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Prospective randomized clinical comparison of femoral transfixation versus bioscrew fixation in hamstring tendon ACL reconstruction—a preliminary report

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Abstract *Purpose*: The purpose of this study is to clinically evaluate hamstring tendon anterior cruciate ligament (ACL)-reconstruction using femoral fixation with bioresorbable interference screws and with a bioresorbable transfixation device. *Hypothesis*: The ACL-reconstruction using the transfixation device at the femoral side leads to less knee laxity and therefore to a better clinical outcome for the patient. *Type of study*: Prospective randomized clinical outcome study. *Methods*: From February 2002 to December 2002, a total of 68 patients with hamstring ACL reconstruction using a femoral fixation once with TransFix ($n = 38$; m:22 and f:16; median age = 28.5 range 15–47) and the second with bioscrew (BS) ($n = 30$; m:20, f:10; median age = 25.5 range 13–61) completed the follow-up period. Patients in each group got a clinical assessment at 3, 6, and 12 months after surgery. The measurement of anterior translation of the tibia has been performed using the Rolimeter® device. *Results*: No significant differences in the knee laxity testing using the Rolimeter device were seen between both groups and over time within these groups. Ninety percent of all patients had functionally normal or near normal International Knee Documentation Committee (IKDC) knee ligament ratings. The TF-group included 17 grade A, 19 grade B, and 2 grade C knees, and the BS-group had 12 grade A, 13 grade B, and 5 grade C knees. The IKDC rating, the OAK-score, the Tegner-activity-score, and the Lysholm-score did not show significant differences between the TF-group and the BS-group. *Conclusion*: We disproved our hypothesis that the transfixation technique leads to less laxity and therefore to a better clinical outcome when compared to the use of BS. The clinical results in this study clarified that this technique is an effective and safe method for femoral hamstring fixation in ACL-reconstruction. However, this technique revealed no advantage compared to the bioscrew fixation technique within the short-term follow-up.

Keywords Anterior cruciate ligament · Hamstrings · Transfix · Interference screw · Clinical outcome

Introduction

The reconstruction of the anterior cruciate ligament (ACL) with hamstring tendons can be performed using different femoral fixation methods. Biomechanical analysis of various fixation devices has shown that the use of extracortical fixation techniques results in a high ultimate failure strength but also clarified the low degree

of stiffness of this construct [2, 23]. Hoher et al. [16] have shown that this phenomenon may lead to a graft-tunnel motion of up to 3 mm during physiological loading. The so called ''Bungy-cord'' and ''windshield-wiper'' effects degrade the bone-tendon healing within the bone tunnel [25] and can lead to a possible tunnel enlargement [21]. The use of bioresorbable interference screws has the advantage of direct tendon-to-bone healing with acceptable initial biomechanical fixation strength [30, 31]. However, the micromotion between the graft and the interference screw within the tunnel during a cycle loading may lead to a slipping of the graft and result in a secondary lengthening and loosening of the graft [2, 13]. The use of a femoral biodegradable transversal fixation technique (TransFix–Arthrex®, Naples, USA) combines the characteristics of a high failure load [2], less loss of tension during repetitive loading cycles [2], and a fixation closer to the joint line [9].

The goal of this study is to evaluate the clinical outcomes using a transfixation technique in hamstring ACL reconstruction. Our hypothesis was that the ACL-reconstruction using the transfixation device at the femoral side would lead to less knee laxity and therefore to a better clinical outcome for the patient.

Methods

Anterior cruciate ligament reconstructions with hamstring tendons using two different fixation methods were performed from February 2002 to December 2002 in 106 consecutive patients. All operations were done by the same surgeon who had extensive experience in both procedures prior to the study period. 76 (72%) patients could be included in this study, fulfilling the inclusion criteria. The inclusion criteria were acute or chronic anterior instability of the knee joint. We also included patients with additional meniscal injuries and/or focal chondral lesions. The exclusion criteria were signs of infection, osteoarthritis, reduced general condition, prior reconstruction, and concomitant injury to the posterior cruciate ligament. These patients underwent a non-blinded randomization. The surgeon pulled a card indicating the fixation technique. 68 of the patients (89% of all randomized patients: TransFix: 38; bioscrew: 30) were available for the complete follow-up period of 12 months consisting of postoperative examination at 3, 6, and 12 months. Patients in the TransFix (TF)-group consisted of 22 men and 16 women. The median age was 28.5 years (range 15–47). The median age of the 20 men and ten women patients in the bioscrew (BS)-group was 25.5 years (range 13–61).

