Clinical assessment and comparison of ACL reconstruction using synthetic graft (Neoligaments versus FiberTape)

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Abstract

Background. Due to the low potential for primary biological healing of the anterior cruciate ligament (ACL), the most popular approach is currently reconstruction using a graft. Recent research indicates that the technique of strengthening a damaged ligament with synthetic tapes (internal bracing) may be an alternative to reconstructive treatment, especially in cases of partial ACL damage.

Objectives. To compare and evaluate the possibility of using a synthetic graft (Neoligaments or FiberTape) to treat partial lesions of the ACL.

Materials and methods. This was a retrospective cohort study. Selected from a pool of 128 patients undergoing primary unilateral intra-articular ACL reconstruction due to partial lesion of the ACL, group I (Neoligaments) and group II (FiberTape) each included 30 patients. Range of motion (ROM), the Lachman test, the anterior drawer test and the pivot-shift test, the Lysholm Knee Scoring Scale, and International Knee Documentation Committee (IKDC) 2000 scale were used for assessment. Follow-up was carried out after 2 years.

Results. The knee joint regained anterior stability in both the subjective and objective assessments in all patients in both groups. The subjective results were respectively: in group I, 97.2 ± 3.2 points on the Lysholm scale and 93.9 ± 6.1 points on the IKDC 2000 scale; in group II, 96.1 ± 4.9 points on the Lysholm scale and 93.2 ± 6.8 points on the IKDC 2000 scale. Group comparison of the results of the IKDC 2000 scale, Lysholm Scale and ROM obtained postoperatively showed no statistically significant differences between groups.

Conclusions. Reconstruction of partial ACL lesions using a synthetic graft allows regained stability of the knee joint. The results of subjective assessment are comparable with the functional assessment results. The comparison between Neoligaments and FiberTape shows the same functional and objective results, although FiberTape is preferable from an economical perspective.

Key words: reconstruction, athletes, anterior cruciate ligament, primary repair, internal bracing

Background

An anterior cruciate ligament (ACL) tear is among the most frequent consequences of knee sprain, with a prevalence of approx. 1/3000.¹ In the USA, there are about 200,000 new cases annually.² An ACL tear is most frequently experienced by professional athletes. The athletes who practice sports such as skiing, football and basketball are at particularly high risk.³ In a modern society, where physical culture is promoted, and, given the trend of regular involvement in physical activity as well as the increasing popularity of extreme sports, the number of patients presenting with ACL injuries is constantly growing.⁴

Untreated ACL tears result in a disturbed biomechanical balance of the knee joint, which leads to knee instability, increased susceptibility to future knee joint injuries and impairment of motion dynamics in the affected lower limb. This translates directly into deterioration of athletic performance or, in certain sport disciplines, makes training impractical and even impossible. More distant consequences include damaging other inner structures of the knee, namely the menisci and the articular cartilage, predisposing the development of arthritis. Given today's overarching trend of a healthy lifestyle and widespread efforts to maintain physical fitness, most patients wish to return to their routine training or hobbies and most often decide to undergo surgery shortly after learning about their diagnosis.

Due to the low potential for primary biological ACL healing, reconstruction using a graft is now the most popular approach. The latest studies show that, apart from reconstruction, especially in cases of partial damage, there is another alternative form of ACL tear treatment, namely, stabilization of the torn ligament with a synthetic graft, either polyethylene terephthalate tapes (Neoligaments, Leeds, UK) or FiberTape® (Arthrex, Warszawa, USA), which is referred to as internal bracing. 11–18

The advantages of the internal bracing technique are reduced morbidity rate at the harvest site, a more rapid rehabilitation and postoperative recovery, lower incidence of postoperative arthrofibrosis, and lower level of postoperative pain. ^{19–21}

The parallel fibers provide a high degree of strength. The mesh is made of pure polyethylene terephthalate (PET), without any additions. It consists of repeating units of the monomer ethylene terephthalate ($C_{10}H_8O_4$). In this approach, the reinsertion procedure involves stabilization of the undamaged ACL structures, fixing the tape along the ligament. The tape strengthens the ligament and protects it against further tears. ²²

Objectives

The goal of the study was to assess, evaluate and compare the viability and opportunities for application of FiberTape compared to Neoligaments in partial ACL tears.

