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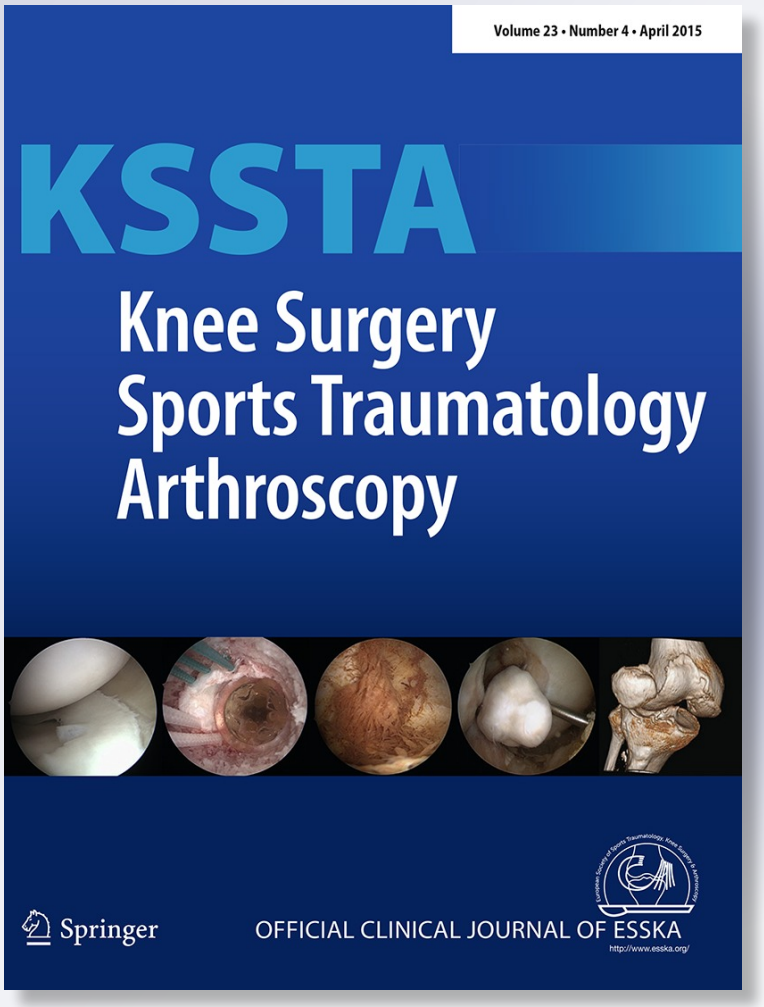

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Role of gracilis harvesting in four-strand hamstring tendon anterior cruciate ligament reconstruction: a double-blinded prospective randomized clinical trial

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Abstract
Purpose Weakness in knee flexion following anterior cruciate ligament (ACL) reconstruction is one of the key issues in the treatment of an ACL tear. The purpose of this study was to examine and compare clinical outcome measures of ACL reconstruction using semitendinosus autograft (ST) versus semitendinosus + gracilis (ST/G) reconstructive techniques.
Methods In a double-blind randomized clinical study, 19 patients with an ACL tear underwent either ST (59) or ST/G (61) and observed for 1 year. Both patients and the final examiner were unaware as to the type of graft received. Patients were evaluated according to subjective criteria, functional assessment tests, knee isometric torques, knee laxity using KT-2000 and knee range of motion.
Results The study included 21 (17.6 %) female and 99 (82.4 %) male patients with a mean age of 29.9 ± 7.8 in the ST group and 32.4 ± 6.3 in the ST/G group. There were no significant differences found in surgical complications; IKD; Knee injury and Osteoarthritis Outcome Score; Lysholm; strength of the knee isometric flexors; and flexion and extension loss between the two groups. At the final visit, 86.9 % of ST group and 89.6 % of ST/G group had side-to-side difference of laxity <3 mm (n.s.).
Conclusions Since anterior cruciate ligament reconstruction using quadrupled ST is more technically demanding than doubled STG and with there being no difference in outcomes and complications, no compulsory advice should be made on the former technique. However, gracilis harvesting may not be necessary based on the function and strength of the knee.
Level of evidence Randomized controlled trial, Level I.