Surgical technique

After separation of the semitendinosus and gracilis tendons, the tendons were harvested with a tendon stripper (Arthrex). Both tendons were prepared using the four-strand method. All tendons were of sufficient length to make quadruple grafts. The femoral and tibial stumps of the torn ACL were removed to allow an anatomic insertion of the new ACL-graft. At the tibial site, a 2.4 mm K-wire was drilled at the correct site of the place of tibial attachment of the ACL using a tibial guide system (Arthrex). The guidewire was overdrilled with a 6 mm reamer and then dilated according to the maximum diameter of the graft. The femoral tunnel was performed as required by the selected fixation method.

TransFix technique

The femoral tunnel was drilled passing the tibial tunnel, with the knee flexed at a 70–90° angle. The insertion site was placed as close as possible to the posterior wall and the 11 o'clock position. After the insertion of a K-wire, a foot print was made using a burr, which was sized to match the graft. A 30-mm depth hole, 1–2 mm smaller than the graft in diameter, was drilled, followed by a dilatation up to the size of the graft. The TransFix guide sleeve was inserted through the tibial tunnel and the lateral pin insertion was prepared step-by-step. We used a bioresorbable TansFix® pin for the femoral fixation. After the final fixation at the tibial site, the harvested cancellous bone plug was inserted into the femoral tunnel using a specific implantation device. The knee was in maximum flexion.

Bioscrew technique

The femoral tunnel was drilled from the antero-medial portal with the knee flexed 130°. The tunnel drilling and dilatation was comparable to the technique described above. We used a 28 mm bioscrew (Arthrex) with the diameter matching the graft size.

The tibial fixation was performed using a bioresorbable deltascrew® (Arthrex), with the leg extended at 0°, and the graft under manual tension. The diameter of the screw was approximately 2 mm larger than the graft.

Postoperative rehabilitation care

The same postoperative rehabilitation protocol was used for patients in both treatment groups. Full weight bearing was allowed from the first day post surgery. In the phase immediately following surgery (days 1–4), continuous passive motion (CPM) was performed using a motorized CPM device. Analgesic treatment was applied if necessary in combination with local cooling and anti-inflammatory medication (non steroidal anti-inflammatory drugs). From the fifth day on, physical

therapy and the CPM device was used to obtain up to 90° flexion and full extension of the knee. Knee protection was provided by a knee brace (Artrocare CTS®, Ormed®, Freiburg, Germany) that was fitted and worn until 6 weeks post surgery without limitation of extension or flexion. More intensive physical therapy aimed at specific muscle development. It was initiated in the third week using muscle sequences and exercises in a closed muscle chain. Beginning at week 7, post-surgery coordination exercises were introduced to improve proprioception. Sports activity (e.g., running and open muscle chain exercise) was permitted after 12 weeks of rehabilitation. However, sports involving contact and/or pivot shifting were not allowed until 6 months post surgery [20].

Clinical assessment

Patients in each group were examined at 3, 6, and 12 months. At each post-operative examination, the following assessment instruments and measurements were used and acquired:

1. Overall International Knee Documentation Committee (IKDC) rating,
2. Lysholm knee scoring scale,
3. Tegner activity scale,
4. Lachmann and pivot-shift laxity test,
5. Measurement of anterior translation of the tibia with manual maximum force using the Rolimeter® device (Aircast®, Summit, NJ, USA) in comparison to the healthy knee with the knee joint at the 30° position, and
6. Range of motion measurement using a protractor.

All questions were answered by the patient without supervision. Two independent examiners, neither of them the operating surgeon, conducted the clinical examinations and patient consultations. Anterior laxity was measured three times by one examiner to determine the intra-reliability for this examiner regarding the current patient. Knee extension was evaluated by range of motion and was compared to the extension angle of the healthy knee.

Radiographs

Standardized radiographs of the knee were made in anterior–posterior views and in lateral views preoperatively, postoperatively, and at the follow-up examination at 12 months. If necessary, MRI of the knee was used for the diagnosis of associated injuries. Furthermore, if possible, an MRI was performed after the 12 months follow-up examination for control of the graft incorporation and tunnel placement.

The placement of the bone tunnels at the femoral site and at the tibial site was evaluated using different assessment techniques. At the femoral site (anterior–posterior view), we looked for the o'clock position according to the description by Sommer et al. [28]. Because of the difference between the left knee and the right knee, we used the right knee for the standard position, whereas the position of the left knee was flipped (i.e., 1:30 o'clock at the left knee approximately 10:30 o'clock for our analysis). The lateral view at the femoral site was evaluated by the femur 4-zone method described by Harner et al. [15]. A similar method was used for the lateral view at the tibial site. According to the suggestions in the literature, we tried to place the tunnels at the 10:30 o'clock position at the femoral anterior–posterior view, and for the lateral view in the fourth (most posterior) zone at the femoral site, and in the third zone at the tibial site. The impingement quotient was calculated using the method described by Staubli and Rauschning [29].

