FLEX CEUs

ACL Repair Surgical Considerations

Comparison of artificial graft versus autograft in anterior cruciate ligament reconstruction: a meta-analysis

Abstract

Background: Critically evaluation and summarization for the outcomes between autografts and artificial grafts using in anterior cruciate ligament (ACL) reconstruction have not been performed currently. The purpose of this study is to compare the clinical outcomes between artificial ligaments and autografts at a short- to mid-term follow-up.

Methods: A computerized search of the databases was conducted including Medline, Embase, and the Cochrane library. Only prospective or retrospective comparative studies with a minimum 2-year follow-up and a minimum sample size of 15 for each group were considered for inclusion. Two independent reviewers performed data extraction and methodological quality assessment. A Mantel-Haenszel analysis was used for pooling of results. Sensitivity analysis was performed in order to maintain the stability of results.

Results: Seven studies were included in this study. The total sample size was 403 (autograft group: 206 patients; synthetic graft group: 197 patients). Four studies were randomized controlled trials. Two studies were retrospective comparative studies and one study was non-randomized prospective comparative study. In terms of instrumented laxity, patient-oriented outcomes and complications, no significant difference was occurred between new artificial ligaments and autografts. But the results of IKDC grades and instrumented laxity were worsen in early artificial ligaments compared to autografts.

Conclusions: The outcomes of new generation of artificial ligaments are similar to autografts at a short- to mid-term follow-up. However, the early artificial ligaments are not suggested for ACL reconstruction compared to autografts.

Keywords: Artificial ligament, Autograft, Anterior cruciate ligament, Reconstruction

Background

Anterior cruciate ligament (ACL) injury is a main cause of recurrent knee instability and may result in secondary damages to other structures of the knee, such as meniscal tears and articular cartilage degeneration [1]. Currently, ACL reconstruction is the gold-standard surgical technique for ACL injury [2]. Reconstruction can be performed by using autograft, allograft or synthetic graft [3]. Despite the vast amount of researches, there still have a great deal of debates concentrating on the clinical outcomes of using different grafts in ACL reconstruction.

Autograft is a well-recognized and widely used material for ACL reconstruction due to a good graft stability and a well return to high-level sports [4]. And bone-patella tendon-bone (BPTB) autograft has historically served as the gold standard for ACL reconstruction based not only on widespread global use but also as the first autograft option. Reconstruction with synthetic grafts has the advantage of eliminating both the donor-site morbidity and disease transmission with fast rehabilitation [5]. High graft failures, no so-called ligamentization and severe synovitis have been reported as major disadvantages of synthetic grafts [6–8].

A few conventional narrative reviews have addressed related issues about the graft selection for ACL reconstruction [9–12]. Firm conclusions regarding the clinical outcomes with autografts or synthetic grafts cannot be drawn from those narrative reviews due to some inherent bias. Moreover, there have already been systematic reviews and meta-analysis which compared the clinical outcomes between allografts and autografts using in ACL reconstruction [13–16]. Critically evaluation and summarization for the outcomes between autografts and synthetic grafts using in ACL reconstruction have not been performed currently.

Using the best available evidence, the purpose of this research is to compare synthetic grafts with autografts in ACL reconstruction by evaluation the clinical outcomes including the results of instrumented laxity, patient-oriented outcomes, complications and graft failures.

Methods

Searching strategy

This research was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [17]. Two researchers searched the international databases independently up to December 30th, 2016, including Medline, Embase, and the Cochrane library. OpenGrey, the World Health Organization International Clinical Trials Registry Platform, the International Standard Randomised Controlled Trial Number (ISRCTN) registry, and Current Controlled Trials were searched to review the trial registry and grey literature. There was no restriction to years of publication and languages.

Eligibility criteria

Eligibility criteria were as follows: 1) a clinical study with a prospective or retrospective comparative design (Level of Evidence I, II, or III) [18]; 2) patients with no limitation of race and sex undergoing primary ACL reconstruction; 3) a study of ACL reconstruction comparing autografts with synthetic grafts and no restriction for types; 4) the outcomes being evaluated including physical examinations, complications, or patient-oriented outcomes etc.; 5) at least 2 years follow-ups; 6) at least 15 sample size for each group [15]. Knee laxity assessments included the arthrometer test and physical examinations (Lachman test and pivot-shift test). The details were shown in Table 1.

Any researches that failed to meet the inclusion criteria were excluded. In addition, a study was excluded if data from the same patients were reported in another study that had longer follow-up.

Data extraction and quality assessment

Two reviewers independently performed data extraction and quality assessment. In case of discrepancies, any controversy was resolved by further discussion with the corresponding author. The extraction included the following: (1) the characteristics of included researches (author, publication date, study design, participants' demography, sample size, and duration of follow-up); (2) the details of methodology (implant type and drilling technique); (3) the details of outcomes. In our research, Newcastle-Ottawa Scale (NOS) was used to assess quality for cohort study while Jadad scale was used to assess quality for randomized controlled trial (RCT) [19, 20].

Statistical analysis

The meta-analysis was conducted using RevMan Manager 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). Using the same format, two reviewers independently collected data and crosschecked the results. Disagreements were discussed with the corresponding author and reached consensus in order to ensure accuracy.

Odds ratio (OR) with 95% confidence interval (CI) was calculated for dichotomous while mean difference (MD) with corresponding 95% CI was calculated for continuous outcomes. Statistical heterogeneity was assessed by calculating the heterogeneity index I^2. When heterogeneity was significant ($I^2 > 50\%$), a Mantel-Haenszel analysis utilizing a random-effects model was used; otherwise a fixed-effects model was used when heterogeneity was considered as low ($I^2 \leq 0.50$). Funnel plots were used to test publication bias and a relatively symmetric funnel plot indicated inexistence of obvious publication bias. Sensitivity analysis was performed in order to maintain the stability of results.

Results

Article selection results

Three hundred and six relevant articles were initially selected according to the search strategy (Fig. 1). There were 161 articles left after checking for duplicates by using the literature management software Endnote X7. One hundred and forty-five articles were removed by screening the title and abstract. After reviewing the full text, 9 articles were excluded through assessment for eligibility. Eventually, 7 articles were included in qualitative and quantitative synthesis [21–27].

Characteristics of selected articles

All eligible studies were written in English from 1993 to 2013 (Table 2). Two studies were conducted in a North American country, and three studies were conducted in a European country. The other two studies were conducted in China. Among these studies, the synthetic

Table 1 Knee laxity assessment of included studies

Included studies	Arthrometer testing			Physical examination		Time from surgery to test/month
	Equipment	Flexion angle/°	Load level/N	Lachman test	Pivot test	
Engstrom 1993	Knee Laxity Tester; Stryker	20	NR	×	√	12–50
Ghalayini 2010	Stryker laxometer; Stryker	NR	NR	√	×	60
Grøntvedt 1995	KT-1000 arthrometer; MEDmetric	20	89	√	√	24
Liu 2010	KT-1000 arthrometer; MEDmetric	30	134	×	×	48–52
Nau 2002	Instrumented Laxity Tester; Telos	20	250	×	×	24
Pan 2013	KT-1000 arthrometer; MEDmetric	30	134	×	×	48–54
Pritchett 2009	KT-1000 arthrometer; MEDmetric	30	134	×	×	84–228

NR not reported

graft used to compare with autograft included the Ligament Advanced Reinforcement System (LARS) artificial ligament (3 studies), the Leeds-Keio (LK) artificial ligament (2 studies), the Ligament Augmentation Device (LAD) (1 study) and the polyglycolic acid Dacron (PGA-Dacron) graft (1 study). The autograft used for comparison was BPTB (6 studies) and hamstring tendon (1 study). The rate of follow-up was ≥90% and the follow-up periods were ≥24 months in all included studies. The total sample size was 403 patients (autograft group: 206 patients; synthetic graft group: 197 patients). The release source and release date of each artificial ligament were shown in Table 3.

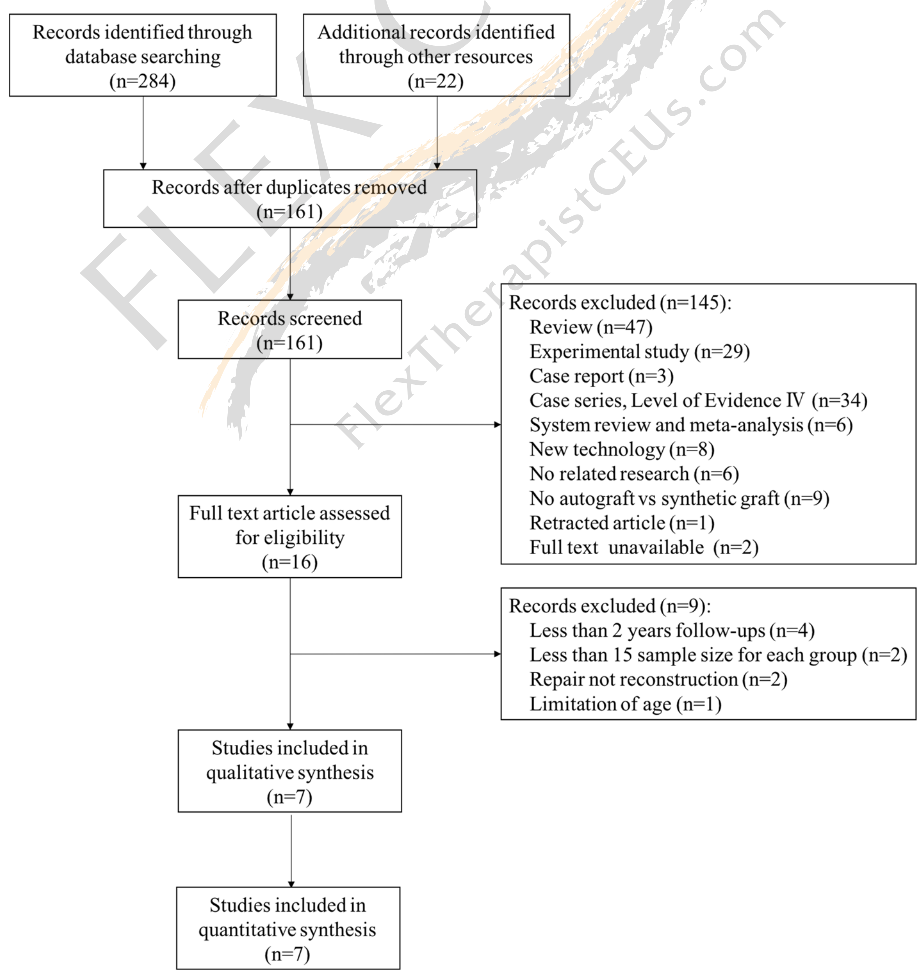

Fig. 1 Flowchart of article selection process

Table 2 Characteristics of Included Comparative Clinical Studies

Study	Journal	Implant		Followups (months)	Autograft			Synthetic graft			Outcome
		Autograft	Synthetic graft		No. of patients	Age	Gender (Male/Female)	No. of patients	Age	Gender (Male/Female)	
Pan 2013	Eur J Orthop Surg Traumatol	BPTB	LARS	50 (48–54)	30	33.9	19/11	32	35.9	25/7	Anterior laxity; IKDC score; Lysholm score; Tegner score
Ghalayini 2010	Knee	BPTB	LK	60	26	30.9	19/7	24	31.7	21/3	Anterior laxity; IKDC score; Lysholm score; Tegner score; one-hop test
Liu 2010	Int Orthop	HT	LARS	49 (48–52)	32	32	24/8	28	36	21/7	Anterior laxity; IKDC score; Lysholm score; Tegner score
Pritchett 2009	J Knee Surg	BPTB	PGADacron	138 (84–228)	35	25	24/11	35	26	23/12	Anterior laxity; IKDC score; Lysholm score; KOOS
Nau 2002	J Bone Joint Surg Br	BPTB	LARS	24	27	30.9	15/12	26	31.0	21/5	Anterior laxity; IKDC score; Tegner score; KOOS
[a]Grøntvedt 1995	Scand J Med Sci Sports	BPTB	LAD	24	26	NR	NR	22	NR	NR	Anterior laxity; Lysholm score; Tegner score; Isokinetic strength
Endstrom 1993	Clin Orthop Relat Res	BPTB	LK	28	30	23.8	14/16	30	23.4	21/9	Anterior laxity; IKDC score; Lysholm score; Tegner score; Muscle performance

BPTB bone-patellar tendon-bone, *LARS* ligament advanced reinforcement system, *LK* Leeds-Keio synthetic graft, *HT* hamstring tendon, *LAD* ligament augmentation device, *PGA-Dacron* polyglycolic acid-Dacron, *IKDC* International Knee Documen- tation Committee, *KOOS* Knee Injury and Osteoarthritis Outcome Score, *NR* not reported

[a]The mean age and the gender distribution were not described separately in this study. The mean age of the patients was 25 years (range 15–42). There were 18 men and 30 women altogether including in this research

Table 3 Details of each artificial ligament in included study

Included studies	Synthetic product name	Release source	Release date
Engstrom 1993	Leeds-Keio graft	Neoligaments, Leeds, UK	1980
Ghalayini 2010	Leeds-Keio graft	Xiros plc formerly Neoligaments Ltd., Leeds, UK	1980
Grøntvedt 1995	LAD	3 M Company, St. Paul, Minnesota, USA	1980
Liu 2010	LARS artificial ligament	Surgical Implants and Devices, Arc-sur-Tille, France	1985
Nau 2002	LARS artificial ligament	Surgical Implants and Devices, Arc-sur-Tille, France	1985
Pan 2013	LARS artificial ligament	Surgical Implants and Devices, Arc-sur-Tille, France	1985
Pritchett 2009	PGA-Dacron graft	Surgitex, Southfield, Mich	NR

LAD ligament augmentation device, *LARS* ligament advanced reinforcement system, *PGA-Dacron* polyglycolic acid-Dacron, *NR* not reported

The synthetic grafts were divided into two groups (Group 1: early generation; Group 2: new generation) for analysis. In this study, the early generation of the artificial ligaments contained the LK artificial ligament and the LAD, while the new generation included the LARS artificial ligament and the PGA-Dacron graft [2, 26]. Among all included articles, 4 articles were related to the new generation and 3 articles were related to the old generation (Table 2).

Quality of selected articles

Assessment of the methodological quality revealed that there were four RCTs (Level I). Two studies were retrospective comparative studies (Level III) and one study was non-randomized prospective comparative study (Level II). Among these four RCTs, only one article was of high quality with scores ≥4 while the other three articles were of low quality with scores ≤3 according to Jadad scale (Table 4). Assessed by NOS scale, two retrospective studies and one prospective study were of high quality. All demographic data were compared between two groups and showed no significant difference in eligible studies.

Meta-analysis

Instrumented laxity

All included studies tested instrumented laxity. The study of Nau et al. was excluded for providing quantitative data other than grade data of instrumented laxity (> 5 mm or ≤5 mm), which could not be compared with other studies [22]. No heterogeneity was found among the studies. Using the fixed-effects model in analysis, the early generation of synthetic grafts had a significant difference in knee laxity compared with autografts and the synthetic graft had a poorer result (OR = 11.44; 95% CI: 2.46, 53.16; $p = 0.98$; $I^2 = 0\%$; Fig. 2a). Conversely, the new generation of synthetic graft showed no significant difference in knee laxity compared with autografts (OR = 0.63; 95% CI: 0.21, 1.93; $p = 0.44$; $I^2 = 0\%$; Fig. 2b).

Table 4 Quality assessment of included studies

Study	Level of evidence	Type	NOS	Jadad scale
Pan 2013	III	Retrospective study	7	
Ghalayini 2010	I	RCT		5
Liu 2010	III	Retrospective study	7	
Pritchett 2009	II	Prospective study	7	
Nau 2002	I	RCT		3
Grøntvedt 1995	I	RCT		1
Endstrom 1993	I	RCT		1

NOS Newcastle-Ottawa Scale, *RCT* randomized controlled trial

Physical examinations

Two studies assessed the anterior stability by Lachman test and two studies evaluated the rotational stability through pivot-shift test (Table 1). All included studies were related to the early artificial ligaments (LK artificial ligament and LAD). The Lachman test showed a poorer result in the early synthetic grafts than in the autografts (OR = 0.02, 95% CI: 0.00, 0.41), indicating a worse anterior stability. The result of pivot-shift test was poor in early synthetic grafts (OR = 0.03, 95% CI: 0.01, 0.16), documenting a worse rotational stability comparing to autografts.

International knee documentation committee (IKDC) grades

Six studies reported postoperative IKDC grades but the study of Nau et al. was excluded for providing the different type of categorical data comparing to other included studies [22]. No heterogeneity was found and a fixed-effects model was used to analysis (Fig. 3). There were 51 patients in the early synthetic graft group and 50 patients in the autograft group. The early synthetic grafts (LK, LAD) had worsen IKDC grades (OR = 3.41; 95% CI: 1.30, 8.89; $p = 0.57$; $I^2 = 0\%$; Fig. 3a). Altogether 95 cases in the new synthetic graft group and 97 cases in the autograft group were reported. The new synthetic grafts (LARS) had no difference in IKDC grades compared to autografts (OR = 0.72; 95% CI: 0.35, 1.48; $p = 0.90$; $I^2 = 0\%$).

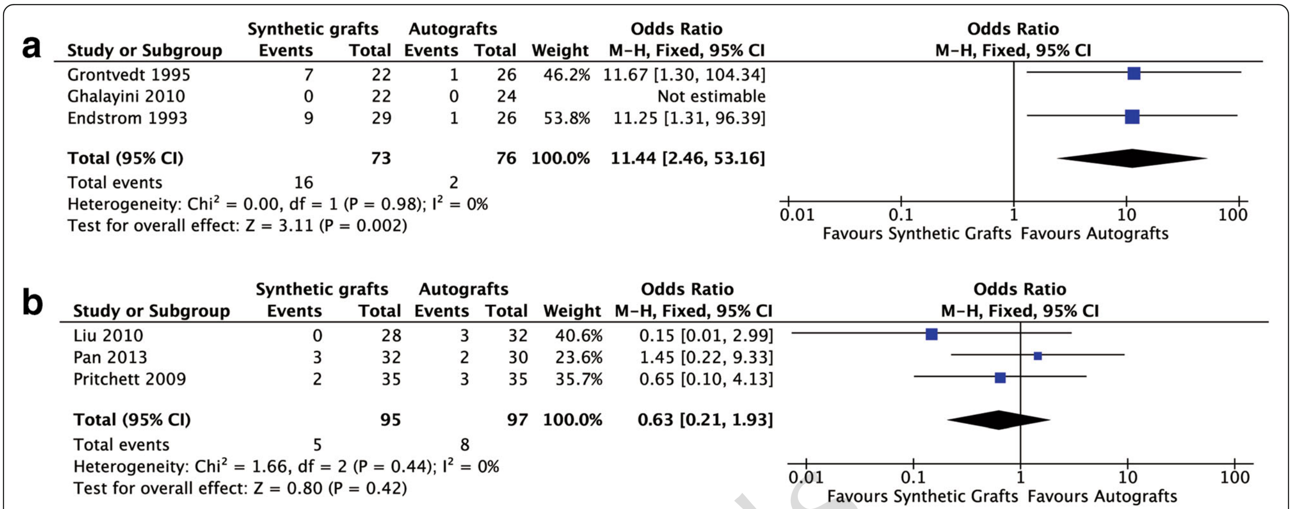

Fig. 2 Forest plot of the instrumented laxity. **a** the early generation of synthetic grafts; **b** the new generation of synthetic grafts

Lysholm scores

Six eligible studies tested postoperative Lysholm scores but the results of two studies could not be analyzed in meta-analysis. One was excluded due to lack of standard deviation and the other was due to suppling Lysholm scores as grade data other than quantitative data [21, 24]. Three studies were in Group 2 while only one study was in Group 1. There were altogether 95 cases in Group 2 and 97 cases in the autograft group. Heterogeneity was not found among these three studies and a fixed-effects model was used (p = 0.88; I^2 = 0%), showing no significant difference in the Lysholm scores between two groups (OR = 1.80; 95% CI: -0.52, 4.13).

Tegner scores

Six studies reported Tegner scores but only 3 studies applied mean scores and standard deviations [23, 25, 27]. The rest three studies documented there was no significant difference between two groups in their longest follow-up time. Two studies were related to the new generation of the synthetic grafts and one study were focused on the old generation. Heterogeneity was not significant and a fixed-effects model was used, no significant difference occurred in new synthetic grafts and autografts (OR = 0.40; 95% CI: -0.09, 0.89).

Complications

Six studies evaluated complications of ACL reconstruction. The study conducted by Endstrom et al. did not report the complications after ACL reconstruction and was excluded for analysis. No heterogeneity was found and a fixed-effects model was used (I^2 = 0%; Fig. 4). Altogether 44 patients were included in the early synthetic graft group and 50 patients were included in

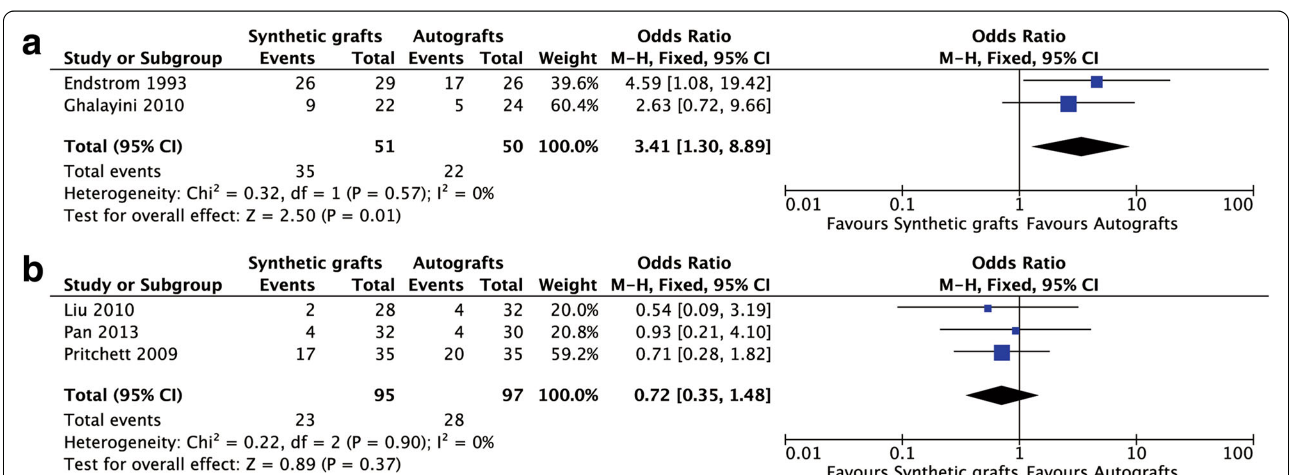

Fig. 3 Forest plot of the IKDC grades. **a** the early generation of synthetic grafts; **b** the new generation of synthetic grafts

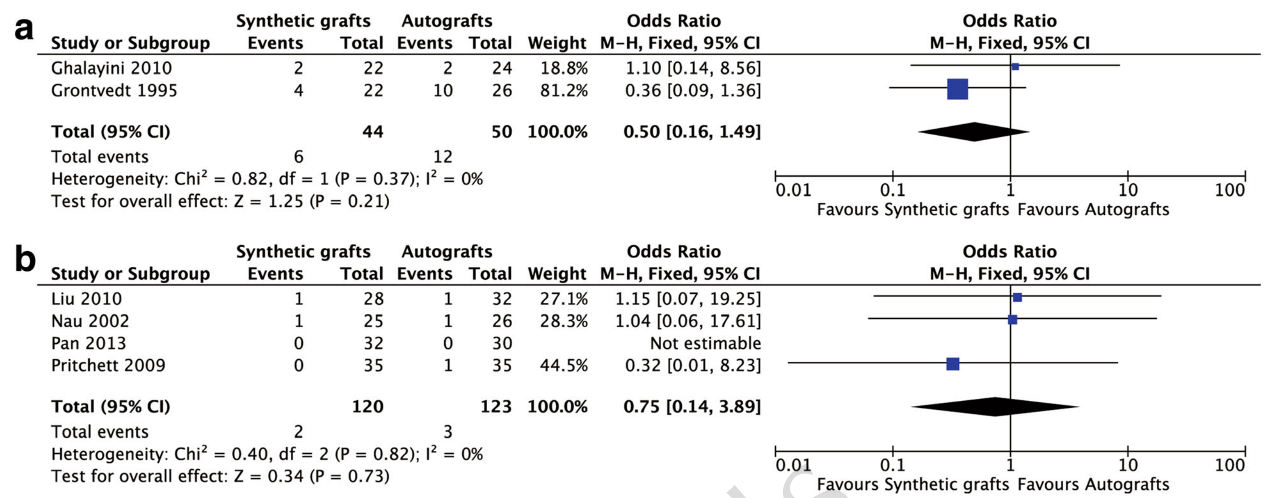

Fig. 4 Forest plot of the complications of anterior cruciate ligament reconstruction. **a** the early generation of synthetic grafts; **b** the new generation of synthetic grafts

the compared group. No significant difference was found in the rate of complications between two groups (OR = 0.50; 95% CI: 0.16, 1.49; Fig. 4a). Similarly, no significant difference occurred in the new synthetic grafts and autografts (OR = 0.75; 95% CI: 0.14, 3.89; Fig. 4b).