Keywords Anterior cruciate ligament reconstruction · Semitendinosus tendon · Gracilis tendon · Hamstring tendon · Functional outcome

Introduction

The purpose of conducting an anterior cruciate ligament reconstruction (ACLR) is to provide function and stability to the knee and to return the patient to the pre-injury level of activity. The more frequently used ACLR techniques are those using bone–patellar tendon–bone (BPTB) and hamstring tendon (HT) autografts [4, 12, 14]. Subjective evaluation, objective function test and stability of the knee in short-term and long-term post-operative periods have shown no considerable differences between the two autograft techniques [5, 17, 20].

One drawback of using the HT technique as compared to the allograft technique is the considerable decrease in knee flexion and tibial rotation strength due to the harvesting of both hamstring tendons [10]. Thus, the importance of harvesting gracilis tendons in ACLR has been questioned in many research studies shedding light on the debate about the role of the gracilis tendon in HT technique [2, 7, 11, 19]. Previous studies indicate that harvesting the gracilis tendon autograft is not only ineffective in the motor control and stability of the knee, but also inefficacious regarding the kinetic muscle torque

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involved in knee flexion [7, 19]. However, the long-term follow-up studies indicate that the strength is gradually recovered [11]. Some research studies, using subjective and functional evaluations, have demonstrated no significant differences between harvesting semitendinosus tendon and semitendinosus and gracilis [1, 2].

The purpose of the present study was to examine and compare the results of the ACLR using only semitendinosus autograft (ST) and the combined use of semitendinosus and gracilis (ST/G). The null hypothesis was that there are no significant differences between the clinical and functional outcomes of the two techniques.

Materials and methods

All the patients had suffered an ACL tear at least 1.5 months prior to the study and gave informed consent prior to enrolment. The exclusion criteria were as follows: previous history of knee surgery (excluding diagnostic arthroscopy); injury to the contralateral lower limb; associated ligament or meniscus injury; chondral lesions grade III–IV according to International Cartilage Repair Society criteria [8]; abnormal knee radiographs; and symptomatic hip and/or ankle.

From March 2011 to March 2012, two hundred and fifty-seven patients underwent ACLR using hamstring tendons. The patients were assigned into either the ST or the ST/G groups using the random blocks method. While blinded to the study design, all the patients were briefed about the pros and cons of both surgical techniques and signed the consent form prior to enrolment. Out of 257 patients, 129 fulfilled the inclusion criteria, of whom, 10 were lost to follow-up. The remaining 119 patients (56 in ST group and 61 in ST/G group) were followed up postoperatively for 1 year until March 2013. All ACLR surgeries, patients' enrolment and randomization were made by the senior author (MMK) (Fig. 1).

All the patients were subjectively evaluated pre-operation and additionally 1 year after surgery observing the level of sport activity, Knee injury and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee Score (IKDC) and Lysholm Score. The objective evaluations included assessment of knee sensory changes; measurement of range of motion (ROM); kneeling pain; pain and sensation over the donor site; palpation for crepitus; knee laxity; and the isometric strength of the hamstring muscles which were evaluated at the final visit. ROM of the knee (flexion and extension loss) was measured using a universal goniometer and compared to the

