7; Cl 4.9–16.5; p < 0.001), in addition to preinjury Tegner score (b = 2.5, Cl 0.8–4.2; p = 0.005)
- and patient age (b = 0.3, CI 0.0–0.6; p = 0.039) (Table 6).
- 224

225 Lysholm score

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

231

232 DISCUSSION

- 233 The most important finding of the study was that, surgeon experience with DIS was associated with
- better patient-reported outcomes, but not with rates of revision ACL surgery or general re-
- 235 operations. Multivariable analysis revealed that patients operated by 'designer surgeons' had
- 236 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

240 repair in this study was observed in 11%, which is higher than typical rates following ACL 241 reconstruction. The latter could be due to three reasons; First, the activity level—a well-known risk 242 factor for ACL injury and failure [28]—is probably higher for patients undergoing DIS than those 243 undergoing ACL reconstruction. Second, the odds of undetected failures are greater in registry 244 studies than in prospective cohort studies. Third, while DIS has the benefit of being less invasive than 245 ACL reconstruction, it relies on the healing capacity of torn ligament remnants, which is less 246 guaranteed than the integrity of a full ACL graft. The failure rate in our study is comparable to rates 247 reported in other studies on DIS: In a series of 50 patients evaluated at a minimum of 2 years, Kohl 248 et al. [24] reported revisions in 10%; In another series of 264 patients also evaluated at a minimum 249 of 2 years, Krismer et al. [26] reported revisions in 10%; A case series of 381 patients evaluated at 250 2.5 years, published by Henle et al. [18], reported revisions in 8%; The most recent study of 26 251 patients, published by Meister et al. [27], reported revisions in 15% at 1 year. In agreement with the 252 aforementioned studies [18, 26], univariable (but not multivariable) analysis found ACL revisions to 253 be significantly associated with young age, higher activity levels (preinjury Tegner score), and central 254 tear locations. First, a higher activity level increases the risk for treatment failure [28]. Even if our 255 study only recorded preinjury activity levels, it is likely that most patients attempted to resume 256 sports at similar levels, which could explain our findings. Second, young age is also known to 257 increase risks of revision following ACL reconstruction [31, 38]. It is important to note that age is 258 often inversely correlated with activity [32] and could be a confounding variable. Finally, tear 259 location was reported to influence outcomes of DIS (odds ratio > 2.4) [18, 26]. From a clinical point 260 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 261 262 results remain inconclusive. First, cases with central tears are less frequent than proximal tears. 263 Second, the blood supply of the ACL remnants was assumed to be sufficient for healing in all cases at 264 index surgery, which took place within 21 days from injury.

265 The literature also reports on re-operations without graft revision following ACL reconstruction, 266 often to repair or remove meniscal tears (7–15%) [10, 13, 14, 22]. Non-revision re-operations in this 267 study were reported in 16%, which is comparable to rates reported in other studies on DIS: In a 268 study with two matched cohorts of DIS and ACL reconstruction, each with 53 patients, Bieri et al. [8] 269 reported non-revision re-operations in 17 and 19% respectively, at a minimum of 2 years; In a series 270 of 26 patients evaluated at 1 year, Meister et al. [27] documented non-revision reoperations in 20%. 271 In another case series of 446 patients, Haeberli et al. [17] reported non-revision re-operations in 272 12%, also at a minimum of 2 years. As with Haeberli et al. [17], we reported re-operations due to 273 new meniscal lesions in only 4%, which is lower than previously described for ACL reconstruction, 274 and could be a benefit of early intervention with DIS [6, 12]. 275 There are considerable variations in patient-reported outcomes following ACL reconstruction, with 276 average IKDC scores between 83 and 100, and average Lysholm scores between 88 and 96 [2, 20]. In 277 this study, mean IKDC and Lysholm scores of 91 and 93, respectively, at a mean follow-up of 2.2 278 years, were observed. High patient-reported scores were consistently reported after DIS: In a case 279 series of 50 patients, Kohl et al. [24] found median IKDC and Lysholm scores of 98 and 100, 280 respectively, at a minimum of 2 years; In another case series of 62 patients also evaluated at a 281 minimum of 2 years, Henle et al. [19] reported mean IKDC and Lysholm scores of 95 and 97, 282 respectively; Most recently, a randomized study of DIS and ACL reconstruction, each with 30 283 patients, Schliemann et al. [30] reported mean IKDC scores of 86 and 85 for DIS and ACL 284 reconstruction, respectively, and mean Lysholm scores of 90 for both groups, at 1 year. Our 285 multivariable regression revealed significantly better IKDC scores for patients operated by 'designer 286 surgeons' (p < 0.001), in addition to associations with preinjury Tegner score (p = 0.005) and patient 287 age (p = 0.039). Multivariable regression also revealed significantly better Lysholm scores for 288 patients operated by 'designer surgeons' (p = 0.005), in addition to an association with preinjury 289 Tegner score (p = 0.010). The higher scores for patients operated by 'designer surgeons' could be 290 due to positively biased attitudes of both the surgeons and the patients towards DIS. The average

