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Femoral tunnel widening is similar between anteromedial portal and transtibial techniques following single-bundle anterior cruciate ligament reconstruction: a systematic review and meta-analysis

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Abstract

Purpose In anterior cruciate ligament (ACL) reconstruction, there is concern regarding the potential risk of femoral tunnel widening in the anteromedial portal (AMP) technique due to the acute graft-bending angle at the aperture and the more elliptical aperture shape of the femoral tunnel compared to the transtibial (TT) techniques. Therefore, the aim of the current systematic review and meta-analysis was to compare the femoral tunnel widening between the AMP and TT techniques in patients who underwent ACL reconstruction.

Methods It should be included the studies that reported on femoral tunnel widening in patients who underwent single-bundle ACL reconstruction, using soft-tissue tendon graft, with AMP and/or TT techniques. Two reviewers independently recorded data from each study, including the sample size and magnitude of tunnel widening after ACL reconstruction.

Results Twenty-one studies were finally included in this meta-analysis. The pooled changes of absolute millimeters of tunnel widening from the immediate postoperative status to the last follow-up did not differ significantly between the AMP and TT techniques at both the aperture [3.31 mm, 95% confidence interval (CI) 1.7–5.0. mm versus 2.9 mm, 95% CI 2.4–3.4 mm, P = n.s.] and the midportion (3.5 mm, 95% CI 0.8–6.3 mm versus 3.0 mm, 95% CI 2.2–3.9 mm, P = n.s.) of the femoral tunnel. No significant difference was observed between the two techniques in the relative percentage of femoral tunnel widening (AMP; 28.8%, 95% CI 14.8–42.9% vs. TT; 29.7%, 95% CI 15.6–43.7%, P = n.s.).

Conclusion No significant difference in femoral tunnel widening was observed between the AMP and TT techniques, both in absolute millimeter and relative percentage, in patients who underwent single-bundle ACL reconstruction. This finding could alleviate the potential concerns associated with femoral tunnels being wider for the AMP than for the TT technique.

Level of evidence III.

Keywords Anterior cruciate ligament reconstruction · Tunnel widening · Anteromedial portal · Transtibial

Introduction

Tunnel widening after anterior cruciate ligament (ACL) reconstruction has gained attention due to the potential for clinical impairments such as instability due to delayed graft–bone healing in the tunnel and the development of complicated environments for femoral drilling in revisional ACL reconstruction due to lack of adequate bone stock [13, 32, 39]. The anteromedial portal (AMP) technique was developed to overcome the shortcomings of the conventional transtibial (TT) technique, including vertical graft and subsequent residual laxity [6, 10, 16]. Nevertheless, some concerns about the AMP technique have been raised, such as the more elliptical aperture shape of the femoral tunnel and acute graft-bending angle at the aperture compared to

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those in the TT technique [11]. Acute graft bending at the elliptical aperture of the femoral tunnel could result in the early graft failure caused by increased intra-graft tension and abrasion at the bony margin of the femoral tunnel aperture [35]. This situation also could affect the tunnel widening, because graft abrasion at the aperture could lead to bone resorption at the marginal wall of the aperture [36]. In addition, the elliptical-shaped aperture of the femoral tunnel in the AMP technique could develop a graft-tunnel mismatch compared with the circular shaped aperture of the femoral tunnel in the TT technique [11, 20], so the influx of synovial fluid into the gap between the graft and the tunnel might occur more readily. These mechanical and biological theories comprise the two main hypothetical causes for tunnel widening following ACL reconstruction. While a number of studies have compared the position and length of the femoral tunnel, graft-bending angle [7, 31], and clinical outcomes between the AMP and TT techniques, there is a lack of studies comparing tunnel widening between these techniques, with conflicting results. It is important to determine the technique that causes the wider femoral tunnel, as the AMP technique is more frequently utilized than the TT technique for femoral drilling.

Therefore, the purpose of the present study was to compare the femoral tunnel widening in patients who underwent ACL reconstruction using the AMP and TT techniques. It was hypothesized that the AMP technique would result in a larger femoral tunnel widening than that of the TT technique in patients with ACL reconstruction.