Materials and methods

This was a retrospective cohort study. The sample was made up of patients who had undergone primary ACL reconstruction, carried out at the Trauma and Orthopedics Department of eMKa Med Hospital in Wrocław, Poland. Out of 128 male patients admitted in 2015–2017 due to a partial lesion of the ACL involving anteromedial bundle damage, and undergoing primary unilateral intra-articular ACL reconstruction using restrictive inclusion and exclusion criteria, 60 patients qualified for the study. Group I consisted of 30 patients treated with Neoligaments, including 26 men and 4 women, aged 27.1 ±4.5 years. Group II involved 30 patients, including 26 men and 4 women, aged 31.3 ±11.8 years, treated with FiberTape.

The study was carried out according to the principles of the Helsinki Declaration, and approved by the Bioethics Committee of Wroclaw Medical University. Each participant was informed about the aim of the study and the applied approach, and each signed their informed consent for participation in the study. An additional goal of the assessment was to present the patient with the technique to be applied.

The ACL capacity was assessed using the 3 tests that are most often applied in clinical practice. The orthopedic assessment concerned the range of motion (ROM) in the knee joint and included the Lachman test, anterior drawer test and pivot-shift test. The assessment was combined with subjective evaluation based on the 2000 International Knee Documentation Committee (IKDC 2000) and Lysholm scales. Ultrasound and magnetic resonance imaging (MRI) were utilized for all patients who sustained knee joint injuries. The period of observation lasted 2 years. The first evaluated limb was a non-traumatic limb, to assess its range of motion and stability, and to familiarize the patient with the examination technique.

Postoperative controls took place on days 7, 14 and 28 after surgery. The examination was made 6, 12 and 24 months after surgery. Stitches were removed during the control procedure. Stress relief and use of the orthosis were recommended for a period of 3 weeks, increasing the range of flexion in the orthosis in a 30°-60°-90° schedule every 7 days. The ROM of the knee was measured bilaterally using a standard goniometer.²³ Anterior knee stability was evaluated manually using the Lachman test and anterior drawer test, according to the ligament examination section of the IKDC 2000 Knee Examination Form. 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).²³ 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).

Surgical technique

All the patients were operated on by the same team, using the same surgical technique and Neoligaments (Neoligaments) (Fig. 1) or FiberTape (Biomet) (Fig. 2) graft. It was fixed using Endobutton (Smith-Nephew, Watford, UK) on the femur and the interference screw, ComposiTCP30 (Biomet), on the tibia. It was prepared using the "outside-in" technique with the aimer device (Fig. 3–8).

Postoperative management

Each patient stayed in hospital for 24 h. After the removal of drains and changing dressings, the patient was verticalized under the control of rehabilitation. Next, the patient

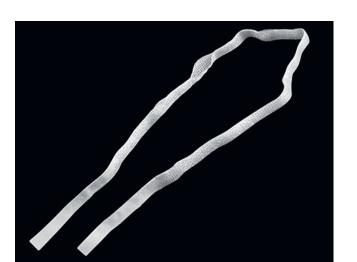


Fig. 1. Neoligaments



Fig. 2. FiberTape

moved using crutches and orthosis, allowing movement within the $0-30^{\circ}$ range. How to perform isometric exercises correctly was demonstrated to the patient. Anti-clotting prophylaxis and oral antibiotic treatment were applied.



Fig. 3. Arthroscopic image. Right knee joint. View of partial rupture of the proximal stump of the anterior cruciate ligament

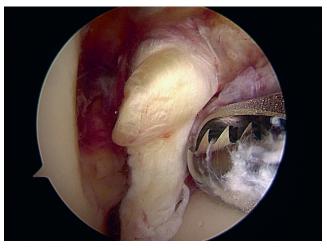


Fig. 4. Arthroscopic image. Right knee joint. View of the Endobutton and loop pull Neoligaments into the femoral canal

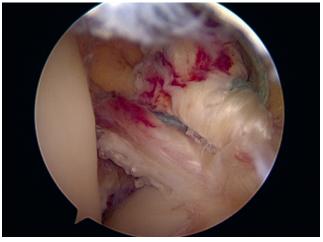


Fig. 5. Arthroscopic image. Right knee joint. View of fixed Neoligaments



Fig. 6. Arthroscopic image. Right knee joint. View of partial rupture of the proximal stump of the anterior cruciate ligament



Fig. 7. Arthroscopic image. Right knee joint. View of FiberTape



Fig. 8. Arthroscopic image. Right knee joint. View of fixed FiberTape

Weight release with crutches and orthosis were recommended within 3 weeks, as well as a gradual increase of flexion range in the orthosis, according to the $30^{\circ}-60^{\circ}-90^{\circ}$ pattern every 7 days.