Sensitivity analysis indicated that the study with regard to four-strand HT graft had no obvious deviation compared to other studies concerning about BPTB in evaluation of knee laxity, patient-oriented outcomes and the rate of complications.

Publication bias

Funnel plots of instrumented laxity and complications were used to evaluate the publication bias, showing the lack of obvious bias among the eligible studies related to new synthetic grafts according to a relative symmetric funnel plot (Figs. 5 and 6).

Discussion

The key findings of present meta-analysis indicated that, in general, the patient-oriented outcomes and the rate of complications of ACL reconstruction with synthetic grafts were not significantly different from those with autograft, especially for new generation synthetic grafts (LARS and PGA- Dacron). However, with regard to knee laxity, ACL reconstruction with early artificial grafts had obviously poorer knee laxity from those with autografts (95% CI: 1.03, 4.72) while new artificial grafts showed no significant difference with autografts (95% CI: 0.21, 1.93).

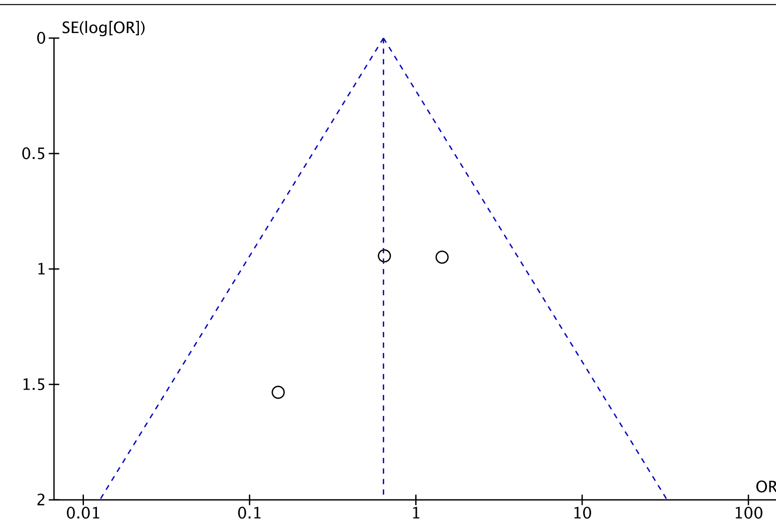

Fig. 5 Funnel plot of publication bias for instrumented laxity in the new generation synthetic graft group

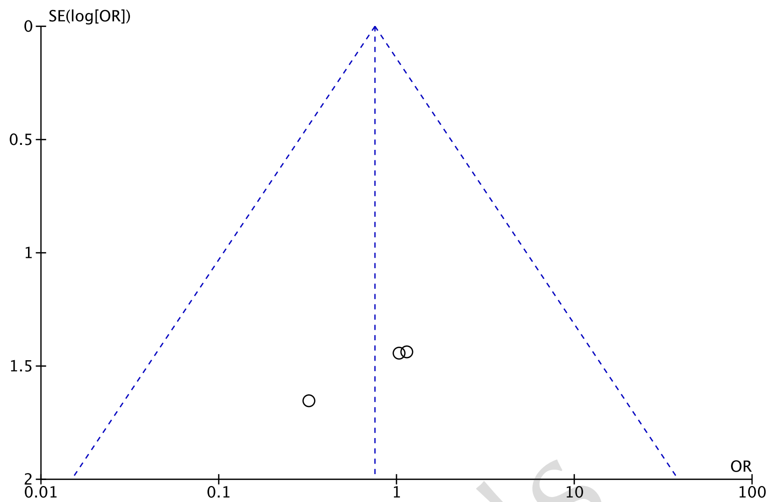

Fig. 6 Funnel plot of publication bias for complications in the new generation synthetic graft group

The LK artificial ligament was a polyester mesh-like structure intended as a scaffold for soft tissue ingrowth [28]. The LAD, a band-like braid of polypropylene, was designed to protect the autogenous graft from excessive stresses [29]. Murray et al. reported that 28% of the group were known to have ruptured the LK ligament and 56% had increased laxity compared to the opposite normal knee at a 10–16 year follow-up [30]. A study conducted since 1983, included 856 patients accepted ACL reconstruction with LAD, showed 63 cases of complications and 73 cases of re-surgery [31]. Long-term follow-up results documented both the LK artificial ligament and the LAD were not suitable as an ACL substitute [30–32]. Moreover, the LAD caused effusions and reactive synovitis in the knee for provoking inflammatory reactions, and was found to delay maturation of autogenous graft [33]. The knee laxity and the IKDC grades were significantly different from autografts and early artificial ligaments, indicating that the short-term outcomes of early artificial ligaments were worsen than autografts. The results of our research for early artificial ligaments were consistent with previous studies. It was not suggested to use early synthetic grafts including the LK artificial ligament and the LAD due to their poor follow-up outcomes.

The LARS artificial ligament was made of polyethylene terephthalate, divided in two parts (intra-articular part and extra-articular part) [34]. Intra-articular part was composed of longitudinal external rotation fibers without transverse fibers as an imitation of ACL anatomic structure while extra-articular part was weaved by longitudinal and transverse fibers in order to avoid ligament deformation. Dericks et al. reported encouraging results in 220 cases of ACL reconstruction used LARS artificial ligament with a mean follow-up of 2.5 years [35]. In 2013, Parchi reported no case of complications and only one case of mechanical graft rupture after using LARS artificial ligament for ACL reconstruction at a mean follow-up of eight years [36]. In 2015, a study with a minimum follow-up of 10 years, showed almost half of the patients (8/18) were subjectively not satisfied with the surgical result using LARS artificial ligament [7]. The clinical outcomes were appealing at short-term but controversy at long-term [36–38]. In our research, 3 studies compared LARS artificial ligament with autografts, showing no significant difference in knee laxity, functions and the rate of complications [22, 25, 27]. The outcomes of LARS artificial ligament used in ACL reconstruction were appealing at least in short-term follow-up. Another new synthetic graft called PGA-Dacron graft, consisted of synthetic braided ligament made of 75% degradable PGA filaments and 25% non-degradable Dacron thread, showed a satisfied result compared to autograft including knee laxity, range of motion, patient-oriented questionnaires, muscle performance, degenerative changes of knee, and the rate of failure and complications [26].

Complications occurred in the autograft group were infection, patellofemoral pain, recurrent effusion and extension loss. In the synthetic graft group, complications included interference screw-related problems (pain and screw loosening), patellofemoral pain and extension loss. There were altogether 12 cases in the autograft group and 8 cases in the synthetic graft group. Extension loss was the most common complication in included studies and it might be associated with graft impingement and a formation of cyclops [39, 40]. Graft impingement was mainly caused by malposition of femoral bone tunnel and a "cyclops" was a fibrous nodule caused by proliferation of fibrovascular tissues similar to a healing scar after

ACL reconstruction [41, 42]. The synthetic grafts were located in a non-anatomic but isometric placement while the autografts were usually located in an anatomic placement. The results of complications showed no significant difference between these two location methods.

Some studies documented that subjective outcomes were not correlated with objective outcomes including instrumented laxity test and clinical examination [43]. Among these included studies, three of them showed difference in objective parameters but no significant difference in patient-oriented outcomes [21, 22, 24]. Meanwhile, the opposite circumstance did not appear (similar in objective outcomes but different in subjective outcomes). Kraeutler et al. suggested that patient satisfaction is the most important measurable index for the outcomes of ACL reconstruction [13]. Only the overall IKDC grades showed better results in the autografts than in the early synthetic grafts and the rest indicators for patient satisfaction showed no significant difference between groups. However, it was still well recognized that a KT-1000 side-to-side difference of >5 mm was defined as a clinical failure [37]. Both objective parameters and subjective outcomes shoulder be considered for assessment of ACL reconstruction.

The limitations of this study were as follows: (1) Until now, there was still lack of high-quality RCT or large-scale multi-center retrospective comparable studies to prove the effectiveness of artificial ligaments compared to autografts. (2) The follow-up time was not sufficiently long for evaluation of ACL reconstruction. (3) In the included studies, the types of grafts used in ACL reconstruction were not the same (Hamstring tendon, BPTB, LK, LAD, LARS and PGA-Dacron). (4) The data included in the research did not cover all included studies due to the lack of relative data.

Conclusions

The outcomes of new generation of artificial ligaments are similar to autografts in terms of knee laxity, patient-oriented outcomes and the rate of complications at a short- to mid-term follow-up. However, the early artificial ligaments (LK, LAD) are not suggested for ACL reconstruction according to worse outcomes in knee laxity and functions compared to autografts.

Double-bundle anterior cruciate ligament reconstruction improves tibial rotational instability: analysis of squatting motion using a 2D/3D registration technique

Abstract

Background: The anterior cruciate ligament-deficient (ACLD) knee requires appropriate treatment for the patient to return to sports. The purpose of this study was to clarify the kinematics of the anterior cruciate ligament-deficient knee in squatting motion before and after double-bundle anterior cruciate ligament reconstruction (DB-ACLR) using a 2D/3D registration technique.

Methods: The subjects of this study were 10 men with confirmed unilateral ACL rupture who underwent DB-ACLR. Computed tomography (CT) of the knee joints was performed before DB-ACLR. Fluoroscopic imaging of the knee motion in squatting before and after DB-ACLR was also performed. The 2D/3D registration technique is a method of calculating positional relationships by projecting the 3D bone model created from the CT data onto the image extracted from the fluoroscopic images. The tibial anteroposterior (AP) and rotational positions were analyzed with reference to the femur.

Results: The tibial AP position of the ACLD knees was significantly anterior to the contralateral knees ($p = 0.015$). The tibial rotational position of the ACLD knees was significantly internally rotated compared to the contralateral knees ($p < 0.001$). Both tibial AP and rotational positions improved after DB-ACLR ($p < 0.001$), with no significant differences compared to the contralateral knees.

Conclusion: DB-ACLR improved not only tibial AP instability but also tibial rotational instability at knee flexion with weight-bearing. DB-ACLR appears to be a useful technique for normalizing the knee joint kinematics of ACLD knees.

Keywords: Knee kinematics, Anterior cruciate ligament, Double-bundle anterior cruciate ligament reconstruction, 2D/3D registration technique

Background

Anterior cruciate ligament (ACL) tear is a common knee injury, with around 100,000 cases in the USA each year [1]. It has been reported that ligament failure after ACL rupture is a risk factor for knee osteoarthritis [1–3]. Abnormal kinematics of rotatory instability and anteroposterior (AP) instability are involved in the development of knee osteoarthritis (OA) in the ACL-deficient (ACLD) knee [4]. Load motion such as walking or crouching may cause arthropathy in such a state. Previous studies have reported that squatting in ACLD knees causes the tibia to move anteriorly and rotate internally [5, 6].

The ACLD knee requires appropriate treatment to prevent the onset and progression of knee arthropathy. In recent years, double-bundle ACL reconstruction (DB-ACLR) using hamstring tendon grafting has been reported to have good clinical outcomes and achieve static knee joint stability [7, 8]. However, the effects of DB-

ACLR on kinematics in load flexion motion have not been fully clarified. The purpose of this study was to clarify the kinematics of the ACLD knee in squatting motion before and after DB-ACLR.

In order to demonstrate the effects of DB-ACLR, a 2D/3D registration technique [9, 10], which is less invasive than bone markers and more accurate than surface markers, was used [11, 12]. To verify the knee kinematics, fluoroscopic images of squatting movements were taken before and after DB-ACLR, and improvements of tibial AP and rotational movements were investigated. We wished to test the hypothesis that DB-ACLR improved the abnormal kinematics of squatting motions of ACLD knees. To test this hypothesis, before and after operative kinematics were measured in 10 DB-ACLR patients using 2D/3D techniques.

Methods

Subjects

This study was a cross-sectional study targeting patients with unilateral ACLD. This study was approved by the ethics committee of our facility. Patients who visited our hospital between 2009 and 2011 and who were diagnosed with ACL rupture were recruited. Ten ACLD patients participated in this study. The case number required was determined by G*Power ver. 3.1 software to complete the power analysis. The effect size was set to 0.33 with reference to our previous research. The sample size necessary for achieving alpha = 0.05 and beta = 0.20 was 8 in comparing the two dependent means.

The inclusion criteria included unilateral ACL rupture diagnosed by MRI. Male patients aged 20 years and over who understood the research contents participated in the research. Exclusion criteria were a history of trauma other than ACL injury, ACL rupture of the contralateral knee, malalignment of the lower extremity, and hip and ankle deformities.

All patients provided their written informed consent. The mean period from ACL injury to preoperative examination was 24.1 ± 37.3 months (range, 2 to 108 months). The mean age at the time of surgery was 29.6 ± 8.8 years (range, 20 to 47 years). The mean preoperative BMI was 23.69 ± 5.1 kg/m^2. The Lachman test was positive in all cases, while the pivot-shift test was positive in eight cases. Based on the reports of Otsubo et al., DB-ACLR was performed using the ipsilateral hamstring tendon [13]. Lateral meniscus injury was confirmed in six knees, and medial meniscus injury was confirmed in four knees on intraoperative examination. Partial resections of three lateral menisci and three medial menisci were performed. The kinematic measurements were performed for the ACLD knees and the contralateral knees before and after DB-ACLR. Static AP stability was measured by a KT-2000 knee arthrometer (MEDmetric Corp., San Diego, CA, USA). The mean period from DB-ACLR to postoperative measurement was 24.6 ± 9.3 months (range, 12 to 37 months).

Kinematic analysis

In vivo kinematics were analyzed using the 2D/3D registration technique proposed by Banks and Hodge [9]. The positional relationship of the femur and tibia is determined by projecting the 3D bone model created from the CT data onto the image extracted from the fluoroscopic image on the computer.

Validity and reliability

Fregly et al. reported that the accuracy of this technique was 0.42 mm for in-plane translation and 1.3° for rotation [14]. Komistek et al. reported that the values were 0.45 mm for in-plane translation and 0.66° for rotation [15]. Moro-oka et al. reported that the accuracy of this technique was 0.53 mm for in-plane translation and 0.54° for rotation [16]. These studies indicated that this technique is accurate enough for evaluating knee kinematics of in-plane translation and rotation.

Bone model creation and coordinate system embedding

Computed tomography (CT) (SOMATOM Definition, Siemens AG, Erlangen, Germany) of all knees was performed to create a 3D bone model. CT was performed with a 0.5-mm slice pitch spanning approximately 150 mm above and below the knee joint line. Then, 3D bone models of the femur and tibia were created from the CT images using 3D-Doctor (Able Software Corp., Lexington, MA, USA). The coordinate system for 3D bone models was 3D-Aligner (GLAB Corp., Higashi-Hiroshima, Japan).

The medial condyle and the lateral condyle of the femur were considered as one cylinder [17]. The central axis of the cylinder was set as the *Z*-axis of the femur. The origin was the midpoint of the central axis of the cylinder that penetrates between the medial and lateral bony surfaces of the femur. A plane through the origin perpendicular to the central axis was defined as the sagittal plane. The *X* and *Y* axes of the femur were set on this plane. The line passing through the origin of the femur and parallel to the central line of the projected femoral shaft to the sagittal plane was the *Y*-axis. The line passing through the origin and perpendicular to the *Z* and *Y* axes was defined as the *X*-axis (Fig. 1).

The tangent was set posterior to the tibial condyle at the top level of the head of the fibula (Fig. 2, line 1). The tangents fitted onto the medial and lateral tibia perpendicular to the posterior tangent (Fig. 2, lines 2 and 3) and the anterior tangent (Fig. 2, line 4) were set to create a rectangle. The rectangle made from lines 1 to 4 was then translated to the tibial plateau. The midpoint of the

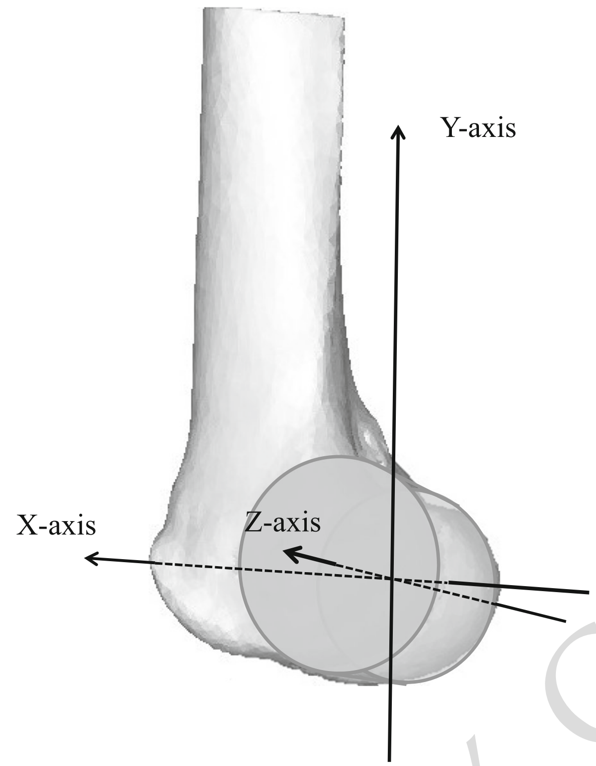

Fig. 1 Coordinate system of the femur. The femoral condyles are regarded as a cylinder. *Z*-axis: the axis of the cylinder. *Y*-axis: the line through the origin parallel to the central line of the femoral shaft projected onto the sagittal plane. *X*-axis: the line perpendicular to the *Z*-axis and the *Y*-axis

rectangle was set as the origin of the tibia. The AP line of the bisector of the rectangle was set as the *X*-axis of the tibia, and the transverse bisector line of the rectangle and perpendicular to the *X*-axis was set as the *Z*-axis of the tibia. A line passing through the origin and perpendicular to the *X*-*Z* plane was set as the *Y*-axis of the tibia (Fig. 2).

Squatting action

Squatting was performed by opening both legs wider than shoulder width, standing so that the left and right feet became 90° to each other, and bearing weight equally on both legs [18]. A squatting period was defined as the movement from the extended knee position to the maximum flexion knee position and returning to the extended knee position. Fluoroscopy was performed for the squatting period after it was practiced several times. The actual flexion knee angle of the subjects was about 100°, and the data up to 85°, to which all 10 cases could flex, were analyzed.

Fluoroscopic imaging

The kinematics of the knee joint were examined using X-ray fluoroscopy with a square, 17-in., flat-panel screen (C-vision Safire, Shimadzu Corp., Kyoto, Japan). The imaging frame rate was 5 Hz, and the image size was 1024 × 1024 pixels. Still images were extracted from the kinematic data. The correction target was also projected on the same field of view of fluoroscopic images for distortion correction and optical calibration.

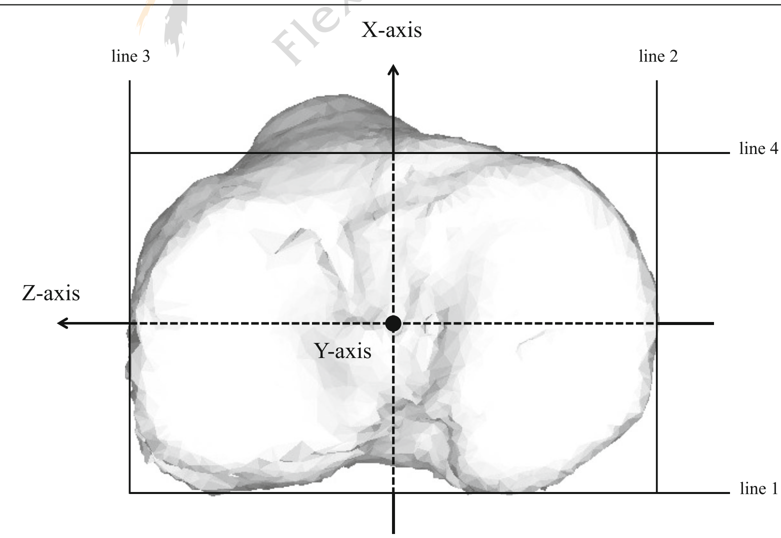

Fig. 2 Coordinate system of the tibia. The tangent is set behind the tibial condyle (line 1) at the top level of the head of the fibula, and it is fitted onto the medial and lateral tangents perpendicular to the posterior tangent (lines 2 and 3), and the anterior tangent is set to create a rectangle (line 4). *Z*-axis: transverse bisector line of the rectangle. *X*-axis: anteroposterior bisector line of the rectangle. *Y*-axis: vertical line to the *X*-*Z* plane

Model registration

The bone model with the coordinate system setup was projected onto the distortion-corrected fluoroscopic image. The silhouette of the bone model was iteratively adjusted to match the silhouette on the fluoroscopic image with the custom Joint Track program (sourceforge.net/projects/jointtrack). Then, six degrees-of-freedom joint kinematics were computed using commercial software (3D-JointManager, GLAB Corp.). AP translation and rotation of the tibia referenced to the femur were measured. The kinematics were analyzed in 5° increments of knee flexion angles after B-spline curve approximation was performed.

X-ray exposure dose

It was confirmed that the X-ray exposure doses of the subjects were 8 mSv with CT and 22 mSv with fluoroscopy. The fluoroscopic examination involved taking the three actions of squatting, kneeling, and knee extension. Only one fluoroscopic examination was performed, considering the exposure dose.

Statistical analyses

Welch's t test and the paired t test were performed using Statcel (OMS Ltd., Saitama, Japan), and post hoc pairwise comparisons were performed using a mixed linear model with repeated measures with SPSS version 22 (SPSS Inc., Chicago, IL, USA). The level of significance was set at $p < 0.05$.

Results

The mean preoperative Lysholm knee scoring scale score was 79.3 ± 11.7, and after surgery, the mean was significantly improved to 98.9 ± 2.1 ($p < 0.001$). Anterior translation of the tibia was measured under anesthesia at DB-ACLR and at the time of the postoperative examination using KT-2000 (Fig. 3). Before DB-ACLR, the average anterior translation of ACLD knees was 13.0 ± 2.3 mm and that of contralateral knees was 7.1 ± 1.7 mm; there was a significant difference between the groups ($p < 0.001$). At the postoperative examination, the average of the DB-ACLR knees was 9.0 ± 2.7 mm, and the average of the contralateral knees was 7.6 ± 1.8 mm; there was no significant difference between the groups ($p = 0.19$). The average difference in the amount of anterior translation of the tibia between affected knees and contralateral knees was 6.0 ± 2.0 mm before the operation and 1.4 ± 2.4 mm after the operation; there was a significant difference ($p < 0.001$).

The mean magnitude of tibial AP translation (range minimum to maximum AP position) analyzed by the 2D/3D registration technique was 5.23 ± 2.70 mm in ACLD knees, 5.15 ± 3.84 mm in the contralateral knees, and 4.27 ± 2.34 mm in DB-ACLR knees; there were no significant differences. The AP position of the tibia of the ACLD knees was significantly different from that of the contralateral knees ($p = 0.015$) and the DB-ACLR knees ($p < 0.001$) on post hoc pairwise comparisons with a mixed linear model with repeated measures on SPSS. There was no significant difference in the AP position of the tibia between DB-ACLR knees and contralateral knees. The AP position of the tibia of ACLD knees was more anterior than that of contralateral knees at all flexion angles. The AP positions of the tibia of DB-ACLR knees were posterior to those of ACLD knees at all flexion angles. In addition, the AP positions of the tibia of DB-ACLR knees were more posterior to those of contralateral knees at 0°–60° of knee flexion, and they were almost the same at angles larger than 65° (Fig. 4).

