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ORIGINAL ARTICLE

Anterior cruciate ligament repair using dynamic intraligamentary stabilization provides a similarly successful outcome as all-inside anterior cruciate ligament reconstruction with a faster psychological recovery in moderately active patients

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Anterior cruciate ligament (ACL) repair has recently regained popularity, as it has been shown that the ligament is capable of healing.[1] Early intervention and patient selection are essential parts of success with this method.[2] After its launch, the dynamic intraligamentary stabilization (DIS) device (Ligamys®, Mathys Ltd., Bettlach, Switzerland), a technique for dynamic augmentation that is one of the primary

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ABSTRACT

Objectives: This study aims to comparatively evaluate early to mid-term clinical results of case-matched patient groups of primary repairs with dynamic intraligamentary stabilization (DIS) or all-inside anterior cruciate ligament (ACL) reconstruction (ACLR) by an independent group.

Patients and methods: Between March 2015 and September 2018, a total of 16 patients operated for ACL injuries with the repair technique were retrospectively identified. Cases were stratified by treatment: DIS technique versus all-inside ACLR and matched at a ratio of 1:2. The ACLR patients were selected from a patient group with an injury-to-operation time interval of fewer than three months. A total of 32 patients were included in the all inside ACLR group. Pre-injury and postoperative International Knee Documentation Committee (IKDC) subjective score, Tegner and Lysholm scores had been obtained. Additionally, ACL-Return to Sport after Injury (ACL-RSI) scale scores, clinical results, and complications were noted.

Results: One (6%) patient in the DIS group and two (6%) patients in the ACLR group were lost-to-follow-up and, for a total of 45 patients, 15 in the DIS group and 30 in the ACLR group, were included in the study. The mean postoperative follow-up was 50.8±13.5 months and 48.2±11.4 months in the DIS and ACLR groups, respectively. The Tegner, Lysholm, and IKDC subjective scores were non-significantly different between the groups at any time points. The ACL-RSI scale scores were significantly higher at six ($p<0.001$) and 12 ($p=0.01$) months in the repair group. The pivot-shift test was negative in all cases postoperatively. One re-rupture occurred in each group. The reoperation rate at any cause was 25% for the repair and 10% for the ACLR group.

Conclusion: Primary ACL repair using the DIS technique provides a similar clinical outcome to these by an all-inside ACLR technique in moderately active patients. The DIS technique is reliable and reproducible, and associated with an early and speedier psychological recovery in a carefully selected, non-athlete patient group as observed by an independent group.

Keywords: Anterior cruciate ligament, anterior cruciate ligament injury, anterior cruciate ligament reconstruction, anterior cruciate ligament repair, return to sport.

repair methods, has seen increased adoption, with several studies reporting successful outcomes.[1,3-9]

Apart from the promising results obtained using the DIS technique, ACL reconstruction (ACLR) remains the gold-standard method of surgical treatment for ACL injuries.[10] All-inside technique, one of the ACLR techniques, is efficient and reliable, with clinical outcomes comparable to those obtained with conventional reconstruction techniques.[11-14] Additionally, all-inside ACLR has several advantages over conventional ACLR, including being less invasive due to the use of sockets rather than bone tunnels, requiring a smaller skin incision, causing less postoperative pain, improving graft incorporation, and preserving the gracilis tendon.[11,15] However, potential disadvantages include suspensory femoral and tibial cortical fixation, more extensive stump excision, and a flatter surgical learning curve.[14]

Return to sports following ACL surgery is dependent on a variety of factors, many of which have been extensively studied in recent years.[16] The majority of studies involved athletes who received extensive physical therapy following surgery, which could help to mitigate the influence of surgical treatment-related factors on failure. Additionally, due to their strenuous activity levels and younger age, these patients face a greater risk of re-rupture.[16] Psychological variables were shown to be unrelated to strength and power scores, providing for a clear distinction between psychological and physical recovery following ACLR. The repair of the ruptured ACL may be beneficial in the former recovery pathway, as it promotes biological healing of the ACL, protects proprioception, and aids patients in recovering confidence to participate in physical activity.