Materials and methods

Literature search

The study design followed the recommendations in the Cochrane Review Methods. According to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement, several comprehensive literature databases, including the PubMed (MEDLINE), EMBASE, and Cochrane Library, were searched for studies evaluating tunnel enlargement in patients who underwent arthroscopic ACL reconstruction up to March 2018. There were no restrictions on language or year of publication. The search terms used in the title, abstract, Medical Subjects Headings (MeSH), and keywords fields included (ACL OR anterior cruciate ligament reconstruction) AND (ACL OR tunnel widening) AND (anterior cruciate ligament reconstruction OR tunnel enlargement). Manual searches were also performed for articles potentially missed by the electronic search.

Study selection

Two reviewers evaluated the titles and abstracts of the retrieved papers and selected relevant studies for a full review. If the abstract did not provide sufficient data to decide, the complete article was reviewed. Studies were included in the analysis if (1) they included patients who underwent primary arthroscopic single-bundle ACL reconstruction, using soft-tissue grafts, with AMP or TT femoral drilling techniques; (2) they evaluated the femoral tunnel widening with validated imaging tools such as plain radiography, computed tomography (CT), and magnetic resonance imaging (MRI); (3) completed reported parameters, including means, standard deviations, and sample numbers. In case of comparison of single and double-bundle reconstruction, the results of single-bundle reconstruction only were included. In assessing and organizing the pooled studies, country and city of the hospital or institution at which the arthroscopic surgeries were performed, the operating surgeon's name in the studies, and the evaluation period were checked to exclude duplicate cohorts of patients. If the same patient cohort was evaluated in more than one study, the latest study with the longest follow-up period was included, whereas the others were excluded.

Data extraction

Two investigators independently extracted data from each study using a predefined data extraction form. Any disagreements unresolved by discussion were reviewed by a third investigator if needed. The main outcome of interest was the magnitude of the femoral tunnel widening in AMP and TT femoral drilling techniques. Tunnel widening was calculated as the change in femoral tunnel diameter compared to measurements by immediate postoperative imaging. If no data were available on the immediate postoperative femoral tunnel diameter, the drill reamer size was substituted for the same. The site of the tunnel widening measurement was recorded as the aperture, midportion, or widest portion of the femoral tunnel. The femoral tunnel widening was described by the absolute change in millimeters at the aperture or midportion compared with that of the immediate postoperative status or by the relative change in percentage from the immediate postoperative status, which was measured at the widest portion of the femoral tunnel. The surgical technique (TT, AMP, and outside-in) and basic patient demographic data, including age, sex, and the time interval from surgery to the measurement of tunnel widening were also recorded for each included study.

Assessment of methodological quality

The original Coleman methodology score (CMS) [9] uses ten criteria to assess the methodology of a given study, resulting in total scores between 0 and 100, with a score of 100, indicating that the study largely avoided important systemic sources of bias and other confounding factors. The subsections that compose the CMS are based on the subsections of the Consolidated Standards of Reporting Trials (CONSORT) statement for randomized-controlled trials [3] but were modified to allow for other study designs [27]. The original CMS was developed for the surgical treatment of tendinopathy, but modified versions of the CMS have been used in other reviews. In this meta-analysis, the modified CMS was used to assess the methodological quality of the included studies. Criteria included in part A of the modified CMS consisted of (1) study size, (2) mean duration of follow-up, (3) number of treatment procedures, (4) type of study, (5) diagnostic certainty, and (6) description of the surgical procedure. Criteria included in part B of the modified CMS consisted of (1) outcomes, (2) procedure for assessing outcomes, and (3) subject selection process. Maximum scores on Parts A and B were 50 and 40 points, respectively, with a maximum total score of 90 points. The quality of each included study was evaluated by two independent investigators using the modified CMS.

