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## Comparison of Bioabsorbable Interference Screws Composed of Poly-L-lactic Acid and Hydroxyapatite (PLLA-HA) to WasherLoc Tibial Fixation in Patients After Anterior Cruciate Ligament Reconstruction of the Knee Joint

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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.** The reconstruction of the anterior cruciate ligament (ACL) of the knee joint is a standard in ACL complete rupture treatment in athletes. One of the weakest points of this procedure is tibial fixation of grafts. **Objectives.** The aim was, firstly, to evaluate patients 3–4 years after primary ACL reconstruction with the use of autologous ipsilateral STGR grafts and with tibial fixation using a bioabsorbable interference screw composed of PLLA-HA or WasherLoc, comparing the postoperative result to the preoperative condition and, secondly, to compare the results between the two groups of patients with different tibial fixation.

**Material and Methods.** Group I consisted of 20 patients with a bioabsorbable interference screw composed of PLLA-HA tibial fixation. In Group II, there were 22 patients after ACL reconstruction with the use of WasherLoc tibial fixation. The Lachman test, pivot-shift test, Lysholm Knee Scoring Scale and 2000 International Knee Documentation Committee (2000 IKDC) Subjective Knee Evaluation Form were used to evaluate the results.

**Results.** The intra-group comparison of the results of the 2000 IKDC Subjective Knee Evaluation Form and Lysholm Knee Scoring Scale obtained in the groups studied showed statistically significant differences between the evaluation performed preoperatively and postoperatively. The inter-group comparison of the results of the 2000 IKDC Subjective Knee Evaluation Form and Lysholm Knee Scoring Scale obtained postoperatively showed no statistically significant differences between the two groups.

**Conclusions.** An evaluation 3–4 years after ACL reconstruction with the use of autologous ipsilateral STGR grafts demonstrated significant progress from the preoperative condition to the postoperative result in patients with tibial fixation using a bioabsorbable interference screw composed of PLLA-HA as well as in patients with WasherLoc tibial fixation. There were no differences found between the two groups of patients after ACL reconstruction in terms of manual stability testing or a subjective assessment of knee joint outcomes (**Polim. Med. 2016, 46, 1, 53–58**).

**Key words:** anterior cruciate ligament reconstruction, bone screws, orthopedic fixation devices.

The reconstruction of the anterior cruciate ligament (ACL) of the knee joint is a standard ACL complete rupture treatment for individuals who want to return to high-level activities [1] and is recommended in order to prevent instability of the knee, further intraarticular disease and recurrent injury [2–4]. The most commonly used grafts for reconstruction of the ruptured ACL

are autologous semitendinosus (ST) or combined ST and gracilis tendon (STGR) grafts or autologous central third patellar tendons with associated bone (BTB) [5, 6]. Even though both grafts show good results after ACL reconstruction and some authors suggest that graft selection should be based on an individual evaluation of patient demands, because of such potential advan-

tages as less donor site morbidity or greater overall graft strength in the case of a quadrupled graft, the ST and STGR grafts have recently become more popular grafts to be used [7–10]. Nevertheless, ST and STGR grafts, in contrast to BTB, are soft tissue grafts which are at higher risk of the slippage and loss of stability caused by slower healing and greater stress at the site of fixation [11], because of which the fixation within the tibia is considered the weakest link of the ACL reconstruction [12]. Polymer-ceramic composite materials made up of poly-L-lactic acid (PLLA) and hydroxyapatite (HA) granules have been introduced as materials with biomechanical properties that are more reliable and closer to the properties of metallic implants but are also bioabsorbable, biocompatible and osteoinductive [13], while the WasherLoc is a washer that, coupled with bone dowel, allows circumferential tendon-tunnel healing [14].

The goal of the present study was two-fold. Firstly, to evaluate patients 3–4 years after primary ACL reconstruction with the use of autologous ipsilateral STGR grafts and with tibial fixation using bioabsorbable interference screw composed of PLLA-HA or WasherLoc tibial fixation, comparing the postoperative results to the preoperative condition, and secondly, to compare the results between the two groups of patients with different tibial fixation.

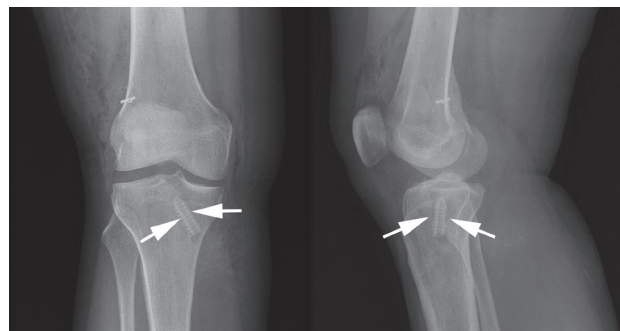
## Materials and Methods

The study was conducted according to the ethics guidelines and principles of the Declaration of Helsinki. Written informed consent forms were signed by all of the participants.