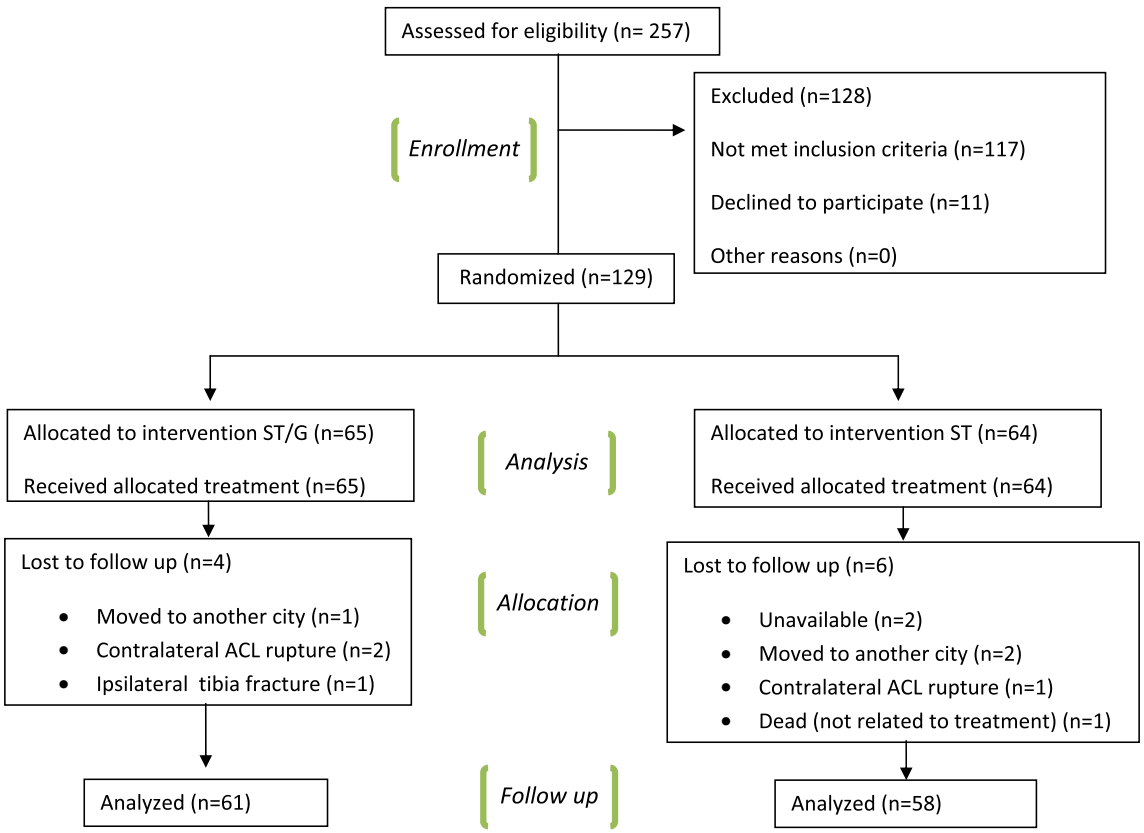

Fig. 1 Patients flow diagram

contralateral knee. Knee laxity for both healthy and injured knees was measured with a *KT-2000* arthrometer in millimetres (MedMetric, San Diego, CA), and the side-to-side difference was recorded. To measure the isometric strength of the hamstring muscle, thepatients were asked to warm-up for 10 min on a stationary exercise bicycle. While in prone position with knee at 90° flexion, varying hamstring movements' (flexion, abduction, extension and adduction) torque were measured in Newton-metres (Nm) with a digital manual dynamometer *MicroFet2* (Hoggan Health, Salt Lake City, UT, USA), in which reliability and validity have been confirmed in a previous study [13], and were compared to the contralateral healthy limb in percentages. Both subjective and objective outcomes were obtained by two other orthopaedists (MKM and AM) with at least 10 years' of experience, both of which were blind to the treatment method.

Knee laxity according to KT-2000 data was assumed to be the primary outcome, and other subjective and clinical findings were considered the secondary outcomes.

Surgical techniques

An anteromedial 2-cm incision was made on the tibia. Subperiosteal area over the tendon insertion was dissected to tendon insertion point on tibial crest to ensure maximum graft length. The tendon was relegated to its maximum length and then stripped of the muscle and measured. Doubled gracilis and semitendinosus tendons in ST/G group and quadrupled semitendinosus in ST group were sutured at the ends using a Krackow suture with #5 Ethibond suture, and its diameter was measured. At first, arthroscopic notch plasty and synovectomy were performed. Tibial and femoral tunnels were reamed using anteromedial portal technique as described previously [14]. Femoral and tibial sides were fixated using *Cortico Femoral Ancrage* and *MISBIO*® bio-absorbable interference screw (both Orthomed, St Jeannet, France), respectively.

Post-operative rehabilitation

A supervised invasive rehabilitation programme was administered for all the patients immediately following the surgery, lasting 4 months and based on early passive ROM and weight bearing. Active quadriceps exercise and passive 90°-knee flexion were encouraged at the first post-operative day. All patients were encouraged to walk while bearing partial weight from the second week post-operatively. Patients were authorized to walk without the brace after 3 weeks. One month after surgery, patients were permitted to fully flex their knees and if tolerated, complete weight bearing was encouraged. If proper muscle strength was achieved, sport activities were introduced by the sixth post-operative month. The patients were allowed to use acetaminophen (325 mg every 6 h maximum) if needed.