Statistical analysis

The data are presented by descriptive statistics (i.e., mean, standard deviation, median, and range). The ordinal variables (i.e., join laxity, range of motion, and pain level) were examined using the chi-square test. The nonparametric Mann–Whitney U test was used to assess variance in the performance scores used to identify possible differences between the two surgical procedures (OAK score, Lysholm score, Tegner score), and the nonparametric Wilcoxon test was used to evaluate differences over time. All significance tests were two-tailed, and statistical significance was set at 0.05.

Results

The demographic data in both groups did not show any difference. The concomitant injuries are listed in Table 1. We had no revision ACL reconstruction in this series. Two superficial infections but no deep infections occurred postoperatively. We have never seen a migration of the implants (bioscrews and the transfix-device), and therefore no hardware re-movement was necessary within the follow up.

The time for the ACL-reconstruction procedures, the TF (80 min.; range 38–150) and BS (80 min; range 43–125) did not differ ($p = 0.8$). Also, the postoperative hospitalization time did not show significant differences ($p = 0.5$) between both groups (TF-group: 8 days, range 6–13; BS-group: 7.5 days, range 5–11).

Table 1 Demographic data of both treatment groups

		TransFix				Bioscrew			
Age		28,5 years (15-47)				25,5 years (13-61)			
Female (n)		16				10			
Male (n)		22				20			
Meniscal injuries (n)		16 (3 x refixed, 13 x resected)				13 (2 x refixed, 11 x resected)			
Chondral lesions	grade:	1	2	3	4	1	2	3	4
	n:	0	4	2	2	2	2	1	3
Graft size		7,7 mm (sd=0,6)				7,7 mm (sd=0,7)			
Pre-injury Sport level		Professional:		6		Professional:		6	
		Amateur:		16		Amateur:		10	
		No organization:		16		No organization:		14	

Knee joint laxity

During the clinical laxity examination conducted 12 months after the surgery, four patients in each group showed a positive result for the pivot-shifting phenomenon. At this time, 90% of all patients had functionally normal or near normal IKDC knee ligament ratings. The TF-group included 17 grade A, 19 grade B, and 2 grade C knees, and the BS-group had 12 grade A, 13 grade B, and 5 grade C knees. No significant difference in the knee laxity testing using the Rolimeter device was seen between the two groups (Table 2).

Tunnel placement

The femoral tunnel placement following ACL-reconstruction revealed no significant differences between the TF-group and the BS-group (Table 3). However, the femoral tunnels of the TF-group tend to be closer to the 12 o'clock position (in a.p.—view) when compared to the femoral tunnels of the BS-group. The tunnels in the BS-group are closer to the 11 (or 13) o'clock position. The evaluation of the postoperative radiographs with a following calculation regarding the impingement quotient for the ACL-graft [17] was positive for four knees in the TF-group and for seven knees in the BS-group. But the chi-square test revealed no significant ($p = 0.14$) differences between these groups. A correlation between the impingement quotient and knee laxity or between impingement quotient and extension deficit was not detected.

Table 2 Values of the laxity test using the Rolimeter

Follow up	Rolimeter	TF group	BS group
3 months	Contralateral side	6.7 ± 1.9 mm	6.8 ± 2.3 mm
	Operated side	$7{,}1 \pm 1.7$ mm	7.8 ± 2.5 mm
	Difference	0.4 ± 2.2 mm	0.9 ± 2.3 mm
	p	0.36	
6 months	Contralateral side	6.4 ± 2.1 mm	7.1 ± 2.3 mm
	Operated side	7.3 ± 1.7 mm	7.6 ± 1.7 mm
	Difference	0.9 ± 2.5 mm	0.5 ± 2.4 mm
	p	0.76	
12 months	Contralateral side	6.5 ± 2.1 mm	7.1 ± 2.3 mm
	Operated side	7.3 ± 1.6 mm	7.6 ± 1.7 mm
	Difference	0.8 ± 2.1	1.2 ± 2.8 mm
	p	0.14	

Thigh muscle and range of motion

Between 3 and 12-months postoperative, there was a clear improvement in knee joint mobility in both groups (Table 4). No significant differences were measured between these groups during the 3, 6, and 12 months postoperative examination. Four patients in the TF-group had an extension deficit in the repaired knee (relative to the healthy knee) at the end of the follow up and two patients in the BS-group. A deficit in flexion ($< 120°$) was seen in 13 patients in the TF-group and in six patients in the BS-group after 12 months. The side-to-side difference of the thigh muscle circumference was in the TF-group: 1.5 cm (0–6) at 3 months, 1 cm (0–4) at 6 months, and 1 cm (0–4) at 12 months. The difference in the BS-group was: 2 cm (0–5) at 3 months, 1 cm (0–3) at 6 months, and 1 cm (0–2.5) at 12 months. No significant differences were calculated at 3 ($p = 0.80$), 6 ($p = 0.69$), and 12 months ($p = 0.45$) between these two

Table 3 Tunnel placement at the femoral site and at the tibial site measured using the *x*-rays

	Femoral zone (a.p. view) [28]	Femoral zone (lateral view) [15]				Tibial zone (lateral view) [15]				Impingement quotient [29]
	O'clock position	4	3	2	1	4	3	2	1	%
TF-group	11:40 (±30 min)	32	6	0	0	0	36	2	0	43 (SD = 3.0)
BS-group	11:10 (±30 min)	24	6	0	0	0	27	3	0	44 (SD = 4.0)
p	0.22	0.90				0.37				0.26

groups. However, only nine patients in the TF-group and five patients in the BS-group reached the same size of muscle on the operated side compared to the non-operated side (Table 5).