Statistical analyses

Statistical analyses were carried out using TIBCO Statistica™ (TIBCO Software Inc., Palo Alto, USA) and Microsoft Office Excel 365 Personal (Microsoft Corporation, Redmond, USA). As for characteristics of the studied sample and the analysis of the knee "giving way", as it is socalled, and the results of the Lachman test, anterior drawer test and pivot-shift test, the number of patients (n) who obtained a given result in each group was determined.

The arithmetic mean (x) and standard deviation (SD) were calculated for the following parameters: active extension and flexion range in both the operated and the uninvolved leg [°] and the total scores obtained from the Lysholm scale (n points) and IKDC 2000 questionnaire. Shapiro–Wilk tests were carried out to determine the normality of distribution for the studied parameters. Statistical significance was set at p < 0.05.

Choosing the type of transplant for each patient

After qualifying each patient for surgical treatment on the basis of the above diagnostics, and following their acceptance of this method of treatment, the choice of graft was discussed with the patient. The final decision as to the choice of the graft, after the operating physician presented the available options along with their pros and cons, was made by the patient.

Results

In group I, patients underwent primary unilateral internal bracing of ACL of the knee using Neoligaments. In group II, patients underwent primary unilateral internal bracing of ACL of the knee with FiberTape.

Clinical evaluation results

The results of the knee giving way, Lachman test, anterior drawer test, and pivot shift test are shown in Fig. 9 and Fig. 10 for both groups. Statistically significant results were found in all tests comparing preoperative examination

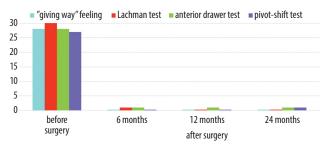


Fig. 9. Analysis of the results of so-called feelings of "giving way", Lachman test, anterior drawer test, and pivot-shift test in group I (Neoligaments) before surgery, and at 3, 6 and 24 months after surgery, respectively

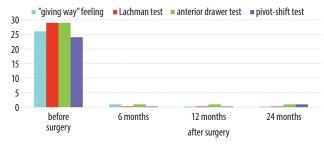


Fig. 10. Analysis of the results of so-called feelings of "giving way", Lachman test, anterior drawer test, and pivot-shift in group II (FiberTape) before surgery and at 3, 6 and 24 months after surgery, respectively

with examinations after 6, 12 and 24 months after surgery. No statistically significant differences were found when comparing results between groups 6, 12 and 24 months after reconstruction, and between groups over identical study periods. The statistical results were similar when comparing the range of motion between the operated and non-operated limb.

For group 1, the ROM of active knee extension before ACL reconstruction was statistically significantly lower (p ≤ 0.001) in the operated limb (x = 9.78 $\pm 2.00^{\circ}$) when compared to the non-operated limb (x = 0.00 $\pm 0.00^{\circ}$). Active starting extension range values for the operated limb in group I differed statistically significantly from measurements carried out subsequently (p ≤ 0.001 ; Table 1).

In group I, prior to surgery, the ROM of the active knee flexion in the operated limb (x = 111.32 $\pm 8.32^{\circ}$) was significantly lower (p \leq 0.001) than that in the non-operated limb (x = 129.19 $\pm 5.81^{\circ}$), as well as at 6 months (p \leq 0.001) and 12 months (p \leq 0.001) following reconstruction. The ROM in the 24th month after reconstruction was lower than in the non-operated limb, but not significantly (p = 0.061),

and such a miniscule difference in obtained values should not be of clinical significance (Table 1).

For group II, prior to undergoing ACL reconstruction, ROM active extension in the operated limb (x = $4.07 \pm 2.08^{\circ}$) was statistically significantly lower (p ≤ 0.001) than in the non-operated limb (x = $0.00 \pm 0.00^{\circ}$). At 6, 12 and 24 months after surgery, the ROM of the operated limp was comparable to that of the non-operated limb (Table 1).

Prior to ACL reconstruction in group II, the ROM of active flexion in the operated limb ($x = 111.33 \pm 10.82^{\circ}$) was also statistically significantly lower ($p \le 0.001$) than in the non-operated limb ($x = 129.19 \pm 5.81^{\circ}$), and this remained the case at 6 and 12 months after the operation (Table 1).