The mean magnitude of the tibial rotation angle (range minimum to maximum rotational position) was 14.91° ±

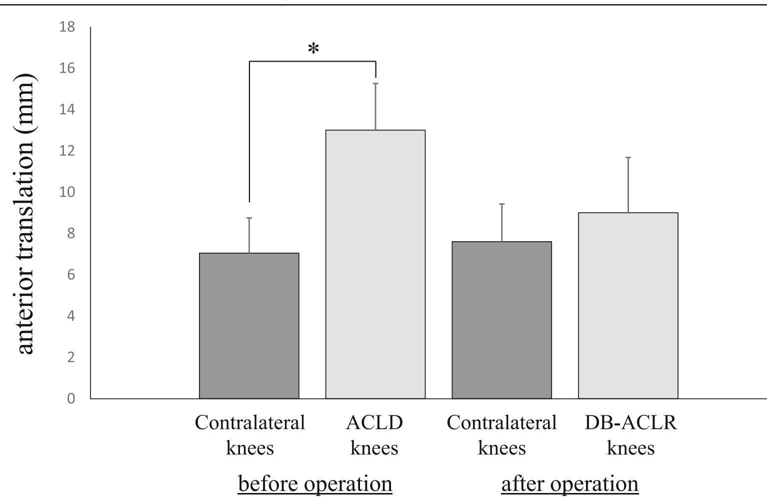

Fig. 3 Anterior tibial translation of the ACLD and contralateral knees measured by KT-2000 knee arthrometer. Average magnitude of tibial anterior translation (mm). There is a significant difference between ACLD knees and contralateral knees before the surgery (Student's t test, $^*p < 0.001$)

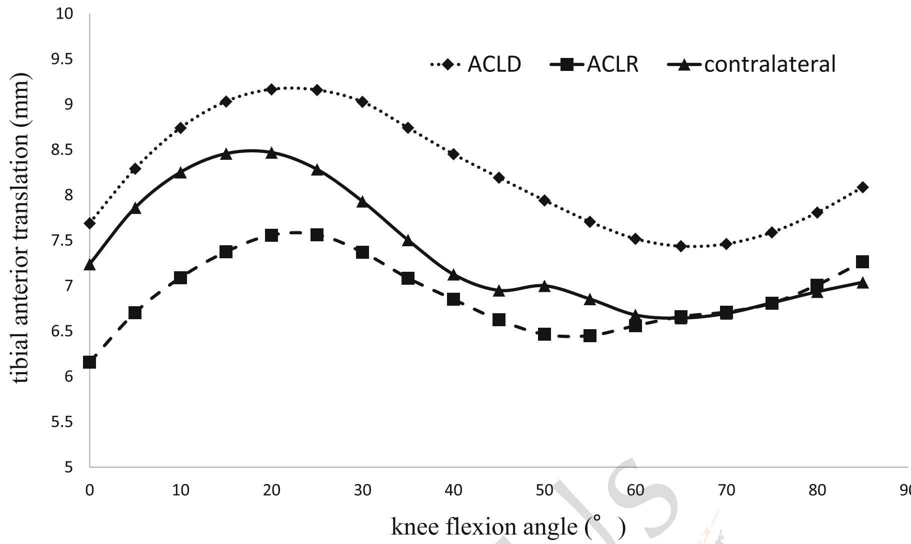

Fig. 4 Anteroposterior translation of the tibia analyzed by 2D/3D registration technique. *Y*-axis: tibial anterior translation (mm). *X*-axis: knee flexion angle (°). Dotted line: ACLD knees. Dashed line: DB-ACLR knees. Solid line: contralateral knees. The anteroposterior position of the tibia of the ACLD knees is significantly different from the contralateral knees and the DB-ACLR knees (post hoc pairwise comparisons with a mixed linear model with repeated measures on SPSS, $p = 0.015$)

6.64° in ACLD knees, 14.54° ± 5.51° in contralateral knees, and 12.87° ± 6.92° in DB-ACLR knees; there were no significant differences. The rotational position of the tibia of the ACLD knees was significantly different from that of the contralateral knees ($p < 0.001$) and the DB-ACLR knees ($p < 0.001$) on post hoc pairwise comparisons using a mixed linear model with repeated measures on SPSS. There was no significant difference in the rotational position of the tibia between DB-ACLR knees and contralateral knees. The tibial positions were more internally rotated in ACLD knees than in contralateral knees at all flexion angles. The tibial rotational positions of DB-ACLR knees and contralateral knees were almost the same at all flexion angles (Fig. 5).

Discussion

In recent years, DB-ACLR using hamstring tendon grafting has been reported to produce good clinical outcome and joint stability [7, 8]. As a reason for the result, we hypothesized that DB-ACLR improved the abnormal

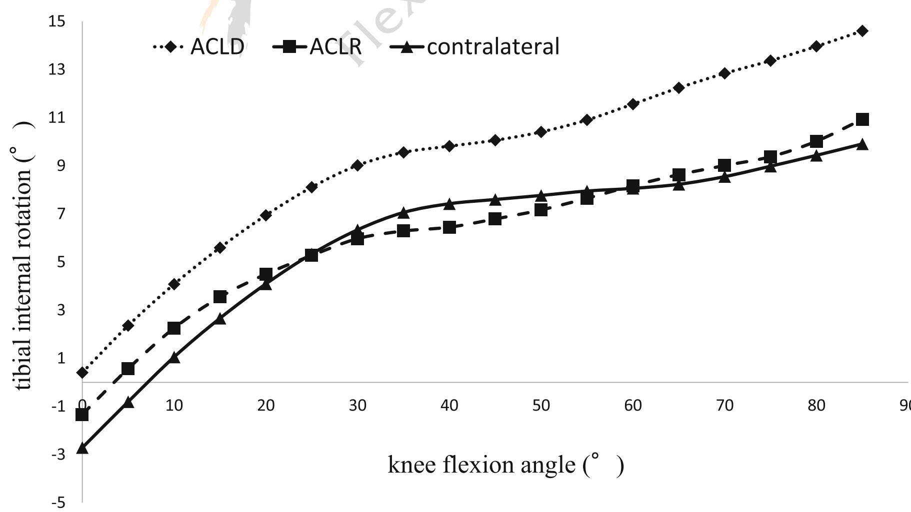

Fig. 5 Rotation of the tibia analyzed by 2D/3D registration technique. *Y*-axis: tibial internal rotation (°). *X*-axis: knee flexion angle (°). Dotted line: ACLD knees. Dashed line: DB-ACLR knees. Solid line: contralateral knees. The rotational position of the tibia is significantly different between ACLD knees and contralateral knees, and between ACLD knees and DB-ACLR knees (post hoc pairwise comparisons with a mixed linear model with repeated measures on SPSS, $p < 0.001$)

kinematics of squatting motions of ACLD knees. To prove this hypothesis, before and after operative kinematics were measured in 10 DB-ACLR patients. We measured the kinematics using less invasive and more accurate 2D/3D registration technique [9–12]. DB-ACLR was found to control the AP translation of the tibia. Furthermore, DB-ACLR also controlled the internal rotation of the tibia. This is the first report to have analyzed the in vivo kinematics after DB-ACLR by comparison with the preoperative knee. The results of this study provide biomechanical support for the usefulness of DB-ACLR.

The 2D/3D registration technique was developed by Banks and Hodge [9]. The cardan angle was used to determine the three-dimensional positional relationship between the femur and tibia [19]. Co-author Gamada had worked with Banks using this method [20]. This method used single-plane fluoroscopic images. As mentioned before, this method is accurate for in-plane but less accurate for out-of-plane. Li et al. compared the ACLD knees and the contralateral knees using bi-plane fluoroscopic images. The results showed that the contact points of ACLD knees were significantly different from the contact points of the healthy side in the mediolateral direction, and ACLD knees had instability in the mediolateral direction [21]. Although bi-plane technique was more accurate, single-plane technique with a wide field of view seemed more convenient to analyze daily activities, such as wide-based squatting.

ACLD knees have rotatory and AP instability and have a risk of secondary damage [1, 3]. For example, Segawa et al. reported that plain radiographs of ACLD knees showed that 63% had OA, 37% of which had joint space narrowing [2]. von Porat et al. reported that radiographic changes were found in 78% of 122 ACLD knees, and of these, the radiographic OA equivalent to Kellgren and Lawrence grade 2 was seen in 41% [22]. There were also reports of abnormal kinematics of ACLD knees. Georgoulis et al. performed 3D optoelectronic gait analysis and reported a significant difference in tibial rotation angle during the initial swing phase in ACLD knees compared with ACL reconstructed and control knees [4]. DeFrate analyzed the forward lunge motion by the 2D/3D registration technique using the bone model constructed by MRI. They reported significant tibial anterior instability in ACLD knees at knee flexion angles of 0° and 15° [23]. They also reported significant tibial internal rotation at a knee flexion angle of 15°.

The squatting motion is one of the knee flexion movements with weight-bearing. It applies a heavy load to knee joints in activities of daily living. There have been a few reports of the kinematics of squatting motion in ACLD knees by the 2D/3D registration technique. Dennis et al. analyzed the medial and lateral condyle contact positions and femoral axial rotation in the squatting motion. The lateral condyle contact point shifted posteriorly, and the femoral axis rotated laterally for both normal knees and ACLD knees [5]. Yamaguchi et al. analyzed the relationship between the femoral and tibial axes. The ACLD knees showed greater tibial anterior translation from – 10° to 80° flexion and significant tibial internal rotation at full extension [6]. Chen et al. analyzed the medial and lateral condyle contact positions. The tibia was positioned significantly anterior at 15° flexion in ACLD knees [24]. Our previous research showed significant anterior translation and internal rotation of the tibia in ACLD knees [18]. In the present study, the same results were obtained.

Little has been reported on the kinematics after ACLR in loading motion [25–27]. Those reports mostly compared knee kinematics after ACLR with that of healthy control knees. To the best of our knowledge, only two reports by Isberg and Lin compared the same knees before and after ACLR. Isberg et al. analyzed medial and lateral femoral condyle translations and tibial rotation in active and weight-bearing knee extension movements by dynamic radiostereometric analysis (RSA) with tantalum markers. They evaluated patients preoperatively and followed them for 2 years after single-bundle anterior cruciate ligament reconstruction (SB-ACLR) using a four-strand ST/G autograft. The medial femoral condyle position after SB-ACLR was posterior to that of the intact knee in flexion angles from 0° to 25°, indicating that the knee was overstabilized in the AP direction. The lateral femoral condyle position was almost the same preoperatively and after ACLR. The tibial rotation kinematics nearly recovered to intact knee levels, but not significantly [11]. Lin et al. analyzed the medial and lateral condyle contact positions in a step-up motion by the 2D/3D registration technique using a bone model constructed by MRI. They evaluated patients preoperatively and followed them up at 6 and 36 months after SB-ACLR using a BTB autograft. There was no significant difference between before and 6 months after the operation. The medial condyle contact position was significantly anterior at 36 months after SB-ACLR. There was no significant change in the lateral condyle contact point among the three periods. They did not analyze tibial rotation [28].

We performed DB-ACLR, which is reported to be able to restore knee functions clinically [13, 29] and in a cadaveric study [30]. This is the first report that analyzed the in vivo kinematics after DB-ACLR by comparison with the preoperative knee. In the present results, the tibial position after DB-ACLR was posterior to the intact knee in flexion angles from 0° to 60°, which indicated that the knee was overstabilized in the AP direction.

These results have almost the same meaning as the results by Isberg, who showed overstabilization in the AP direction in shallow flexion angles [11]. AP stabilization at shallow flexion angles is important in the treatment of ACL injury because the ACL injury often occurs at such flexion angles. Overstabilization at shallow flexion angles after ACLR may be reasonable for patients to return to sports, though long-term follow-up will be needed. On the other hand, in the present study, tibial rotation of DB-ACLR knees was almost the same as that of contralateral knees at all knee flexion angles. DB-ACLR could reconstruct the posterolateral bundle of the ACL, which is thought to play a more important role for knee joint rotational instability; thus, in the present study, tibial rotation was well controlled. However, Isberg et al. [11] and Ristanis et al. [31] reported that clinical outcomes were good even if tibial rotation was not improved. Longo et al. performed a systematic review of the papers comparing SB-ACLR and DB-ACLR [32, 33]. When comparing the clinical results of SB and DB, they reported that there was a statistically significant but no clinically significant difference in the results of KT arthrometer, and there was no statistically significant difference in the result of pivot-shift test. They recommended simple SB-ACLR until stronger evidence for DB-ACLR will be produced.

The limitations of this study are as follows. First, the subjects were only men. Although ACL tears occur frequently as noncontact-type injuries in women in their teens, there was concern about radiation exposure to young female participants, and only men were targeted in the study. However, female subjects are more likely to have hypermobility, which may alter the results. Second, since fluoroscopic imaging before and after surgery was performed once, the problem of reproducibility should be considered, but this protocol took into account the effects of radiation exposure. The subjects practiced the motions several times in order to take fluoroscopic images of stable motion. Third, these data were continuous data of static images. Thus, there was a possibility that they would be different from dynamic data. Fourth, subjects were not categorized according to the period from injury to survey or the state of the meniscus. These might have affected knee kinematics.

Based on the results of this study, DB-ACLR appears to be a useful technique for improving knee joint kinematics, especially for rotational instability. In the future, verification with non-load motion, deep flexing motion, etc., is also expected. It is significant that the usefulness of DB-ACLR was proven for load-flexing movement in activities of daily living. Based on this result, the long-term clinical results and the OA prevention effect of DB-ACLR are expected to be confirmed in the future.

Conclusions

This is the first report to have analyzed the in vivo kinematics after DB-ACLR by comparison with the preoperative knee. Squatting motion was analyzed before and after DB-ACLR in ACLD knees using a 2D/3D registration technique. DB-ACLR improved not only tibial AP instability but also tibial rotational instability. DB-ACLR appears to be a useful technique for normalizing the knee joint kinematics of ACLD knees.

Anterior cruciate ligament reconstruction with quadriceps tendon-patellar bone allograft: matched case control study

Abstract

Background: Quadriceps tendon-patellar bone (QTPB) autograft is an excellent graft option with good clinical outcome. Use of QTPB autografts have increased because they minimize donor-site morbidity including anterior knee pain, while providing adequate mechanical strength. Although, there were many clinical results about allografts that used in anterior cruciate ligament (ACL) reconstruction, it have never been reported about the clinical outcome of ACL reconstruction with QTPB allograft.
The purpose of this study is to evaluate the clinical outcome of ACL reconstruction with QTPB allograft and to compare with QTPB autograft. We hypothesized that ACL reconstruction with QTPB allograft had good functional outcomes and stability and no significant difference compared to the ACL reconstruction with QTPB autograft.

Methods: From February 2009 to January 2014, 213 cases who received ACL reconstruction with QTPB grafts were included. Forty-five patients who received ACL reconstruction with QTPB allograft were individually matched in age, sex, direction of the injured knee and body mass index (BMI) to a control group of 45 patients who received QTPB autograft. Clinical results were evaluated using International Knee Documentation Committee (IKDC) score, Lysholm score, Tegner scale, Knee injury and Osteoarthritis Outcome Score (KOOS) and ligament laxity. An average follow-up time was 31.2 months.

Results: The functional scores and ligament laxity improved from initial to the last visit in those with ACL reconstruction with QTPB allograft ($p < 0.05$). No significant statistical difference was found in clinical outcomes and complications including re-rupture between the QTPB allograft and autograft groups ($p > 0.05$). Laxity using anterior drawer test, Lachman test and KT-2000 showed no significant difference. No significant difference was found between the two groups in quadriceps peak extension torque, except at 60° per second at 6 months.

Conclusion: QTPB allograft achieved good clinical outcome with no difference compared with QTPB autograft. QTPB allograft for ACL reconstruction is promising alternative to selected and compliant patients. Long-term follow-up needs to further evaluate the clinical outcomes and complications including re-rupture rate.

Keywords: Arthroscopy, Anterior cruciate ligament, Quadriceps tendon-patellar bone, Allograft, Autograft

Background

ACL reconstruction can be performed using several kinds of autograft or allograft tissue. Although, some recent research showed ACL reconstruction with autograft leads to lower retear rates in younger individuals [1], whether the outcomes of these two graft materials differ significantly is unclear [2–4] and the choice of the optimal graft for ACL reconstruction remains still controversial.

Good clinical results of ACL reconstruction have been achieved using proper graft materials, such as bone-patella tendon-bone (BPTB) or hamstring tendons, as well as quadriceps tendon-patellar bone (QTPB) [5–9]. The QTPB autograft is long established as a viable graft option with good clinical outcome [7, 10–18]. The use of QTPB autografts has increased in recent years because they minimize donor-site morbidity including anterior knee pain, while providing adequate mechanical strength as a graft [7, 12, 19, 20]. Several reports have suggested a biomechanical test for quadriceps tendon is comparable to that for BPTB [21–23]. However, QTPB allograft has been the least studied. Previous studies have compared other allografts with autografts in primary ACL reconstruction with results showing inconsistent clinical equivalency [16, 24, 25] and no study has directly compared QTPB allograft to autograft.

The purpose of this study is to evaluate the clinical outcomes of ACL reconstruction with QTPB allograft regarding anteroposterior knee stability, activity, and functional scores. We also evaluated whether the outcomes differed with QTPB allograft and autograft used for ACL reconstruction. We hypothesized that ACL reconstruction with QTPB allograft had good functional outcomes and stability and no significant difference compared to the ACL reconstruction with QTPB autograft.

Methods

This is a retrospective study with ethically approved by the institutional review board of Seoul National University Hospital (No. H-1604-033-753). From February 2009 to January 2014, 278 patients diagnosed as ACL total ruptures who received ACL reconstruction with QTPB grafts were screened. The choice of the graft was determined by full discussion between the patient and the physician. We included patients followed-up more than 2 years after ACL reconstruction. Exclusion criteria were patients who had previous ligament injury and who had concomitant meniscus or ligament injury of the affected knee, except for a Grade I or II medial collateral ligament injury. Revision ACL reconstructions were also excluded. Finally, 45 patients who had QTPB allografts and 168 patients who had QTPB autografts met these criteria. The 45 patients in the QTPB allograft group were matched for age and body mass index (BMI) with 45 patients in the QTPB autograft group (Fig. 1).

Ligament laxity was evaluated with anterior drawer test, Lachman test, pivot shift test and a KT-2000 arthrometer (MedMetric Inc., San Diego, CA) preoperatively, postoperatively at 1, 3 and 6 months and annually thereafter. Quadriceps peak extension torque was checked at 60° and 180° per second using an isokinetic testing device (Cybex, Ronkonkoma, NY) at 6, 12 and 24 months. Functional outcomes including International Knee Documentation Committee (IKDC) score [26], Lysholm Knee Score [27], Tegner score [28] and Knee Injury and Osteoarthritis Outcome Score (KOOS) [29] were evaluated preoperatively and at the postoperative follow-ups.

QTPB allografts were provided by Community Tissue Services (Kettering, OH), a certified soft tissue bank. Allografts were the non-gamma irradiated fresh frozen type. Serological and microbiological tests were performed on the donors in accordance with American Association of Tissue Bank (AATB) standards. On the day of surgery, the allograft was transported from the local distributor to the operating room adding dry ice for below zero temperature conditions (− 70 to − 60 °C). The state of packaging and expiry dates were checked before use and the grafts soaked in sterile saline, warmed to 37 °C for 30 min. A trapezoidal bone block measuring 10 mm in width, 20- to 25 mm in length and 7 mm in thickness was obtained using an oscillating saw. A strip of the quadriceps tendon measuring 10 mm in width, 6-8 mm in thickness and 6 cm in length was excised from the proximal portion of the patellar bone block (Fig. 2).

The QTPB autograft was harvested through a 4 cm midline incision centered over the patella proximal border and prepared by the same method of used for the QTPB allograft. We were cautioned not to approach the suprapatellar pouch by saving part of the vastus intermedius tendon. If the suprapatellar pouch was damaged, the synovial lining was repaired with an absorbable suture. Superficial layers of the cut surface of the tendon were closed transversely with absorbable sutures and the defect was left as a potential space. The bone defect was left in empty space. A hole was drilled in the bone block from the patella base and two absorbable sutures were passed through. The tendinous portion of the graft was secured with two Number 5 Ethibond™ sutures (Ethicon Inc., Somerville, NJ) using the Krackow method with an extension of approximately 30 mm (Fig. 2).

After a graft had been prepared, ACL reconstruction was performed by the modified transtibial technique [30]. A tibial tunnel 10 mm in diameter was drilled and the intra-articular opening of the tunnel was placed in the center of the ACL attachment using an ACL endoscopic guide system (Smith and Nephew, Inc., Andover, MA). A femoral tunnel that was also 10 mm in diameter was drilled through the tibial tunnel in the 10:30 to 11

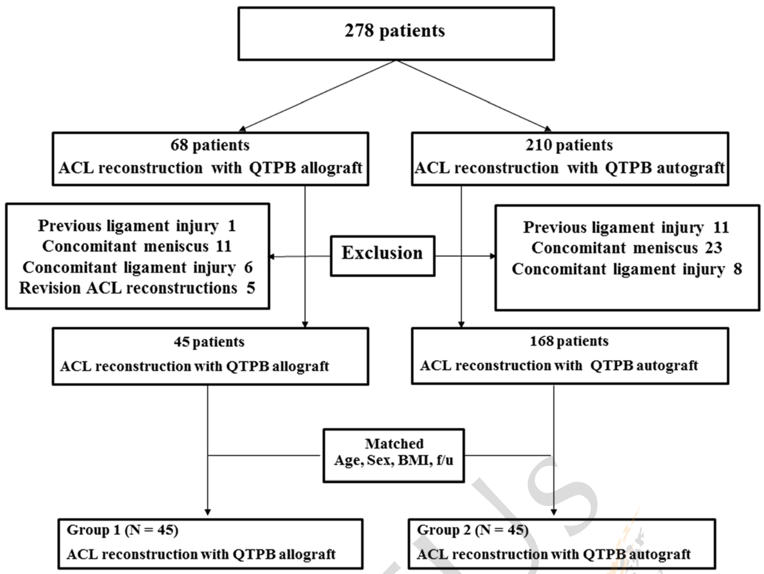

Fig. 1 Flow diagram of patients screened and grouped

o'clock position for the right knee. The posterior cortex of the femoral tunnel was approximately 2 mm thick. Notchplasty was performed to prevent graft impingement if needed. After the graft had been passed through the femoral tunnels, a 8 mm diameter, 25 mm length metal interference screw (Linvatec, Largo, FL) was used to fix the bone block on the femoral side. The ACL reconstructed knee was moved in flexion and extension 15 to 20 times through a full range of motion under tensioning the graft. The tendinous portion was fixed on the tibial side with a 10 mm diameter, 25 mm length metal interference screw (Synthes, West Chester, Pennsylvania) augmented by tying sutures over a cortical screw with the knee extended.

The same rehabilitation protocol was applied for both groups. Patients were taught quadriceps setting exercise and straight leg raising prior to surgery and exercise commenced soon after surgery. Kinetic exercise and weight-bearing progressed as tolerated. Passive range of motion of the ACL reconstructed knee was started from 45° knee flexion and full extension within 3 days after surgery. Patients put on the ACL knee brace 1 week after surgery when swelling decreased. An ACL brace set at 0° to 90° was worn for 3 weeks and then set at 0° to full flexion for an additional 3 weeks postoperatively. Full flexion was allowed at postoperative 7 weeks. Patients usually returned to normal daily activity 3 months after ACL reconstruction and strenuous exercise was approved 6 months postoperatively.