291 differences were 7 points for the IKDC score and 6 points for the Lysholm score, which do not exceed 292 the minimum clinically important difference (MCID). The minimal detectable change for the IKDC 293 score was reported between 8.8 and 15.6, and the MCID is between 10 and 20. The minimal 294 detectable change for the Lysholm score was reported between 8.9 and 10.1 (the MCID was not 295 reported) [9]. The slight effects of preinjury Tegner score and patient age on patient-reported 296 outcomes could be attributed to various factors that this study did not account for, including 297 different rehabilitation programs or tissue healing capabilities in younger and more active patients 298 [15, 37].

299 The principal limitation of the present study is its small sample size, with relatively few events, which 300 could invalidate our inferences. While the study is sufficiently powered to compare differences in 301 IKDC scores, the present sample size does not allow statistical implications for ACL revision rates. It is 302 important to note, however, the difficulty of obtaining sufficiently large samples in the first decade 303 following the launch of a novel medical device. Moreover, greater losses to follow-up were 304 documented for 'non-designers' and hence some revisions or re-operations may be unrecorded. 305 Another limitation is the relatively short follow-up, by virtue of the novelty of DIS, which leave 306 uncertainties regarding long-term outcomes. Finally, the study did not consider all intrinsic (biologic) 307 and extrinsic (rehabilitation) factors that could influence outcomes and survival. The main strengths 308 of the study are, however, its prospective and multi-centric design, and its original distinction 309 between patients by 'designer surgeons' versus 'non-designer surgeons'.

310

311 CONCLUSION

Surgeon experience with DIS was not associated with rates of revision ACL surgery or general reoperations. 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.

317 **REFERENCES**

- 318 1. Andernord D, Desai N, Bjornsson H, Ylander M, Karlsson J, Samuelsson K (2015) Patient predictors
- of early revision surgery after anterior cruciate ligament reconstruction: a cohort study of 16,930
- 320 patients with 2-year follow-up. Am J Sports Med 43:121–127
- 321 2. Anderson MJ, Browning WM 3rd, Urband CE, Kluczynski MA, Bisson LJ (2016) A systematic
- 322 summary of systematic reviews on the topic of the anterior cruciate ligament. Orthop J Sports
- 323 Med 4:2325967116634074
- 324 3. Ateschrang A, Ahmad SS, Stockle U, Schroeter S, Schenk W, Ahrend MD (2017) Recovery of ACL
- 325 function after dynamic intraligamentary stabilization is resultant to restoration of ACL integrity
- and scar tissue formation. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s0016
- 327 7-017-4656-x
- 4. Barrett GR, Luber K, Replogle WH, Manley JL (2010) Allograft anterior cruciate ligament
- reconstruction in the young, active patient: Tegner activity level and failure rate. Arthroscopy
 26:1593–1601
- 331 5. Biau DJ, Tournoux C, Katsahian S, Schranz PJ, Nizard RS (2006) Bone-patellar tendon-bone
- autografts versus hamstring autografts for reconstruction of anterior cruciate ligament: meta analysis. BMJ 332:995–1001
- 334 6. Bieri KS, Scholz SM, Kohl S, Aghayev E, Staub LP (2017) Dynamic intraligamentary stabilization
- 335 versus conventional ACL reconstruction: a matched study on return to work. Injury. https
- 336 ://doi.org/10.1016/j.injur y.2017.03.004
- 337 7. Borchers JR, Pedroza A, Kaeding C (2009) Activity level and graft type as risk factors for anterior
- 338 cruciate ligament graft failure: a case-control study. Am J Sports Med 37:2362–2367

339	8.	Buchler L, Regli D, Evangelopoulos DS, Bieri K, Ahmad SS, Krismer A et al (2016) Functional
340		recovery following primary ACL repair with dynamic intraligamentary stabilization. Knee 23:549-
341		553