Statistical analysis

The main outcomes of the meta-analysis were the mean differences in tunnel widening after single-bundle ACL reconstruction between AMP and TT femoral drilling techniques. Random-effects meta-analyses were performed to pool the outcomes of tunnel widening across the included studies by estimating mean differences and their 95% confidence intervals (CIs) as absolute change in width, in millimeters, at the aperture or midportion relative to the width immediately after surgery, or as relative change, in percentage, from the with immediately after surgery, measured at the widest portion of the femoral tunnel. Interrater reliability in assessing methodological quality was evaluated by kappa (κ), with values of ≤ 0.40, 0.41–0.60, 0.61–0.80, and 0.81–1.00 indicating no, moderate, substantial, and almost perfect agreement, respectively. Heterogeneity was determined by estimating the proportion of between-study inconsistencies due to actual differences between studies, rather than differences due to random error or chance, using the I^2 statistics, with values of 25%, 50%, and 75% considered low, moderate, and high heterogeneity, respectively. Sensitivity analyses were performed on studies that utilized X-ray imaging to measure tunnel widening, while excluding studies without immediate postoperative data. A meta-regression analysis was performed to assess the effect of the follow-up period on absolute change (in millimeters) of tunnel widening at the aperture and midportion and the relative percentage widening at the widest portion. Analyses were performed using R statistical software version 3.4.0 (metafor package: a Meta-Analysis Package for R; R Foundation for Statistical Computing, Vienna, Austria) and RevMan version 5.2 (Copenhagen, the Nordic Cochrane Centre, The Cochrane Collaboration, 2012). A P value < 0.05 was considered significant.

Results

Study identification, study characteristics, and methodological quality

Figure 1 shows the details of the study identification, inclusion, and exclusion. The 21 included studies evaluated 1783 patients with ACL tears, with 1224 and 464 undergoing ACL reconstruction using the TT and AMP techniques, respectively. Of these 21 studies, eight reported the absolute widening in millimeters of the femoral tunnel at both the aperture and midportion. Another eight studies reported the absolute widening in millimeters only at the aperture. The remaining five studies reported the relative percentages of femoral tunnel widening. The sample size, imaging tool, graft choice, femoral drilling technique, follow-up periods, and MCMS are summarized in Table 1. The total mean (SD) MCMS of the included studies was 75 (5.9) (range 64–88) of 100, indicating good quality. Of the 21 studies, 16 had a mean CMS > 70 (good or excellent quality) and no studies had a mean score < 55 (poor quality). Interrater reliabilities (κ values) for all items of CMS ranged from 0.72 to 0.87, indicating at least more than substantial agreement between two investigators.

Absolute tunnel widening at the aperture and midportion

The 16 studies that reported the femoral tunnel widening as absolute millimeters included 224 and 181 patients who underwent single-bundle ACL reconstructions by AMP and TT, respectively. The pooled changes in femoral tunnel widening from immediate postoperative status to the last follow-up at the aperture were 3.3 mm (95% CI 1.7–5.0 mm) and 2.9 mm (95% CI 2.4–3.4 mm) for the AMP and TT techniques, respectively, a difference that was not statistically significant (n.s., Fig. 2). The pooled changes in tunnel widening at the midportion in these two group were 3.5 mm (95% CI 0.8–6.3 mm) and 3.0 mm (95% CI 2.2–3.9 mm), a difference that was also not statistically significant (n.s., Fig. 3).