In the present study, we aimed to compare the outcomes of individuals who underwent ACL surgery within four weeks of injury with two new techniques, DIS repair technique or all-inside reconstruction with a semitendinosus autograft. We hypothesized that the DIS technique would have a comparable success rate in terms of clinical patient-reported outcome measures, examination results, and complications in a selected and case-matched patient group as the all-inside ACLR. The repair group was expected to demonstrate a greater psychological readiness as measured by the ACL-Return to Sports Index (ACL-RSI) score than the ACLR group.

PATIENTS AND METHODS

This single-center, retrospective cohort study was conducted at Istanbul Memorial Hospital, Department of Orthopedics between March 2015 and September 2018. Patients operated for ACL injuries by an experienced sports medicine-trained surgeon were reviewed. Data were collected in a prospective fashion during the trial phase. The indications for ACL repair with DIS were an acute injury with a maximum time to an intervention of less than four weeks and proximal or middle third ACL ruptures. Concomitant ligamentous or meniscal injuries necessitating repair were excluded (n=3). A total of 15 patients (12 males, 3 females, mean age: 27.8±9.5, range, 16 to 47 years) were included in the repair group. Cases were stratified by treatment: The DIS technique versus all-inside ACLR and were matched 1:2 on age, sex, pre-injury Tegner score, and concomitant injuries. Matched ACLR patients were selected from a patient group with an injury-to-operation time interval of less than three months. A total of 30 patients (24 males, 6 females, mean age: 27.4±10.2, range, 17 to 49 years) were included in the all-inside ACLR group. Subjective International Knee Documentation Committee (IKDC)

FIGURE 1. Anteroposterior roentgenography of anterior cruciate ligament repair with dynamic intraligamentary stabilization.

FIGURE 2. (a, b) Anterior cruciate ligament repair with dynamic intraligamentary stabilization device.

and Lysholm scores were obtained from all patients before the injury.

Surgical technique

ACL repair with DIS

The DIS device was implanted as instructed by the developers.[17] The ruptured ACL tibial stump was tied with 4 to 5 retaining threads (PDS No.2-0, Ethicon; Ethicon Inc., Somerville, NJ, USA). The tibial tunnel was drilled using an aiming device with a 2.4 mm diameter drill. An outside-in tibial socket was formed from the distal tibial cortex, leaving at least 2 cm bone to the intraarticular area. The Ligamys® Monoblock device was placed within the tibial socket (Figure 1). Next, the femoral tunnel was created using a 2.4-mm drill with the knee in deep flexion (Figure 2a). Following the formation of the femoral tunnel, threads of the tied tibial stump were led through the femoral tunnel. The Ligamys® braid was, then, pulled distally from the femoral side and through the femoral and tibial tunnel to the tibial side. Using the designated tensioning device, the braid was tensioned to maximal load and released, followed by an 80 N tensioning (Figure 2b). Notch was microfractured in all cases following the implantation.[1,17]

All-inside ACL reconstruction

All-inside reconstructions were done using a previously described GraftLink® technique in all cases.[18] Only the semitendinosus tendon was harvested and quadrupled. Femoral and tibial sockets were created using a retrograde drilling device (FlipCutter, Arthrex, Naples, FL, USA). The graft was initially fixed on the femoral side with an adjustable-graft loop cortical suspensory fixation device and then on the tibial side (ACL TightRope®, Arthrex, Naples, FL, USA). The graft was eventually tensioned, as required (Figure 3).

Postoperative rehabilitation

The standardized postoperative rehabilitation protocol focused on immediate knee extension and a three-month return to running. Return to pivoting sports was aimed latest at the 12-month follow-up. The only difference between the groups was that the repair group tolerated locking the knee in extension for five days (to keep the blood cloth on repaired ACL stump)

FIGURE 3. Anteroposterior roentgenography of all-inside anterior cruciate ligament reconstruction.

with weight-bearing.[1,19] The rehabilitation protocol comprised an active range of motion exercises until the third week and muscle strengthening exercises following the third week to achieve equivalent muscle mass by the sixth postoperative week.[14,19]

Postoperative clinical evaluation

Follow-up was performed on patients three weeks, six weeks, three and 12 months after ACL repair. Tegner, Lysholm®, IKDC, and ACL-RTS scores were obtained postoperatively at 6 and 12 months, as well as at the most recent follow-up. Stability was assessed using the Lachmann and Pivot-Shift tests by a clinician who was blind to the surgical technique. All complications, reoperations, and failures were noted.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 23.0 software (IBM Corp., Armonk, NY, USA). The sample size was calculated using the G*Power version 3.1 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The a-priori calculation was based on one-sided non-inferiority of ACL repair compared to ACLR in terms of IKDC subjective score. Standard deviation (SD) was set to 9, and the clinically relevant difference was set to 11.5.[1,20] The calculation revealed that a minimum of 11 patients in the ACL repair and 23 in the reconstruction group would provide a power of 96% with an alpha of 0.05.

