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Application of two types of suspensory fixation in reconstruction of anterior cruciate ligament with a semitendinosus-gracilis graft – A randomized prospective study

Primena dva tipa suspenzione fiksacije kod rekonstrukcije prednje ukrštene veze semitendinozus-gracilis graftom – randomizirana prospektivna studija

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Abstract

Background/Aim. Injury to the anterior cruciate ligament (ACL) of the knee is the most common ligament injury that requires operative treatment. So far, multiple ACL reconstruction (ACLR) techniques using a variety of graft types and implants that fixate the grafts have been described. The aim of the study was to compare two different ACLR techniques using two implant types for suspensory graft fixation in the femoral tunnel. **Methods.** This randomized-prospective study encompassed 60 patients/subjects who underwent ACLR in the period between January 2015 and December 2017 at the Department of Orthopaedics and Traumatology of Military Hospital "Dr Vladan Djordjević" Niš. The ACLR in all patients included in the study was performed using a quadruple semitendinosus-gracilis (STG) graft with two types of suspensory fixation on the lateral femoral cortex, whereas the graft fixation in the tibial tunnel was performed using an osteoconductive bioresorbable screw. The post-operative knee stability was assessed 24 months after surgery using the Lachman test and the lateral pivot shift test, as well as the KT-1000 arthrometer test. **Results.** In patients whose graft was fixated using a fixed-length loop implant, the mean post-surgery knee stability, measured with the KT-1000, was 1.167 ± 0.780; in patients whose graft was fixated using an adjustable-length loop implant, the mean value of the KT-1000 was 1.100 ± 0.894 (p = 0.605). The mean post-surgery International Knee Documentation Committee (IKDC) score for the fixed-length loop group was 84.887 ± 9.0207, while for the adjustable-length loop the score was 88.327 ± 7.302. The mean Lysholm score was 93.50 ± 6.872 for the fixed-length loop group of patients and 94.00 ± 5.527 for the adjustable-length loop group of patients. **Conclusion.** Both types of implants can be used with success during ACLR, because the functional results of operative treatment using both implants were identical after surgery.

Key words:
anterior cruciate ligament; anterior cruciate ligament reconstruction; orthopedic procedures; treatment outcome; transplants.

Apstrakt

Uvod/Cilj. Oštećenje prednje ukrštene veze kolena je najčešća povreda ligamenata koje zahteva operativno lečenje. Do sada je opisano više tehnika rekonstrukcije prednje ukrštene veze raznim tipovima graftova i implantanata kojima se graftovi fiksiraju. Cilj rada bio je da se uporede dve različite tenike rekonstrukcije prednje ukrštene veze korišćenjem dva tipa implantata za suspenzionu fiksaciju grafta u femoralnom tunelu. **Metode.** Ovom randomizovanom, prospektivnom studijom obuhvaćeno je 60 pacijenata podvrgnutih rekonstrukciji prednje ukrštene veze u periodu januar 2015–decembar 2017. godine, na Odeljenju za ortopediju i traumatolgiju Vojne bolnice "Doktor Vladan Đorđević" u Nišu. Jednoj polovini pacijenata urađena je fiksacija grafta u femoralnom tunelu implantatom sa fiksnom, a drugoj polovini sa promenljivom dužinom omče. Postoperativna stabilnost kolena procenjivana je 24 meseci posle operativnog zahvata Lachman, Lateral Pivot Shift testom, kao i merenjem artrometrom KT 1000. **Rezultati.** Kod pacijenata kojima je izvršena fiksacija grafta implantatom sa fiksnom dužinom omče srednja vrednost stabilnosti kolena posle operativnog zahvata merena artrometrom KT 1000 iznosila je 1,167 ± 0,780, dok je kod pacijenata sa varijabilnom dužinom omče ista iznosila 1,100 ± 0,894 (p = 0,605). Srednja vrednost *International Knee Documentation*

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Committee (IKDC) skora postoperativno za grupu sa fiksnom omčom iznosila je 84,887 ± 9,0207, a kod onih sa promenljivom omčom 88,327 ± 7,302. Srednja vrednost Lysholm skora za grupu pacijenata sa fiksnom omčom je bila 93,50 ± 6,872, a za grupu sa promenljivom dužinom omče 94,00 ± 5,527. **Zaključak.** Oba implantata se mogu uspešno koristiti prilikom rekonstrukcije prednje ukrštene veze jer su funkcinalni rezultati operativnog lečenja uz njihovo korišćenje pokazala identičan postoperativni rezultat.

