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Postoperative Knee Joint Stability Following Anterior Cruciate Ligament Reconstruction Using the Ligament Advanced Reinforcement System

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A – research concept and design; **B** – collection and/or assembly of data; **C** – data analysis and interpretation; **D** – writing the article; **E** – critical revision of the article; **F** – final approval of the article

Abstract

Background. One of the goals of the synthetic materials used in knee joint reconstruction of the anterior cruciate ligament (ACL) is to improve the strength and stability of the graft immediately after the reconstruction. One of the synthetic grafts is a non-absorbable synthetic ligament device made of terephthalic polyethylene polyester fibers, the Ligament Advanced Reinforcement System (LARS).
Objectives. The aim of the study was to assess postoperative knee joint stability in patients who had undergone ACL reconstruction using the LARS graft.
Material and Methods. The study group was comprised of 20 males who had undergone primary unilateral intraarticular ACL reconstruction using LARS. The patients were evaluated one day before the reconstruction and an average of six weeks postoperatively. Knee stability was evaluated manually using the Lachman test, anterior drawer test and pivot-shift test. Knee active range of motion (ROM) was measured.
Results. Preoperatively, the Lachman test indicated abnormal/2+ results in the vast majority of the patients. The postoperative results in most of the patients were normal/0. The anterior drawer test results were also abnormal/2+ preoperatively and normal/0 postoperatively. The pivot-shift test was positive in all of the patients before the ACL reconstruction and negative after the surgery. In general, no differences were found in the ROM between the involved and uninvolved limbs and in the between-measurement comparison.
Conclusions. The evaluation demonstrated significant progress from the preoperative to postoperative results in reducing anterior translation and anterolateral rotational instability of the tibia in patients who had undergone ACL reconstruction using the synthetic LARS graft. In the short-term follow-up assessments, restoration of anterior and anterolateral rotational stability of the operated knee joints was observed **(Polim. Med. 2016, 46, 2, 155–161).**

Key words: Lachman test, LARS, pivot-shift test, synthetic graft, terephthalic polyethylene polyester.

The anterior cruciate ligament (ACL) of the knee joint plays a complex role in the stabilization of the knee joint, resisting anterior displacement and excessive rotation of the tibia relative to the femur [1]. Reconstruction of the ACL of the knee joint [2] followed by a postoperative physiotherapeutic procedure [3] is the standard ACL injury treatment for individuals wishing to return to high-level sports activities. There are numerous current treatment options for ACL reconstruction, and in choosing the technique, the surgeon's experience and numerous patient-specific factors, as well as cost and efficacy, are taken under consideration [4, 5]. Broadly, the available graft options include autografts and allografts, as well as synthetic ligaments. The autograft choices consist of the patellar, hamstring (Fig. 1), and quadriceps tendons, while allografts include the quadriceps, patellar, Achilles, hamstring, anterior and posterior tibialis tendons, and the fascia lata [5]. The advantages of allografts include shorter surgical and anesthesia times, fewer postoper-

Fig. 1. A hamstring tendon graft prepared for reconstruction of the ACL of the knee joint

ative complications, reduced morbidity at the harvest site, faster postoperative recovery, lower incidence of postoperative arthrofibrosis and less postoperative pain [4, 6]. On the other hand, the use of allografts may entail higher rates of rerupture, limited availability, delayed healing and ligamentization in comparison to autografts, as well as a risk of disease transmission and high cost [7–9]. The synthetic materials used in ACL reconstruction aim to improve the strength and stability of the graft immediately after the reconstruction, reduce donor site morbidity and eliminate the potential for disease transmission [1–3]. The first synthetic grafts were characterized by high rates of failure and synovitis reactivation [2, 4], but with advancing technology, new synthetic grafts have been developed. One of these grafts is a non-absorbable synthetic ligament device made of terephthalic polyethylene polyester fibers, the Ligament Advanced Reinforcement System (LARS, made by The LARS Company, Arc-sur-Tille, France) [4, 5].

The aim of the study was to evaluate postoperative knee joint stability, assessed manually as anterior tibial translation and anterolateral rotation, in patients who had undergone ACL reconstruction using a synthetic LARS graft.