Second, a post-hoc calculation was based on the results of ACL-RTS at six months. The analysis showed that the results obtained in this study have a power of 97% at an alpha error rate of 5%. Descriptive data were expressed in mean ± standard deviation (SD), median (interquartile range [IQR]) or number and frequency, where applicable. All variables were analyzed for normal distribution using the Shapiro-Wilk test. Nominal values between groups were compared using the chi-square test. Independent group variables were analyzed using an unpaired t-test or Mann-Whitney U test depending on the distribution. A p value of <0.05 was considered statistically significant.

RESULTS

One (6%) patient in the DIS group and two (6%) patients in the ACLR group were lost-to-follow-up and a total of 45 patients, 15 in the DIS group and 30 in the ACLR group were included. The mean duration of postoperative follow-up was 50.8±13.5 (range, 26 to 65) months in the DIS group and 48.2±11.4 (range, 26 to 67) months in the ACLR group. Minimum follow-up time was 26 months in both groups. Between the two groups, there were no significant differences in sex, age, preoperative Tegner and Lysholm scores, and concomitant injuries (Table I).

There were no significant differences between the groups, when failures were excluded, according to the Tegner Activity score (Table II). At the final follow-up, the IKDC subjective score decreased from 100 (IQR=100-100) to 95.8 (IQR=83.8-99) in the DIS group and from 100 (IQR=100-100) to 93 (IQR=86.3-98.9) in the ACLR group.

TABLE I
Baseline demographics of the study population

	All-inside group (n=30)				Repair group (n=15)				
	%	Mean±SD	Median	Min-Max	%	Mean±SD	Median	Min-Max	p
Age (year)		27.4±10.2				27.8±9.5			NS
Sex									
Male	80				80				NS
Mean body mass index (kg/m^2)		23.2±3.2				23.6±2.5			NS
Time to surgery (weeks)		7.1±2.8				2.2±2.0			<0.001
Side of injury (right)	63				67				NS
Concomitant injuries									
Meniscal injuries	20				13				NS
Chondral injuries (Grade 1-2)	7				13				NS
Collateral ligament sprain	-				7				NS
Follow-up time (months)		48.2±11.4				50.8±13.5			NS
Pre-injury Tegner score			4.5	3-7			5	3-9	

SD: Standard deviation; NS: Non-significant.

TABLE II
Preoperative and postoperative patient-reported outcomes of the patients

Timepoint	Pre-injury or preoperative*			At 6th months			At 12th months			At last follow-up		
Evaluation criteria	ACLR	DIS	*p*	ACLR	DIS	*p*	ACLR	DIS	*p*	ACLR	DIS	*p*
Tegner	4.5 (3-7)	5 (3-9)	NS	3 (2-6)	4 (2-5)	NS	4 (2-6)	4 (3-7)	NS	4.5 (3-7)	5 (3-7)	NS
Lysholm preoperative	66.8±8.5	67.3±7.5	NS	78.1±9.6	87.1±6.2	NS	91.5±5.1	93.4±4	NS	95.1±3	96.3±2.6	NS
IKDC subjective	99.1±1.3	99.3±1.4	NS	71.9±6.6	82±6	NS	86.1±7.6	88.8±4.2	NS	94.6±3.7	95.4±2.8	NS
ACL-RSI	-	-	-	50.3±7.2	57.6±6.3	<0.001	70.7±6.9	74.8±5.2	0.01	84.3±4.7	86±5	NS

* Preoperative for Lysholm and preinjury for Tegner and IKDC scores; ACL-R: Anterior cruciate ligament reconstruction; DIS: Dynamic intraligamentary stabilization; IKDC: International Knee Documentation Committee; ACL-RSI: ACL-Return to Sports Index; NS: Non-significant.