Ključne reči:
ligament, prednji, ukršteni; rekonstrukcija; ortopedske procedure; lečenje, ishod; graftovi.

Introduction

Injury to the anterior cruciate ligament (ACL) of the knee is the most common ligament injury that requires operative treatment. It is usually a non-contact injury, occurring due to dynamic knee valgus [1]. Untreated injuries can progress to early osteoarthrosis, which is why prompt and proper treatment is required [2]. Patient treatment can be nonoperative and operative. Nonoperative treatment is prescribed for patients who do not have demanding functional requirements and who are prepared to accept certain functional limitations [3]. The goals of operative treatment are to achieve complete functional recovery of the injured knee and to reduce the risk of early osteoarthrosis and damage of other knee structures [4]. So far, multiple ACL reconstruction (ACLR) techniques using a variety of graft types and implants that fixate the grafts have been described. The functional result of treatment depends on graft type and quality, tunnel position, and graft fixation stability [5, 6]. Since 1995, titanium buttons with a loop have been used as implants for suspensory fixation of the graft in the femoral tunnel during ACLR. There are two types of titanium buttons in use: one with a fixed-length loop and the other with an intraoperative adjustable-length loop [7].

The aim of the study was to compare two different techniques of ACLR using two types of implants for suspensory fixation of the semitendinosus-gracilis (STG) graft in the femoral tunnel.

Methods

This randomized-prospective study encompassed 60 patients who underwent ACLR in the period between January 2015 and December 2017 at the Department of Orthopaedics and Traumatology of Military Hospital "Dr. Vladan Djordjević" Niš. The ACLR in all patients included in the study was performed using a quadruple STG graft with two types of suspensory fixation on the lateral femoral cortex, whereas the graft fixation in the tibial tunnel was performed using an osteoconductive bioresorbable screw. One half of the patients had their femoral tunnel graft fixated using an implant with adjustable-length loop, while the other half had their graft fixated with a adjustable-length loop implant (Figure 1). The choice of implant for the purpose of graft fixation in the femoral tunnel, with either a fixed-length or an adjustable-length loop, was made based on randomization using a table generated by a random number by means of Stat Trek random number generator [8]. Only the scrub nurse was familiar with the randomized list. On the day of each surgery, she would inform the surgeon about which implant for graft fixation in the femoral tunnel should be used according to the randomized table. The fixed-length loop implant used was the VersiTomic G-Lok (Stryker, Kalamazoo, Michigan, USA), while the adjustable-length loop used was the ACL TightRope RT (Arthrex, Naples, Florida, USA). The anatomic ACLR in each patient from both groups was performed identically, by creating three portals, and the graft fixation in the tibial tunnel was performed by means of a bioresorbable screw. The femoral portion of the graft was 25 mm long for both groups of subjects, whereas the graft socket length was determined differently for each group [9].

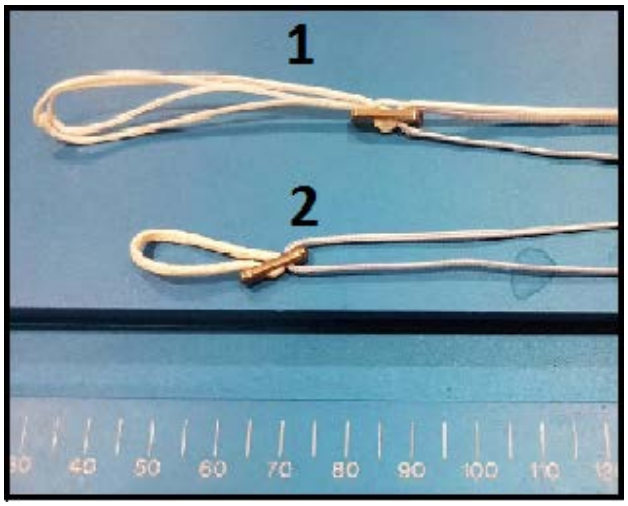

Fig. 1 – Femoral cortical suspension devices:
1) Adjustable-length loop device;
2) Fixed-length loop device.