Material and Methods

The study had a retrospective design. The evaluation was performed in patients who had undergone ACL reconstruction at the eMKaMED Medical Center in Wroclaw, Poland, performed by the same two senior surgeons. The study was carried out at the Center of Rehabilitation and Medical Education according to the ethics guidelines and principles of the Declaration of Helsinki. All the participants in the present study were informed of the goal of the study and approach to be used. The study was approved by the Bioethics Committee of the College of Physiotherapy in Wrocław, and written informed consent forms were signed by all of the participants prior to the study.

Material

The study group was comprised of participants who had undergone primary unilateral intraarticular ACL reconstruction using LARS. All of the patients had been operated on by the same two senior surgeons.

The inclusion criteria were primary unilateral intraarticular ACL reconstruction with the use of a LARS graft, and no injuries of the contralateral limb. Exclusion criteria were extraarticular ACL reconstruction, revision ACL reconstruction, medial (MM) and/or lateral (ML) meniscal total/subtotal resection or transplant, an autograft or allograft used for the reconstruction, a synthetic graft other than LARS used for the reconstruction, posterior cruciate ligament (PCL) or/and medial- or/and lateral-contralateral ligament repair, extensor mechanism surgery, patellofemoral surgery other than cartilage debridement, articular cartilage injury grade 3 and/or 4 according to International Cartilage Repair Society (ICRS) criteria, osteochondritis dissecans lesions, and any injuries in the contralateral limb.

The final sample consisted of 20 male patients. The mean age in the study group was 35.00 ± 8.55 years; 10 right knees and 10 left ones were involved. Based on the information obtained from the patients, the mean time of postoperative physiotherapy in the study group was 12 weeks.

Surgical Procedures

The arthroscopic procedure for reconstruction of the ACL was carried out according to the graft manufacturer's instructions, with the graft fixed at both ends using LARS cannulated titanium interference screws. The femoral tunnel was created using the anteromedial portal technique (Fig. 2). A guide pin was drilled from the isometric point across the femur and out the lateral thigh. A small incision was enlarged using graduated telescopic tubes, and the tunnel was reamed from the

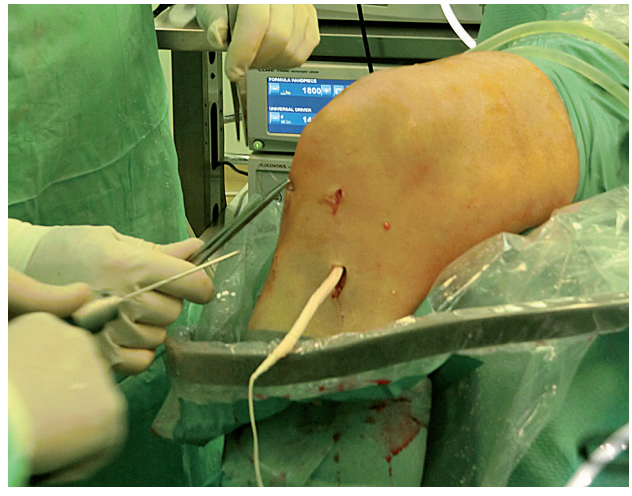

Fig. 2. The femoral tunnel for the new ACL graft

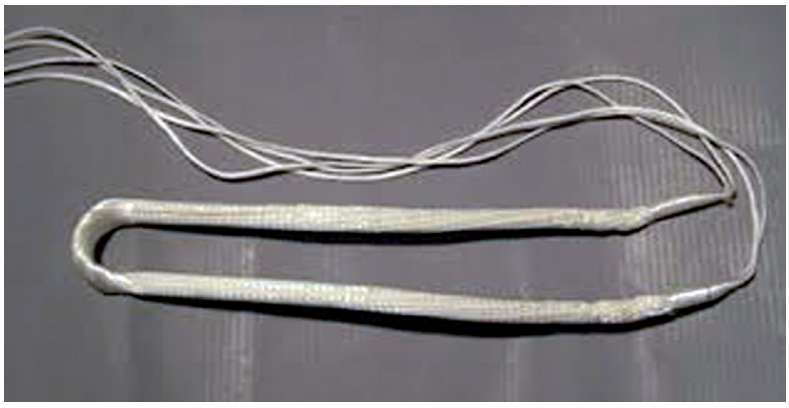

Fig. 3. The LARS ligament prepared for reconstruction of the ACL of the knee joint