TABLE III
Comparing the preoperative and postoperative Lachman's test

	ACL repair		All-inside ACL-R		
Lachman's test	n	%	n	%	*p*
Preoperative					
Grade 2 (5-10 mm)	7	47	16	53	NS
Grade 3 (>10 mm)	8	53	14	47	NS
Postoperative					
Grade 0	9	60	29	97	NS
Grade 1 (<5 mm)	4	26	-	-	
Grade 2 (5-10 mm)	1	7	-	-	
Grade 3 (>10 mm)*	1	7	1	3	

ACL-R: Anterior cruciate ligament reconstruction; * Ruptured cases; NS: Non-significant.

Two (13%) patients in the repair group experienced a temporary extension deficit of 5 to 10°, which resolved spontaneously within a month. One (7%) patient in the repair group had a cyclops lesion that was removed during second-look arthroscopy, while removing the tibial implant. At the final follow-up, neither group experienced arthrofibrosis or extension deficits.

Subjective instability and a side-to-side anterior tibial translation difference (ATT) of >3 mm were used to define failure.[9] At the final follow-up, the mean side-to-side difference was not statistically different between the groups and was 1.9±2 in the repair group and 1.6±1.2 in the reconstruction group. In one patient in the repair group, the ΔATT (difference in ATT) was greater than 3 mm, but there was no subjective instability. Findings related to manual Lachman test can be found in Table III. The patient with a Lachman ++ finding demonstrated a generalized joint laxity. The pivot-shift test was negative in all cases postoperatively, with the exception of re-ruptured cases.

In the repair group, one repair failed (7%), whereas the ACLR group had one graft fail (3%). In the repair group, the patient had a midsubstance ACL tear, a Tegner preinjury score of 9, and was 17 years old. A failure occurred two years after surgery due to sports-related injury. One case of failure in the ACLR group was attributed to a second trauma three years after surgery. The patient was 21 years old and had a pre-injury Tegner level of 7.

Excluding the patients who required revision ACLR surgery due to failure, three (21%) of the repair

group underwent re-arthroscopy at least one year postoperatively to remove the tibial device at the patient's request, one of whom also had a cyclops lesion. No other cyclops lesion or infection was observed in either group. In the ACLR group, no re-arthroscopy was required for any reason. Two patients were operated for lateral extraarticular tenodesis within one year following ACLR.

DISCUSSION

The ACL repair with the DIS technique demonstrated comparable patient-reported outcomes and clinical examination findings to semitendinosus grafted all-inside technique in carefully selected patient groups at a mean follow-up time of 50.8 months. The second significant finding of this study is that ACL repair resulted in a faster recovery at 6 and 12 months of follow-up, although this effect diminished after 12 months.

To the best of our knowledge, only one study compared the two techniques.[1] Hoogeslag et al.[1] compared the DIS technique to an all-inside ACLR in a randomized-controlled trial. The authors reported comparable outcomes in terms of IKDC subjective, Tegner, and Lysholm scores. However, the authors also reported a greater reoperation rate related to the use of DIS. Reoperations in four patients in the repair group were due to cyclops lesion (10%) and residual synovitis (10%), whereas the former was the sole cause of all three cases (14%) in the ACLR group reoperations. The aforementioned study comprised a relatively active patient group than the current study, with a mean Tegner score of above 8 for each treatment group, compared to 4.5 and 5 in the current study. Although no significant differences were detected in any of the scoring tools evaluated, the authors reported that 58% of the repair group and only 43% of the ACLR group had returned to preinjury Tegner levels at one year, which may indicate a more rapid return to sports for the repair group on an individual basis.[1] In the current study, six-month evaluations revealed that the repair group had higher IKDC subjective, Tegner, and ACL-RSI scores. The results of this study are similar to our study, but as the selected patient group was the patient group with moderate physical activity, the rupture rate was lower in the repair group.