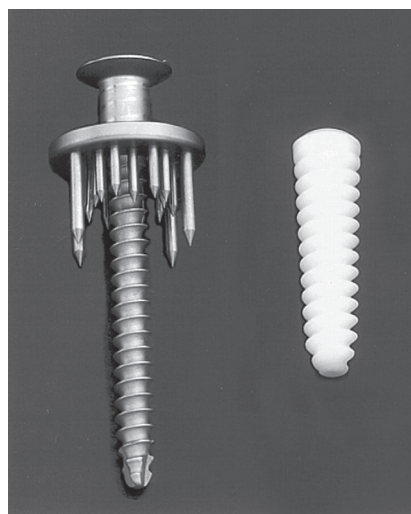
### Material

The studied material was comprised of 2 groups of participants after primary single-bundle ACL reconstruction with the use of autologous ipsilateral combined STGR grafts. Group I consisted of 20 patients (12 males, 8 females) with a bioabsorbable interference screw composed of PLLA-HA tibial fixation (Fig. 1, Fig. 2 right side). In Group II there were 22 patients (11 males, 11 females) after ACL reconstruction with the use of WasherLoc tibial fixation (Fig. 2 left side, Fig. 3). The two tibial fixations were done according to the manufacturer specifications.

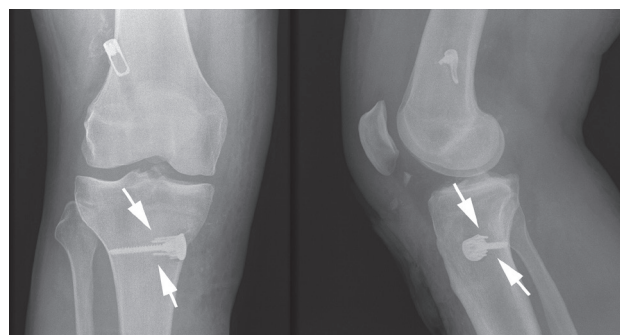
The initial sample was comprised of 56 patients after ACL reconstruction operated on by the same two surgeons in the years 2012 and 2013. Participants were recruited to the study on the inclusion criteria below and then divided into particular groups based on the tibial fixation method used in the reconstruction. The inclusion criteria were: primary unilateral intraarticular ACL reconstruction with the use of autologous ipsilateral STGR graft, no additional injuries of the involved knee joint between the surgery and the second measurement.



**Fig. 1.** X Ray (AP, lateral) of a right knee after ACL reconstruction with the use of bioabsorbable interference screw tibial fixation



**Fig. 2.** WasherLoc (on the left) and bioabsorbable screw (on the right) tibial fixations



**Fig. 3.** X Ray (AP, lateral) of a right knee after ACL reconstruction with the use of WasherLoc tibial fixation

Exclusion criteria were: revision ACL reconstruction, medial (MM) and/or lateral (ML) meniscal total/subtotal resection or transplant, contralateral graft or allograft used for the reconstruction, other than hamstring graft 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 or/and 4 according to ICRS, osteochondritis-dissecans lesions, additional injuries of the involved lower limb between the surgery and the second measurement.

The mean age difference between the two groups studied was statistically insignificant (Group I:  $31.25 \pm 11.96$  years, Group II:  $33.11 \pm 12.11$  years). In Group I, in 13 cases the operated knees were right and in 7, left. In Group II there were 12 right knees and 10 left operated on. The difference between the mean time of postoperative physiotherapy in both groups studied was statistically insignificant (Group I:  $12 \pm 03$  weeks. Group II:  $13 \pm 25$ ).

## Methods

All of the participants of the study underwent clinical evaluation two times. The first assessment in both groups studied was performed one day before the ACL reconstruction. The mean time between the ACL reconstruction and the second assessment was  $3.97 \pm 0.94$  years in Group I and  $3.82 \pm 0.80$  in Group II. The difference of that time between the groups was statistically insignificant. The participants were evaluated manually using a Lachman test and pivot-shift test, Lysholm Knee Scoring Scale and 2000 International Knee Documentation Committee (2000 IKDC) Subjective Knee Evaluation Form.

## Statistical Analysis

Statistical analysis was performed with the use of IBM SPSS Statistics 20. The mean value (x) and standard deviation (SD) of the Lysholm score and 2000 IK-

DC Subjective Knee Evaluation Form were calculated for each studied group. Data distributions were tested for normality with the use of the Shapiro-Wilk test [15]. For the intra-group comparison between the preoperative and postoperative evaluation, the Student's t-test was used and for the inter-group comparison, a parametric test for independent samples was used. Differences were considered significant if  $p < 0.05$ . The intra- and inter-group comparison of the results of manually anterior tibial translation testing was based on the incidence of inter-limb difference of more than 3 mm anterior tibial translation in the Lachman test and more than +glide result of the Pivot Shift test.