The range of active extension movement in the operated limb in group I was significantly increased at 6 months after the reconstruction of the ACL, compared to the result obtained prior to the surgery (p \leq 0.001). There was no significant change in the range of extension movement between 6 and 12 months after surgery, or between the results 12 and 24 months after surgery (Table 1).

The ROM active flexion in the operated limb in group I was significantly increased at 6 months after the reconstruction compared to the results obtained prior to surgery (p \leq 0.001), and between 6 and 12 months after the reconstruction (p = 0.012). There was a slight decrease between 12 and 24 months, which was not a significant difference (Table 1).

The ROM of active extension in the operated limb in group II was significantly larger within 6 months following the ACL reconstruction in comparison to pre-reconstruction values. There were no significant changes in the operated limb values from 6 months to 24 months after surgery (Table 1).

Table 1. Comparative analysis values of the measurement of the active flexion and extension in the operated and non-operated limb in group I (Neoligaments) and group II (FiberTape) before reconstruction of the ACL, and at 6, 12 and 24 months after surgery

Variable	Group I			Group II		
	operated limb	non-operated limb	p-value	operated limb	non-operated limb	p-value
Extension [°]						
Before surgery	9.78 ±2.00	0.00 ±0.00	0.001	4.07 ±2.08	0.00 ±0.00	≤0.001
6 months after surgery	0.52 ±1.15	0.00 ±0.00	0.072	0.48 ±1.20	0.00 ±0.00	0.098
12 months after surgery	0.00 ±0.00	0.00 ±0.00	1.000	0.00 ±0.00	0.00 ±0.00	1.000
24 months after surgery	0.00 ±0.00	0.00 ±0.00	1.000	0.00 ±0.00	0.00 ±0.00	1.000
p-value	≤0.001	1.000	-	≤0.001	1.000	
Flexion [°]						
Before surgery	111.32 ±8.32	129.19 ±5.81	≤0.001	111.33 ±10.82	129.19 ±5.81	≤0.001
6 months after surgery	121.94 ±10.46	129.19 ±5.81	≤0.001	114.50 ±16.10	129.19 ±5.81	≤0.001
12 months after surgery	123.55 ±5.80	129.19 ±5.81	≤0.001	124.00 ±7.36	129.19 ±5.81	≤0.001
24 months after surgery	126.23 ±2.75	129.19 ±5.81	0.061	127.61 ±6.16	129.19 ±5.81	0.119
p-value	≤0.001	1.000	-	≤0.001	1.000	-

Values expressed as the arithmetic mean \pm standard deviation (SD).

Comparison of the ROM of flexion in the operated limb in group II demonstrated a drastic, significant change in measurements ($p \le 0.001$) (Table 1).

Functional assessment results

Within 24 months of the reconstruction of the ACL, the average number of points obtained on the Lysholm group I scale was 95.70 ± 4.25 points. In group II, patients obtained an average of 95.5 ± 4.18 points over the same period since surgery (Fig. 11). A comparative analysis of the results of the functional assessment based on the Lysholm scale did not show statistically significant differences between the examined groups (p = 0.94).

Within 24 months of the reconstruction of the ACL, the average total number of points on the IKDC 2000 scale obtained in group I was 94.79 ± 6.54 points. In group II, patients obtained an average of 94.81 ± 5.63 points over the same period since surgery (Fig. 12). A comparative analysis of the results of the functional assessment did not show a statistically significant difference between the examined groups (p = 0.98).

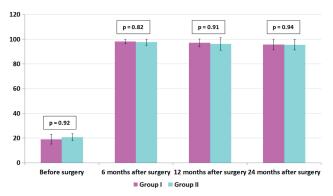


Fig. 11. Comparative analysis of the total number of points on the Lysholm scale obtained in group I (Neoligaments) and group II (FiberTape)

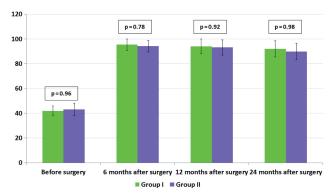


Fig. 12. Comparative analysis of the total number of points on the IKDC 2000 scale obtained in group I (Neoligaments) and group II (FiberTape)

Discussion

Numerous reports on ACL reconstruction draw different conclusions on the optimum term of surgical treatment, selection of graft and graft fixation approach, the way of preparing bone canals, or the choice of postoperative rehabilitation approach. ^{1,12,20,24} There are numerous advantages of using internal bracing techniques, and these are essential not only from the patient's perspective, but also from the perspective of a surgeon. ²⁵ Firstly, the period of rehabilitation is truncated, and it is possible to increase the range of motion in the operated knee joint at an early stage. ²⁰ It allows the maintenance of natural biomechanics and deep sensibility (contrary to reconstruction techniques with no correctly functioning proprioceptors in the autograft). ²⁶ The pain experienced is not so intense, and there are fewer undesirable symptoms in comparison with the augmentation approach.