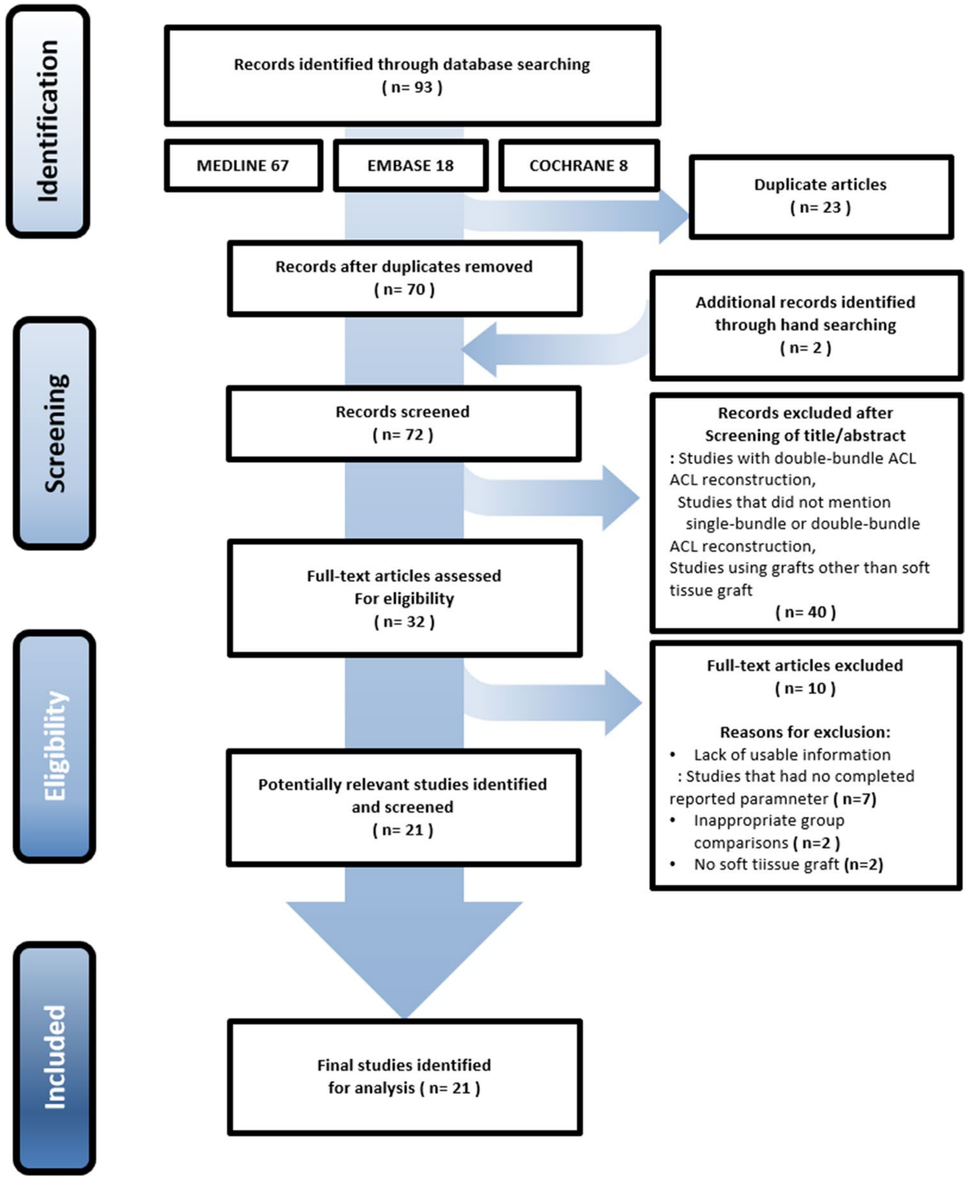

Fig. 1 Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) flow diagram of the identification and selection of the studies included in the meta-analysis

Relative percentages of tunnel widening

Five included studies evaluated the femoral tunnel widening as the relative percentage of change in femoral tunnel widening at the widest portion in the last follow-up compared to the immediate postoperative status, with measurements of the widest portion of the femoral tunnel. The pooled relative percentage in the change in femoral tunnel widening was 28.8% (95% CI 14.8–42.9%) for the AMP technique and 29.7% (95% CI 15.6–43.7%) for the TT technique, respectively, a difference that was not statistically significant (P = n.s., Fig. 4).

Sensitivity and meta-regression analyses

In assessing femoral tunnel widening at both the aperture and midportion, sensitivity analysis showed that the imaging modality used to measure tunnel widening and the assumption of drill reamer size immediately after surgery did not significantly influence the results of the original analysis, which showed no difference in femoral tunnel widening following the use of the two techniques (Table 2). The results of the meta-regression analyses are shown in Table 3. The follow-up period did not affect the mean absolute value in millimeters of tunnel widening from the immediate postoperative status up to the last follow-up at both the aperture and the midportion. Furthermore, the mean relative percentage