## Results

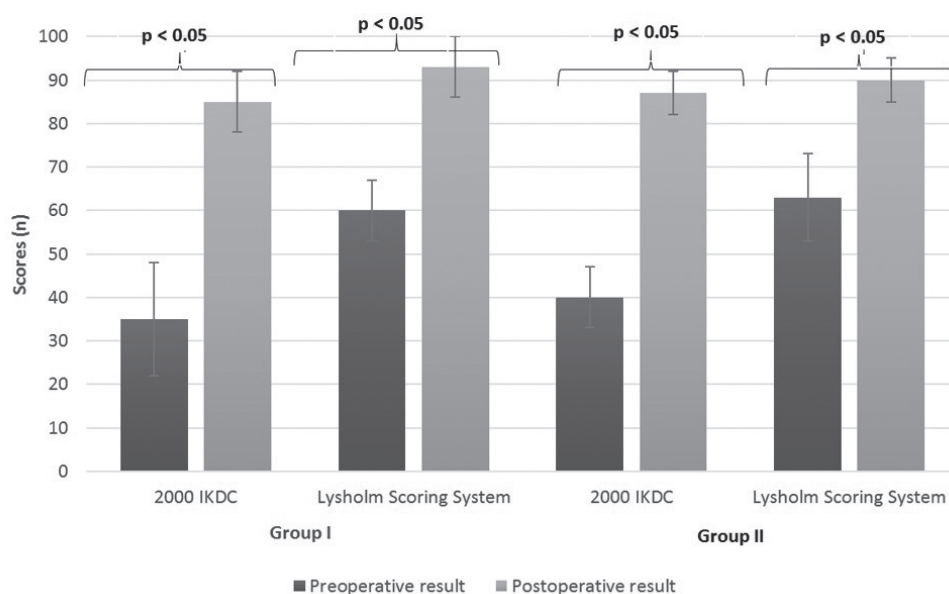
The intra- and inter-group comparison of the results of manually anterior tibial translation testing based on the incidence of inter-limb difference of more than 5 mm anterior tibial translation in the Lachman test and more than +glide result of the Pivot Shift test showed a difference between the preoperative and postoperative measurement, nevertheless it showed no differences between the studied groups (Table 1).

The intra-group comparison of the results of the 2000 IKDC Subjective Knee Evaluation Form and Lysholm Knee Scoring Scale obtained in the groups studied showed statistically significant differences between the evaluations performed preoperatively and postoperatively (Fig. 4).

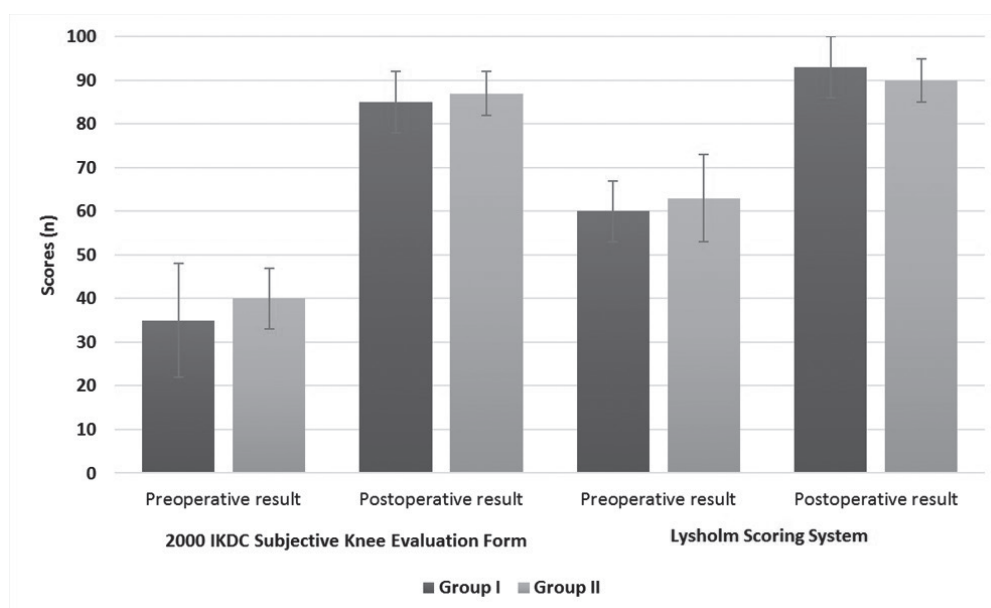
**Table 1.** Intra- and inter-group comparison of the incidence of inter-limb difference of more than 3 mm anterior tibial translation in Lachman test and more than +glide result of Pivot Shift test

	Lachman test (n)		Pivot Shift test (n)	
	preoperatively	postoperatively	preoperatively	postoperatively
Group I (n = 20)	20	4	20	4
Group II (n = 22)	22	5	22	4

n: number of individuals.