Our analysis of stability assessment in the knee joint using Lachman, anterior drawer and pivot-shift tests showed proper stability of the operated knee joint, much like in other reported studies. ^{27,28} No difference was found between the 12- and 24-month assessment results under the abovementioned clinical conditions. The results of a subjective assessment carried out at 12 and 24 months after stabilizing the ACL using FiberTape were comparable to the results of the primary ACL reconstruction, as reported by other authors, ²⁹ based on the Lysholm and IKDC 2000 scales.

Similarly, good subjective postoperative results after primary ACL reconstruction, using both allografts and autografts, are presented by other authors. ^{30,31} Some authors report better results based on the Lysholm and IKDC 2000 scales in patients operated on using internal bracing. Many authors emphasize that time is one of the most important factors contributing to patients' return to full physical fitness and ability where training continuation is concerned. ³²

Surgery is the initial phase of treatment and most convalescence time is dedicated to rehabilitation. However, it is the surgical technique which determines the duration and course of rehabilitation. As for the internal bracing technique, the authors emphasize the opportunity of a quick recovery.³³

The promising results achieved show how the next generation of treatments will be utilized. In ligament diseases and discontinuity, a material is required that acts as a three-dimensional scaffold. Polytape is made of woven multifilament high-tenacity polyester fiber. The openweave structure acts as a matrix and leaves space for tissue ingrowth. The parallel fibers provide a high degree of strength. The mesh is made of pure polyethylene terephthalate (PET), without any additions. Its physical properties are as follows: tensile strength 55–75 MPa; elastic limit 50-150%; glass transition temperature 67-81°C, with a softening point of 265°C. It is lightweight, strong and impact-resistant, as well as hygroscopic (absorbing water from its surroundings). Years of experience with similar polymers provide reproducible results. The infection rate is very low and recurrence is rare. Hypersensitivity to implant materials occurs infrequently. For these reasons, the use of the tape in tendon and muscle injury seems to be

safe. There is no data suggesting heterotopic ossification or muscle fibrosis. ²²

The use of polytape in ACL ligament ruptures is also promising. The technique is similar to what has been described above, similarly reproducible and not difficult. In the future, polytape may be applied in the reconstruction of other tendons, i.e., in the biceps brachii tendon or the Achilles tendon.

A final, very important issue is the full cost of this implant. As is apparent, the implant is more expensive than autograft. However, if both tapes are compared, there is a monumental difference between Neoligaments and FiberTape (depending on the country). As similar results are obtained in both cases, we recommend FiberTape as a cheaper, yet equivalent method to Neoligaments. Following promising clinical results, the use of polytapes in ligament surgery is very likely to gain popularity. The main limitation of most studies, however, is that there is only short-term follow-up of recovery. 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.

At present, there are a multitude of studies being conducted that focus on emphasizing genetic predisposition to cruciate ligament injuries. The ACL "suture" techniques need additional testing and studies, and require a greater amount of scientific material. Research on the application of stem cells, scaffolds, plasma rich in platelets, and xenografts are also breaking into new territory. These present trends in the constant progression and evolution of ACL surgery will lead to a far more individualized method of operation and treatment.

Limitations

The main limitation of this study is the short-term follow-up. In the future, studies involving long-term follow-up with patients that have undergone anterior cruciate ligament reconstruction procedures and a comprehensive clinical and functional evaluation need to be taken into account. Additionally, the results should be referred to the control group, consisting of the patients after anterior cruciate ligament reconstruction using autogenous grafts.

Conclusions

Stabilizing the ACL using a synthetic graft with only partial damage enables the restoration of stability to the knee joint. The results of subjective assessment do not differentiate far from the functional assessment results. Comparing Neoligaments and FiberTape treatment shows the same functional and objective results; however, FiberTape is preferable from a price point of view.

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