Qualitative evaluation

The IKDC rating did not show significant differences ($p = 0.3$) between the TF-group and the BS-group. 76% of the knees in the TF-group and 73% of the knees in the BS-group had normal or near normal function after 12 months (Table 6). Average OAK-scores were calculated at each follow-up examination and revealed no differences between both fixation techniques during the follow up (Fig. 1). Also the pain profile, deduced from the OAK-score, was low and did not show differences at 3 months ($p = 0.85$), 6 months ($p = 0.30$), or 12 months ($p = 0.89$). The Lysholm score demonstrated similar results (Fig. 2) with no significant differences at all time points (3 months: $p = 0.90$; 6 months: $p = 0.20$; and 12 months: $p = 0.09$). The degree of activity was determined using the Tegner activity scale (maximum score = 10 points). No significant differences between the two treatment groups were found preoperatively at 3 months ($p = 0.93$), 6 months ($p = 0.53$), or 12 months ($p = 0.74$) post surgery. However, there was a significant ($p < 0.05$) decrease in the activity scores within both groups found during each follow-up examination (Fig. 3), while the level of sport activity prior to the accident was similar in both treatment groups (Table 1), only 63% of the patients in the TF group could regain similar level of sport activity as compared to the preinjury level after 12 months, whereas 83% of the patients in the BS-group were able to participate at the same sport level compared to the preinjury level (Table 6). The p value was 0.06.

Table 4 Range of motion during 3, 6, and 12 months postoperative examination

Follow up		TF group	BS group	*p*
3 months	Extension deficit	4 ± 2.9	6 ± 3.4	0.35
	Flexion deficit	12 ± 8.3	10 ± 7.9	0.1
6 months	Extension deficit	2 ± 3.0	3 ± 3.2	0.67
	Flexion deficit	7 ± 7.4	7 ± 6.4	0.59
12 months	Extension deficit	2 ± 2.9	1 ± 2.8	0.22
	Flexion deficit	5 ± 6.2	4 ± 4.9	0.55

Discussion

Our results have shown that the use of the transfixation technique at the femoral site has not led to significant differences in clinical outcome when compared to the use of bioscrews. The parameters for laxity, the IKDC-score, the OAK-score, the Lysholm-score, and the Tegner activity score were similar between both groups and comparable with the results in the literature. The fixation devices, the bioscrew and the TransFix devices, as well, have shown a low complication rate.

The interference screw fixation of a quadrupled hamstring graft results in a low linear stiffness, which may result at submaximal loads in fixation failure [1]. The micromotion between graft and screw during repetitive loading in the early postoperative phase may lead to elongation of the graft, slippage, and secondary graft loosening [13]. Recent biomechanical analysis [2, 6]

Table 5 IKDC-rating score during the 3, 6, and 12 months postoperative examination

Follow up	IKDC—scoring	TF group (*n*)	BS group (*n*)	Significance
3 months	A	0	0	$p = 0.43$
	B	12	7	
	C	21	21	
	D	5	2	
6 months	A	0	0	$p = 0.42$
	B	26	18	
	C	9	11	
	D	3	1	
12 months	A	7	7	$p = 0.70$
	B	22	15	
	C	8	8	
	D	1	0	

Table 6 Sport level after 12 months compared to the sport level before torn the ACL ($p = 0.06$)

	TF	BS
Similar sport level	24 (63%)	25 (83%)
Lower sport level	14 (37%)	5 (17%)