**Fig. 4.** Intra-group comparison of the results of 2000 IKDC Subjective Knee Evaluation Form and Lysholm Knee Scoring Scale obtained preoperatively and postoperatively



**Fig. 5.** Inter-group comparison of the results of 2000 IKDC Subjective Knee Evaluation Form and Lysholm Knee Scoring Scale obtained preoperatively and postoperatively

The inter-group comparison of the results of the 2000 IKDC Subjective Knee Evaluation Form and Lysholm Knee Scoring Scale obtained preoperatively and postoperatively showed no statistically significant differences between the two groups studied (Fig. 5).

## Discussion

At a minimum 3-year follow up, patients after ACL reconstruction using both types of the graft fixation methods relevant to this study showed significant progress from preoperative to postoperative assessment results. There were no differences found between the two groups of patients after ACL reconstruction in terms of manual stability testing or a subjective assessment of knee joint outcomes.

The clinical outcomes of ACL reconstruction are affected by such elements of the reconstruction technique as femoral tunnel positioning, type of graft used for the reconstruction and the method of graft fixation [16–18]. Femoral tunnel position may have a significance in better reproducibility of the native ACL anatomy [18] as the tunnel drilling technique has an influence on achieving a more anatomic femoral tunnel, nevertheless the outcomes still remain inconsistent [16]. The types of grafts used for the ACL reconstruction are also of interest [19].

Hamstring graft fixation in the ACL reconstruction is recognized as one of the factors influencing long-term ACL reconstruction success as the graft has to withstand force loading during the early stages of the physiotherapeutic procedure [20]. Thus graft fixation affects the stability and healing of the construct. Because of the facts that forces are in line with the tibial tunnel and the tibia metaphysis is characterized by lower bone densi-

ty in comparison to the femur, there is much concern about the strength of tibial fixation [11, 21].

Bioabsorbable interference (BioRCI) screws were first described by Lambert and Kurosaka et al. [22, 23]. According to an Ambrose and Clanton [24] review, the bioabsorbable implants provide strong fixation of the graft, the possibility of revision surgery, a low level of inflammatory response, a low incidence of adverse reactions and good biological incorporation of the graft into the tunnel. Nevertheless, they have some limitations in comparison to metallic implants, such as lower strength, higher cost and sometimes an undesired biological response. Polymer-ceramic composite materials composed of PLLA-HA are characterized by biomechanical properties that are more reliable and closer to the properties of metallic implants but are also bioabsorbable, biocompatible and osteoinductive [13], as one of the main HA features is providing a scaffold on which new bone is growing due to forming crystal deposits arranged in a cells' network subsequently colonized by osteoblasts [25]. After use of first-generation bioabsorbable PLLA implants, cyst formation and lack of osseous ingrowth have been noted [26].

The WasherLoc technique, introduced in 1997, is a multi-spiked washer with four long peripheral spikes and multiple shorter spikes. The long spikes engage the cortical bone while the shorter ones purchase the soft tissue graft. The WasherLoc is fixed in a counterbore recess of the tibia tunnel which, coupled with a bone dowel, allows circumferential tendon-tunnel healing, which then makes aggressive and brace-free postoperative physiotherapeutic procedures possible and affects the snugness of fit [14, 27]. The WasherLoc combined with bone dowel results in superior fixation properties (945 N strength, 565 N/mm stiffness and high resistance to slippage) [28].



According to Scannell et al. [29], comparing 4 tibial fixation devices, Intrafix as characterized by superior strength in tibial hamstring graft fixation, followed closely by WasherLoc. Interference screws, used as sole devices, demonstrated low load to failure, decreased stiffness and high residual displacement. The authors suggested that confounding factors that may affect the performance of the interference screws are the bone density of porcine tibia, length of the interference screw and location of screw placement [29]. The results of the study may have a crucial impact on early stages of the physiotherapeutic procedures, indicating the possibility of more aggressive procedures in the case of WasherLoc fixation [29].

The main limitations of the present study are lack of instrumented ligament examination, MRI follow up

which could help to assess the degradation, biological behavior and osteointegration process [13] of the fixation methods studied, and some objective functional assessment methods being used in a comprehensive evaluation of the patient after ACL reconstruction [30].

Evaluation 3–4 years after ACL reconstruction with the use of autologous ipsilateral STGR graft demonstrated significant progress from preoperative condition to postoperative result in patients with tibial fixation using bioabsorbable interference screws composed of PLLA-HA as well as in patients with WasherLoc tibial fixation.

There were no differences found between the two groups of patients after ACL reconstruction in terms of manual stability testing or a subjective assessment of knee joint outcomes.

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