The length of the femoral graft socket in the femoral tunnel during fixation with a titanium button with a fixed-length loop was determined according to the following formula: planned graft length in the femoral tunnel + 10 mm. Implant loop length was determined according to the formula: total tunnel length (TTL) – socket length (SL). The first loop that was longer than the value obtained by applying the formula was used to fixate the graft (Figure 2).

In titanium implants with an adjustable-length loop, the femoral tunnel length was fixed at 27 mm. The implant was introduced up to 25 mm, while 2 mm were left for additional graft tensioning after fixation in the tibial tunnel. The tunnel position was verified postoperatively through X-ray imaging, which encompassed knee images, tunnel images during a 40-degree knee flexion, and a lateral image of a fully extended knee. The femoral tunnel position was determined according

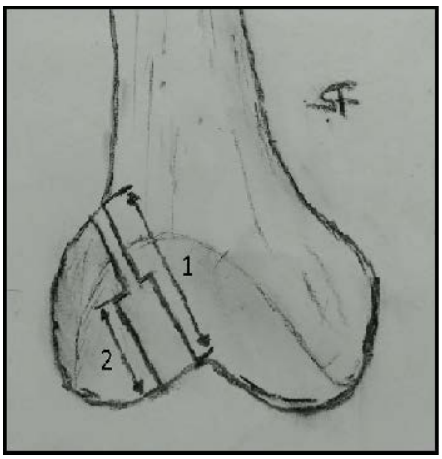

Fig. 2 – Calculation for femoral cortical suspension devices with fixed-loop length: 1) Total tunnel length (TTL); 2) Socket length (SL). Loop length = TTL−SL (use first larger size of loop).

to the method by Sommer et al. [10], who designed the ACL ruler for use in clinical practice. The ruler consists of a template for femoral tunnel verification in anterior-posterior (AP) and lateral knee X-rays. The lateral X-ray is used to identify and draw the Blumensaat line (B-line) and the line that cuts it perpendicularly and is drawn over the final curve of the intercondylar notch roof. The ruler is placed on the lateral X-ray such that the horizontal line follows the Blumensaat line and the ruler marker follows the perpendicular line, after which the values from the schematic representation on the ruler are read (Figure 3). To assess the femoral tunnel position in the frontal plane, another part of the ruler is placed over the AP radiograph. It is necessary to position the template horizontally by placing the ruler circle over the middle of the notch and then to read the tunnel position, which is schematically divided into four types (Figure 4).

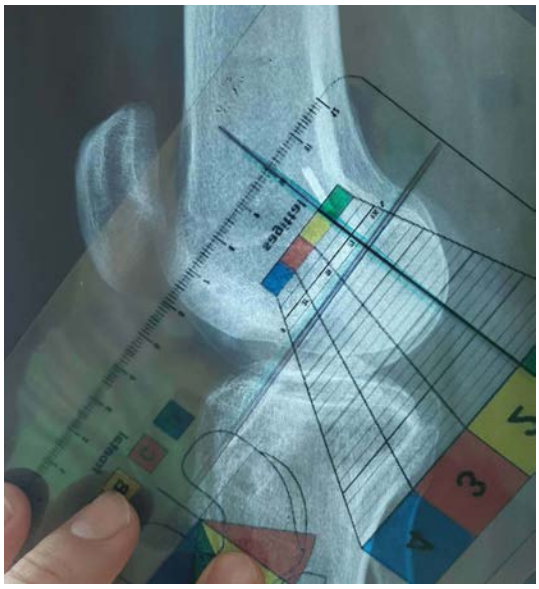

Fig. 3 – Femoral tunnel placement measurement on the lateral plane with anterior cruciate ligament (ACL) ruler.