We used SPSS for Windows version 20.0 (SPSS Inc., Chicago, IL) for statistical analyses. The independent t-test was used for the comparison of continuous variables (IKDC score, Lysholm score, Tegner score, KOOS score, extensor strengths and KT-2000 arthrometry), and the chi-squared test was used for the categorical variables (grades of ligament stability including anterior drawer test, Lachman test, pivot shift test). Paired t-test was used for comparing the data before and after the ACL reconstruction. The significance level was set at $P < 0.05$. A post-hoc analysis was performed by G-Power, and confirmed 42 patients in each group to detect one standard deviation difference at 80% power. The ligament laxity

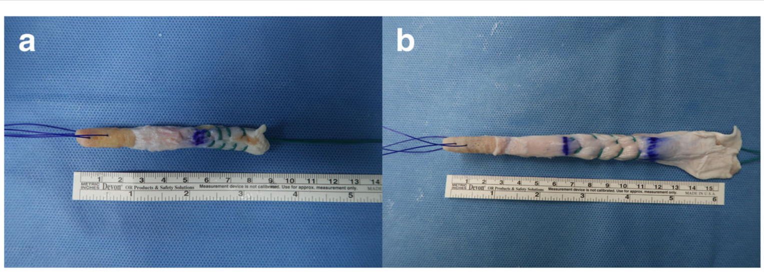

Fig. 2 Quadriceps tendon-patellar bone autograft (**a**) and allograft (**b**)

checked by KT-2000 was primary outcome in which the sample size was based. This study was approved by the institutional review board.

Results

As we mentioned above, 45 patients in each groups were included in this retrospective study. An average follow-up time was 31.2 months.

There were no differences in preoperative demographic data between the two groups (Table 1). Comparisons of knee laxity and clinical outcome between two groups are summarized in Tables 2 and 3. According to the anterior drawer test, Lachman test, and pivot-shift test, there was no significant difference between the two groups preoperatively and at final follow-up (Table 2). All grades of instability were improved from the initial to final visit in both groups ($P < 0.001$). The mean side-to-side differences in anterior laxity during manual maximum testing using KT-2000 arthrometry were similar in the QTPB allograft and autograft groups preoperatively (4.8 ± 1.9 and 4.5 ± 1.8 mm; $P = 0.370$) and postoperatively (1.8 ± 1.6 mm and 1.4 ± 1.2 mm; $P = 0.458$). The KT-2000 measurements at postoperative 2 years follow-up were significantly improved than at preoperative in both groups (both $P < 0.001$).

Forty-one patients, and greater than 5 mm in 12 patients. One patient per group showed grade II in Lachman test, which generally considered clinical failure [31, 32]. However, anterior drawer test, pivot-shift test and KT-2000 measurements showed no instability and had no subjective instability in both 2 patients. Therefore, we decided not to have revision surgery.

No significant differences in functional scores including IKDC score, Lysholm score, Tegner score, KOOS were found between the two groups at preoperative and postoperative 2 years (Table 3). Mean preoperative functional scores in QTPB allografts group and autografts group were improved at postoperative 2 years follow-up ($p < 0.001$).

Quadriceps peak extension torque at 60°and 180° per second increased with time at 6, 12, 24 months in both groups. No significant differences were found the two groups, except the value of the quadriceps peak extension torque at 60° per second at 6 months ($P = 0.042$) (Fig. 3).

In both groups, there were no postoperative complications during follow-ups such as arthrofibrosis, rerupture or infection. In the QTPB autograft group, two patients had paresthesia on the lateral side of the knee. The paresthesia completely disappeared about 2 months after ACL reconstruction. Two patients in the QTPB allograft group and three patients in the QTPB autograft group felt a clicking sensation in the knee during activities, and this symptom was relieved after an average of 3 months.

Table 1 Patient demographic data

	Allograft group (*n* = 45)	Autograft group (*n* = 45)	*p-value*
Age[a]	34.5 ± 12.8	34.5 ± 12.8	1.000
Sex (Male/Female)	38/7	38/7	1.000
Right/Left	20/25	22/23	0.833
BMI (kg/m^2)[a]	25.2 ± 4.0	25.3 ± 4.5	0.905
F/U (months)**	32.6 ± 7.4 (27.5 − 39.5)	29.8 ± 6.5 (24.9 − 44.3)	0.300

Values are expressed as mean ± standard deviation[a] or mean ± standard deviation (range)**

Discussion

This is the first study comparing the knee stability and clinical outcomes of the QTPB allografts and autografts. The most important finding in this study was ACL reconstruction with QTPB allografts showed good clinical outcomes and had no significant differences compared with QTPB autografts. There was no difference about rerupture rate in short-term follow-up. However, 6 months after ACL reconstruction, quadriceps muscle power recovery was relatively good in ACL reconstruction with QTPB allograft.

Several studies have compared ACL reconstruction with QTPB autograft to other autografts and reported comparable results concerning knee stability and functional outcomes [10, 12–14, 19, 20]. Most clinical outcomes about ACL reconstruction with QTPB autograft in these studies were relatively good, which is also shown in our study.

Two studies have compared biomechanical properties of QTPB allograft to other grafts. One study compared the biomechanical properties of 12 QTPB allografts to 11 BPTB allografts [21]. The authors found that the cross-sectional area of the QTPB allografts was nearly twice that of the BPTB allografts and ultimate load to failure and stiffness was significantly higher for the QTPB allografts. The variability in the cross-sectional area was similar in both tendon groups. In the other study, quadriceps and Achilles tendon pairs from nine research-consented donors were tested [33]. All specimens were processed to reduce bioburden and terminally sterilized by gamma irradiation. The authors found that QTPB allografts displayed significantly higher displacement at maximum load and significantly lower stiffness than achilles allografts. Maximum stress, strain at maximum stress, modulus and cyclic elongation exhibited no significant differences between two tendon types. On the basis of these two biomechanical studies, QTPB allograft is judged to be a biomechanically qualified graft for ACL reconstruction.

Several studies have reported allograft rerupture rates were higher than autograft after ACL reconstruction. One study reported a 7% rate of late allograft traumatic

Table 2 Evaluation of knee instability

	Preoperative			Postoperative 2 years		
	Allograft group	Autograft group	*p-value*	Allograft group	Autograft group	*p-value*
Anterior drawer test			0.826			0.652
Grade 0	5 (11.1%)	4 (8.9%)		29 (64.4%)	32 (71.1%)	
Grade 1	16 (35.6%)	15 (33.3%)		16 (35.6%)	13 (28.9%)	
Grade 2	17 (37.8%)	21 (46.7%)		0 (0.0%)	0 (0.0%)	
Grade 3	7 (15.6%)	5 (11.1%)		0 (0.0%)	0 (0.0%)	
Lachman test			0.717			0.404
Grade 0	1 (2.2%)	3 (6.7%)		26 (57.8%)	29 (64.4%)	
Grade 1	17 (37.8%)	14 (31.1%)		18 (40.0%)	15 (33.3%)	
Grade 2	19 (42.2%)	19 (42.2%)		1 (2.2%)	1 (2.2%)	
Grade 3	8 (17.8%)	9 (20.0%)		0 (0.0%)	0 (0.0%)	
Pivot shift test			0.258			0.823
Grade 0	6 (13.3%)	4 (8.9%)		31 (68.9%)	29 (64.4%)	
Grade 1	16 (35.6%)	22 (48.9%)		14 (31.1%)	16 (35.6%)	
Grade 2	21 (46.7%)	14 (31.1%)		0 (0.0%)	0 (0.0%)	
Grade 3	2 (4.4%)	5 (11.1%)		0 (0.0%)	0 (0.0%)	
KT-2000 (mm)[a]	4.8 ± 1.9	4.5 ± 1.8	0.392	1.8 ± 1.6	1.4 ± 1.2	0.235
KT-2000 (No. of patients)						
< 3 mm	2 (4.4%)	5 (11.1%)		39 (86.7%)	34 (75.6%)	
3 – 5 mm	26 (57.8%)	30 (66.7%)		6 (13.3%)	11 (24.4%)	
> 5 mm	17 (37.8%)	10 (22.2%)		0 (0.0%)	0 (0.0%)	

[a]Values are expressed as mean ± standard deviation

rupture versus none in autografts [34]. Another study reported that allograft showed a threefold increase in rerupture rate relative to the autograft (12.7% vs. 4.3%) [35]. There are several possible explanations. Sterilization processes that influence remodeling of the allograft in vivo can cause a higher rate of rerupture in ACL reconstruction done with allograft ACL [36]. In addition, allograft patients may participate in a higher level of activity earlier after surgery, secondary to less pain including donor site pain, with more consequent stress on their grafts, than in autograft patients [37]. In this minimum 2-year follow-up study, there was no rerupture case in ACL reconstruction with QTPB allograft. However, long- term follow-up and further evaluation will be planned.

Although the QTPB autograft has less donor-site morbidity than other autografts, quadriceps graft harvest can cause temporal quadriceps weakness [14, 38–40]. In order to evaluate quadriceps muscle power, we used a Cybex isokinetic testing device. In our study, quadriceps peak extension torque at 60° per second in the QTPB autograft group at postoperative 6 months was less than in the QTPB allograft group. However, there was no significant difference in later follow-up.

In general, unlike primary reconstruction, in revision cases the choice of graft can be determined by the nature of the graft that was previously used, and an allograft may be an appealing situation to use [32]. ACL reconstruction with QTPB allograft showed good clinical

Table 3 Outcomes of functional score

	Preoperative			Postoperative		
	Allograft group	Autograft group	*p-value*	Allograft group	Autograft group	*p-value*
IKDC score	42.3 ± 16.1	42.7 ± 22.6	0.928	70.1 ± 12.5	67.3 ± 16.8	0.366
Lysholm score	65.0 ± 9.1	62.4 ± 8.4	0.166	88.7 ± 6.4	87.0 ± 5.3	0.170
Tegner scale	3.2 [2-4.8]	2.8 [1.8-4]	0.203	7 [6.0-8.0]	7.2 [6.3-8.2]	0.434
KOOS	245.1 ± 87.5	273.8 ± 95.1	0.163	413.2 ± 40.6	423.1 ± 50.9	0.334

Values are expressed as mean ± standard deviation in IKDC score, Lysholm score, KOOS; Values are expressed as the median and interquartile ranges in Tegner scale
IKDC International Knee Documentation Committee, *KOOS* Knee injury and Osteoarthritis Outcome Score

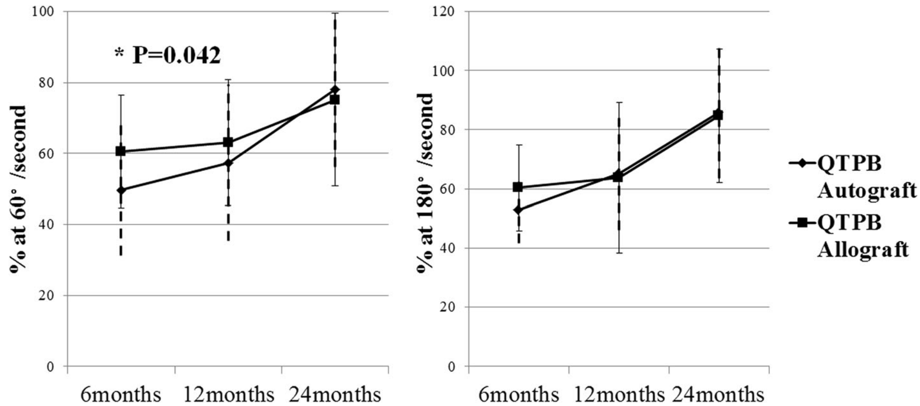

Fig. 3 Side to side ratio of peak torque values by Cybex isokinetic testing at 60° (left) and 180° (right) per second. Vertical full line indicates the standard deviation of the peak extension torque in QTPB allograft group. Vertical dotted line indicates the standard deviation of the peak extension torque in QTPB autograft group. QTPB = quadriceps tendon patellar bone

results in this study, then also possible options in revision ACL reconstruction.

This study has some limitations. First, this study has a retrospective design and the patients were not assigned randomly, increasing selection bias. However, there were several strengths in this study, including the matched demographic features of these patients, same surgical techniques, fixation method and rehabilitation program, which increased the power of statistical results. Furthermore, this is the first study reporting the clinical outcome of QTPB allograft and matched case-control study compared with QTPB allograft. Second, our study includes a relatively small number of patients especially on allograft group and has a short-term follow-up period. According to one study [41], at least 100 patients were required to detect a difference for the majority of outcome measures, and over 800 to detect a difference in return to pre-injury activity level. Comparing to this study, our study has limitations. In order to overcome these limitations, long-term follow up, large scaled, randomized controlled study will be scheduled to confirm the efficacy of this study. Third, our study does not include MRI evaluation of reconstructed ACL to confirm the ligamentizations of ACL. However, we could make an assumption by clinical results including anterior drawer test, Lachman test, pivot shift test and a KT-2000 arthrometer.

Conclusions

ACL reconstruction with QTPB allograft achieves good knee stability and functional outcomes with no difference compared with QTPB autograft at 2 years follow-up. Therefore, QTPB allograft for ACL reconstruction is promising alternative to selected and compliant patients. Long-term follow-up needs to further evaluate the clinical outcomes and complications including re-rupture rate.

Immediate post-operative pain in anterior cruciate ligament reconstruction surgery with bone patellar tendon bone graft versus hamstring graft

Abstract

Background: Pain in the immediate post-operative period after anterior cruciate ligament (ACL) surgery, apart from an unpleasant experience for the patient, can act as a barrier for static quadriceps contractions and optimum execution of the initial rehabilitation protocol resulting in slow recovery and a later return to full function for a sportsperson. There is no report in the literature comparing pain in the immediate post-operative period after using the two most widely used autografts, bone patellar tendon bone (BPTB) graft and hamstring graft.

Methods: The present study compared the visual analogue scale (VAS) pain score in the immediate post-operative period after arthroscopic ACL reconstruction with the BPTB and hamstring autografts. Both groups consisted of 50 patients each. The mean age of the BPTB and hamstring cohorts was 26.9 ± 7.3 years (age range 18–59 years) and 26.7 ± 9.0 years (age range 17–52 years), respectively. Unpaired *t* test was applied to compare pain scores between the BPTB and hamstring cohorts.

Results: In the present study, patients in the BPTB cohort showed higher mean pain scores across all the post-operative time intervals except at 6 h. However, the difference in the mean VAS pain score at post-operative 6, 12,18, 24, 36 and 48 h in the two groups was statistically not significant (*p* value of 1, 0.665, 0.798, 0.377, 0.651 and 0.215 at 6, 12, 18, 24, 36 and 48 h, respectively).

Conclusions: Our study concludes that the arthroscopic ACL reconstruction with BPTB autograft and hamstring autograft is associated with similar pain in the immediate post-operative period. As a result, aggressive physiotherapy regime is not affected by the type of graft being used for ACL reconstruction, as the pain scores in the immediate post-operative period are similar for both techniques.

Trial registration: Clinical Trials Registry-India, CTRI/2016/01/006502

Keywords: Pain score, Immediate post-operative, BPTB graft, Hamstring graft, ACL surgery

Background

Pain in the immediate post-operative period, due to surgical trauma, can be an important barrier for starting an early rehabilitation programme after anterior cruciate ligament (ACL) reconstruction surgery, which can in turn delay the restoration of quadriceps contractions and range of motion at the knee joint. Additionally, the post-operative pain can result in an unpleasant experience of surgery for the patient. Whether there is any difference between the two most commonly used grafts for ACL reconstruction, the BPTB and hamstring grafts, in terms of pain in the immediate post-operative period, has not been reported in the international literature so far.

The relative merits of these two autograft types have been extensively investigated in the long term. The

BPTB autograft has the reported advantage over the semitendinosus-gracilis (STG) autograft of having bone plugs on each end of the graft that provide excellent fixation points for the graft-screw interface and rapid healing within bone tunnels [1–7]. However, the BPTB graft is associated with more morbidities than the STG graft such as anterior knee pain, kneeling pain and higher chances of osteoarthritis of the knees, risk of patellar fracture and patellar tendon weakness or rupture [1, 8–12].

Thus, there is enough data in the literature comparing the results of ACL reconstruction using the BPTB and STG autografts. However, there is still no consensus regarding the superiority of one graft over the other [13, 14].

The present study was designed to compare pain in the immediate post-operative period after arthroscopic ACL reconstruction by the same surgeon using hamstring tendon autograft and patellar tendon autograft while following a similar aggressive post-operative rehabilitation protocol in both groups. In this study, we hypothesized that the use of the STG autograft in ACL reconstruction is associated with less pain in the immediate post-operative period as compared to the BPTB autograft.

Methods

After approval by the Government Medical College and Hospital ethics committee (Chandigarh) and obtaining written informed consent from all the patients, 100 male patients presenting with ACL tear were enrolled in the study. The diagnosis of ACL tear and associated injuries was based on clinical examination (Lachman test, anterior drawer test and pivot shift test) and magnetic resonance imaging (MRI) of knee joint. Out of 100 patients, 50 patients underwent arthroscopic ACL reconstruction surgery using BPTB graft [15] and 50 patients underwent arthroscopic ACL reconstruction surgery using STG graft [16]. Patients were excluded, if they had previously been operated upon the same knee, with previous infective pathology in the same knee, an associated injury to posterior cruciate ligament or any other ligaments in the same knee, patients with any history of psychiatric illness or receiving any medications for such illness, patients on analgesics for any other ailment, patella fracture during graft harvesting, skeletally immature patients and patients operated under anaesthesia other than spinal anaesthesia.

The study design was prospective, randomized and controlled. Using a computer-generated random number table, patients were randomly allocated to either group A ($n = 50$) or group B ($n = 50$). Allocation concealment was done using sequentially numbered coded sealed envelopes. In group A, ACL reconstruction was done by using BPTB graft, in which the size of the bone plug was 10 mm in all the patients. In group B, ACL reconstruction was done by using quadrupled STG graft.

All the patients were administered subarachnoid block using 2 ml of 0.5 % w/v bupivacaine in 8 % dextrose (hyperbaric solution) by an anaesthesiologist having more than 5-year experience in anaesthesia practice. No intravenous analgesics were given in the intraoperative period. The surgical and anaesthetic technique, post-operative rehabilitation and pain management were standardized in all the patients. The CONSORT flow diagram for the study is given in Fig. 1.

Post-operative management

After surgery, both groups underwent the same rehabilitation protocol. A long knee brace was applied to all patients. Isometric quadriceps exercises, knee bending and active straight leg raising were started on day 0 as per tolerance of pain by the patient immediately after surgery when the motor block of spinal anaesthesia had regressed and patients were encouraged to bear the full weight depending upon pain tolerance. Patients were advised to walk with a brace locked in full extension. In case any patient experienced severe pain, injection of tramadol hydrochloride (100 mg) by intravenous route was administered as rescue analgesia.

Outcome evaluation

In each patient, a generic unidimensional pain questionnaire with visual analogue scale (VAS) scores was recorded, starting at 6 h post-surgery (when the effect of the spinal anaesthesia had regressed), every 6 h for the first 24 h post-surgery and then every 12 h till 48 h post-surgery. The VAS used was a continuous scale comprising of a horizontal line, 10 cm (100 mm) in length, anchored by two verbal descriptors, one for each symptom extreme. For pain intensity, the scale was anchored by "no pain" (score of 0) and "pain as bad as it could be" or "worst imaginable pain" (score of 10) on a 10-cm scale [17].

Statistical analysis

We performed unpaired t tests to compare pain scores between the BPTB and STG cohorts. All tests of significance were two-sided, and the results were considered to be significant at $p < 0.05$. For pain scores, we calculated 95 % confidence intervals (CIs) of the difference of the means.

Results

Participants

The mean age of the BPTB cohort was 26.9 ± 7.3 years (age range 18–59 years). The mean age of the STG cohort was 26.7 ± 9.0 years (age range 17–52 years). Both groups were statistically comparable with respect to age (p value = 0.146). All participants of the study were male patients.

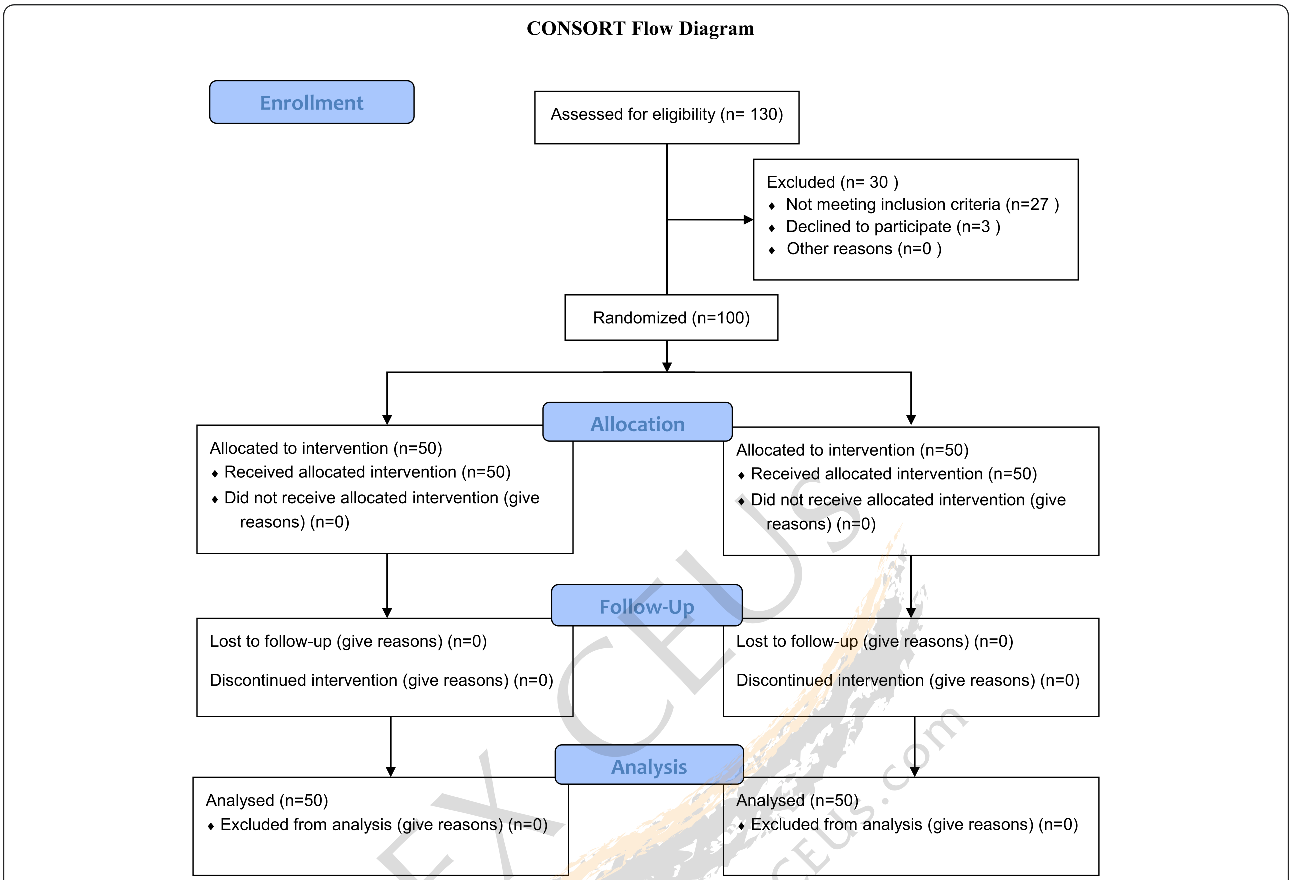

Fig. 1 CONSORT flow diagram

Duration of surgery

The mean duration of surgery for the BPTB cohort was 55.46 ± 0.93 min (range 40–60 min). The mean duration of surgery for the STG cohort was 40.66 ± 0.64 min (range 30–50 min). The difference in the mean duration of surgery for the two groups was found to be statistically significant (p value = 0.0131).

BPTB versus STG: VAS scores for pain

Patients in the BPTB cohort showed higher mean pain scores across all the post-operative time intervals except at 6 h. However, the difference in the mean VAS pain score at post-operative 6, 12,18, 24, 36 and 48 h in the two groups was statistically not significant (p value of 1, 0.665, 0.798, 0.377, 0.651 and 0.215 at 6, 12, 18, 24, 36 and 48 h, respectively). The details of the mean VAS scores for the two groups over the 48-h post-operative period are as shown in Fig. 2 and Table 1.