Prior to the study, the Ethics Committee of Kerman University of Medical Sciences approved the study (reference number K/90/420), and it was registered with the Iranian Registry of Clinical Trials (IRCT201105166497N1). The study was also in accordance with the ethical standards of Helsinki and Consolidated Standards of Reporting Trials (CONSORT) statement [18].

Statistical analysis

The statistical analysis was performed using *SPSS for windows version 19.0* (SPSS Inc., Chicago, IL, USA). Independent samples *t* test was performed to analyse normally distributed quantitative variables (VAS, flexion and extension loss, and isometric muscle torque). For the nonparametric variables (KOOS, IKDC, Lysholm and KT-2000 side-to-side difference), we used the Mann–Whitney *U* test as a comparison. The qualitative (gender and complications) variables were compared using the chi-square and Fisher's exact tests. Required sample size was calculated considering the minimum clinical significance of antero-posterior knee laxity (KT-2000 side-to-side difference) which was assumed to be 3 mm [2, 12]. With regard to these studies, the minimum sample size of 49 patients per group was needed to find a significant difference between groups at an alpha level of 0.05 and power of 90 %.

Results

Out of 119 patients, twenty-one were women (17.6 %) and ninety-eight were men (82.4 %). Demographic characteristics and baseline assessments were compared, and no significant difference was observed between the two groups (Table 1).

The mean sport activity resumption of ST/G group was 25.1 ± 2.4 weeks; it was 24.8 ± 3 weeks for the ST group (n.s.). There were no statistically significant differences between the two groups based on the complications found in clinical examinations after the 1-year follow-up (Table 2).

The results of the IKDC subjective, KOOS and Lysholm Scores were evaluated again in the final follow-up, and it was demonstrated that there were no significant differences between the two groups (Table 3). No significant differences were observed between the two groups with regard to isometric torque of hamstring muscles (Table 3).

Table 1 Summary of demographic characteristics and baseline assessments of ST/G and ST groups

	ST/G	ST	*p* value
Gender, female [*n* (%)]	11 (18)	10 (17.2)	n.s.
Age, years (mean ± SD)	29.7 ± 7.9	28.8 ± 8.2	n.s.
Height, cm (mean ± SD)	174.8 ± 7.8	175.2 ± 7.4	n.s.
Weight, kg (mean ± SD)	76.4 ± 12.7	75.3 ± 11.5	n.s.
BMI, kg/m^2 (mean ± SD)	24.9 ± 4	23.4 ± 3.3	n.s.
Time between injury and surgery, month (mean ± SD)	2. 7 ± 1.9	2.8 ± 1.6	n.s.
Graft diameter, mm (mean ± SD)	7.9 ± 0.7	7.2 ± 0.8	n.s.
Sport activities [*n* (%)]			
Soccer	36 (59)	33 (58.9)	n.s.
Martial arts	13 (21.3)	12 (21.4)	n.s.
Others	6 (9.8)	5 (8.9)	n.s.
IKDC subjective score (mean ± SD)	61.4 ± 8.64	62.58 ± 9.54	n.s.
Lysholm Score (mean ± SD)	57.4 ± 9.3	55.1 ± 8.9	n.s.
KOOS Score (mean ± SD)			
Symptoms	64.7 ± 7.8	66.1 ± 7.3	n.s.
Pain	68.2 ± 9	67.8 ± 8.7	n.s.
Function in daily living	69.2 ± 8.6	63.1 ± 9.6	n.s.
Sports and recreation	59.1 ± 8.3	56.8 ± 8.9	n.s.
Quality of life	58.5 ± 6.6	55.2 ± 7.1	n.s.