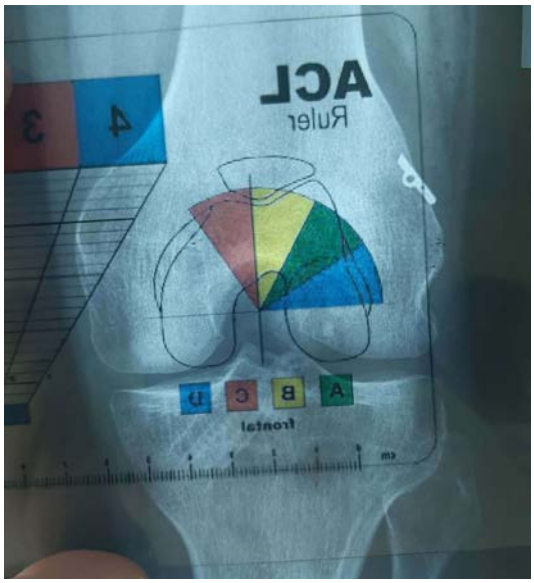

Fig. 4 – Femoral tunnel placement measurement on the anterior-posterior plane with a anterior cruciate ligament (ACL) ruler.

Tunnel position in the tibia was determined in relation to the M-point in the central plane (Figure 5) and in relation to the B-line during full knee extension (Figure 6). The M-point is the cross point between the vertical line that starts from the medial intercondylar tubercle and the horizontal joint line of the tibia. The tunnel position on the AP X-ray is divided into three types: Type A – medial position of the tunnel in relation to the M-point; Type B – the tunnel passes through the M-point; and Type C – lateral position of the tunnel in relation to the M-point [11].

The B-line is a straight line drawn through the roof of the femoral intercondylar notch on the lateral X-ray. The tunnel position was classified into four types: Type I – the tibial tunnel was entirely placed in front of the B-line; Type II – the tibial tunnel axis was anterior to the B-line; Type III – the tibial tunnel axis was behind the B-line; and Type IV –

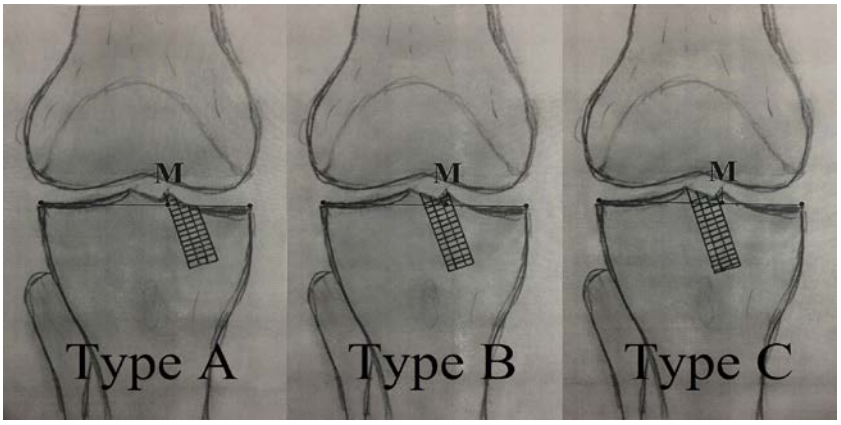

Fig. 5 – Types of tibial tunnel position in the frontal plane in relation to the M-point.