- 342 9. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM (2011) Measures of knee function:
- 343 International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee
- 344 Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score
- 345 Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale
- 346 (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and
- 347 McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner
- 348 Activity Score (TAS). Arthritis Care Res (Hoboken) 63(Suppl 11):S208-228
- 349 10. Dunn WR, Lyman S, Lincoln AE, Amoroso PJ, Wickiewicz T, Marx RG (2004) The effect of anterior
- cruciate ligament reconstruction on the risk of knee reinjury. Am J Sports Med 32:1906–1914
- 351 11. Eggli S, Roder C, Perler G, Henle P (2016) Five year results of the first ten ACL patients treated

352 with dynamic intraligamentary stabilisation. BMC Musculoskelet Disord 17:105

- 353 12. Fithian DC, Paxton EW, Stone ML, Luetzow WF, Csintalan RP, Phelan D et al (2005) Prospective
- trial of a treatment algorithm for the management of the anterior cruciate ligament-injured knee.
- 355 Am J Sports Med 33:335–346
- 13. Frobell RB, Roos EM, Roos HP, Ranstam J, Lohmander LS (2010) A randomized trial of treatment
 for acute anterior cruciate ligament tears. N Engl J Med 363:331–342
- 358 14. Grindem H, Eitzen I, Engebretsen L, Snyder-Mackler L, Risberg MA (2014) Nonsurgical or surgical
- 359 treatment of ACL injuries: knee function, sports participation, and knee reinjury: the Delaware-
- 360 Oslo ACL cohort study. J Bone Jt Surg Am 96:1233–1241
- 361 15. Guo S, Dipietro LA (2010) Factors affecting wound healing. J Dent Res 89:219–229

- 362 16. Haberli J, Henle P, Acklin YP, Zderic I, Gueorguiev B (2016) Knee joint kinematics with dynamic
- augmentation of primary anterior cruciate ligament repair—a biomechanical study. J Exp Orthop
 364 3:29
- 365 17. Haeberli J, Jaberg L, Bieri KS, Eggli S, Henle P (2017) Reinterventions after dynamic
- 366 intraligamentary stabilization in primary anterior cruciate ligament repair. Knee.
- 367 https://doi.org/10.1016/j.knee.2018.01.003
- 18. Henle P, Bieri KS, Brand M, Aghayev E, Bettfuehr J, Haeberli J et al (2017) Patient and surgical

369 characteristics that affect revision risk in dynamic intraligamentary stabilization of the anterior

- 370 cruciate ligament. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s0016 7-017-
- 371 4574-y

378

- 19. Henle P, Roder C, Perler G, Heitkemper S, Eggli S (2015) Dynamic intraligamentary stabilization
- 373 (DIS) for treatment of acute anterior cruciate ligament ruptures: case series experience of the
- 374first three years. BMC Musculoskelet Disord 16:27
- 375 20. Herrington L (2013) Functional outcome from anterior cruciate ligament surgery: a review. OA
 376 Orthop 1:12
- 21. Kaeding CC, Pedroza AD, Reinke EK, Huston LJ, Consortium M, Spindler KP (2015) Risk factors and

predictors of subsequent ACL injury in either knee after ACL reconstruction: prospective analysis

- of 2488 primary ACL reconstructions from the MOON cohort. Am J Sports Med 43:1583–1590
- 380 22. Kartus J, Magnusson L, Stener S, Brandsson S, Eriksson BI, Karlsson J (1999) Complications
- following arthroscopic anterior cruciate ligament reconstruction. A 2-5-year follow-up of 604
- 382 patients with special emphasis on anterior knee pain. Knee Surg Sports Traumatol Arthrosc 7:2–8
- 23. Kohl S, Evangelopoulos D, Schär M, Bieri K, Müller T, Ahmad S (2016) Dynamic intraligamentary
- 384 stabilisation. Bone Jt J 98:793–798

385 24. Kohl S, Evangelopoulos DS, Schar MO, Bieri K, Muller T, Ahmad SS (2016) Dynamic