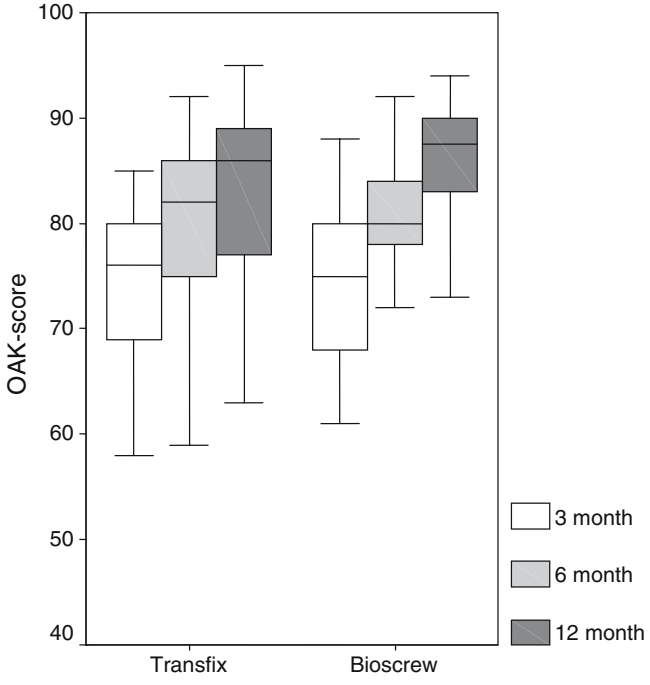

Fig. 1 OAK-score

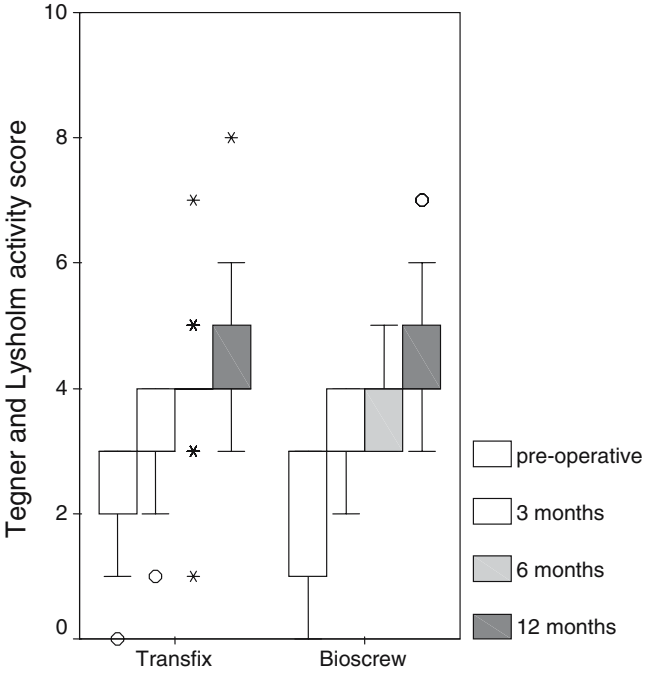

Fig. 3 Tegner and Lysholm activity score

have shown that the transfix device provides less laxity but greater stiffness and pull-out strength when compared to bioscrews. With this in mind, we expected a stiffer construct and a more stable knee using the transfixation technique. In the present study, we used the Rolimeter device to quantify posterior–anterior translation. This device is easy to use and is comparable to the KT arthrometer in terms of diagnostic specificity and sensitivity [5, 12]. We found that the laxity during the first 12 months postoperative was similar between both fixation techniques, thus disproving our hypothesis. First, the anterior translation of the tibia showed no differences during the follow-up examination at 3, 6, and 12 months between both groups. Second, the translation of the tibia did not significantly increase between 3 and 12 months in either group. It seems that the so-called slippage of the graft by using bioscrews cannot be confirmed by our methods in clinical practice. We were not able to prove that the graft became loose during the period between the transplantation and the first follow-up examination after 3 months. However, the comparable values of the tibia translation between both groups reveal no advantage for one fixation technique over the other regarding the laxity.

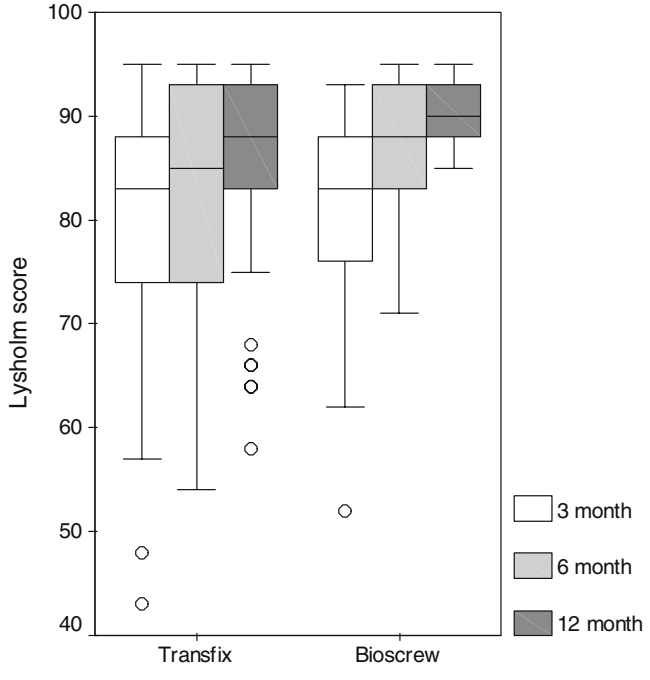

Fig. 2 Lysholm score

The ideal drill tunnel position from the lateral view is the zone IV (posterior quarter) of the femur and at 42% of the tibia plateau [15]. The correct position for the femoral insertion point in the anterior–posterior view is recently described at the 10:30 o'clock position for the right knee (at 1:30 o'clock position for the left knee) to reach best stability for the anterior–posterior translation as well as for the internal rotation [22]. We used the method of transtibial drilling for placement of the femoral insertion point. This method bears the risk of a high