Schliemann et al.[21] compared ACLR with complete tunnel technique and ACL repair using DIS. According to IKDC, Tegner, and Lysholm scores, early functional outcomes were similar in both groups. The mean pre-injury Tegner scores in the DIS and ACLR groups were 6.1 and 6.2, respectively. The authors also analyzed gait pattern characteristics after surgery. The only significant difference between both treatment groups was the higher early postoperative step count observed in the repair group. Another randomized-controlled trial compared DIS repair to complete tunnel hamstring autografted ACLR and found comparable functional outcomes. Tegner, IKDC, and Lysholm scores were similar between the two groups at all time points. Return to pre-injury Tegner results in both groups was reported as in the current study.[9]

The results obtained in the all-inside ACLR group were comparable to those obtained in earlier published studies. Benea et al.[22] reported similar IKDC scores between all-inside and complete tibial tunnel groups at short-term follow-up. Similarly, Volpi et al.[20] reported comparable outcomes in terms of PROMs consisting of IKDC, Tegner, and Lysholm, between all-inside and complete tunnel techniques at the second postoperative year. Others compared all-inside and full tunnel techniques in a randomized-controlled trial using allograft ACL. All IKDC scores were comparable between groups at any time point.[11] Desai et al.[14] randomized patients into an all-inside or complete tibial tunnel reconstruction using hamstring autografts. The authors reported comparable Tegner, Lysholm, and IKDC scores at a minimum of two years follow-up between both groups.

In the current study, Tegner scores of the patients in both groups were not statistically different. Moreover, excellent IKDC subjective score and Lysholm scores at the final follow-up in both groups indicated that minimal to no symptoms existed following surgery, and a high level of knee performance was obtained. These results further support the high efficiency of both procedures in a young and moderately active patient group. However, patients had an overall improvement in reported outcomes, most notably between 6 and 12 months postoperatively. Based on the available data, minimal clinically important difference (MCID) was reached for subjective IKDC at 6, 12, and 24 months and Lysholm knee score at 24 months, supporting the notion that the all-inside technique increases patient satisfaction and knee stability and has excellent functional and clinical outcomes.[15]

The DIS failure was shown to be related to high pre-injury activity level and young age.[23] Over time, the operating surgeon has opted for the current guidelines regarding inclusion criteria for DIS repair. As such, professional athletes and younger patients with ACL tears were not offered the repair option

using DIS. However, a recent paper has outlined possible indications for primary ACL repair using DIS.[9] Henle et al.[24] 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 sports activity as well as increased laxity after DIS was also found to be a significant risk factor for failure. The authors 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 re-tear after. The high failure rate of 9% (DIS repair) versus 19% (ACLR) reported in this study might be related to patient selection criteria. The authors reported that 54.2% of the patients in the repair group, and 58.3% of the ACLR group had a pre-injury Tegner score of 8 to 1,0 and mean patient age was 21 versus 22 years, both of which were previously reported as risk factors for ACL surgery.[1]

Clinical failure rates were non-significantly different and 16.3% versus 12.5%, in DIS and ACLR groups, respectively.[9] For all-inside groups, graft re-tear was reported as 2.47%,[15] and general complications were reported as 5.89%.[15] Eight (9.8%) patients in the all-inside group and 10 (18.5%) patients in the complete tibial tunnel group experienced graft failure requiring revision surgery before final follow-up. The mechanism for injury for all grafts in this study was either sports-related injury or trauma, consistent with the reports of prior studies.[14]

No patient had an extension deficit. One patient encountered temporarily. Other studies showed higher extension deficit rates, and we believe that it depends on the postoperative care, where we keep the knee in extension in the early postoperative phase. Extension loss of 1 to 10° for all-inside ACLR group has been reported as 1.14%.[15] The authors also reported that 20.8% of patients in the DIS repair and 19% in the all-inside ACLR group experienced extension deficit, pain, and swelling between 0 and 10 months postoperatively, which spontaneously resolved.[1]

The main limitation to this study is its retrospective design. Additionally, surgeries were conducted by a single surgeon at a single center with a small sample size. Despite these limitations, preoperative patient characteristics analysis and patient-reported outcomes may have provided valuable information.

In conclusion, primary ACL repair using the DIS technique yields comparable results in terms of patient-reported outcomes and clinical results as by an all-inside ACLR technique in moderately active patients. The DIS technique is reliable and reproducible and associated with an early and speedier psychological recovery in a carefully selected, moderately active patient group.

Ethics Committee Approval: Approval: The study protocol was approved by the Istanbul Memorial Şişlis Hospital Ethics Committee (date/no: 26.02.2021/03). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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