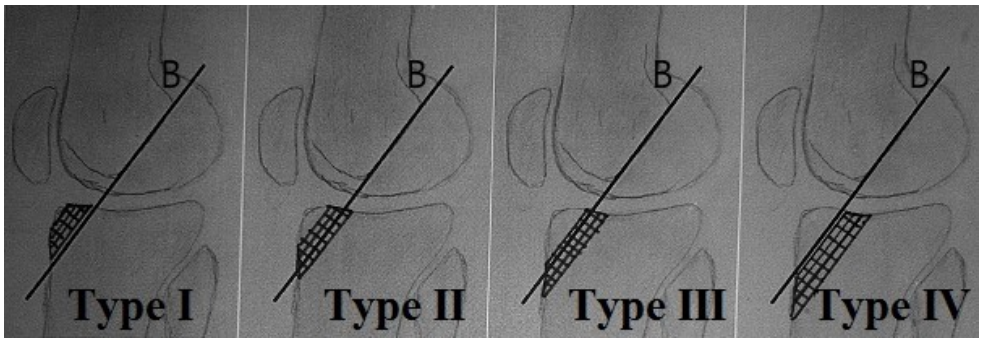

Fig. 6 – Type of tibial tunnel position in the sagittal plane in relation to the B-line.

the tibial tunnel was entirely placed behind the B-line (Figure 6).

All patients included in the study had identical tunnel positions. The following criteria needed to be met for inclusion in the study: patients with a unilateral lesion of the knee ACL that occurred no more than 10 months prior to reconstruction; with or without a minor lesion of the medial or lateral meniscus (up to 50% of the surface); without arthrotic changes and neuromuscular diseases; with 1A femoral tunnel position, with 4B tibial tunnel position; with a willingness to participate in the study and to adhere to the rules for clinical and functional evaluation and for rehabilitation.

The postoperative rehabilitation treatment was conducted according to a previously devised plan and program, and it began the first day after surgery with certain limitations. The most notable limitations include not allowing the patients to lean on the operated leg one month after the surgery and allowing them to run only in a straight-line three months after and with direction change six months after the surgery. Complete return to the preinjury physical activities was allowed nine months after the surgery, while the functional knee testing was performed 24 months after the surgery.

Both groups of patients had identical grafts, tibial fixation, tunnel position, and postoperative rehabilitation treatment, the only difference being the manner of fixation in the femoral tunnel. There were no reports of postoperative complications among patients included in our study.

A special form to be filled out was designed for the purpose of this study. One portion of the form, pertaining to sociodemographic characteristics, was filled out by the patients themselves. For the purpose of a more reliable analysis of the functional results, the patients also filled out authorized scoring tools for the functional assessment of the knee: the International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form and the Lysholm Knee Scoring Scale. The other portion of the form was filled out by a given physician based on the interview with the patient and the physical examination. KT-1000 arthrometer (MEDmetric, San Diego, California, USA) was used to measure objective knee stability and the results were then written in the form.

The Mann-Whitney *U* test, the Fisher's exact test, and the *t*-test were used for statistical analysis of the results. All the results were statistically processed by means of SPSS software (SPSS for Windows release 12.0; IBM Corp). The values of $p < 0.05$ were considered statistically significant.

Results

The sociodemographic characteristics of the patients included in the study, shown in Table 1, indicate that there were no statistically significant differences between the two groups of patients with regard to sex, age, left/right leg, and the time from injury to ACLR surgery.

Table 1

Sociodemographic characteristics of the patients underwent to anterior cruciate ligament construction (ACLR)

Parameter	Fixed loop (n = 30)	Adjustable loop (n = 30)	*p*
Age (years), mean ± SD	27.87 ± 6.902	26.87 ± 6.388	0.563[1]
Sex (male/female), n	26/4	27/3	1.00[2]
Side (left/right), n	12/18	14/16	1.00[2]
Time from injury to ACLR (months), mean	4.173	4.7	1.00[2]

SD – standard deviation;
[1]Mann-Whitney *U* test; [2]Fisher's Exact Test.