placement of the femoral tunnel in the intercondylar notch, thus failing to replicate important portions of the ACL [11]. The fact that a graft placement lower than 11 o'clock is more effective when compared to the placement higher than 11 o'clock, especially for rotatory loads, should advocate the bioscrew with more placement varieties. In our study, the femoral tunnel was consistently closer to 12 o'clock when using the transfix device compared to the bioscrew. The difference between both groups was not significant, but in this series we tried to place the tunnel at 11 o'clock. With this in mind, we were unable to reach this target when using the transfix technique, but we reached the target for placement of the graft, close to 11 o'clock, when using the bioscrew. Different mechanical boundary conditions between both groups may exist due to the more lateral position of the graft. Thus, the femoral fixation was not the only difference between both treatment groups.

Recent studies favour a more lateral placement (10:30 o'clock) of the femoral insertion point of the ACL [4, 22], which is hard to perform when drilling through the tibial tunnel. A modified technique, drilling the femoral tunnel through the anteromedial portal in 120–130° of knee flexion to choose the ideal femoral insertion point of the graft, could avoid making compromises in the tibial or femoral tunnel placement [11]. The tunnel placement for the lateral view at the femoral site and at the tibial site is well standardized [15]. The placement of the tunnels was acceptable in all cases in both fixation techniques. In 12 cases, the radiographic impingement sign [29] was positive whereas the examination during the surgical procedure never confirmed this finding and no graft loosening was seen in these cases during the follow up. Furthermore, there was no correlation between a limitation of range of motion and a positive impingement sign.

We know from our previous study that the use of hamstring tendons for ACL-repair leads to a decreased range of motion in the early postoperative rehabilitation period when compared to the use of bone-tendon-bone grafts. We hypothesized that harvesting the semitendinosus-gracilis tendon may have impacted the function of the lower extremity (particularly the flexion) more severely than harvesting the ligamentum patellae. Furthermore, multiple tendon harvest may affect the range of active knee flexion [24]. In this series we confirmed these findings since the range of motion was more reduced by using the transfixation technique, even after 12 months. We hypothesize that the lateral insertion technique of the transfix hardware, in which the ileotibial tract is affected, could lead to a dysfunction of the extensor muscles, causing reduced range of motion.

Before discussing the clinical results, we should prove whether the two groups are comparable in age, gender, concomitant injuries (meniscal and chondral lesions including the therapeutic procedure), preoperative sport level, and the graft size. As seen in Table 1, there is no difference in the criteria from one group to the other. Therefore, the BS-group and the TF-group are appropriate for comparing the postoperative results.

There was a high rate for returning to a similar or higher preoperative sport activity level after 12 months follow up. This is in common with the study by Smith et al. [27], where a similar result was achieved in competitive athletics. We assume that the high motivation, the generally good constitution, and the accelerated rehabilitation schedule are responsible for this satisfactory result in patients following ACL-reconstruction. However, patients undergoing a graft fixation with a bioscrew showed an increased ability to return to their pre-operative sport level. Coherence between the irritation of the extensor muscles due the transfix device, the following reduced range of motion, and the lower sport level after ACL-reconstruction should be discussed.

Despite the good functional results, only every fifth patient reached the same muscle volume of the reconstructed site comparing to the healthy site, with no differences between both groups after 12 months. The muscle performance will improve over time, improving faster when using hamstring tendons as using bone-tendon-bone grafts, but may not even reach the same degree of strength present on the healthy side [19]. We know from previous studies [3] that thigh circumference underestimates atrophy and is not correlated with cross-sectional thigh muscle area by MRI or strength in operated extremities. A recent study [8] has shown that the marked reduced muscle strength is not caused by the ACL rupture itself but is caused by ACL reconstruction [18]. Furthermore, the loss of knee flexor strength following the harvest of the hamstring tendons may be more significant than has been previously estimated [24]. However, the pathophysiology causing the decrease in thigh muscle size and quadriceps femoris strength, followed by ACL reconstruction, is still unclear and remains an unsolved problem.

Total assessment scores have been demonstrated to be useful in creating a common basis for comparing individual surgical outcomes [7]. The OAK-score, the Lysholm-score, and the IKDC-score are well-accepted criteria for evaluating the knee function following ACL-reconstruction.