- intraligamentary stabilisation: initial experience with treatment of acute ACL ruptures. Bone Jt J
 98-B:793–798
- 388 25. Kosters C, Herbort M, Schliemann B, Raschke MJ, Lenschow S (2015) Dynamic intraligamentary
- 389 stabilization of the anterior cruciate ligament: Operative technique and short-term clinical
- 390 results. Unfallchirurg 118:364–371
- 391 26. Krismer AM, Gousopoulos L, Kohl S, Ateschrang A, Kohlhof H, Ahmad SS (2017) Factors
- 392 influencing the success of anterior cruciate ligament repair with dynamic intraligamentary
- 393 stabilisation. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s0016 7-017-4445-6
- 394 27. Meister M, Koch J, Amsler F, Arnold MP, Hirschmann MT (2017) ACL suturing using dynamic
- 395 intraligamentary stabilisation showing good clinical outcome but a high reoperation rate: a
- 396 retrospective independent study. Knee Surg Sports Traumatol Arthrosc.
- 397 https://doi.org/10.1007/s0016 7-017-4726-0
- 398 28. Noyes FR, Barber SD (2010) Noyes' knee disorders: surgery, rehabilitation, clinical outcomes.
- 399 Elsevier, Philadelphia, pp 213–256
- 400 29. Nyland J, Gamble C, Franklin T, Caborn DNM (2017) Permanent knee sensorimotor system
- 401 changes following ACL injury and surgery. Knee Surg Sports Traumatol Arthrosc 25:1461–1474
- 402 30. Schliemann B, Glasbrenner J, Rosenbaum D, Lammers K, Herbort M, Domnick C et al (2017)
- 403 Changes in gait pattern and early functional results after ACL repair are comparable to those of
- 404 ACL reconstruction. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s0016 7-017-

405 4618-3

- 406 31. Schlumberger M, Schuster P, Schulz M, Immendorfer M, Mayer P, Bartholoma J et al (2015)
- 407 Traumatic graft rupture after primary and revision anterior cruciate ligament reconstruction:

408 retrospective analysis of incidence and risk factors in 2915 cases. Knee Surg Sports Traumatol

409 Arthrosc 25(5):1535–1541

410 32. Shelbourne KD, Gray T, Haro M (2009) Incidence of subsequent injury to either knee within 5

411 years after anterior cruciate ligament reconstruction with patellar tendon autograft. Am J Sports

412 Med 37:246–251

- 33. Sullivan GM, Artino AR Jr (2013) Analyzing and interpreting data from likert-type scales. J Grad
 Med Educ 5:541–542
- 415 34. Tegner Y, Lysholm J (1985) Rating systems in the evaluation of knee ligament injuries. Clin Orthop
 416 Relat Res 198:43–49
- 417 35. Tejwani SG, Chen J, Funahashi TT, Love R, Maletis GB (2015) Revision risk after allograft anterior

418 cruciate ligament reconstruction: association with graft processing techniques, patient

419 characteristics, and graft type. Am J Sports Med 43:2696–2705

420 36. Toy BJ, Yeasting RA, Morse DE, McCann P (1995) Arterial supply to the human anterior cruciate

421 ligament. J Athl Train 30:149–152

- 422 37. van Melick N, van Cingel RE, Brooijmans F, Neeter C, van Tienen T, Hullegie W et al (2016)
- 423 Evidence-based clinical practice update: practice guidelines for anterior cruciate ligament
- 424 rehabilitation based on a systematic review and multidisciplinary consensus. Br J Sports Med

425 50:1506–1515

- 426 38. Webster KE, Feller JA (2016) Exploring the high reinjury rate in younger patients undergoing
- 427 anterior cruciate ligament reconstruction. Am J Sports Med 44:2827–2832

TABLES

- **Table 1:** Patient demographics
- 432 Data presented as mean ± standard deviation, or number (percentage)
- 433 ^a Patients that had one or more adjuvant procedures in addition to DIS
- 434 ^b Note that some patients had two or three concomitant adjuvant procedures in addition to DIS

	Total $(n=96)$	Designer surgeons $(n=53)$	Non-designer sur- geons $(n=43)$	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	-

Table 2: Incidence of revision ACL surgery and of any re-operation

439 Data presented as number (percentage)

		Total (<i>n</i> =96)	Designer surgeons $(n=53)$	Non-designer sur- geons $(n=43)$	p value
	Revision ACL surgery	11 (11%)	7 (13%)	4 (10%)	n.s
110	Any re-operation	26 (27%)	17 (31%)	9 (22%)	n.s
440					

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

Table 3: Uni- and multi-variable regression analysis of factors associated with any re-operation.

Table 4: Uni- and multi-variable regression analysis of factors associated with revision ACL surgery

Variable	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

449 Data presented as mean ± standard deviation

	Total (<i>n</i> =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

Table 6: Uni- and multi-variable regression analysis of factors associated with postoperative IKDC

452 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 7: Uni- and multi-variable regression analysis of factors associated with postoperative Lysholm

457 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

FIGURE

Figure 1: Flow chart.