Discussion

The mean duration of surgery in the BPTB group was statistically higher as compared to the STG group. Further, harvesting of the BPTB graft involves the cutting of bone and periosteum on the patellar as well as tibial sides, thereby increasing the severity of surgical trauma in comparison to the STG graft. The longer duration of surgery and more surgical trauma in BPTB graft patients can be a cause of more pain in these patients as compared to STG patients. In the present study, patients in the BPTB cohort showed higher mean pain scores across all the post-operative time intervals except at 6 h (Table 1). We feel that the pain score at 6 h may have some confounding due to a residual analgesic effect of the spinal anaesthesia [18]. However, the difference in pain scores, even at other time intervals, in our study could not reach a statistically significant level.

The success of ACL surgery depends upon post-operative rigorous rehabilitation [19]. The role of surgical procedure is only to re-establish the physical structure of the ligament, whereas an early rehabilitation helps to maintain the physical and psychological capabilities of the athlete [20]. We, at our institution, follow an accelerated rehabilitation programme which has been shown to be safe and effective by various studies [19, 20]. According to this programme, patients are supposed to begin immediate post-operative weight bearing, move the knee from 0° to 90° of

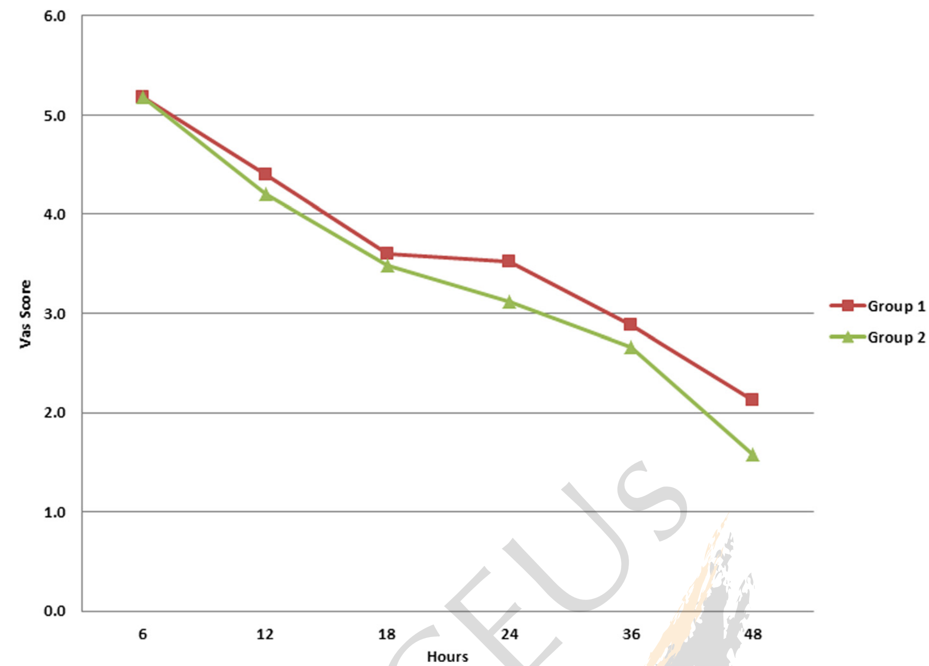

Fig. 2 Graph showing comparison of the mean VAS pain score for the two groups at specified intervals of time

flexion and perform closed-chain strengthening exercises. Thus, a surgical procedure, which can provide less pain in the immediate post-operative period, will be more useful for the accelerated rehabilitation programme.

The decision regarding the choice of graft is currently an important point of debate in the treatment of ACL injury [13]. Although the long-term advantages and disadvantages of the BPTB and STG grafts are well known, there was no evidence in the literature as to which of the two grafts would provide less pain in the immediate post-operative period.

The residual analgesic effect of the central neuraxial block in the first few hours of the post-operative period may act as one of the confounding factors while appraising the pain intensity by the type of surgical procedure. Hence, an extended period of evaluation was done in the present study [18]. Various clinical trials have evaluated pain scores during the immediate post-operative period, with durations varying from 8 to 96 h [21–28]. In the present study, we evaluated pain intensity for the immediate 48-h post-operative period, because all the patients start full weight bearing and knee bending beyond 90° of flexion within the first 48 h as per the accelerated rehabilitation protocol followed by us.

McDonald et al. conducted a study in which a comparison of pain scores and opioid/analgesic medication use in the post-operative period, in patients undergoing single-bundle and double-bundle ACL reconstruction, was done. The study concluded that there was no difference in pain scores in the two groups; however, opioid use/analgesic medication use was more in the double-bundle group. Further, the patients who underwent surgery under spinal anaesthesia experienced less pain in the post-operative period than those who received

Table 1 BPTB vs STG mean VAS pain score (in centimetres) at specified intervals of time

Post-operative time (h)	Mean ± SD VAS score		Mean difference	*p* value
	Group A (*n* = 50) BPTB	Group B (*n* = 50) STG	(95 % CI)	
6	5.2 ± 2.5	5.2 ± 2.4	0 (−0.97 to 0.97)	1
12	4.4 ± 2.3	4.2 ± 2.3	0.2 (−0.71 to 1.11)	0.665
18	3.6 ± 1.9	3.5 ± 2.0	0.1 (−0.67 to 0.87)	0.798
24	3.5 ± 2.4	3.1 ± 2.1	0.4 (−0.49 to 1.29)	0.377
36	2.9 ± 2.3	2.7 ± 2.1	0.2 (−0.67 to 1.07)	0.651
48	2.1 ± 2.1	1.6 ± 1.9	0.5 (−0.29 to 1.29)	0.215

general anaesthesia, as evidenced by significant difference in the consumption of analgesics amongst the two groups [29]. We operated on all the patients in both groups under spinal anaesthesia to remove this bias and its effects on pain scores in the post-operative period.

For the study, the major limitation is the use of tramadol hydrochloride to relieve pain. It was administered in a total of 12 patients amongst the two groups in the first 6 h only (7 and 5 in the BPTB and STG groups, respectively), and the use was comparable ($p < 0.05$). However, additional data in terms of the total dose of consumption and the time to first dose of rescue analgesia should be recorded to make the data more credible.

Since in our study the difference in pain scores could not reach a statistically significant level at any time interval, our hypothesis that the use of hamstring tendon autograft in ACL reconstruction is associated with less pain in the immediate post-operative period as compared to bone patellar tendon bone autograft could not be proved.

Conclusions

Aggressive physiotherapy regime is not affected by the type of graft (BPTB or STG) being used for ACL reconstruction, as the pain scores in the immediate post-operative period are similar for both the techniques.

Outcomes of simultaneous high tibial osteotomy and anterior cruciate ligament reconstruction in anterior cruciate ligament deficient knee with osteoarthritis

Abstract

Background: We aimed to evaluate clinical and radiological results after simultaneous open-wedge high tibial osteotomy (HTO) and anterior cruciate ligament (ACL) reconstruction in patients with ACL deficiency combined with medial uni-compartmental osteoarthritis (OA) and varus deformity.

Methods: This retrospective study was performed using data collected from 2005 to 2011 on a total of 24 patients who were diagnosed with ACL injury and medial unicompartmental OA with varus deformity, and who subsequently underwent simultaneous open-wedge HTO and arthroscopic ACL reconstruction. The mean follow-up duration was 5.2 years. For clinical outcomes, we evaluated Lysholm score, Tegner activity score, range of motion, Lachmann test, and pivot-shift test, and for radiological outcomes, we evaluated the degree of varus deformity, progression of medial OA, tibial posterior slope, anterior instability, and postoperative complication.

Results: There were no limitations in range of motion found in any cases. Three patients showed progressive osteoarthritis on the medial compartment. The mechanical femorotibial angle was significantly corrected from varus 7.0 degrees to valgus 1.2 degrees, and the tibial posterior slope was not significantly changed. The Lysholm and Tegner activity scores were significantly improved after surgery (from 58 to 94 points on the Lysholm scale and from 4.0 to 5.3 points on the Tegner activity scale). Although the Lachman test and the pivot-shift test showed significant improvements after surgery, instability greater than Gr II was observed in three patients on the Lachman test and in four patients on the pivot-shift test. The side-to-side difference improved from 9.6 mm to 4.2 mm postoperatively as assessed using a Telos® arthrometer. There were no cases of nonunion or fixation loss.

Conclusions: Simultaneous open-wedge HTO and ACL reconstruction in patients with ACL injury with medial compartmental OA showed satisfactory functional outcomes and postoperative activity level scores. However, some patients showed residual instability and progression of OA.

Keywords: Knee, High tibial osteotomy, Anterior cruciate ligament reconstruction

Background

Anterior laxity in anterior cruciate ligament (ACL) deficient knees is a precursor to degenerative osteoarthritis (OA) [1, 2]. The risk of developing radiologically evident OA of at least Kellgren- Lawrence grade 2 is reported to be five-fold higher in the setting of anterior laxity than in uninjured knees [1, 3]. For patients with concomitant varus deformity, ACL reconstruction may restore the stability of the knee, but it cannot prevent the progression of medial compartmental OA [4, 5]. Furthermore, varus alignment adds an adduction moment while patients are walking [6]. This adduction moment force translates to varus thrust on the knee joint during the heel strike [6, 7]. This may stress the reconstructed ACL graft, causing early failure. The success of valgus high tibial osteotomy (HTO) in treating unicompartmental OA in young adults encouraged the authors to attempt the procedure in knees with ACL injuries in order to restore stability and prevent the progression of OA [8–10]. Such a procedure should theoretically unload the medial compartment and decrease the stress on the newly reconstructed ACL graft. However, such a procedure may also increase the risk of morbidity and delay the rehabilitation from the ACL reconstruction. Further, valgus HTO is known to increase the posterior slope of the proximal tibia, which may further accentuate the stress on the reconstructed graft [11, 12]. The indications and benefits of this combined surgery therefore remain unclear in the literature. Variability in pathology, the follow-up period, and clinical scores used for evaluation makes comparisons between the available data difficult [13].

The aim of our study was to evaluate radiological and functional outcomes in patients with ACL deficient knees and medial unicompartmental OA undergoing simultaneous ACL reconstruction and HTO.

Methods

The institutional review board (Chonnam National University Hospital) approved this retrospective study prior to the commencement of this study. We reviewed the records of all patients who underwent simultaneous ACL reconstruction and HTO from 2005 to 2011 and got the written consents from the patients. The inclusion criterion for the study was an ACL deficient knee with varus deformity (more than 5 degrees) on full-leg length standing radiography as well as radiographically-proven (X-ray or MRI) isolated medial unicompartmental osteoarthritis (≥ Kellgren-Lawrence Gr I) with a minimum follow-up period of 3 years. Other ligamentous laxities, degenerative arthritis of the lateral compartment, tears of the lateral meniscus, inflammatory knee arthritis, and a follow-up period shorter than 3 years were regarded as exclusion criteria.

Two senior authors operated on all patients. Diagnostic arthroscopies were carried out prior to ACL reconstruction and osteotomy in all cases. Cartilage defects on the medial side were dealt with using micro-fractures (eight cases) when it is necessary. Partial meniscectomies (nine cases) or meniscal repair (five cases) were performed whenever deemed necessary by the surgeon. Quadrupled hamstring autografts were harvested from the ipsilateral side in all cases. After the drilling of a femoral tunnel through the outside-in technique using an ACL guide (Linvatec, Largo, FL, USA), medial opening biplanar high tibial osteotomy was performed as described in the literature [14]. The starting point of osteotomy on the medial side was shifted more distally than typically described to allow enough space for the tibial tunnel. The osteotomy was opened to the point at which the mechanical axis passed through the 62.5% point of the tibial plateau. This was fixed with two Aescula plates (Medysey, Seoul, Korea), non-locking plates with rectangular metal wedges. To maintain the tibial slope, the anterior plate was smaller than the posterior plate. A cancellous bone chip allograft was performed when the tibial opening was larger than 10 mm. This was followed by the drilling of a tibial tunnel. The graft was then passed through both the femoral and tibial tunnels and secured using a closed loop Endobutton (Smith & Nephew, Andover, MA, USA) or an adjustable loop TightRope (Arthrex, Naples, FL) on the femoral side and an interference screw on the tibial side. The tibial attachment was further secured using a spiked washer and a cortical screw. Range of motion exercises were begun as soon as possible. Knees were kept in a range of motion brace for 4 weeks. Toe touch partial weight bearing was allowed for the first 4 weeks after surgery, after which progressive tolerable weight bearing was encouraged.

An independent orthopedic fellow who was not directly involved in patient management collected all data. Preoperative and postoperative radiological and clinical records were evaluated. Range of motion, Lyslohm scores, Tegner activity scores, pivot-shift test, and Lachman tests were estimated in the clinical records. A Telos® device (Austin & Associates, Fallston, MD, US) was used to evaluate stress tests. Anterior laxities were evaluated in 30-degree flexion with 15Lb anterior stresses using the Telos device by side to side difference compared with a normal contralateral knee. The anterior-posterior and lateral radiographs were screened for the progression of osteoarthritis and for changes in posterior slope. Lastly, full-leg length standing radiographs taken preoperatively and 3 months postoperatively were assessed for preoperative and postoperative lower limb alignment.

Table 1 Preoperative and postoperative clinical and radiological results

	Preoperative	Final follow-up	*P*-value
Mechanical axis (in degree)	7.0 ± 2.3	−1.2 ± 1.4	< 0.001
Tegner activity score	4.0 ± 1.1	5.3 ± 0.9	< 0.001
Lysholm score	58.5 ± 12.0	94.0 ± 5.9	< 0.001
Anterior laxity on Telos stress radiography (in mm)	9.6 ± 2.8	4.2 ± 2.6	< 0.001
Posterior slope	9.1 ± 1.4	10.2 ± 2.3	0.092
Range of motion	137.3 ± 6.2	136.5 ± 6.0	0.691

-; valgus

Statistical analysis

All variables are expressed as means +/− standard deviations. The difference between preoperative and postoperative values was assessed using a paired-t test for continuous variables and a Chi-square test for categorical variables. A *p* value less than .05 was considered to be significant. SPSS software version 22 (IBM, Armonk, NY, USA) was used for all analysis.

Results

Our records yielded 24 patients that satisfied the inclusion criterion, consisting of 20 males and four females. The average age of our patients was 40.2 years (range, 29–52 years). The mean follow-up period was 5.2 years (range, 3–9 years). None of the patients required conversion to arthroplasty.

Table 1 presents the preoperative and final postoperative clinical and radiological outcomes of our study. At the final follow up, none of the patients had any range of motion (ROM) limitations. Clinical scores improved in all cases to pre-injured levels. The mechanical axis was corrected from preoperative varus 7.0 to a mean of valgus 1.2 degrees. None of the patients showed significant changes (more than three degrees from preoperative values) in posterior slope.

Clinically, anterior laxity was improved in all patients except for three who showed grade 2 laxity on the Lachman test and four who had a positive pivot-shift test (Table 2). Stress radiography confirmed the clinical findings of improved laxity, with a significant decrease in side-to-side difference in anterior laxity compared to preoperative values.

At the final follow-up, three patients showed progression of medial unicompartmental osteoarthritis (Table 3, Fig. 1). Two of them had medial meniscal damage and one had full thickness cartilage defect on medial femoral chondyle at the time of index surgery.

Three patients complained of hyperesthesia in the antero-lateral part of the proximal tibia and one patient had pain in the incision site. There was no case of non-union of the osteotomy site. No other major complications were noted in our series.

Discussion

The most important finding of our study was that simultaneous ACL reconstruction and valgus HTO showed relatively good clinical and radiological outcomes in ACL deficient knees with osteoarthritis. However, some patients showed a moderate degree of instability or a progression of OA in spite of ACL reconstruction. Further studies are warranted to clearly define a patient subgroup that would benefit from the combined procedure.

Patients with combined laxity and medial compartmental OA tend to be young and therefore retaining their natural knee is a priority [15]. With the aim of restoring the laxity and alignment of the knee, many authors have suggested a combined ACL reconstruction and valgus osteotomy procedure [8–10]. Consistent with the results previously published by most authors, we found that none of our cases required conversion to total knee arthroplasty over a mid-term follow-up of an average of 5 years [8–10, 12, 16]. This substantiates the role of the combined procedure in such knees.

Most previous authors reported improved functional scores following combined surgery. We had a similar experience as we found Lysholm scores and Tegner activity scores to be significantly better after the operation

Table 2 Improvement of anterior instability based on Lachman and pivot shift test

Grade	Lachman test		P-value	Pivot-shift test		P-value
	Preoperative	Final follow-up		Preoperative	Final follow-up	
0	0	14	< 0.001	0	15	< 0.001
I	3	7		9	5	
II	14	3		11	4	
III	7	0		4	0	

Table 3 Progression of osteoarthritis on medial compartment

Grade	Preoperative	Final follow-up	P-value
I	10	8	0.682
II	9	10	
III	5	6	
IV	0	0	

than they were before the operation [8–10, 16–18]. All patients subjectively reported better stability of the knee. Despite these encouraging results, six patients (25%) showed progressive medial compartmental osteoarthritis on serial radiographs. Similarly, four patients (17%) had a positive pivot shift test, three of whom also had a positive grade 2 Lachman test. Complication rates in the literature are variably defined. In line with our experience, Zaffanigni et al. [19] reported 22% progression in medial compartmental OA after a 6.5-year follow-up. In contrast, Dejour et al. [20] found no difference in the OA rate preoperatively vs. postoperatively in a retrospective study.

A similar discrepancy exists in the rate of anterior laxity. Lattermann reported that 31% of patients developed graft insufficiency [8]. Consistent with our results, Schuster et al. [21] reported graft insufficiency in 18% of patients. However, others have described a 0% rate of graft insufficiency following the combined procedure [22]. Finally, contrary to our results, Dean et al. [23] conducted a systemic review and identified knee stiffness as the most common complication. We observed no loss of movement in any patient. These differences between reports may be the result of the use of different surgical techniques as well as differences in preoperative patient conditions, timings of the surgeries, rehabilitation protocols, and/or follow-up periods. The published data is heterogeneous regarding each of the above parameters, making comparisons difficult. Such wide differences in complication rates highlight the currently inadequate understanding of the true pathological nature of ACL deficiency with unicompartmental OA. It further stresses the need for future studies to define indications for the combined procedure. In addition, the combined procedure is a complex technique that requires meticulous preoperative planning, skilled intraoperative techniques, and an aggressive postoperative rehabilitation protocol.

Changes in tibial slope following high tibial osteotomy are well known to occur and may affect the stresses on a reconstructed graft [11]. We observed no significant differences between preoperative and postoperative values. However, despite maintenance of the slope in all cases, we observed graft insufficiency in 17% of cases, indicating that a non-mechanical mechanism may be involved in preventing graft healing. Consistent with our experience, Schuster et al. hypothesized that severe osteoarthritic changes and an associated catabolic intra-articular milieu may play a role in insufficient graft integration or compromise graft functionality [18].

There are a few limitations to our study. First, it is a retrospective study and is therefore subject to the associated usual biases. Secondly, the sample size is too small

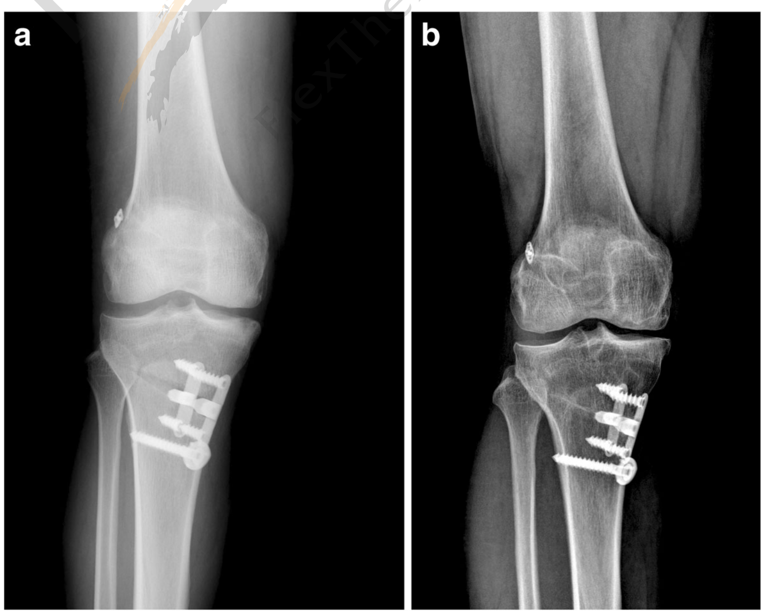

Fig. 1 a Immediate operative knee x-ray showing medial compartment osteoarthritis following ACL reconstruction and valgus high tibial osteotomy. **b** Knee x-ray taken three years following ACL reconstruction and valgus high tibial osteotomy that shows the progression of arthritis of medial compartment to draw any definitive conclusions about the outcomes of this combined procedure. Thirdly, we carried out abrasion chondroplasty in the same setting, and as its role on ACL healing is still debatable, it may act as a confounding factor. The last limitation was that the majority of our patients were male and only four patients were female. Despite these limitations, our study strongly indicates a need for caution when choosing patients and performing combined ACL reconstruction and valgus HTO surgery, because of the possibility of a high complication rate.

Conclusions

Simultaneous open wedge HTO and ACL reconstruction showed satisfactory correction angles and improved knee joint function, delaying the need for arthroplasty. However, this combined procedure should be undertaken with caution, as it is associated with a high rate of laxity and the progression of osteoarthritis.

Laser-guided transtibial technique improved single-bundle reconstruction of anterior cruciate ligament

Abstract

Background: The transtibial tunnel technique achieves equal length reconstruction of the anterior cruciate ligament (ACL). This study aimed to investigate whether transtibial tunnel technique can achieve anatomical reconstruction of ACL.

Methods: For 25 corpses, the anterior soft tissue of the knee joint was detached so that the ligamentous surface was fully exposed, then the knee joint was fixed at 90° with an external fixator and the anterior cruciate ligament was removed. Double-sided laser technology was used to establish spatial conformation of ACL.

Results: The male to female ratio of the subjects was 19:6, with an average age of 59.52 ± 11.13 years. Patellar tendon length was 35.23 ± 5.10 mm, tibial eminence length and width was 15.75 ± 2.44 and 7.80 ± 1.28 mm, respectively, and femoral attachment length and width was 15.40 ± 2.17 and 8.97 ± 1.61 mm, respectively. When the flexion turned 90°, the tibial tunnel length was 31.83 ± 4.09 mm and the distance to the tibial plateau, patellar tendon, and medial collateral ligament was 16.33 ± 4.56, 10.79 ± 5.85, and 23.12 ± 5.99 mm, respectively.

Conclusions: With the aid of double-sided laser technology, transtibial tunnel technique can safely achieve single-bundle reconstruction of ACL.

Keywords: Anterior cruciate ligament, Transtibial tunnel technique, Anatomical reconstruction, Double-sided laser technology

Background

The injury of anterior cruciate ligament (ACL) has high incidence in sports medicine. The annual incidence of ACL is about 1‰ in general population in Sweden, and the average age is only 32 years old [1]. In China, the incidence of ACL injury has increased recently. Long-term conservative treatment will result in unstable joints, injury of attached structures, and osteoarthritis [2]. Therefore, surgery is usually recommended, and ACL reconstruction based on transtibial tunnel technique is the most common surgical method [3, 4]. However, the femoral tunnel is relatively high, and the graft is too vertical to control the rotation, which will result in the injury of the meniscus and osteoarthritis [5, 6]. Anatomical reconstruction may solve this problem by reconstructing the natural ACL spatial structure analogy [7].

Several studies have shown that anatomical structure reconstruction, whether single bundle or double bundles, could effectively improve the stability of joints, increase the recovery rate and sustain the time, and prevent abnormal rotation and joint laxity [8, 9]. Therefore, anatomical reconstruction becomes a new trend of ACL reconstruction [2]. Currently, there are two main techniques for anatomical reconstruction: trans-portal (TP) and outside-in (OI) [10, 11]. Different techniques have different advantages and disadvantages [12, 13]. Traditional transtibial tunnel (TT) technique has advantages such as fewer incisions and ease to place graft, but it is still questioned because of its non-anatomical position [6]. Current literatures support that it is impossible to conduct anatomical reconstruction of ACL using TT technique [14–16].