Overall, the results in this study regarding these assessment scores revealed a satisfactory result and are comparable to the findings in the literature [10, 23, 26]. Despite the slight differences of the range of motion and the ability to regain the sport level, no differences between both treatment groups could be achieved. It seems that the minimal differences of knee function do not affect the daily living of the patient.

The limitation of this study is the relative short-term follow up. However, the final laxity of the graft can be

assessed after 12 months when the osseous integration is completed. Furthermore, we do believe that differences between the fixation methods would be expected at the early follow-up examination because of the use of the similar graft. Since no clinical differences were present at the early follow-up examination, no differences would be expected later on. Also the slight differences in the patient's ability to regain their previous level of athletics will probably not increase at a later time point.

The technical procedure for both fixation techniques is demanding and the skill of the surgeon will increase with experience. The ACL-reconstruction in this study was performed by one surgeon who was familiarised with both surgical techniques. However, the surgeon reported a higher "failure" rate (e.g., missing the proximal hole of the femoral guide, sling-rupture of the guide wire) and a lower learning curve by using the transfixation technique. This was probably caused by a higher number of surgical steps which are needed to place the femoral transfixation device compared to the fixation using the bioscrew. Finally, in this study, all cases of the femoral fixation were successful and no switching of the fixation method was necessary. Furthermore, the complication rate in both fixation techniques was very low. We had no migration problems of the bioresorbable TransFix device, in contrast when using titanium TransFix technique, as reported in the study by Harilainen et al. [14].

In conclusion, this is the first prospective randomized clinical outcome study about the bioresorbable transfixation technique for ACL-reconstruction using hamstrings. We disproved our hypothesis that the ACL-reconstruction using the transfixation device at the femoral side leads to less knee laxity and therefore to a better clinical outcome for the patient. The clinical results in this study clarified that this technique is an effective and safe method for femoral hamstring fixation in ACL-reconstruction. However, further studies are needed to confirm these findings during a longer follow up.

Reference

1. Adam F, Pape D, Steimer O, Kohn D, Rupp S (2001) Biomechanical properties of interference screw implantation in replacement of the anterior cruciate ligament with patellar and hamstring transplants. An experimental study using roentgen stereometry analysis (RSA). Orthopade 30:649–657
2. Ahmad C, Gardner T, Groh M, Arnouk J, Levine W (2004) Mechanical properties of soft tissue femoral fixation devices for anterior cruciate ligament reconstruction (in process citation). Am J Sports Med 32:635–640
3. Arangio GA, Chen C, Kalady M, Reed JF III (1997) Thigh muscle size and strength after anterior cruciate ligament reconstruction and rehabilitation. J Orthop Sports Phys Ther 26:238–243
4. Arnold MP, Kooloos J, van Kampen A (2001) Single-incision technique misses the anatomical femoral anterior cruciate ligament insertion: a cadaver study. Knee Surg Sports Traumatol Arthrosc 9:194–199
5. Balasch H, Schiller M, Friebel H, Hoffmann F (1999) Evaluation of anterior knee joint instability with the Rolimeter. A test in comparison with manual assessment and measuring with the KT-1000 arthrometer [see comments]. Knee Surg Sports Traumatol Arthrosc 7:204–208
6. Becker R, Voigt D, Starke C, Heymann M, Wilson GA, Nebelung W (2001) Biomechanical properties of quadruple tendon and patellar tendon femoral fixation techniques. Knee Surg Sports Traumatol Arthrosc 9:337–342
7. Breitfuss H, Frohlich R, Povacz P, Resch H, Wicker A (1996) The tendon defect after anterior cruciate ligament reconstruction using the midthird patellar tendon—a problem for the patellofemoral joint? Knee Surg Sports Traumatol Arthrosc 3:194–198
8. Chmielewski TL, Stackhouse S, Axe MJ, Snyder-Mackler L (2004) A prospective analysis of incidence and severity of quadriceps inhibition in a consecutive sample of 100 patients with complete acute anterior cruciate ligament rupture. J Orthop Res 22:925–930
9. Clark R, Olsen RE, Larson BJ, Goble EM, Farrer RP (1998) Cross-pin femoral fixation: a new technique for hamstring anterior cruciate ligament reconstruction of the knee. Arthroscopy 14:258–267
10. Corry IS, Webb JM, Clingeleffer AJ, Pinczewski LA (1999) Arthroscopic reconstruction of the anterior cruciate ligament. A comparison of patellar tendon autograft and four-strand hamstring tendon autograft. Am J Sports Med 27:444–454
11. Galla M, Uffmann J, Lobenhoffer P (2004) Femoral fixation of hamstring tendon autografts using the TransFix device with additional bone grafting in an anteromedial portal technique. Arch Orthop Trauma Surg 124:281–284
12. Ganko A, Engebretsen L, Ozer H (2000) The rolimeter: a new arthrometer compared with the KT-1000. Knee Surg Sports Traumatol Arthrosc 8:36–39
13. Giurea M, Zorilla P, Amis A, Aichroth P (1999) Comparative pull-out and cyclic-loading strength tests of anchorage of hamstring tendon grafts in anterior cruciate ligament reconstruction. Am J Sports Med 27:621–625
14. Harilainen A, Sandelin J, Jansson KA (2005) Cross-pin femoral fixation versus metal interference screw fixation in anterior cruciate ligament reconstruction with hamstring tendons: results of a controlled prospective randomized study with 2-year follow-up. Arthroscopy 21:25–33
15. Harner CD, Marks PH, Fu FH, Irrgang JJ, Silby MB, Mengato R (1994) Anterior cruciate ligament reconstruction: endoscopic versus two-incision technique. Arthroscopy 10:502–512
16. Hoher J, Livesay G, Ma C, Withrow J, Fu F, Woo S (1999) Hamstring graft motion in the femoral bone tunnel when using titanium button/polyester tape fixation. Knee Surg Sports Traumatol Arthrosc 7:215–219
17. Jager A (1998) Impingement Index: a new calculation tool to predict an intercondylar notchimpingement after anterior cruciate ligament reconstruction in knee flexion. Orthop Res Soc 23:1114
18. Keays SL, Bullock-Saxton J, Keays AC, Newcombe P (2001) Muscle strength and function before and after anterior cruciate ligament reconstruction using semitendonosus and gracilis. Knee 8:229–234