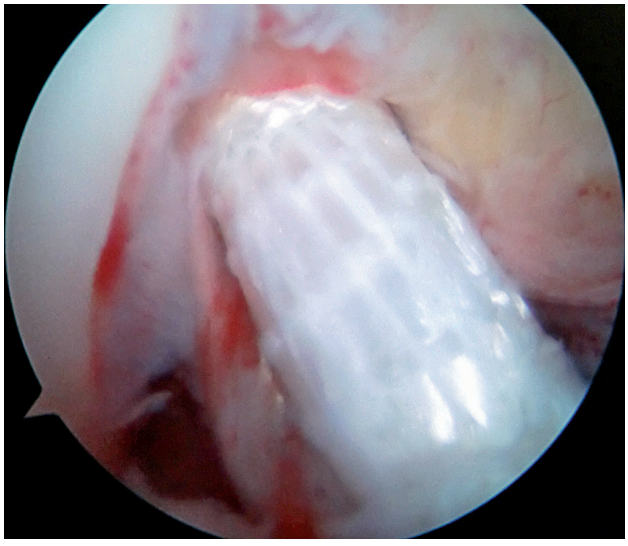

Fig. 4. Arthroscopic view of the final LARS implementation

outside in. Next, the tibial tunnel guide pin was placed at the center of the ACL footprint using an ACL guide set at approximately 65° to the tibial plateau in the sagittal plane. The guide pin was then overreamed with a drill. The LARS ligament presented in Fig. 3 was inserted through the tunnels and fixed on the femoral side with a LARS interference screw and tensioned. Fixation on the tibial side was performed using a LARS interference screw at 20° of flexion with a posterior drawer force applied to the tibia (Fig. 4). When the fixation was completed, the redundant extremities of the graft were cut flush with the bone.

Evaluation Methods

All of the patients in the study group underwent clinical assessment. The first evaluation was performed one day before the ACL reconstruction and the second assessment was carried out an average of 5.50 ± 3.10 weeks postoperatively. The assessment was carried out bilaterally.

The active range of motion (ROM) of the knee was measured bilaterally using a standard goniometer [10]. Anterior knee stability was evaluated manually using the Lachman test and anterior drawer test, according to the ligament examination section of the 2000 International Knee Documentation Committee (IKDC) Knee Examination Form [11]. The inter-limb difference in anterior tibial dislocation obtained from the Lachman test and anterior drawer test was rated as normal (0; 0–2 mm), nearly normal (1^+; 3–5 mm), abnormal (2^+; 6–10 mm) or severely abnormal (3^+; > 10 mm) [11]. Anterolateral rotational knee stability was assessed manually with the pivot-shift test. The pivot-shift was considered negative when, according to the ligament examination section of the 2000 IKDC Knee Examination Form, the anterolateral rotational dislocation of the tibia relative to the femur was equal in both lower limbs and positive when the difference between the limbs was rated as + (glide), ++ (clunk) or +++ (gross).

Statistical Analysis

The statistical analysis was performed using IBM SPSS Statistics 20 software. The arithmetic mean (x) and standard deviation (SD) of the patients' age, the time between the surgery and measurements, and ROM were calculated for the study group. Data distributions of ROM values were tested for normality using the Shapiro-Wilk test [12]. For the intra-group comparison of ROM values between the involved and uninvolved knees and between the preoperative and postoperative values, the Wilcoxon test was used. Differences were considered significant if $p < 0.005$. The between-limb and inter-measurements comparison of the results of manual knee stability testing was based on the incidence of inter-limb difference in anterior tibial dislocation.

Results

The mean values of active knee extension that were obtained indicated no statistically significant differences between the involved and uninvolved limbs in the preoperative and postoperative measurements. No differences in active knee extension values were noted

when comparing the values obtained preoperatively and postoperatively in the involved and uninvolved limbs (Table 1). Postoperatively, a statistically significant loss of knee flexion in the involved knee was found compared to the results obtained before the reconstruction and in comparison to the uninvolved knee. Nevertheless, a difference amounting to three degrees of knee flexion does not seems to have any clinical relevance (Table 1).

The analysis of the results of manual anterior tibial translation testing based on the Lachman test revealed differences between the preoperative and postoperative anterior tibial translation. The vast majority of the patients had abnormal/2^+ test results preoperatively. The postoperative result in most of the patients was normal/0 (Table 2).