In this study, we hypothesized that TT technique can be applied safely to anatomical reconstruction of ACL when the knee is secured at 90° of flexion and ACL spatial structure analogy could be simulated by double-sided laser technique to precisely depict the position of the tibial-femoral tunnel.

Methods

Subjects

This study was approved by The Affiliated Suzhou Hospital of Nanjing Medical University Ethics Committee. No written/verbal consent was needed for this study because cadavers were used. Forty-nine intact knees of 25 cadavers were used in this study because one knee was found to have slight osteoarthritis and was excluded. The subjects included 19 males and 6 females, mean age was 59.52 ± 11.13 years old, and mean height was 164.92 ± 7.27 cm.

Dissection

The body was put in a supine position, the skin and the fat tissue were carefully removed, and the quadriceps femoris and patellar tendon were identified. The patellar tendon was cut after its length was measured and stripped along the patella, close to the femur and underneath the quadriceps femoris until the shaft of the femur was exposed. Next, synovial membranes and fat pads were cleaned carefully and ACL was exposed.

Measurement

The knee flexion angle was measured with a digital goniometer (0–200 mm, ELECALL). One arm of the goniometer was aligned with the long axis of femur shaft, and the other arm of the goniometer was aligned with the long axis of tibia shaft. The measurement was taken at 90° of knee flexion (Fig. 1). No horizontal and lateral torques were applied. The position of tibia and femur was evaluated to avoid the rotation of tibia and femur. Single-side external fixation supporter was used to hold the internal and external of the knee joint securely and avoid the translocation of the knee joint. After fixation, ACL was removed carefully. The central point in footprints was chosen as the central point of the tunnel. Two high-accuracy laser transmitters (Yuan Ad LASER, 650 nm, type YD-L650P100-26-110) were used to create a laser plane. The central point of ACL was located and marked with gentian violet. The point C and D was aligned to create plane A using high-accuracy surface-type laser transmitter; The point C and D was aligned to create plane B using another high-accuracy surface-type laser transmitter; Plane A and B intersected a spatial line L, and line L passed through point C and D, and point C and D defined the ACL spatial configuration. Line L passed through tibial exit point and femoral exit point as E and F, respectively. If the tunnel is straight, then CDEF is on the same line (Fig. 2). The measurement of the tibia and femur was demonstrated in Figs. 3 and 4, respectively.

Fig. 1 Measurement with the knee secured at 90°

Statistical analysis

Statistical analysis was performed using SPSS 21.0 (SPSS, Inc., Chicago, IL, USA). Data were presented as X ± SD. The continuous variables were tested by Kolmogorov–Smirnov to analyze the normality and by Levene's test to analyze the homogeneity. Groups were compared by independent *T* test. $P < 0.05$ indicated significant difference.

Results

In this study, we examined 49 knees from 25 subjects, the male to female ratio was 19:6, the mean age was 59.52 ± 11.13 years old, the mean height was 164.92 ± 7.27 cm, the length of the patellar tendon was 35.23 ± 5.10 mm, the tibial transverse diameter was 73.50 ± 4.89 mm, the tibial anteroposterior diameter was 45.18 ± 4.01 mm; the length of tibial attachment was 15.75 ± 2.44 mm; the width of tibial

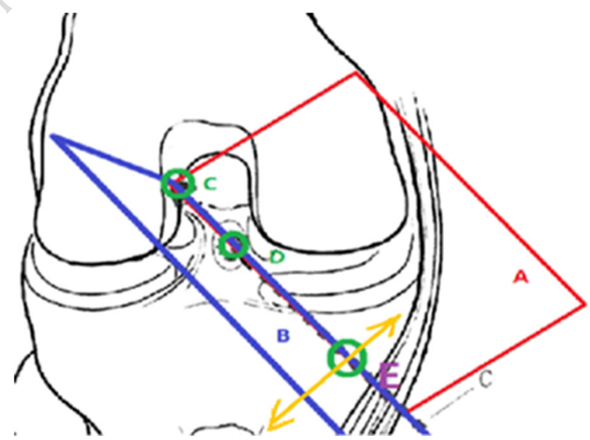

Fig. 2 Double-sided laser technology. One of the ACL spatial configuration locating methods. The central point of ACL was located and marked with gentian violet. The point C and D was aligned to create plane A using high-accuracy surface-type laser transmitter; The point C and D was aligned to create plane B using another high-accuracy surface-type laser transmitter; Plane A and B intersected a spatial line L, and line L passed through point C and D, and point C and D defined the ACL spatial configuration. Line L passed through the tibial exit point and femoral exit point as E and F, respectively. If the tunnel is straight, then CDEF is on the same line

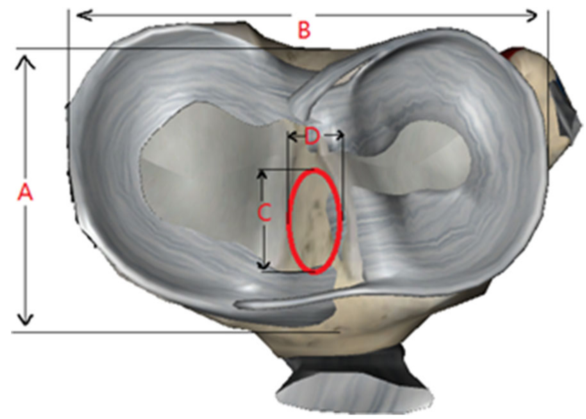

Fig. 3 The measurement of the tibia (**a**). Transverse diameter (**b**). Anteroposterior diameter (**c**, **d**). The anteroposterior length and the maximum width of the right knee ACL tibial attachment, respectively

attachment was 7.80 ± 1.28 mm; and the distance from the femoral attachment to the posterior wall was 2.61 ± 0.62 mm. The occurrence of the lateral intercondylar eminence was 76%, and the occurrence of the lateral furcatus eminence was 49%.

For ACL tunnel reconstruction, at the 90° of flexion, Kirschner wires were drilled through point D and E into the central point of the femoral ACL footprint, then drilled out around point F. The mean distance to point F was 1.14 ± 0.82 mm, the length of the tibial tunnel was 31.83 ± 4.09 mm, the distance to the tibial plateau was 16.33 ± 4.56 mm, and the distance to the patellar tendon was 10.79 ± 5.85 mm; the distance to the medial collateral ligament was 23.12 ± 5.99 mm; and the length of the femoral tunnel was 42.70 ± 7.83 mm. The comparison of left knees and right knees showed no significant difference (Table 1).

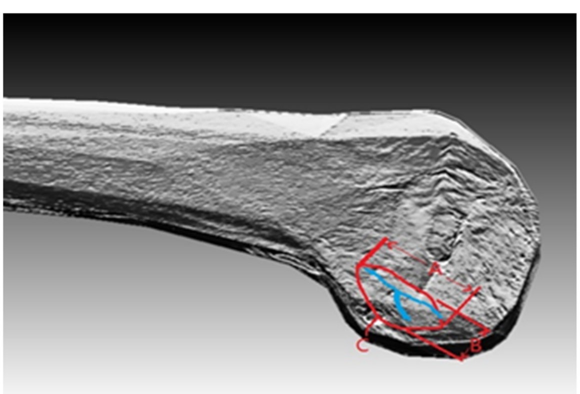

Fig. 4 The measurement of the femur. **a** The length of the femoral attachment. **b** The width of the femoral attachment. **c** The distance from the femoral attachment to the posterior wall. The lateral intercondylar eminence and lateral furcatus eminence were indicated by blue

Discussion

According to the anatomical reconstruction, the bundle could be classified to single bundle, double bundles, and triple bundles. In this study, we used single-bundle because we found that the length of ACL tibial attachment was 15.75 ± 2.44 mm and the length of femoral attachment was 15.40 ± 2.17 mm, which were not the indication for the use of double bundles. Previous studies suggested that the double bundles can be safely conducted if the long axis of the anatomical footprint is greater than 16 mm. However, if the width of ACL footprint is less than 14 mm, the double bundle cannot be conducted [17, 18]. In addition, the double-bundle technique cannot be applied to severe open bone contusion, notch structure, severe arthritis, or multiple injuries, and the surgery is complicated [19].

A meta-analysis of 22 studies compared the difference between single- and double-bundle anatomical reconstruction and found that the double-bundle anatomical reconstruction only had the advantage of rotational stability, and most clinical function outcomes except IKDC score showed no significant difference between single- and double-bundle ACL reconstruction [7]. Therefore, in this study, we chose the single-bundle ACL anatomical reconstruction.

Recent studies showed that the thicker graft has a lower failure rate for ACL reconstruction [20–22]. However, the width of the grafts should be limited. A recent study suggested that the size of the tunnel was determined by the size of ACL footprint. For example, if the length of the tibial attachment in implant position was 18 mm and the width was 8 mm, 8-mm width was recommended as the diameter of the tunnel [23]. In this study, the width of the tibial attachment was 7.80 ± 1.28 mm and the width of the femoral attachment was 8.97 ± 1.61 mm in the subjects. Thus, the width for ACL single-bundle reconstruction should be around 7.8 mm for people in our region.

In this study, we chose tibial tunnel technique to conduct anatomical reconstruction. This technology is simple and safe, has decreased risk of revision compared to anteromedial technique, and has been widely applied [24, 25]. However, some researchers doubted the possibility of transtibial tunnel technique to achieve anatomical reconstruction of ACL [26, 27]. Several studies showed that revised transtibial tunnel technique could achieve anatomical reconstruction of ACL [28, 29]. In this study, we successfully used transtibial tunnel technique to achieve anatomical reconstruction of ACL.

The occurrence of the lateral intercondylar eminence was 76% and that of the lateral furcatus eminence was 49%; these anatomical markers are

Table 1 The comparison of left and right knee anatomical data

	Left knee	Right knee	*T*	*P*
Length of patellar tendon	35.28 ± 4.87	35.30 ± 5.49	− 0.01	0.99
Tibial anteroposterior diameter	45.33 ± 4.06	45.04 ± 4.13	0.24	0.81
Tibial transverse diameter	73.25 ± 5.14	73.71 ± 4.82	− 0.32	0.75
Length of tibial attachment	15.74 ± 2.31	15.95 ± 2.48	− 0.31	0.76
Width of tibial attachment	7.96 ± 1.25	7.98 ± 1.35	− 0.06	0.96
Length of femoral attachment	15.33 ± 2.15	15.34 ± 2.21	0.01	0.99
Width of femoral attachment	8.97 ± 1.74	8.89 ± 1.50	0.18	0.86
Distance from the femoral attachment to the posterior wall	2.61 ± 0.68	2.61 ± 0.59	0.04	0.97
Distance from laser point to Kirschner wire point	1.06 ± 0.85	1.21 ± 0.81	− 0.60	0.55
Length of tibial tunnel at 90°	31.94 ± 4.26	31.47 ± 3.88	0.39	0.47
Distance from point E to joint line at 90°	16.01 ± 4.12	16.92 ± 4.92	− 0.69	0.90
Distance from point E to patellar tendon at 90°	10.92 ± 5.57	10.81 ± 6.30	0.06	0.11
Distance from point E to medial collateral ligament at 90°	23.63 ± 5.74	22.63 ± 6.42	0.57	0.57
Length of femoral tunnel at 90°	42.54 ± 7.86	42.33 ± 7.88	0.09	0.92

The unit was millimeter

permanent and could be used as the markers of ACL anatomical reconstruction. We used double-sided laser technology in our measurement, which is simple, accurate, and cheap and can evaluate the tunnel from different angles. The distance from Kirschner wires' exit position to the lateral point of the femur was only 1.14 ± 0.82 mm.

This study has several limitations. First, the age of the subjects is biased and all subjects were middle-aged or elders. Second, the sample size is limited. Third, we could not exclude some confounding factors that affect the measurement of ACL. Further large-scale studies are needed to prove the application of double-sided laser technology and transtibial technique to single-bundle anatomical reconstruction of ACL.

Conclusions

In summary, our study suggests that for subjects in the southern region of Jiangsu, China, transtibial tunnel technique can be used to achieve single-bundle ACL anatomical reconstruction. Because tibial tunnel restrains the direction and the angle of the femoral tunnel, great care should be taken during the reconstruction. We recommend the use of new type of ACL locator with laser positioning during drilling to decrease the failure rate. Lateral intercondylar eminence can be used as the anatomical marker during the reconstruction.

Single-bundle versus double-bundle autologous anterior cruciate ligament reconstruction: a meta-analysis of randomized controlled trials at 5-year minimum follow-up

Abstract

Background: Both single-bundle (SB) and double-bundle (DB) techniques were widely used in anterior cruciate ligament (ACL) reconstruction recently. Nevertheless, up to now, no consensus has been reached on whether the DB technique was superior to the SB technique. Moreover, follow-up of the included studies in the published meta-analyses is mostly short term. Our study aims to compare the mid- to long-term outcome of SB and DB ACL reconstruction concerning knee stability, clinical function, graft failure rate, and osteoarthritis (OA) changes.

Methods: This study followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The PubMed, Embase, and the Cochrane Library were searched from inception to October 2017. The study included only a randomized controlled trial (RCT) that compared SB and DB ACL reconstruction and that had a minimum of 5-year follow-up. The Cochrane Collaboration's risk of bias tool was used to assess the risk of bias for all included studies. Stata/SE 12.0 was used to perform a meta-analysis of the clinical outcome.

Results: Five RCTs were included, with a total of 294 patients: 150 patients and 144 patients in the DB group and the SB group, respectively. Assessing knee stability, there was no statistical difference in side-to-side difference and negative rate of the pivot-shift test. Considering functional outcome, no significant difference was found in proportion with International Knee Documentation Committee (IKDC) grade A, IKDC score, Lysholm scores, and Tegner scores. As for graft failure rate and OA changes, no significant difference was found between the DB group and the SB group.

Conclusion: The DB technique was not superior to the SB technique in autologous ACL reconstruction regarding knee stability, clinical function, graft failure rate, and OA changes with a mid- to long-term follow-up.

Keywords: Mid- to long-term outcome, Anterior cruciate ligament, Reconstruction, Single-bundle, Double-bundle, Meta-analysis

Background

Anterior cruciate ligament (ACL) injuries destroy the normal kinematics of the knee and may be more likely to cause secondary injuries including meniscal injuries and knee osteoarthritis (OA) [1, 2]. ACL reconstruction is widely used to restore knee laxity, reestablish biomechanical homeostasis, and prevent the long-term joint degeneration [3–5]. In recent years, both single-bundle (SB) and double-bundle (DB) techniques were commonly used in ACL reconstruction [6, 7]. However, up to now, no consensus has been reached on whether the DB technique was superior to the SB technique.

It is well known that the ACL may be divided into two functional bundles, the anteromedial bundle (AMB) and the posterolateral bundle (PLB) [5, 8]. These two grafts cross each other inside the joint, acting separately at different knee angles. Theoretically, the AMB may prevent an anterior tibial translation at higher flexion angles, while the PLB may additionally restrain anterior tibial loads as well as a combined rotatory load at lower flexion angles [9]. Several biomechanical studies [10–14] reported that the DB technique could rebuild both the AMB and the PLB and thus might reproduce knee stability and kinematics closer to the native knee than the SB technique in ACL reconstruction. However, other biomechanical studies of Kondo et al. [15] as well as Lorbach et al. [16] showed that the DB reconstruction might not offer significant further advantages than the SB reconstruction. Previous clinical studies with short-term follow-ups also got an inconsistent result when comparing DB with SB ACL reconstruction. On the one hand, several studies [8, 17, 18] reported that the DB technique could achieve a superior result in both knee stability and clinical functions. Meanwhile, some literature [19–23] indicated that the DB technique could acquire better knee stability, but get comparable postoperative functions to the SB technique. On the other hand, several researchers [6, 22, 24–28] found that both knee stability and clinical functions had no significant difference between the two techniques in ACL reconstruction. Given the diverse results of previous studies, it is imperative to pool the data to compare the DB and SB techniques and thus provide a reference for ACL reconstruction.

A recent meta-analysis [29] of 26 randomized controlled trials (RCTs) showed that the DB technique could yield a better outcome in both functional outcome and stability of the knee than the SB technique in ACL reconstruction. In another meta-analysis, Li et al. [30] found that the DB ACL reconstruction had a better outcome in rotational stability, while there was no great difference in functional outcome between the DB and SB techniques. However, the above two studies [29, 30] failed to assess some outcome parameters, such as graft failure and OA changes, between the two techniques. Furthermore, the follow-up of most of the included studies in both meta-analyses is short term. It is well known that OA is a chronic progressive degenerative disease, which can be found through X-ray as early as 4 to 5 years postoperatively [31]. It is more persuasive and reliable to compare the DB and SB techniques in ACL reconstruction with a longer-term follow-up.

The purpose of this meta-analysis was to determine whether there is a significant difference in postoperative knee stability, clinical function, graft failure rate, and OA changes for DB versus SB technique in ACL reconstruction with a minimum of 5-year follow-up.

Methods

Literature search

This study was designed and conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [32]. The PubMed, Embase, and the Cochrane Library were reviewed for all English language studies from inception to October 2017. Two independent reviewers (HTC and BC) searched each database using the following strategy: ("anterior cruciate ligament" OR ACL) AND (single-bundle OR "single bundle") AND (double-bundle OR "double bundle"). A manual search for references of included articles was also conducted to ensure no eligible studies were missed.

Inclusion criteria and exclusion criteria

Inclusion criteria were as follows: (1) subject—all patients who underwent arthroscopy-assisted ACL reconstruction, with no limitation to sex or race; (2) intervention method—comparison of clinical outcome between the SB and DB technique in autologous ACL reconstruction; (3) outcome parameters—side-to-side difference (SSD), pivot-shift tests, International Knee Documentation Committee (IKDC) grade A, IKDC scores, Lysholm scores, Tegner scores, graft failure, and OA changes; (4) study type—RCT.

The exclusion criteria were as follows: (1) non-prospective trials (e.g., retrospective studies, observational studies, case series, and reviews); (2) animal or cadaver studies; (3) comparisons that were not between SB and DB method in ACL reconstruction; (4) follow-up less than 5 years; and (5) allograft ACL reconstruction.

Data extraction

Data from eligible studies were extracted independently by the two same reviewers according to predefined selected criteria, including article information (author and publication date), participant demographics, follow-up period, sample size, implant, femoral drilling technique, fixation type, and outcome parameter. The KT-1000 and

KT-2000 arthrometers in the included studies were reported in the form of SSD. Disagreements on data extraction were resolved by discussion.

Assessment of risk of bias

Two reviewers independently assessed the risk of bias for all included studies using the Cochrane Collaboration's risk of bias tool, which contains six items as follows: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias. Each of included studies was rated as having a low, unclear, or a high bias regarding the above items. Publication bias was not detected because of the limited number of included studies. Disagreements were resolved by discussion.

Statistical analysis

The meta-analysis was conducted using Stata/SE version 12.0. When the outcome indicator was dichotomous outcomes, relative risk (RR) was calculated for effect size. For continuous outcomes, a weighted mean difference (WMD) was calculated when the same measurement criterion was used; otherwise, a standardized mean difference (SMD) was calculated both used 95% confidence intervals (CI). The intervening effect of an indicator was considered as zero difference if 95% CI for WMD or SMD contained 0 and 95% CI for RR contained 1. The statistical heterogeneity was tested with the chi-square test and I^2. If heterogeneity was low ($P > 0.1$ or $I^2 \leq 50\%$), a fixed effects model was used. If heterogeneity was significant ($P < 0.1$, $I^2 > 50\%$), sensitivity analysis, subgroup analyses, and meta-regression were conducted to find the source of the heterogeneity. If the heterogeneity could not be eliminated, a random effects model would be used when the result of meta-analysis had clinical homogeneity, or descriptive analysis would be used.

Results

Article selection results

Seven hundred eighty-two relevant articles were initially selected according to the search strategy. Three hundred fifty-three were excluded after checking for duplicates with the literature management software Endnote X7. Three hundred ninety-eight were excluded after reviewing the titles and the abstracts, 26 published articles were excluded by reviewing their full content as 25 studies had less than 5 years' follow-up and data in one study were the same as those in another study with a longer follow-up. Finally, five articles [33–37] were included in the meta-analysis. A summary of the review process is presented in Fig. 1.

Description of included studies

All five selected articles were written in English, which compared the clinical outcomes of the DB and SB techniques in ACL reconstruction. All follow-up periods in the included articles were ≥5 years. There was a total of 294 patients: 150 patients and 144 patients in the DB group and the SB group, respectively. All basic article information is reported in Table 1, and the mid- to long-term outcome measures of the two techniques are reported in Table 2.

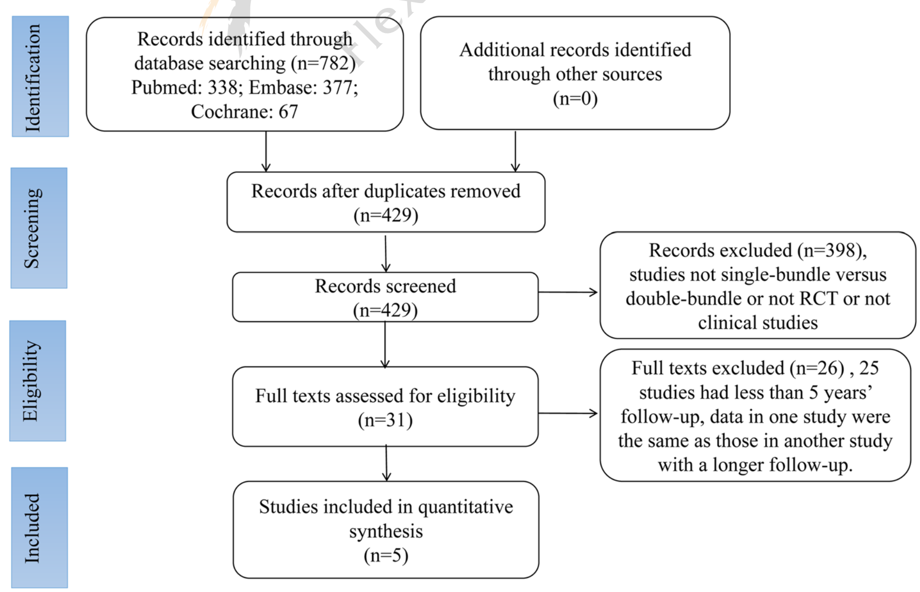

Fig. 1 Flowchart of article selection process

Table 1 Characteristics of included studies

Study	Age, year Mean (SD)	Follow-up, year	*n* (the last follow-up)	Femoral drilling	Implant	Fixation		Outcome
						FS	TS	
Jarvela (2017) [33]	DB: 34 ± 10 SB: 30 ± 8	10	DB: 24 SB: 23	AM	HT (AU)	BIS	BIS	Lysholm score; IKDC score; IKDC grade A; pivot-shift test; KT-1000 (SSD); OA changes; revision surgery (graft failure)
Beyaz (2017) [34]	DB: 33.53 ± 5.47 SB: 31.06 ± 5.48	8	DB: 15 SB: 16	AM	HT (AU)	EB	BIS	Tegner activity scale; IKDC score; Lysholm score; OA changes; tunnel widening; Isokinetic muscle strength
Adravanti (2017) [35]	DB: 26.4 ± 8.5 SB: 28.3 ± 6.2	6	DB: 25 SB: 25	DB: TT (AMB), outside-in (PLB); SB:TT	HT (AU)	EB	BIS	Lysholm score; IKDC grade A; KT-2000 (SSD); OA changes; graft rerupture (graft failure)
Karikis (2016) [36]	DB: 33.53 ± 5.47 SB: 31.06 ± 5.48	5	DB: 46 SB: 41	AM	HT (AU)	MIS	BIS	Tegner level; Lysholm score; Single-legged hop test; KOOS Outcomes; KT-1000 (SSD); Lachman test; pivot-shift test; OA changes
Zaffagnini (2011) [37]	DB: 27 ± 9 SB: 26 ± 9.5	8	DB: 40 SB: 39	DB: medial portal; SB: AM	DB: HT (AU) SB: BPTB(AU)	IS	IS	IKDC grade A; pivot-shift test; Tegner level; KT-2000 (SSD)

SD standard deviation, *DB* double-bundle, *SB* single-bundle, *AM* anteromedial portal technique, *TT* transtibial technique, *HT* hamstring tendon, *BPTB* bone-patellar tendon-bone, *AU* autologous, *FS* femoral side, *TS* tibial side, *BIS* bioabsorbable screw, *MIS* metal interference screws, *IS* interference screws, *IKDC* International Knee Documentation Committee, *SSD* side-to-side difference, *KOOS* Knee injury and Osteoarthritis Outcome Score, *OA* osteoarthritis, *ROM* range of motion

Assessment of risk of bias

The results of the assessment of the risk of bias on included studies are summarized in Fig. 2. The study by Adravanti et al. [35] used a block randomization scheme to group the two treatments randomly, and thus this study was rated as having a high risk of selection bias, whereas the remaining studies were rated as having a low risk of selection bias. All included studies [33–37] failed to conduct the blinding therapists regarding DB or SB technique, and thus these were rated as having a high risk of performance bias. The studies by Beyaz et al. [34] and Zaffagnini et al. [37] did not describe the blinding of outcome assessment, and thus these were rated as an unknown risk for detection bias. One study [34] lost more than 20% of enrolled patients during follow-up and was regarded as having a high risk of attribution bias. All included studies [33–37] offered insufficient information to judge selective outcome reporting, and thus these were rated as having an unknown risk of reporting bias. One study [34] included only male patients and one study [37] used hamstring for DB technique ACL reconstruction and used bone-patellar tendon-bone for SB technique ACL reconstruction, and thus these were rated as having a high risk of potential other bias.