ST/G semitendinosus and gracilis tendons autograft group, *ST* semitendinosus only autograft group, *SD* standard deviation, *n.s.* non significant ($p > 0.05$)

Table 2 Complications found in physical examinations of both ST/G and ST groups after 1-year follow-up

Test	ST/G	ST	*p* value
Sensory changes, *n* (%)	5 (8.2)	4 (6.9)	n.s.
Kneeling pain, *n* (%)	2 (2.2)	3 (5.2)	n.s.
Crepitus, *n* (%)	4 (4.4)	4 (6.9)	n.s.
Donor site morbidity, *n* (%)	3 (3.3)	2 (3.4)	n.s.
>10° flexion loss, *n* (%)	3 (3.3)	4 (6.9)	n.s.
>5° extension loss, *n* (%)	2 (2.2)	3 (5.2)	n.s.

ST/G semitendinosus and gracilis tendons autograft group, *ST* semitendinosus only autograft group, *n.s.* non significant ($p > 0.05$)

The side-to-side mean differences using KT-2000 were ST = 1.2 ± 1.1 mm and ST/G = 1.4 ± 1.2 mm (Table 4). There were no significant differences between the two groups.

Discussion

The principal finding of the study deduced insignificant difference between the two techniques of ACLR using single versus double hamstring tendon autografts. The null hypothesis states that the results of the objective clinical examinations (such as KT-2000) and subjective scores (such as IKDC Score) of the ACLR with double-strand semitendinosus–double-strand gracilis (4S-ST/G) are not significantly different from those of the ACLR with quadruple strand semitendinosus (4S-ST). The hypothesis was not rejected, and after the 1-year follow-up, no statistical significant differences were observed in the clinical examinations between the two techniques. One major concern regarding ACLR with HT is loss of knee flexion strength. Gifstad et al. [5], in a 7-year follow-up study of the patients who had undergone ACLR, found that total flexion work decreased more among the patients in the ST/G group than those in BPTB; however, anterior knee pain was observed in BPTB more than with the ST/G. This was observed especially during the first few years following the operation. Both techniques were recommended in the treatment of an ACL tear. Kim et al. [10], in a separate 15–52 months of follow-up study, compared the results of the clinical examinations and functional tests of ST/G versus allograft and found a decrease in knee flexion strength in both techniques. The weakness, as compared to the contralateral healthy limb, was significantly more in the autograft (ST/G) technique. Apart from this difference, they found no significant anomalies among the other scores between the two techniques.

Conversely, two other review articles suggest that semitendinosus and gracilis tendons regenerated among a significant number of patients who had undergone ACLR with the ST/G technique [3, 16]. However, there is doubt as to whether the regeneration occurs at the anatomic site and whether or not this affects knee flexion strength. In one recent study, Janssen et al. [9] observed 22 patients who had undergone ACLR with 4S-HT for 1 year and used an MRI to assess tendon regeneration. They reported the regeneration of gracilis tendons in all the patients and the

Table 3 Results of the questionnaires and isometric torque in both ST/G and ST groups after 1-year follow-up

Outcome measures	ST/G (mean ± SD)	ST (mean ± SD)	*p* value
IKDC subjective score side-to-side (%)	80.8 ± 6.8	83.5 ± 6.3	n.s.
Lysholm Score side-to-side (%)	85.3 ± 4.9	86.2 ± 4.6	n.s.
KOOS Score side-to-side (%)			
Symptoms	87.9 ± 4.4	89.1 ± 5	n.s.
Pain	97.2 ± 2.6	96.9 ± 3.1	n.s.
Function in daily living	97.4 ± 2.6	97.9 ± 2.3	n.s.
Sports and recreation	86.1 ± 4.5	83.9 ± 5.2	n.s.
Quality of life	81.1 ± 3.7	78.7 ± 3.9	n.s.
Isometric torque at 90° flexion side-to-side (%)			
Flexion	65.5 ± 8.6	68.3 ± 9.1	n.s.
Extension	73.7 ± 11.8	71.8 ± 10.5	n.s.
Abduction	84.2 ± 9.9	80 ± 11.3	n.s.
Adduction	76.5 ± 11.1	79.2 ± 9.8	n.s.