Table 1 Characteristics of the included studies

Study	Year	Technique	Sample size	Time of measurement(months)	Imaging tool	Graft	Femur fixation device	Measurement level and method	Initial tunnel size measurement method	MCMS (90)
Anteromedial portal technique										
Achtnich et al. [1]	2013	AMP	43	8	MRI	HT auto	Fliptack	Absolute millimeter (aperture)	MRI on POD 1 or 2	74
Aga et al. [2]	2017	AMP	42	12	CT	HT auto	EB	Absolute millimeter (aperture-midportion)	CT on POD 1	74
Mermerkaya et al. [23]	2014	AMP	72	17	X-ray	HT auto	EB or Bioabsorbable IF	Absolute millimeter (aperture-midportion)	X-ray on POD 1	69
Mirzatolooei et al. [24]	2013	AMP	46	3	CT	HT auto	TransFix	Absolute millimeter (aperture-midportion)	CT on POD 0	69
Moisala et al. [25]	2008	AMP	42	24	MRI	HT auto	Bioabsorbable or metal screw	Absolute millimeter (aperture)	Drill size	88
Robbrecht et al. [30]	2014	AMP	35	1	CT	HT auto /TA allo	EB	Absolute millimeter (aperture)	Drill size	69
Sabat et al. [31]	2011	AMP	17	6	CT	HT auto	TransFix or EB	Relative percentage (widest portion)	CT on POD 14	79
Siebold et al. [38]	2008	AMP	26	4.1	CT	HT auto	EB	Absolute millimeter (aperture)	CT on POD 2	76
Surer et al. [40]	2016	AMP	50	12	X-ray	Allo	EB	Absolute millimeter (aperture-midportion)	X-ray on POD 0	66
Xu et al. [45]	2011	AMP	19	12.8	X-ray	HT auto	EB	Relative percentage (widest portion)	Drill size	75
Transtibial technique										
Asik et al. [4]	2007	TT	271	12	X-ray	HT auto	TransFix	Relative percentage (widest portion)	Drill size	76
Baumfeld et al. [5]	2008	TT	46	43.3	X-ray	HT auto	EB or Rigid-fix	Absolute millimeter (aperture-midportion)	X-ray on POD 0	64
Choi et al. [8]	2017	TT	117	12	X-ray	HT auto	EB or Tight-Rope	Relative percentage (widest portion)	X-ray on POD 0	79
Hollis et al. [12]	2009	TT	27	7.7	X-ray	HT auto	EB	Absolute millimeter (aperture)	Drill size	82
Kawaguchi et al. [17]	2011	TT	72	24	X-ray	HT auto	EB	Relative percentage (widest portion)	X-ray on POD 0	67
Kong et al. [18]	2012	TT	91	56.7	X-ray	HT auto	Rigid-fix or EB	Absolute millimeter (aperture)	X-ray on POD 0	82
Lanzetti et al. [19]	2017	TT	22	24	CT	HT auto	TightRope	Absolute millimeter (aperture-midportion)	Drill size	79

Table 1 (continued)

Study	Year	Technique	Sample size	Time of measurement(months)	Imaging tool	Graft	Femur fixation device	Measurement level and method	Initial tunnel size measurement method	MCMS (90)
Lind et al. [21]	2009	TT	240	12	X-ray	HT auto	EB	Absolute millimeter (aperture)	Drill size	79
Nebelung et al. [26]	2012	TT	59	61	MRI	HT auto	BioTransfix	Absolute millimeter (aperture-midportion)	Drill size	79
Sabat et al. [31]	2011	TT	17	6	CT	HT auto	TransFix or EB	Relative percentage (widest portion)	CT on POD 14	79
Saygi et al. [34]	2016	TT	93	40.7	X-ray	HT auto	Cross-pin or Tog-gleLoc	Absolute millimeter (aperture)	Drill size	75
Uzumcugil et al. [42]	2012	TT	67	29.7	X-ray	HT auto	Aperfix/Transfix or EB	Absolute millimeter (aperture- midportion)	X-ray on POD 7	79
Xu et al. [45]	2011	TT	53	12.3	X-ray	HT auto	EB	Relative percentage (widest portion)	X-ray on POD 0	75

TT transtibial, *AMP* anteromedial portal, *HT* hamstring tendon, *TA* tibialis anterior tendon, auto autograft, allo allograft, *EB* endobutton, *MCMS* modified Coleman methodology score, *POD* postoperative day

of tunnel widening was also not influenced by the follow-up period.

Discussion

The most important findings of the current study indicated that the femoral tunnel widening after single-bundle ACL reconstruction was similar between the AMP and TT techniques, in terms of both absolute millimeters at both aperture and midportion and the relative percentages of the widest portions. This finding was contrary to our hypothesis that the AMP technique would result in a greater femoral tunnel widening after single-bundle ACL reconstruction than that of the TT technique. These results alleviate potential concerns that the AMP technique might cause greater tunnel widening than the TT technique.