SSD

Four studies reported postoperative SSD, and no heterogeneity was found among the studies ($P = 0.139$, $I^2 = 45.5\%$). Using the fixed effects model, 135 patients in the DB and 128 patients in the SB group were analyzed with no significant difference in SSD (WMD = 0.17, 95% CI (− 0.13, 0.48), $P = 0.27$) (Fig. 3).

Pivot-shift test

Postoperative pivot-shift tests were conducted in four studies. The analysis of negative pivot shift results showed some heterogeneity among the studies ($P = 0.008$, $I^2 = 79.2\%$). By using a random effects model, 100 patients in the DB group and 107 patients in the SB group were analyzed with no significant difference in postoperative negative pivot-shift (RR =1.09, 95% CI (0.88, 1.35), $P = 0.441$) (Fig. 4). Subsequently, to explore the potential source of heterogeneity, the pivot shift test was subjected to a sensitivity analysis by omitting one article at a time and calculating the pooled RRs for the remaining studies. It was found that there were no great changes in effect when any one study was excluded.

IKDC grades

Three studies included IKDC grades, and no heterogeneity was found among the studies ($P = 0.359$, $I^2 = 2.4\%$). Eighty-nine patients in the DB group and 87 patients in the SB group were analyzed using the fixed effects model, with no significant difference being found in proportion with IKDC grade A (RR = 1.15, 95% CI (0.95, 1.38), $P = 0.156$) (Fig. 5).

IKDC scores

Two studies demonstrated postoperative IKDC scores, with no heterogeneity being found between the studies ($P = 1$, $I^2 = 0\%$). Thirty-nine patients in the DB group and 39 patients in the SB group were analyzed using the fixed effects model, and no significant difference was found in the postoperative IKDC scores (WMD = 0, 95% CI (− 0.57, 0.57), $P = 1$) (Fig. 6).

Table 2 Mid- to long-term outcome measures of two techniques

Study	*N*	SSD[a] (mm)		PS test (N/P)		IKDC A (Y/N)		IKDC scores[a]		Lysholm scores[a]		Tegner scores[a]		Graft failure (Y/N)		OA changes (Y/N)	
		DB	SB	DB	SB	DB	SB	DB	SB	DB	SB	DB	SB	DB	SB	DB	SB
Jarvela (2017) [33]	47	−0.1 ± 2	0.6 ± 1.9	23/1	23/0	19/5	18/5	9 ± 2	9 ± 2	94 ± 7	95 ± 7	–	–	1/23	7/16	12/12	8/15
Beyaz (2017) [34]	31	–	–	–	–	–	–	7.1 ± 0.91	7.1 ± 0.94	81.43 ± 6.45	81.94 ± 7.15	3.43 ± 1.34	3.47 ± 1.12	–	–	7/8	5/11
Adravanti (2017) [35]	50	1.4 ± 0.6	1.3 ± 0.8	–	–	13/12	13/12	–	–	96.4 ± 17.3	94.2 ± 15.3	–	–	1/24	0/25	3/22	2/23
Karikis (2016) [36]	87	2.2 ± 2.7	2.3 ± 2.7	32/4	38/7	–	–	–	–	90.1 ± 9.1	84.3 ± 21.2	5.7 ± 1.3	5.7 ± 1.5	–	–	8/30	11/34
Zaffagnini (2011) [37]	79	1.1 ± 1.9	0.4 ± 0.6	36/4	26/13	35/5	26/13	–	–	–	–	6 ± 2	4 ± 2	–	–	–	–

SSD side-to-side difference, *DB* double-bundle, *SB* single-bundle, *PS* pivot-shift, *N/P* negative/positive, *IKDC* International Knee Documentation Committee, *Y/N* yes/no, *OA* osteoarthritis

[a]The value is given as mean ± standard deviation

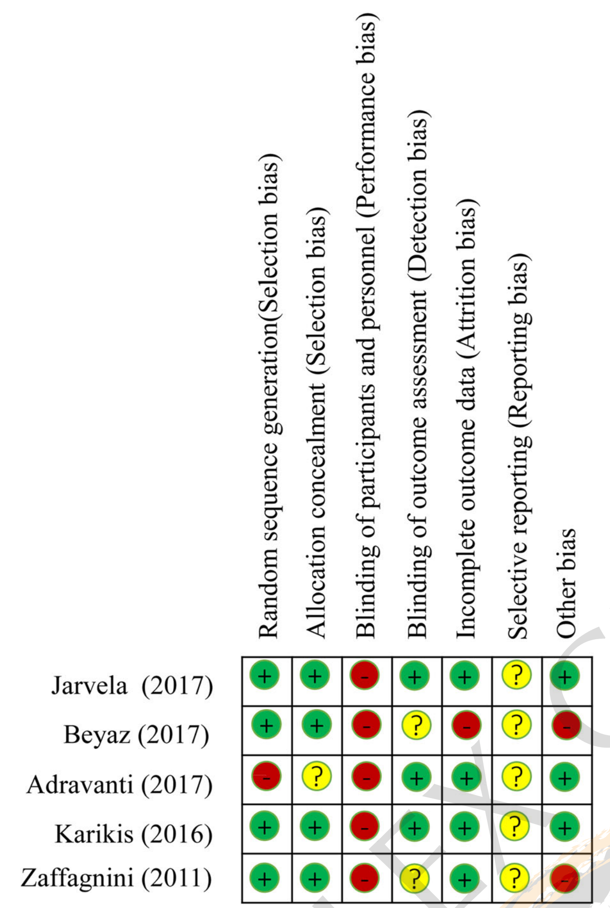

Fig. 2 Assessment of risk of bias. +, low risk; –, high risk; ?, unknown risk

Lysholm scores

Four studies reported postoperative Lysholm scores, with no heterogeneity being found among the studies ($P = 0.385$, $I^2 = 1.5\%$). One hundred ten patients in the DB and 105 patients in the SB group were analyzed using the fixed effects model, and no significant difference was found in the postoperative Lysholm scores (WMD = 0.44, 95% CI (– 2.25, 3.12), $P = 0.75$) (Fig. 7).

Tegner scores

Three studies reported postoperative Tegner scores, and obvious heterogeneity was found among these studies ($P = 0$, $I^2 = 86.9\%$). The random effects model was used to analyze 101 patients in the DB group and 96 patients in the SB group, showing no significant difference in postoperative Tegner scores (WMD = 0.63, 95% CI (– 0.61, 1.87), $P = 0.317$) (Fig. 8). Subsequently, to explore the potential source of heterogeneity, the Tegner scores were subjected to a sensitivity analysis by omitting one article at a time and calculating the pooled WMDs for the remaining studies. It was found that there were no great changes in effect when any one study was excluded.

Graft failure

Graft failure was conducted in two studies, with obvious heterogeneity between the studies ($P = 0.106$, $I^2 = 61.7\%$). The random effects model was used to analyze 49 patients in the DB group and 48 patients in the SB group, showing no significant difference in postoperative graft failure rate (RR =0.5, 95% CI (0.05, 9.91), $P = 0.649$) (Fig. 9).

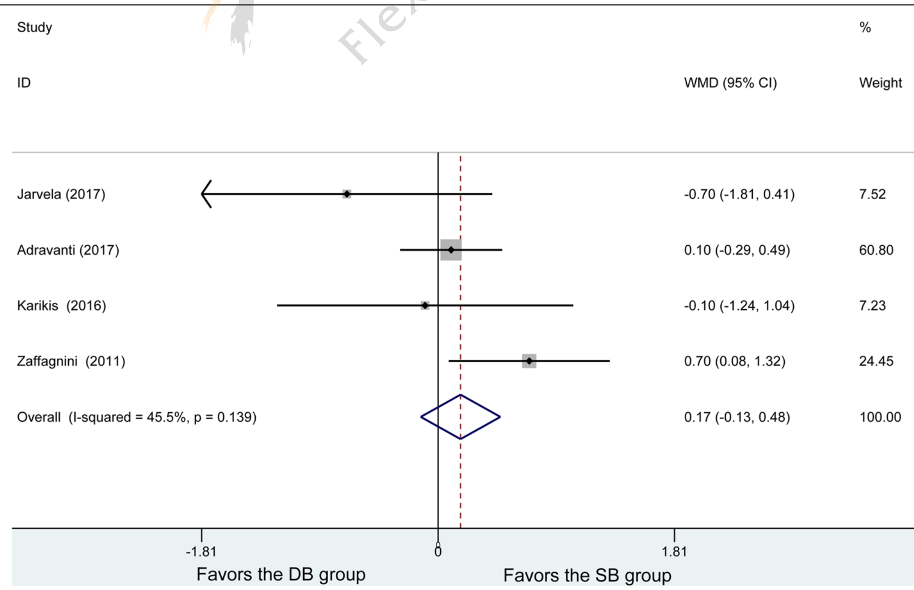

Fig. 3 Forest plot of SSD. WMD, weighted mean difference

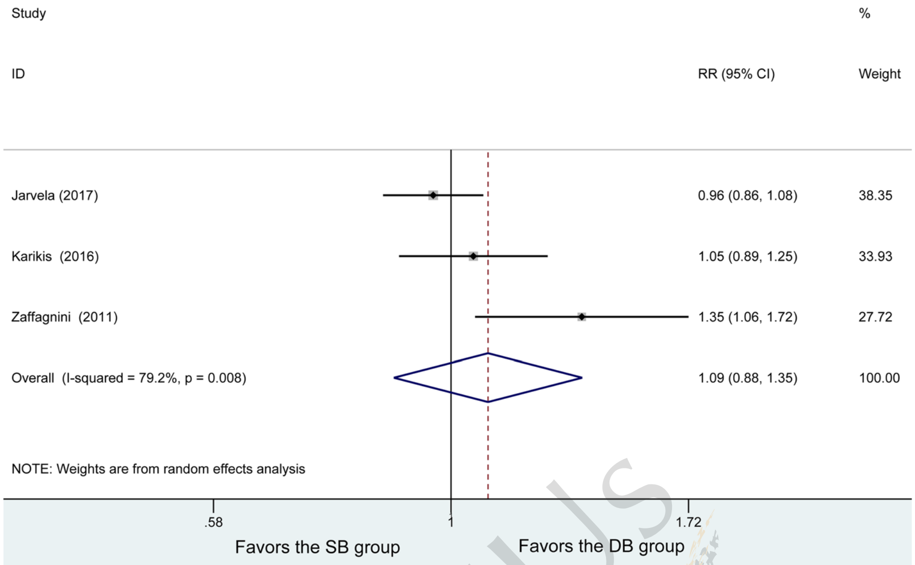

Fig. 4 Forest plot of pivot-shift test

OA

Four studies included OA, and no heterogeneity was found between the studies ($P = 0.756$, $I^2 = 0\%$). The 102 patients in the DB group and 109 patients in the SB group were analyzed using the fixed effects model, with no significant difference being found in OA changes (RR = 1.22, 95% CI (0.79, 1.89), $P = 0.37$) (Fig. 10).

Discussion

This meta-analysis was performed to compare the mid- to long-term outcome of the DB and SB techniques in autologous ACL reconstruction. The analysis included five RCTs involving 294 patients with at least 5 years of follow-up. The results revealed that there was no significant difference in knee stability, clinical function, graft rupture, and OA changes between the DB and SB techniques in autologous ACL reconstruction.

It is important to restore both the anterior and rotational stability in ACL reconstruction, which may be correlated with risk of meniscus and cartilage injury, as well as graft rupture and OA changes [2]. In our current study, all four included studies [33, 35–37] found that no statistical difference was found in anterior stability regarding KT-1000 or KT-2000 measurements. It was in

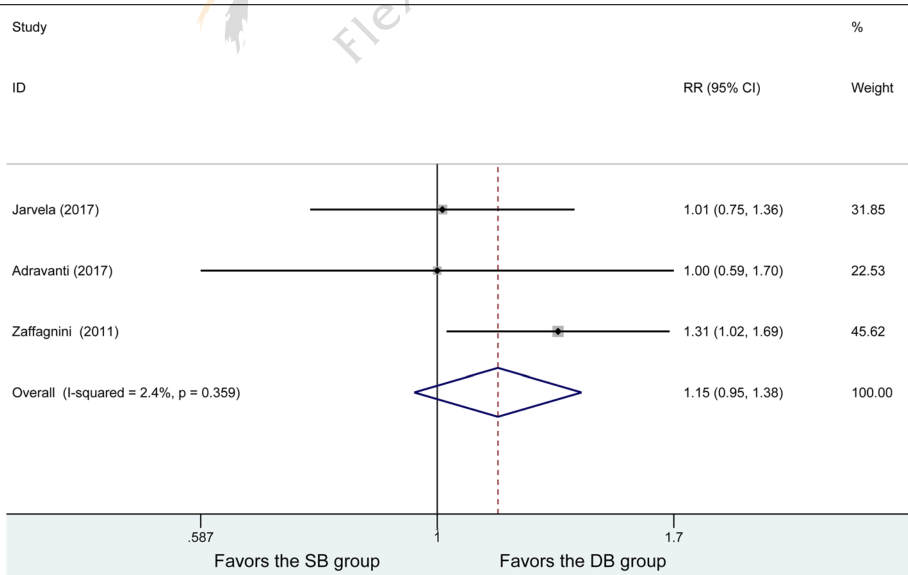

Fig. 5 Forest plot of IKDC grades

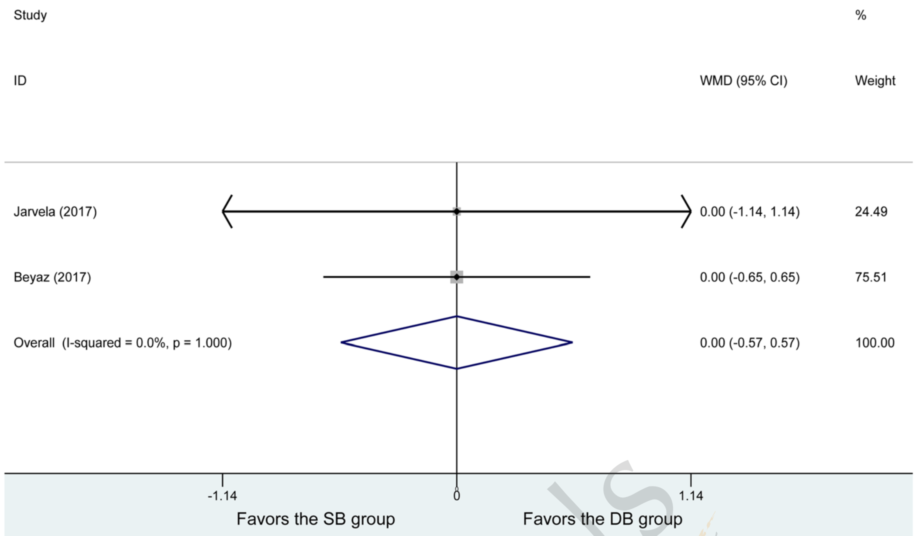

Fig. 6 Forest plot of IKDC scores

line with the previous studies [6, 24, 31]. The authors of these studies reported that both the DB and SB techniques could closely imitate the AMB in ACL reconstruction and thus acquire comparable anterior stability. As for the rotational stability, two included studies [33, 36] found no great difference between the DB and SB techniques in ACL reconstruction, whereas one included study [37] showed that the DB technique could yield superior result than the SB technique. Theoretically, the DB technique also reconstructed the PLB, which functioned at extension and contributed more to rotational stability. However, our meta-analysis indicated that there was no significant difference between the DB and SB techniques in rotational stability. Hemmerich et al. [38] thought that the ACL could restrict the rotation of the knee, but its contribution to joint stability was limited under isolated torsional load. Furthermore, other authors [39, 40] suggested that peripheral knee structures, such as collateral ligaments and the musculature that crosses the knee joint, along with ACL played an important role in rotational stability.

In our study, clinical function showed no statistical difference between the DB and SB techniques in autologous ACL reconstruction. Four included articles [33–36] found that the DB technique in ACL reconstruction was not superior to the SB technique regarding the function

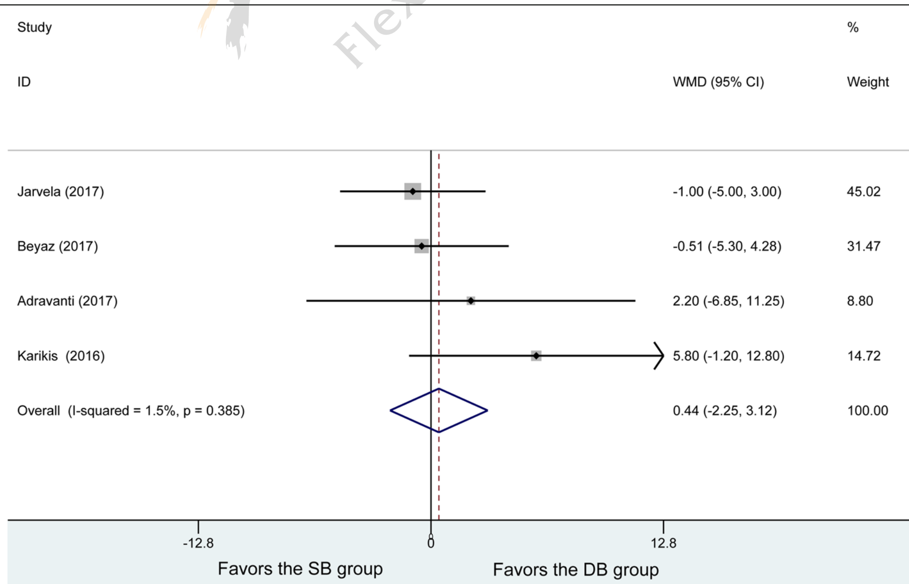

Fig. 7 Forest plot of Lysholm scores

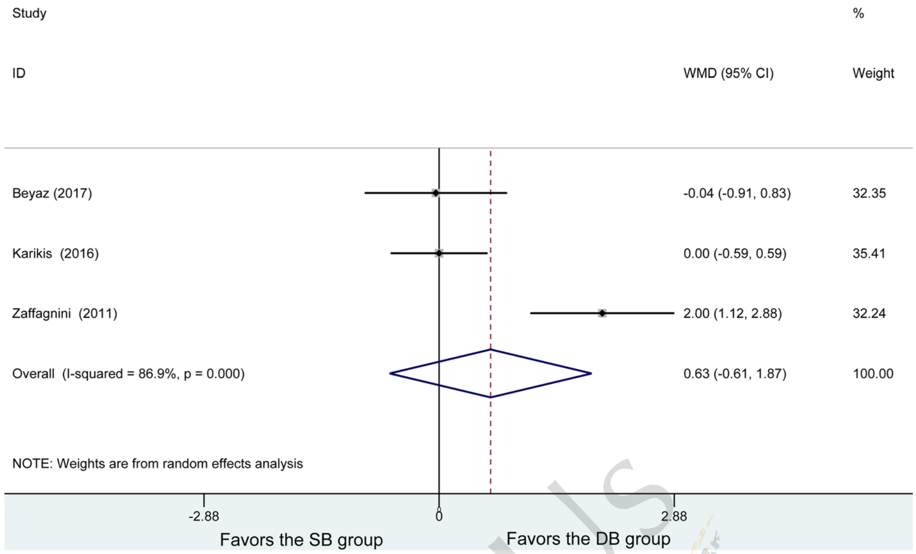

Fig. 8 Forest plot of Tegner scores

parameters, including the Lysholm scores, the proportion with IKDC grade A, IKDC scores, and the Tegner scores. One included study [37] show that the DB technique could yield better functions than the SB technique in ACL reconstruction. In this study, the DB ACL reconstruction used an anatomical technique, while the SB ACL reconstruction used a non-anatomical technique. Furthermore, the grafts were also different in ACL reconstruction. That is, autologous hamstring graft was used in the DB technique, whereas autologous bone-patellar tendon-bone graft was used in the SB technique. This subtle difference of femoral drilling techniques and types of graft might influence the assessment of functional outcome and thus affect the accuracy of the result. Meanwhile, it might account for the difference between the one and the other four included studies.

Graft failure increases the future economic burden and individual suffering. Unfortunately, 0.7–20% of patients experience recurrent instability due to graft failure [41, 42]. In our meta-analysis, graft failure was referred to in two included studies. One study [33] reported that the DB ACL reconstruction resulted in significantly fewer graft failures than the SB ACL reconstruction. In this study, Jarvela et al. thought that the DB graft was stronger and might mimic the normal ACL anatomy more closely than the SB graft, and thus the DB technique was less likely to cause graft failure. However, the other study [35] found no great difference between the two techniques. In general, it is noteworthy

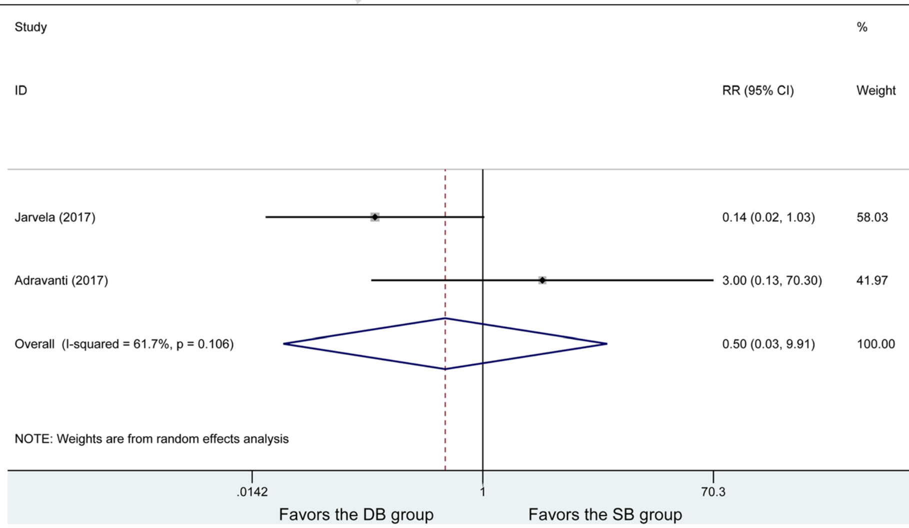

Fig. 9 Forest plot of graft failures

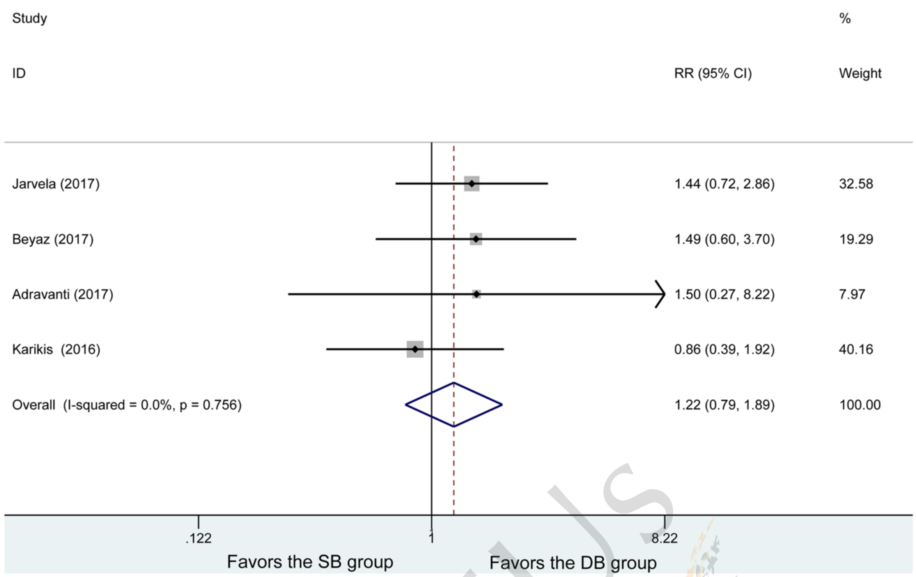

Fig. 10 Forest plot of OA

that the cause of graft failure after ACL reconstruction is not solely influenced by the DB and SB techniques but also largely influenced by other risk factors, such as new knee trauma, infection of implanted graft, returning too soon to pivoting sports, and radical rehabilitation program [33]. In our current study, the DB technique had no obvious advantage in graft failure than the SB technique.