19. Kobayashi A, Higuchi H, Terauchi M, Kobayashi F, Kimura M, Takagishi K (2004) Muscle performance after anterior cruciate ligament reconstruction. Int Orthop 28:48–51
20. Kvist J (2004) Rehabilitation following anterior cruciate ligament injury: current recommendations for sports participation. Sports Med 34:269–280
21. L'Insalata J, Klatt B, Fu F, Harner C (1997) Tunnel expansion following anterior cruciate ligament reconstruction: a comparison of hamstring and patellar tendon autografts. Knee Surg Sports Traumatol Arthrosc 5:234–238
22. Loh JC, Fukuda Y, Tsuda E, Steadman RJ, Fu FH, Woo SL (2003) Knee stability and graft function following anterior cruciate ligament reconstruction: Comparison between 11 o'clock and 10 o'clock femoral tunnel placement. Arthroscopy 19:297–304
23. Ma C, Francis K, Towers J, Irrgang J, Fu F, Harner C (2004) Hamstring anterior cruciate ligament reconstruction: a comparison of bioabsorbable interference screw and endobutton-post fixation. Arthroscopy 20:122–128
24. Nakamura N, Horibe S, Sasaki S, Kitaguchi T, Tagami M, Mitsuoka T, Toritsuka Y, Hamada M, Shino K (2002) Evaluation of active knee flexion and hamstring strength after anterior cruciate ligament reconstruction using hamstring tendons. Arthroscopy 18:598–602
25. Nebelung W, Becker R, Urbach D, Ropke M, Roessner A (2003) Histological findings of tendon-bone healing following anterior cruciate ligament reconstruction with hamstring grafts. Arch Orthop Trauma Surg 123:158–163
26. Rose T, Engel T, Bernhard J, Hepp P, Josten C, Lill H (2004) Differences in the rehabilitation period following two methods of anterior cruciate ligament replacement: semitendinosus/gracilis tendon vs. ligamentum patellae. Knee Surg Sports Traumatol Arthrosc 12:189–197
27. Smith FW, Rosenlund EA, Aune AK, MacLean JA, Hillis SW (2004) Subjective functional assessments and the return to competitive sport after anterior cruciate ligament reconstruction. Br J Sports Med 38:279–284
28. Sommer C, Friederich NF, Muller W (2000) Improperly placed anterior cruciate ligament grafts: correlation between radiological parameters and clinical results. Knee Surg Sports Traumatol Arthrosc 8:207–213
29. Staubli HU, Rauschning W (1994) Tibial attachment area of the anterior cruciate ligament in the extended knee position. Anatomy and cryosections in vitro complemented by magnetic resonance arthrography in vivo. Knee Surg Sports Traumatol Arthrosc 2:138–146
30. Weiler A, Hoffmann R, Bail H, Rehm O, Sudkamp N (2002) Tendon healing in a bone tunnel. Part II: histologic analysis after biodegradable interference fit fixation in a model of anterior cruciate ligament reconstruction in sheep. Arthroscopy 18:124–135
31. Weiler A, Peine R, Pashmineh-Azar A, Abel C, Sudkamp N, Hoffmann R (2002) Tendon healing in a bone tunnel. Part I: biomechanical results after biodegradable interference fit fixation in a model of anterior cruciate ligament reconstruction in sheep. Arthroscopy 18:113–123