There are several possible explanations. Despite not being explanatory in cases using cross-pin fixation, shorter tunnels could decrease the distance of the cortical fixation device from the joint space, thus reducing the windshield-wiper and bungee effects [33]. Another possible reason could be due to the fact that the AMP technique could result in a more acute graft-bending angle than that of the TT technique. A recent three-dimensional CT study [37] comparing the graft-bending angles in single-bundle ACL reconstruction using three different techniques showed results that were contrary to the popular belief. In that study, the graft-bending angles of single-bundle ACL reconstruction using the AMP technique were more acute in the coronal plane but less acute in the sagittal and axial planes than those of the TT technique. The relatively less acute graft-bending angle in the sagittal and axial planes than our previous assumption may reduce the graft-bending stress and abrasion at the femoral tunnel aperture, resulting in the similar tunnel widening between the AMP and TT techniques in our study. Another study comparing graft-bending angle according to ACL reconstruction technique found that the anatomic ACL reconstruction technique resulted in a steeper graft-bending angle than the TT technique, with a steeper angle thought to induce higher stress on the graft–bone interface [41]. Differences in frictional forces when performing the femoral drilling also could explain our results. During femoral tunnel placement with the TT technique, the guide pin and drill more often need to be torqued and drilling is not concentric, because the femoral tunnel placement is forced by the tibial tunnel [7], the increased torque in the TT technique is more likely to cause heat necrosis than that in the AMP technique. Thus, greater thermal bone resorption in the TT technique could offset the tunnel widening effect of the AMP technique due to the acute graft-bending angle and more elliptical-shaped femoral tunnel aperture.

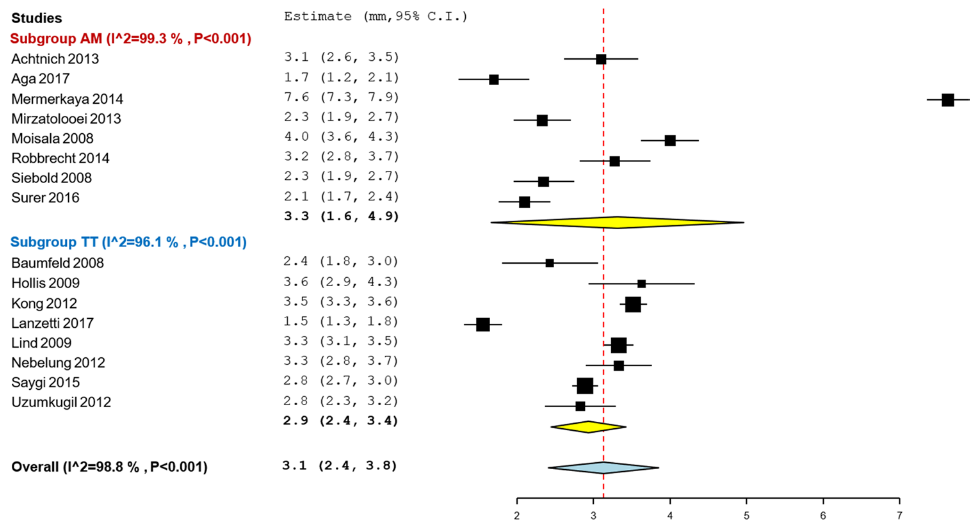

Fig. 2 Forest plot showing the absolute millimeters of femoral tunnel widening at the aperture in single-bundle ACL reconstruction using the anteromedial portal (AMP) and transtibial (TT) techniques. The pooled changes in tunnel widening at the midportion were 3.3 mm (95% CI 1.7–5.0 mm) in the AMP technique and 2.9 mm (95% CI 2.4–3.4 mm) in the TT technique, a difference that was not statistically significant (*P* = n.s.)