OA changes were also discussed in our meta-analysis. Three included studies found no great difference between the DB and SB techniques, whereas one included study showed more OA changes in the SB ACL reconstruction. The DB technique, in theory, could better delay the degeneration of knee than the SB technique in ACL reconstruction. Tajima et al. [43] and Morimoto et al. [14], for example, thought that SB ACL reconstruction might result in a significantly smaller patellofemoral and tibiofemoral contact area and higher pressures and thus had more OA changes. However, Jarvela et al. [33] found that the delay from the primary injury to ACL reconstruction affected OA changes. Also, some studies [31, 35, 44] reported the concomitant injury, such as meniscal or another ligament tear, as well influenced OA changes. In our study, the DB technique had no great difference with the SB technique in OA changes. Tunnel widening may lead to the inability of the implanted graft, long-term joint laxity, and difficulty in revision surgery [34, 45]. However, only one included RCT touched upon tunnel widening, and thus it was not suitable for conducting a meta-analysis. More prospective long-term RCTs are needed for future meta-analysis as for tunnel widening.

The advantage of this meta-analysis is that all the included studies were prospective RCTs with a minimal 5-year follow-up. Graft failure and OA changes usually needed to be assessed with a longer-term follow-up. Furthermore, a mid- and long-term result could offer a more persuasive and believable assessment of the stability and functional outcome and thus provide a reference for the choice of techniques in ACL reconstruction.

The limitations of this study were as follows: (1) The whole sample size was not large, and the outcome indicator was not unified, which may have influenced the outcome. (2) The femoral drilling technique and fixation technique in the studies were not all the same, which may not have been sufficiently homogeneous to evaluate the differences between the DB and SB techniques. (3) Several indicators, including KOOS outcomes, Lachman test, and tunnel enlargement were referred to in only one of the included study and could not be used as outcome parameters in the present study.

Conclusion

The DB technique is not superior to the SB technique in autologous ACL reconstruction regarding knee stability, clinical function, graft failure rate, and OA changes with a mid- to long-term follow-up.

Self-reported functional recovery after reconstruction versus repair in acute anterior cruciate ligament rupture (ROTOR): a randomized controlled clinical trial

Abstract

Background: Anterior cruciate ligament (ACL) reconstruction is today's surgical gold standard for ACL rupture. Although it provides satisfactory results, not all patients return to their previous activity level and moreover, early posttraumatic osteoarthritis is not prevented. As such, a renewed interest has emerged in ACL suture repair combined with dynamic augmentation. Compared to ACL reconstruction, the hypothesized advantages of ACL suture repair are earlier return to sports, reduction of early posttraumatic osteoarthritis and preservation of the patient's native ACL tissue and proprioceptive envelope of the knee. In recent literature, ACL suture repair combined with dynamic augmentation tends to be at least equally effective compared to ACL reconstruction, but no randomized comparative study has yet been conducted.

Methods/design: This study is a prospective, stratified, block randomized controlled trial. Forty-eight patients with an ACL rupture will be assigned to either a suture repair group with dynamic augmentation and microfracture of the femoral notch, or an ACL reconstruction group with autologous semitendinosis graft and all-inside technique. The primary objective is to investigate the hypothesis that suture repair of a ruptured ACL results in at least equal effectiveness compared with an ACL reconstruction in terms of patient self-reported outcomes (IKDC 2000 subjective scale) 1 year postoperatively. Secondary objectives are to evaluate patient self-reported outcomes (IKDC 2000, KOOS, Tegner, VAS), re-rupture rate, rehabilitation time required for return to daily and sports activities, achieved levels of sports activity, clinimetrics (Rolimeter, LSI, Isoforce) and development of osteoarthritis, at short term (6 weeks, 3, 6 and 9 months and 1 year), midterm (2 and 5 years) and long term (10 years) postoperatively.

Discussion: A renewed interest has emerged in ACL suture repair combined with dynamic augmentation in the treatment of ACL rupture. Recent cohort studies show good short- and midterm results for this technique. This randomized controlled trial has been designed to compare the outcome of suture repair of a ruptured ACL, combined with DIS as well as microfracture of the femoral notch, with ACL reconstruction using autologous semitendinosus.

Trial registration: Clinical Trials Register NCT02310854 (retrospectively registered on December 1st, 2014).

Keywords: Anterior cruciate ligament (ACL), ACL reconstruction, ACL suture repair, Dynamic augmentation, Knee injury

Background

Rupture of the anterior cruciate ligament (ACL) is one of the most common injuries of the knee [1]. Reported incidence varies between 0,3 and 0,8 per 1000 [2, 3] and most patients with ACL ruptures are young sportively active individuals (males 15–34 years; females 14–21 years) [4]. ACL rupture is a serious injury of the knee with high probability of the occurrence of dynamic instability, accompanying lesions and early post-traumatic osteoarthritis [5–10].

The treatment of ACL ruptures is aimed at achieving return to previous activity levels by resolving the instability of the affected knee, and preventing the development of post-traumatic osteoarthritis. The surgical gold standard is ACL reconstruction [11]. However, Biau et al. [12] concluded in a meta-analysis that only 40% of patients return to their previous activity levels after ACL reconstruction surgery. Moreover, the incidence of re-rupture of the reconstructed ACL is 3–22% within 2 years after surgery [13–15] and the risk of early posttraumatic osteoarthritis is still present [8–10].

In order to optimize the clinical results after ACL rupture, a renewed interest has emerged in ACL suture repair. In contemporary repair techniques, the sutured ACL is augmented with a strong, small diameter braid. In a biomechanical study, Kohl et al. demonstrated that, in contrast to static augmentation, dynamic augmentation is able to restore anterior-posterior stability of the knee directly postoperative as well as after cyclic loading [16]. In a pilot study, ACL suture repair combined with dynamic augmentation and microfracture in the femoral notch resulted in satisfactory clinical and radiological healing of the torn ACL at one and 5-year follow-up [17, 18]. Also, in three prospective cohort studies, two with one-year follow-up in 26 and 45 patients and one with 2 years follow-up in 69 (of 278) patients, ACL repair with dynamic augmentation provided successful functional recovery and patient self-reported outcomes [19–21]. Moreover, patients could return to their previous level of sports within 5 months after surgery [17, 20]. In terms of complications, the failure rate seems comparable to the re-rupture rate of ACL reconstruction. The pilot study of Eggli showed one failure in 10 patients after a 2 year follow-up and two failures in 10 patients after a 5 year follow-up [17, 18]. A larger cohort study of Henle showed 4% failure rate in 69 (of 278) patients after 2 years follow-up [20].

Ergo, ACL suture repair with dynamic augmentation seems to be a promising technique. However, to date no randomized comparative study has been conducted in which ACL suture repair with dynamic augmentation is compared with the gold surgical standard, ACL reconstruction. This study aims to investigate the hypothesis that suture repair of a ruptured ACL, combined with dynamic augmentation as well as microfracture of the femoral notch, will result in at least equal effectiveness compared with ACL reconstruction using autologous semitendinosus in terms of patient self-reported outcomes (IKDC 2000 subjective scale) 1 year postoperatively.

Methods

Study design

This study is a Medical Ethical Committee approved, (Medical Ethics Committee 'Twente', reference number NL50116.044.14/P1426) prospective, stratified and block randomized controlled trial: patients will be allocated to undergo either ACL suture repair or ACL reconstruction. The study will be conducted at the Centre for Orthopaedic Surgery OCON, Hengelo, The Netherlands.

Patients will be recruited at the outpatient department of OCON and informed about the study by their orthopaedic surgeon. After 2–3 days of reflection, an independent investigator will check eligibility and obtain informed consent. One orthopaedic surgeon will operate all patients. Blinding of the surgeon, physiotherapist who will conduct clinimetrics and patient is not used due to practical reasons. All patients will receive identical rehabilitation after surgery, apart from bracing in extension lock for the first 5 days postoperative in the repair group; the standard nationally used physiotherapy protocol regarding ACL reconstruction is given to the patient and their own physiotherapist. Patients will be followed-up in the outpatient clinic preoperatively as well as 6 weeks, 3, 6, 9 months, 1, 2, 5 and 10 years postoperatively (Fig. 1), where all the outcome measurements will be conducted. With weekly data management patients will be contacted in case of no show in order to minimize loss to follow-up. Protocol modifications will be communicated via amendments according to the guidelines of the Medical Ethical Committee.

Study sample

Patients eligible for enrolment in this study are sportively active patients between 18 and 30 years with a proven primary ACL rupture, confirmed by means of history, physical examination and MRI, for whom an indication for ACL reconstruction surgery exists and who can undergo surgery within 21 days of injury. Exclusion criteria are concomitant large meniscal injury needing repair, cartilage injury requiring surgical intervention or ligamentous lesions of the ipsilateral knee, pre-injury Tegner score below 5, history of knee surgery of the ipsilateral knee, pre-existing significant malalignment of the ipsilateral knee, hypersensitivity to cobalt, chromium or nickel, muscular, neurological or vascular abnormalities, osteoarthritis, use of prednisone or cytostatics, tendency to form excessive scar tissue, pregnancy, osteoporosis or infection.

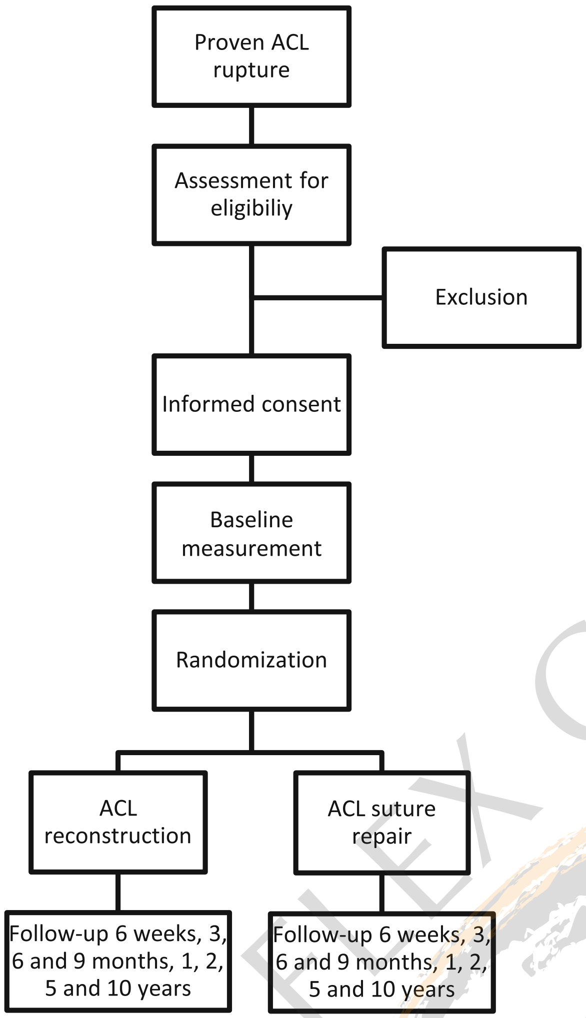

Fig. 1 Flowchart of patient inclusion

Patients can withdraw from the study at any time. They will receive appropriate treatment according to standard-care.

Intervention

ACL suture repair

ACL suture repair will be performed within 21 days after injury. The dynamic intraligamentary stabilisation (DIS) technique will be used (Ligamys, Mathys Medical, Bettlach, Switzerland). The procedure is started with standard arthroscopy to assess all compartments for concomitant injury. When a patient meets one of the exclusion criteria, they will be excluded from the study. Patients will receive further standard care including ACL reconstruction after meeting the Millet criteria. Otherwise, the procedure will be continued and the ACL rupture type will be classified. The tibial attachment of the ACL is identified using an intra-articular guide. A guide wire is overdrilled in the metaphysis and the monoblock is screwed in place. A suture to secure the ACL remnant is inserted through the screw and passed through the ligament and pulled through the femur. The femoral attachment is then marked using a guide from the antero-medial portal. A polyethylene wire will be pulled distally through the femur towards proximal tibia. The wire is stabilized at the femoral position with a cortical suspension button. The polyethylene wire is pulled through the tibia and tightened before final tension is applied. The procedure will be completed by microfracture of the femoral attachment.

Removal of the Ligamys spring will take place in day care, no earlier than after recording of the primary outcome measure 1 year after surgery. The previous antero-medial incision will be used.

ACL reconstruction

ACL reconstruction will be performed when the patient meets the Millett criteria [22], usually approximately 6 weeks after injury. If necessary, additional physiotherapy will be given and patients will be rescheduled for a retest. In that case, the measurements of the retest where the Millet criteria are met will be used as baseline measurement during the study. An all-inside technique (Arthrex, Naples, Florida, USA) will be used. The semitendinosus tendon from the ipsilateral leg will be harvested and quadrupled. A standard arthroscopy will be performed for diagnosis and treatment of concomitant injuries and evaluation of ACL rupture morphology. When a patient meets one of the exclusion criteria, he will be excluded from the study, but the surgical procedure will be continued. ACL rupture will be classified. After removing ACL remnants, the tibial and femoral tunnel will be prepared. The graft will be positioned in the femoral tunnel first and fixed with a cortical suspension button with variable loop length. After, the graft will be placed in the tibial tunnel and fixed with a cortical suspension button, with the knee in 0 degrees of extension while anterior translation of tibia in relation to femur is eliminated. Positioning and tension of the graft will be verified under vision, and if necessary, the graft will be tightened.

Main study parameter/endpoint

The primary objective of this non-inferiority study is to determine whether ACL repair will result in at least equal effectiveness compared with ACL reconstruction in terms of the self-reported functional outcome measured by the International Knee Documentation Score 2000 subjective knee evaluation score (IKDC Subjective) 1 year postoperative (Table 1) [23–25].

Secondary study parameters

Secondary outcomes of this study are: to determine any between group differences in self-reported functional

Table 1 Oversight of the investigations and follow-up moments

	B	OR	6w	3 m	6 m	9 m	1y	2y	5y	10y
X-ray	x	x					x	x	x	x
MRI	x									
IKDC 2000 Subjective	x		x	x	x	x	x	x	x	x
IKDC 2000 Current health	x	x	x	x	x	x	x	x	x	x
IKDC 2000 History	x	x	x	x	x	x	x	x	x	x
IKDC 2000 Demographic form	x	x	x	x	x	x	x	x	x	x
IKDC Physical examination	x		x	x	x	x	x	x	x	x
KOOS	x		x	x	x	x	x	x	x	x
Tegner score	x		x	x	x	x	x	x	x	x
VAS satisfaction	x		x	x	x	x	x	x	x	x
AP laxity	x		x	x	x	x	x	x	x	x
LSI power tests	x				x	x	x	x	x	x
LSI jump tests					x	x	x	x	x	x
Sport specific fatigue test							x			
Concomitant injury		x								
Rupture pattern		x								
Quality repair		x								
Complications & side effects		x	x	x	x	x	x	x	x	x
Re-rupture			x	x	x	x	x	x	x	x

B baseline, *OR* peri-operative, *w* weeks, *m* months, *y* years, *IKDC* International Knee Documentation Score, *KOOS* Knee Injury and Osteoarthritis Outcome Score, *VAS* Visual Analog Scale, *AP* anteroposterior, *LSI* leg symmetry index

outcomes, clinimetrics and development of osteoarthritis at 6 week, 3, 6 and 9 months, 2, 5 and 10 years after surgery and secondly, whether between groups differences exist, both with respect to perioperative classification of the ACL rupture type and onset of failure of the ACL repair or reconstruction.

Differences in baseline characteristics will be recorded by the use of IKDC 2000 demographic form, IKDC 2000 Current Health, IKDC 2000 History and reported complications and side effects.

Patient self reported outcomes will assess the patients' perceived level of functional recovery (IKDC Subjective Scale) [23–25], daily life activities (Knee Injury and Osteoarthritis Outcome Score (KOOS)) [26], level of physical activity (Tegner Activity Level) [27, 28], knee pain (Visual Analogue Scale (VAS)) and satisfaction with the outcome of surgery. Clinimetrics will be assessed by the IKDC 2000 physical examination score [23–25], including instrumented anteroposterior laxity (Rolimeter) [29–32] as well as leg symmetry index (LSI) for Gustavsson's jump test battery and isokinetic quadriceps and hamstrings force measured by a dynamometer (Isoforce) [33].

Additional secondary outcomes are knee kinematic parameters (i.e. degree of flexion and varus/valgus angles) 1 and 2 year(s) after surgery; the jump tests will be instrumented and patients will be equipped with inertial sensors (Xsens Technologies) for these tests. Furthermore, in order to explore the role of long lasting exertion (one-hour running and pivoting protocol) on neuromuscular fatigue and knee kinematics, a sport-specific fatigue test with EMG measurement of quadriceps and hamstring activity, and inertial biomechanical sensors to measure functional biomechanical parameters (Xsens Technologies) will be performed in a subgroup 1 year after ACL suture repair.

Two independent radiologists will evaluate the Kellgren and Lawrence score for radiologic signs of osteoarthritis on anteroposterior and lateral weight baring X-rays [34].

Failure, defined as the occurrence pathological laxity or subjective instability, or the discontinuity of the ACL suture repair or reconstruction based on MRI or arthroscopy, as well as other complications will be recorded. Also, perioperative classification of ACL rupture type (tear location (proximal, midsubstance, distal rupture), rupture pattern (single strand, two bundles, three or more strands), and synovial sheath (completely intact, > 50% intact, < 50% intact)) [20] as well as perioperative classification regarding quality of the repair (anatomical, nearly-anatomical, non-anatomical) will be assessed [35].

Randomization

After inclusion, patients will be randomized into an experimental group (repair) or a control group (reconstruction), in blocks with varying sizes ($N = 2$ and $N = 4$) by an independent investigator with PASS (Power Analyses and Sample Size Software; rand.exe version 6.0). The extent of physical activity in daily life poses a potential risk to repair/graft failure. To make sure both groups have an equal risk of failure, patients will be stratified based on physical activity level using the Tegner score (moderate: Tegner 5-7; high: Tegner 8-10) [27, 28].

Sample size determination

In order to detect non-inferiority of ACL repair compared to ACL reconstruction surgery in terms of patient self-reported functional outcome measured by the IKDC Subjective score, to achieve a power of 90% and an alpha of 5%, a sample size of 20 patients in each study group is required. According to literature, it seems relevant to consider a standard deviation at nine in both groups [36]. A difference of 11, 5 points in score of IKDC 2000 is suggested as clinically relevant [37]. The margin of equivalence 10 lies within this clinically relevant effect size.

Considering a lost-to-follow-up rate of 20%, it is planned to include 24 patients per randomization group. Thus, in total 48 patients will be included in the study.

Statistics

The identified data will be entered into and analysed with SPSS version 23 (IBM SPSS, Chicago, Illinois, USA) by the trialcoordinator who is not involved in data collection and therefore not blinded to group allocation of participants. Trial results will be published in scientific journals.

Descriptive statistics

Baseline characteristics will be presented as mean ± SD or median (range) for continuous data and as numbers with corresponding percentages for categorical data as appropriate. Comparisons between randomized groups will be analysed using X^2 or Fisher's exact test for categorical variables and the Student T-test or Mann-Whitney U test for continuous variables, with normality verified by the Shapiro-Wilk test and histograms.

Primary study parameter

Differences between IKDC 2000 at baseline and one-year post-operative will be determined for each group, as well as differences between the groups at each follow-up. In case of clinically meaningful differences between groups (> 10 points on the IKDC2000), the non-inferiority hypothesis will be rejected. In case of non-inferiority, superiority analyses will be conducted. For normally distributed data mixed models analyses for repeated measures will be used. In case of non-normally distributed data, the Friedman test for differences within groups, and Mann-Whitney Y test for differences between groups, will be used. A distinction will be made between short term (6 weeks, 3, 6, 9 months and 1 year), mid-term (2 and 5 year) and long-term (10 year) postoperative outcomes.

Secondary study parameters

For IKDC 2000, KOOS, Tegner, VAS, IKDC 2000 physical examination, AP-laxity, LSI for jump tests, isokinetic quadriceps and hamstring force as well as re-rupture, the same statistics as described above will be used. Re-rupture of 10% or more is considered to be clinically relevant. For the sport-specific fatigue protocol repeated measures ANOVA with SIDAK t-test post hoc test will be performed.

Discussion

This paper reports on the study design of the ROTOR (RecOnsTruction Or Repair) trial, which will compare the subjective, objective and functional outcomes of hamstring autograft, the current gold-standard surgery for ACL rupture, with those for suture repair while following the participants from short to long term. The conduct of this study is important, since there is growing evidence that suture repair of the ruptured ACL augmented with a dynamic joint bridging stabilisation technique combined with micro fracturing in the femoral notch leads to good short and midterm results [16–21]. The hypothesis of this study is that suture repair will result in at least as satisfactory outcomes as ACL reconstruction. A proposed mechanism for this thesis is the retention of the patient's ACL resulting in healing of ligament tissue, the restitution of native ligament proprioception and restoration of postero-anterior laxity, whereas reconstruction with the process of ligamentization of harvested tendon provides biomechanical stability only.

However, despite several prospective cohort studies, no high quality randomized controlled trial (RCT) comparing ACL suture repair with dynamic augmentation and ACL reconstruction have been published so far. In this RCT a broad range of parameters will be evaluated, including patient self-reported outcomes (IKDC 2000, KOOS, Tegner, VAS), re-rupture rate, rehabilitation time required for return to daily and sports activities, achieved levels of sports activity, clinimetrics (Rolimeter, LSI, Isoforce) and development of osteoarthritis, at short term, midterm and long term postoperatively. The use of intertial sensors for jump tests may provide insight in increased neuromuscular knee control, which is considered an advantage of ACL suture repair due to retaining of the proprioceptive function, compared to ACL reconstruction. Follow-up will take place at short term, midterm and long term postoperative.

To our knowledge, this is the first randomized controlled trial to investigate the functional recovery after ACL suture repair in comparison to ACL reconstruction. This trial has the potential to demonstrate, with a good level of evidence, the effectiveness of ACL suture repair combined with dynamic augmentation as well as microfracture of the femoral notch compared to the gold standard ACL reconstruction using autologous hamstring. As it is not yet clarified what the exact indications for this procedure are and in order to minimize the possible influence of confounding factors on the effectiveness of repair or reconstruction, patients suffering from severe common concomitant injury in ACL rupture, i.e. large meniscal injury needing repair or cartilage injury requiring surgical intervention, were excluded in the current study. Despite the fact that it might limit the generalisability of our findings, it does provide a higher intrinsic validity. If proven at least equally effective, ACL suture repair with dynamic joint bridging stabilisation can be considered as an innovative treatment for ACL ruptures.