Table 2

Postoperative knee stability and functional results for both group of patients

Parameter	Fixed loop (n = 30)	Adjustable loop (n = 30)	*p*
KT-1000 arthrometer* measurement (mm), mean ± SD	1.167 ± 0.781	1.100 ± 0.894	0.605[1]
Lysholm Score, mean ± SD	93.50 ± 6.872	94.00 ± 5.527	0.994[1]
2000 IKDC score, mean ± SD	84.887 ± 9.021	88.327 ± 7.303	0.123[1]
Lachman test, n (%)			1.00[2]
stable	23 (76.66)	25 (83.33)	
gradus 1	7 (23.34)	5 (16.67)	
gradus 2	0 (0)	0 (0)	
Pivot-shift test, n (%)			1.00[2]
stable	28 (93.33)	30 (100)	
gradus 1	1 (3.33)	0 (0)	
gradus 2	1 (3.33)	0 (0)	

***KT-1000 knee ligament artrometer (MEDmetric, San Diego, California); IKDC – International Knee Documentation Committee.**
[1]Mann-Whitney *U* test; [2]Fisher's Exact Test.

Table 2 shows the postoperative knee stability and functional results for both groups of patients, again with no established statistically significant differences between the groups. For the subjects whose graft was fixated with a fixed-length loop implant, the mean value of postoperative knee stability measured using the KT-1000 arthrometer was 1.167 ± 0.780, whereas the same value for the subjects with adjustable-length loop was 1.100 ± 0.894. The mean value of the postoperative IKDC score was 84.887 ± 9.0207 for the fixed-loop group and 88.327 ±7.302 for the adjustable-loop group. The mean Lysholm score was 93.50 ± 6.872 for the fixed-loop group and 94.00 ± 5.527 for the adjustable-loop group.

Discussion

There have been numerous studies attempting to determine which graft type and fixation method is the best, but there is yet to be a consensus among researchers, which is why there is still a broad range of options when choosing a suitable graft type and fixation method [12]. The time that has passed from injury to the ACLR surgery is a factor that significantly impacts the postoperative result [13].

Shelbourne et al. [14] state that at least three weeks should pass between the injury and ACLR to reduce the risk of arthrofibrosis. On the other hand, Bottoni et al. [15] believe that satisfactory clinical results can also be achieved if the ACLR is performed soon after the injury, although they do not claim that all reconstructions should be performed in the acute stage. There is currently no consensus about how much time needs to pass between the injury and the ACLR nor about when the ACLR should be considered "early" and when "delayed" [16]. There is also no consensus about the definition of early and delayed ACLR. Meighan et al. [17] define early ACLR as one performed within two weeks from injury, whereas Hur et al. [18] define it as one performed within the first three weeks from injury. For Church and Keating [19], however, early ACLR is performed up to 12 months from injury, and they believe that this is the optimal period to perform the surgery. The mean time from injury to ACLR in the present study was different between the two considered groups: 4.125 months for the fixed-loop group and 4.7 months for the adjustable-loop group. The surgery was performed after at least one month after injury for both groups, and the longest periods between injury and surgery were 9 months in the fixed-loop group and 10 months in the adjustable-loop group.

Investigation of the preferences regarding graft type and surgical technique used by the surgeons from the Magellan Society revealed that they most often choose STG graft (58%) for primary ACLR, form the tunnel anatomically (62%), prevalently as a single bundle (75%), and use suspensory fixation as the graft fixation method (52%) [20]. This corresponds to the surgical technique as well as graft and implant selection discussed in the present study. Pokharel et al. [21] as well as Boyle et al. [22], independently compared the

treatment outcome for two groups of patients who had undergone ACLR with fixed- and adjustable-length loop implants. They concluded that both patient groups showed significant improvements in their functional results after the surgery without any statistically significant differences between the groups. The analysis of the results obtained in the present study led to the same conclusion: there was a significant improvement in the functional results across both groups and there was no statistically significant difference regarding knee stability and functional results between the two groups.

Similarly, Mariscalco et al. [9] also did not find any statistically significant differences in functional results between the group of patients who underwent ACLR with graft length in the femoral tunnel less than 25 mm and the group whose graft length in the femoral tunnel was 25 mm or longer. In the present study, the minimum intratunnel graft length in the femoral tunnel for the ACLR was 25 mm.