The anterior drawer test results also showed preoperative abnormal/2^+ and postoperative normal/0 anterior tibial translation in most of the patients (Table 3).

The pivot-shift test was positive in all of the patients before the ACL reconstruction and negative after the surgery (Table 4).

Table 1. A comparison of the active range of motion values between the involved and uninvolved limbs and between the preoperative and postoperative measurements`

Active range of motion of the knee joint [°]						
	studied limb	preoperatively		postoperatively		
		x	SD	x	SD	p
Extension	involved	0.35	1.18	0.35	0.88	1.00
	uninvolved	0.00	0.00	0.00	0.00	1.00
	p	0.180		0.102		
Flexion	involved	134.75	5.50	132.25	4.13	0.013
	uninvolved	135.50	3.94	135.50	3.94	1.00
	p	0.180		0.002		

p – significance level; SD – standard deviation; x – arithmetic mean. The statistically significant p values were written in bold.

Table 2. The preoperative and postoperative incidence of inter-limb differences in anterior tibial translation in the Lachman test

Lachman test (n)				
	normal	nearly normal	abnormal	severely abnormal
Preoperatively	0	1	10	9
Postoperatively	14	6	0	0

n – number of individuals. Lachman test grading: normal (0; 0–2 mm), nearly normal (1+; 3–5 mm), abnormal (2+; 6–10 mm) or severely abnormal (3+; > 10 mm) [11].

Table 3. The preoperative and postoperative incidence of inter-limb differences in anterior tibial translation in the anterior drawer test

Anterior drawer test (n)				
	normal	nearly normal	abnormal	severely abnormal
Preoperatively	0	1	10	9
Postoperatively	14	6	0	0

n – number of individuals. Anterior drawer test grading: normal (0; 0–2 mm), nearly normal (1^+; 3–5 mm), abnormal (2^+; 6–10 mm) or severely abnormal (3^+; > 10 mm) [11].

Table 4. The preoperative and postoperative incidence of inter-limb differences in negative and positive results of the pivot-shift test

Pivot-shift test				
	negative		positive	
	preoperatively	postoperatively	preoperatively	postoperatively
Number of individuals	0	20	20	0

Pivot-shift test grading: negative (equal), positive (+ glide, ++ clunk, +++ gross) [11].

Discussion

The findings of the present study indicated significant progress from preoperative to short-term postoperative result in reducing anterior translation and anterolateral rotational instability of the tibia relative to the femur in patients who had undergone ACL reconstruction with a synthetic LARS graft. The postoperative manual knee stability assessment revealed recovery of anterior tibial translation and anterolateral rotational stability in the operated knee joint on the level of the uninvolved knee.

The ACL of the knee joint is attached to a facet on the anterior part of the intercondylar area of the tibia and ascends posteriorly, attaching to a facet on the back of the lateral wall of the intercondylar fossa of the femur. The ligament consists of two distinct functional bundles that are characterized by their spatial relationships throughout knee flexion and their different roles in biomechanics and stability: the anteromedial (AM) and posterolateral (PL) bundles [1, 13, 14]. Some authors have described a third intermediate (IM) bundle [15, 16].

The ACL plays a complex role in stabilizing the knee joint, resisting anterior displacement and excessive rotation of the tibia relative to the femur [1]. The primary clinical tests for ACL deficiency are carried out manually and thus user-dependent, subjective and difficult to reproduce: the Lachman test and anterior drawer test, assessing anterior tibial translation relative to the femur, and the pivot-shift test, involving the application of valgus and internal rotation of the tibia to evaluate anterolateral rotation of the knee [11, 17, 18].

The aim of ACL reconstruction is to reinstate functional knee stability, and in turn, to reduce the risk of further damage to the menisci and degenerative osteoarthritis [19, 20]. Even though the first-line treatment in ACL injury most often uses patellar or hamstring tendon grafts [21], the optimal graft material remains controversial, regardless of the graft tissue selected. Synthetic grafts are among the options in ACL reconstruction [5].

Numerous synthetic grafts used in ACL reconstruction were developed in the mid-1980s, when the gold standard in treatment of a ruptured ACL was an open patellar tendon graft with 6 weeks of postoperative immobilization. The concept of sterile, off-the-shelf synthetic ligaments, without the need for postoperative immobilization, seemed promising [22]. Nevertheless, the first synthetic ligaments were associated with high rates of failure and reactive synovitis [23–25].