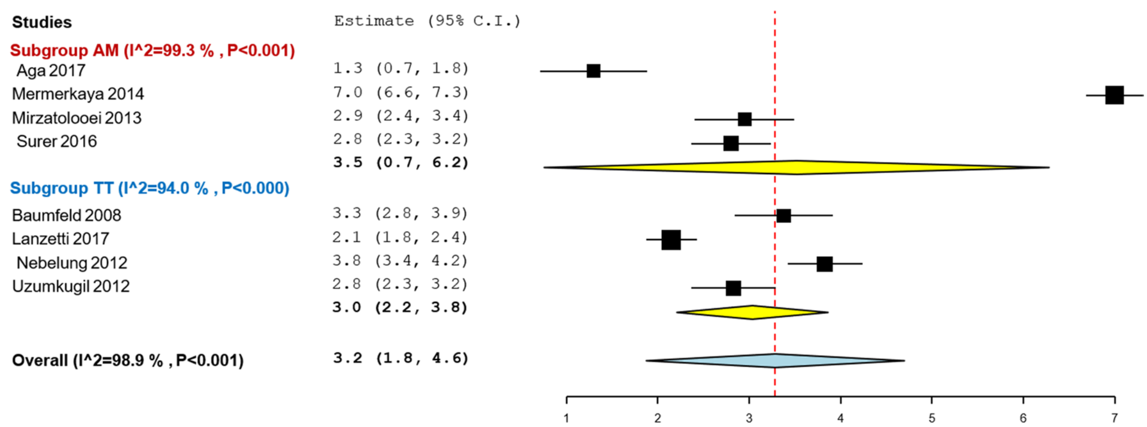

Fig. 3 Forest plot showing the absolute millimeters of femoral tunnel widening at midportion in single-bundle ACL reconstruction using the anteromedial portal (AMP) and transtibial (TT) techniques. Although the pooled femoral tunnel widening was 3.5 mm (95% CI, 0.8–6.3 mm) in the AMP technique and 3.0 mm (95% CI 2.2–3.9 mm) in the TT technique, the difference was not statistically significant (*P* = n.s.)

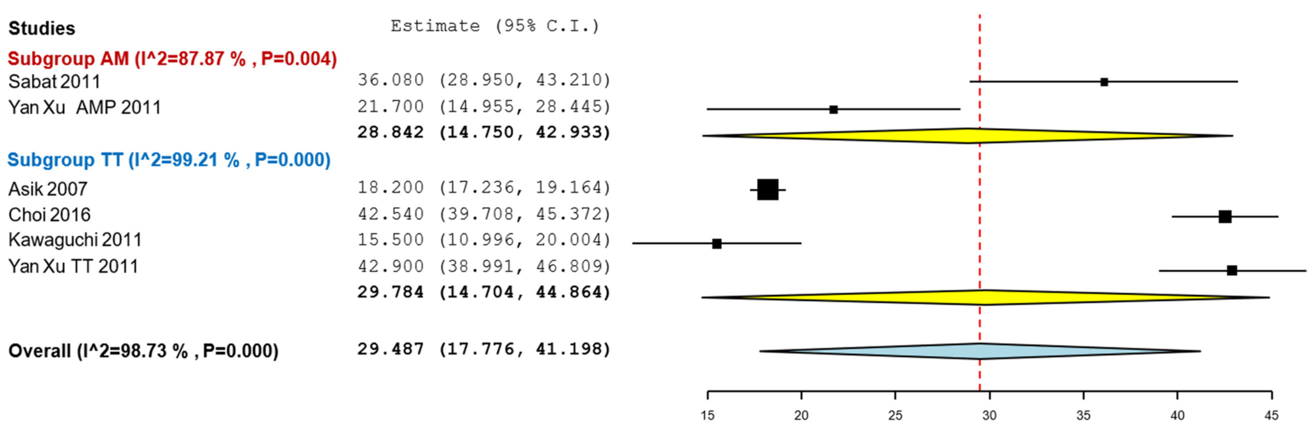

Fig. 4 Forest plot showing the relative percentages of femoral tunnel widening at the widest portion in single-bundle ACL reconstruction using the anteromedial portal (AMP) and transtibial (TT) techniques. The pooled relative percentages in changes in femoral tunnel widening were 28.8% (95% CI 14.8–42.9%) in the AMP technique and 29.7% (95% CI 15.6–43.7%) in the TT technique, with no statistically significant difference (*P* = n.s.)

Table 2 Weighted mean differences of outcomes following subgroup analysis comparing the anteromedial portal and transtibial techniques

Outcome or subgroup		Number of studies	Participants	ES (95% CI) Mean value (mm)	I^2 (%)	*P* value
Absolute TW (aperture)						
All	AMP	8	356	3.3 (1.7–5.0)	99	n.s
	TT	8	645	2.9 (2.4–3.4)	96	
Subgroup analysis						
Measured by X-ray	AMP	2	122	4.5 (0.6–10.3)	99	n.s
	TT	6	564	3.3 (2.8–3.4)	87	
Only including studies with immediate postoperative tunnel widening data	AMP	6	279	3.2 (1.0-5.4)	99	n.s
	TT	2	158	3.2 (2.5–3.8)	87	
Absolute TW (midportion)						
All	AMP	4	210	3.5 (0.8–6.3)	99	n.s
	TT	4	194	3.0 (2.2–3.9)	94	
Measured by X-ray	AMP	2	122	4.9 (0.8–9.0)	99	n.s
	TT	2	113	3.1 (2.6–3.6)	57	
Only including studies with immediate postoperative tunnel widening data	AMP	4	210	3.5 (0.8–6.3)	99	n.s
	TT	4	113	3.3 (2.4–4.3)	90	