Standard suspensory technique of titanium button fixation with a fixed-length loop requires a specific tunnel length that exceeds the length of the intratunnel portion of the graft [23, 24]. The extra space is necessary for the button to go through the entire tunnel and back in order to fixate the graft; however, it also creates conditions for the so-called "bungee cord" effect, which is considered to be a major cause of graft tunnel dilatation and graft loosening, which in turn diminishes the functional result. With the said implant, there is no compression to the tunnel walls, which negatively affects both the primary tightness of fixation and the biological incorporation of the graft. In contrast to the fixed-length loop implant, a new generation implant with intraoperatively adjustable loop length potentially resolves the aforementioned issues by completely filling the formed femoral tunnel with the graft, which provides compression to all tunnel walls including the tunnel roof, leaving no empty space to be filled with synovial fluid and ultimately enabling a faster and more secure graft incorporation [25–27]. In addition, when the entire tunnel length is filled by the graft, the graft-tunnel interface increases, which in turn increases the surface area of collagen that anchors the graft in the tunnel, thus reducing the probability of graft slippage – this directly impacts later functional result [28]. In the present authors' opinion, this is one of the more relevant issues, which requires further investigation. It was not possible to conduct postoperative multislice computed tomography (MSCT) monitoring of the patients included in this study, but they nevertheless showed no clinical signs of graft loosening. The patients were monitored clinically 24 months after the surgery.

Eguchi et al. [29] suspect that when implants with an adjustable-length loop are used, the loop can loosen postoperatively, which could later cause graft loosening and consequently diminish functional result. This postoperative complication was not registered in the present study. As opposed to Eguchi et al. [29], Smith et al. [30] conducted a controlled *in-vitro* biomechanical study comparing multiple types of implants and concluded that the initial strength and elongation of implants with a fixed-length and adjustable-length loops are equal. Wise et al. [28] also assessed the results of ACLR with fixed- and adjustable-length loops. Their study showed that the clinical laxity, or the measure of anterior tibial translation in the injured knee obtained from the KT-1000, which was 3 mm larger than in a healthy knee, was found in 6.1% of the adjustable-loop patients and in 12.5% of the fixed-loop patients. The present study did not include any patient with a postoperative laxity larger than 3 mm compared to a healthy knee.

Based on the results from numerous studies, including the present one, it can be concluded that an implant with an intraoperatively adjustable loop length is more advantageous than the fixed-length loop device, as it provides more freedom to the surgeon to form the femoral tunnel by eliminating the need to calculate the length of the femoral tunnel and the loop [12]. Furthermore, implants with adjustable-length loops enable intraoperative graft retensioning after fixation in the tibial tunnel, which allows poor graft tension to be corrected [27].

Accordingly, in addition to making a decision on which graft type and tunnel position to choose, the surgeon can also control graft tension during the entire surgical procedure and thus put the entire preoperative plan into effect.

Limitations of the study

The minimum postoperative time for patient monitoring in this study was only two years. Knee computed tomography was not performed, even though it is the most reliable method for assessing tunnel dilatation, because the rules of the healthcare institution where the study was conducted prohibit this diagnostic method for postoperative monitoring of patients who do not suffer from any other health issues.

Conclusion

Based on the results obtained in the course of the presented study, it can be concluded that both types of implants discussed can be used with success in ACLR, because the functional results after operative treatment of ACLR with both implants were identical. After knee stability measurements and the assessment of functional results by means of scores and tests, the study did not establish any statistically significant differences in the results of anterior crucial ligament reconstruction between the patients with fixed-length loop and those with adjustable-length loop titanium implants. This study focused on knee stability assessment after anterior crucial ligament reconstruction using two different implant types, but there is ample room for further research in terms of the stability of the implant itself and tunnel dilatation, which can be conducted with the aid of additional diagnostic methods and over a longer monitoring period.

Conflict of interest

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial, non-financial interest in the subject matter or materials discussed in this manuscript.

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