Synthetic grafts have been used as scaffolds, stents and prostheses [5]. Scaffolds, for example the carbon fiber scaffold ligament, aim to stimulate fibrous tissue ingrowth and contribute to the ultimate strength of the new ligament [26]. One of the first examples of a synthetic stent used in ACL reconstruction was the Kennedy ligament augmentation device (LAD), which was sutured to an autologous graft and fixed to the bone at both ends. The LAD aimed to support and protect the autologous graft during the healing phase, when the autologous tissue is the weakest. However, the LAD had a tendency to stress the autologous graft, leading to failure [26]. According to a review by Mascarenhas and MacDonald, the main disadvantages of the LAD were a weak implant/graft interface, and a propensity to cause intra-articular inflammatory response and resulting synovitis and effusions [24]. An example of a prosthetic graft was the Gore-Tex graft. In order to (theoretically) avoid the bending forces at the entrance to a femoral tunnel, the Gore-Tex graft was placed in a nonanatomic position over the top of the femur [5]. Another example of a complete replacement graft was the Stryker Dacron graft, placed through anatomical tunnels in the femur and tibia [22]. The ABC graft, made of a combination of polyester and carbon fiber, was also placed through anatomical bony tunnels. The Leeds-Keio graft was a polyester mesh graft designed to augment an autogenous graft that was placed through a bony tunnel and fixed outside the tunnel with staples. The Trevira polyester graft resembled the LAD in design but was placed in a nonanatomic position [22].

Another polyester graft was the Ligostic graft, which evolved into the LARS graft [27]. As Dericks wrote: "The LARS is a non-absorbable synthetic ligament made of terephthalic polyethylene polyester fibers and is highly cleaned to remove potential machining residues and oils to further encourage soft tissue in-growth and reduce the risk of reactive synovitis. The ligament intra-articular portion/scaffold is built of multiple parallel fibers that are twisted at 90 degree angles' [27]. The scaffold aims to provide a meshwork for the injured ligament to heal and repair [18]. The LARS device is the third generation of synthetic ligament and according to the manufacturer it has been designed to avoid the complications of older synthetic grafts [28]. Cellular ingrowth into the LARS ligament was first described by Trieb et al. in a study based on biopsies taken from LARS grafts 6 months after implantation. The study found fibroblasts and osteoblast-like cells encapsulating the fibers by building a cellular net around them, and the authors suggested that this might be an explanation of the strength and the inert behavior of the LARS ligament without the synovialitis shown in clinical studies [18].

Hamido et al. used LARS to augment the short length and small diameter of double-strand gracilis and semitendinosus harvested hamstring tendons. The authors found the synthetic ligament to be a useful and satisfactory treatment option for ACL reconstruction in cases of short and/or small hamstring tendons. Within the 5-year follow up no LARS ruptures, screw loosening, tunnel widening or reactive synovitis were reported [29]. A short-term evaluation of patients who had

undergone ACL, posterior cruciate ligament (PCL) and combined ACL and PCL reconstruction using LARS was performed by Huang et al. based on functional patient-oriented assessments and tibial translation measurements with a KT-1000 arthrometer also found good results [30].

A review by Newman and Atkinson indicated the support of the current literature for the use of LARS in the short to medium term in patients who have undergone ACL reconstruction. However, the authors highlighted the need for high-quality studies with long-term follow-up to determine whether the use of LARS is preferable to autologous grafts [28].

The main limitations of the present study are a lack of instrumented ligament examination and objective measurement of tibial dislocation relative to the femur, as well as a lack of some of the objective functional assessment methods used in a comprehensive evaluation of a patient following ACL reconstruction [31]. The short-term follow-up may also be considered a study limitation. In the future, studies involving long-term follow up with patients that have undergone fully supervised physiotherapeutic procedures and a comprehensive clinical and functional evaluation should be considered.

Conclusions

Postoperative manual ligament evaluation of the knee joint demonstrated significant progress from preoperative to postoperative results in reducing anterior translation and anterolateral rotational instability of the tibia relative to the femur in patients who had undergone ACL reconstruction with a synthetic LARS graft. The short-term postoperative follow-up assessments revealed restoration of anterior tibial translation and anterolateral rotational stability of the knee joint involved.

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