ES effect size, *TW* tunnel widening, *AMP* anteromedial portal, *TT* transtibial

Table 3 Effect of follow-up period on absolute millimeter of tunnel widening (TW) in the aperture and midportion and the relative percentage of the widest portion: results of meta-regression analyses

Independent variable	Follow-up period		
Dependent variable	TW difference in aperture (mm)	TW difference in midportion (mm)	TW difference in widest portion (%)
Coefficient	0.006	0.015	−1.316
Standard error	0.022	0.042	1.191
P value	n.s	n.s	n.s
95% CI	−0.036 to 0.049	−0.068 to 0.097	−3.649 to 1.017

Recent review articles have compared clinical outcomes after ACL reconstruction using the AMP and TT techniques [22, 29]. However, those articles compared the clinical outcomes based on scoring system, knee laxity tests, and physical examination, whereas the present study focused on femoral tunnel widening using the AMP and TT techniques. Our findings may provide important baseline data on tunnel widening for further studies assessing any possible correlation between femoral tunnel widening and subsequent residual laxity after ACL reconstruction.

The present study had some limitations. First, the methods of evaluating tunnel widening differed in each enrolled trial. We, therefore, performed a subgroup analysis according to tunnel location (aperture or midportion) and units (mm or %) of measuring tunnel widening, respectively. Second, some of the included studies assumed the drill reamer diameter as the immediate time zero postoperative measurement of the femoral tunnel size as the baseline value for analyzing the change in tunnel widening at last follow-up without performing immediate postoperative imaging. This assumption might lead to an error in the immediate postoperative femoral tunnel size. However, a recent study reported high reliability between the drill reamer diameter and femoral tunnel size in CT performed immediately postoperatively [14, 43]. In addition, a sensitivity analysis, which excluded studies that did not measure immediate postoperative femoral tunnel size, demonstrated that our assumption, that the diameter of the drill reamer was equal to the immediate postoperative femoral tunnel size, did not substantially influence the findings of the original analysis, which found no difference in absolute tunnel widening between the AMP and TT techniques. Third, studies differed in the imaging tool used to measure tunnel widening (e.g., plain radiography, CT, or MRI). However, measurements of tunnel widening by the conventional radiography showed good correlations with measurements on CT or MR imaging [15, 38, 44]. Moreover, our sensitivity subgroup analysis, which included only those studies using plain radiographs to measure tunnel widening, showed no significant differences in absolute tunnel widening between the AMP and TT techniques, similar to results from all included studies. Fourth, tunnel widening was not evaluated based on anatomic and non-anatomic tunnel positions. This factor has been shown to affect tunnel widening after ACL reconstruction [28]. Finally, we could not entirely exclude other factors that may influence the tunnel widening, such as graft type, femoral fixation device, and measurement time point, which could explain the high heterogeneity in the results of the present study. However, this study only included single-bundle ACL reconstruction using soft-tissue tendon grafts to minimize this heterogeneity. In addition, the results of the meta-regression analysis in our study showed that the time point of tunnel widening measurement did not affect the mean change in femoral tunnel widening after ACL reconstruction, irrespective of the measurement location (aperture or midportion) and quantification parameter (absolute millimeters or relative percentages). Despite these limitations, the results of the present study could alleviate the potential concerns associated with femoral tunnels being wider for the AMP than for the TT technique.

Conclusion

Femoral tunnel widening by absolute millimeter and relative percentage did not differ significantly between the AMP and TT techniques in patients with single-bundle ACL reconstruction. This finding could alleviate the concerns associated with greater tunnel widening following AMP femoral drilling than the TT techniques.

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Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict interest.

Ethical approval This article does not contain any studies with human participants performed by any of the authors.

Informed consent For this type of study, formal consent is not required.

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