All variables are presented as percent of contralateral healthy lower limb

ST/G semitendinosus and gracilis tendons autograft group, *ST* semitendinosus only autograft group, *SD* standard deviation, *n.s.* non significant ($p > 0.05$)

Table 4 Results of the side-to-side difference of laxity assessment using KT-2000 according to the treatment type

	<3 mm	3–5 mm	<5 mm	*p* value
ST/G, *n* (%)	53 (86.9)	6 (9.8)	2 (3.3)	n.s.
ST, *n* (%)	52 (89.6)	5 (8.6)	1 (1.8)	n.s.

ST/G semitendinosus and gracilis tendons autograft group, *ST* semitendinosus only autograft group, *n.s.* non significant ($p > 0.05$)

regeneration of semitendinosus tendons in 14 of the 22 patients. This regeneration of tendons had no significant effect on the scores of IKDC, Tegner, Lysholm, KT-1000, or the isometric and isokinetic tests of hamstring muscles.

Based upon the notable decrease in muscle strength, some clinical trials have investigated whether the harvesting of the gracilis tendon in addition to the semitendinosus tendon would affect the results. Nakamura et al. [15] investigated active knee flexion strength and hamstring strength among patients undergoing either ST or ST/G techniques during a follow-up of 2 years. The knee flexion torque at 90° in ST and ST/G groups was 80.2 and 78.8 %, respectively. This difference was not significant. The only notable difference between the two groups in Nakamura's study was the maximum standing knee flexion ratios. These were reported to be 95.8 and 91.9 % of the contralateral healthy limb in ST and ST/G groups, respectively. In this study, we did not observe significant differences in knee flexion torque at 90° between the two groups. The higher torque reported in Nakamura et al. may be due to a longer follow-up and consequently additional time for the muscle to restore its strength. Ko et al. [11], contemplating the relationship between restoration of the hamstring muscle strength and knee functional performance test (FPT) following ACLR using ST/G technique, reported that knee hyperflexion strength deficit was compensated in the second year following operation. Compared to the first year, the weakness of maximum peak torque of flexor muscles had no effect on the knee FPT. Gobbi et al. [7] compared the IKDC and Lysholm knee scores as well as laxity and knee isokinetic rotation torque in ST and ST/G groups and reported no significant differences between the two groups except in isokinetic tests. The isokinetic internal rotation test was significantly better in the ST group. Yosmaoglu et al. [19] also reported better outcomes measured of isokinetic torque of knee flexors in the ST group.

The results of the areas under present investigation were in agreement with those of the aforementioned studies. The studies [7, 19] recommend using one tendon in ACLR and the avoidance of using two tendons as much as possible. Gobbi [6], in a review article, concluded that harvesting the gracilis tendon not only has no positive therapeutic outcome, but also results in the weakening of deep knee flexion internal rotation which may contribute to reinjures to the ACL in sports requiring deep knee flexion.

In Ardern et al.'s [1] study, the mean decreases in isometric knee flexor torques at 90° were 23.8 and 18.5 % of the contralateral healthy limb in ST and ST/G groups, respectively. This has been relatively close to the results obtained in our study. In Barenius's [2] study, the mean torques reduced to 17.3 and 17.4 % in ST and ST/G groups, respectively. However, the greater differences in the torques of the involved knee and the healthy one could be attributed to our short follow-up period. Arden et al. [1] found that the outcome measures of the IKDC, knee laxity, isokinetic knee flexor peak torque and range of motion were not significantly different in ST and ST/G groups. Gracilis harvest had no positive or negative effect on the outcome measures of ACLR according to the findings of Barenius et al. [2].

One of the limitations of study was the failure to examine the isokinetic torque of knee flexors. An

additional drawback was the limited number of female patients, possibly due to the cultural issue of lower participation of women in contact sports in our country. The patients were audited for a 1-year period leading to what could be perceived as another limitation. Further randomized clinical trials aimed at examining long-term complications of ACLR (such as tunnel widening, graft failure and need to revision) in both ST and ST/G techniques is recommended.

Since ACLR using quadrupled ST is more technically demanding than doubled STG and with there being no difference in outcomes and complications, no compulsory advice should be made on the former technique. However, with enough experience, one might advise the ST over STG method due to its' lesser invasiveness.

Conclusion

No significant differences in clinical complications of ACLR using ST or ST/G methods were found. Gracilis harvesting may not be necessary based on the function and strength of the knee.

Conflict of interest None.

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