Systematic Review

Graft Tensioning in Anterior Cruciate Ligament Reconstruction: A Systematic Review of Randomized Controlled Trials

Shalinder Arneja, M.D., M.H.Sc.(Epi), Mark O. McConkey, M.D., Kishore Mulpuri, M.B.B.S.(Ortho), M.H.Sc.(Epi), Patrick Chin, M.D., F.R.C.S.C., Michael K. Gilbart, M.D., F.R.C.S.C., William D. Regan, M.D., F.R.C.S.C., and Jordan M. Leith, M.D., M.H.Sc.(Epi), F.R.C.S.C.

Purpose: The purposes of this study were to (1) perform a systematic review of randomized controlled trials evaluating graft tensioning in anterior cruciate ligament (ACL) reconstruction, and (2) determine the scientific quality of published randomized controlled trials evaluating graft tensioning in ACL reconstruction. Methods: The search strategy included a computerized literature search, a citation search, and a manual search of key journals and conference proceedings. Eligible studies were randomized controlled trials evaluating the effect of graft tensioning on the outcomes of ACL reconstruction. Two reviewers independently performed the literature searches. The validity of the trials was scored using the Detsky quality scale. Consensus was achieved by a study committee of 3 investigators. Results: Five randomized controlled trials met the inclusion criteria. The mean standardized Detsky score was 61.3 ± 15.2%. Only 2 of the studies scored ≥75%. All trials consisted of autogenous graft sources, with 3 involving a bone-patellar tendon-bone graft, 1 involving a 5-strand semitendinosus-polyester (5STP) graft, and 1 involving a semitendinosus-gracilis-polyester (STGP) graft. Conclusions: Based on the evidence in this systematic review, there is a trend that suggests that 80 N of tension is the most effective amount of tension to apply during ACL reconstruction using hamstring-polyester graft sources. For ACL reconstruction using semitendinosus-gracilis or patellar tendon graft sources, there is no clear trend in terms of statistically significant or clinically relevant differences in terms of the amount of applied tension to apply to the graft during graft fixation. We are unable to provide recommendations as to the amount of tension to apply to 4-strand semitendinosus-gracilis autografts without polyester augmentation because there has been no randomized clinical trial conducted to determine the most effective amount of tension to apply when using this graft source. Level of Evidence: Level II, systematic review of Level I studies with inconsistent result. Key Words: Anterior cruciate ligament-Patellar tendon-Reconstruction-Semitendinosus gracilis—Systematic review—Tensioning.

Successful anterior cruciate ligament (ACL) reconstruction depends on several factors including the type and source of graft, 1-3 tunnel position, 4,5 knee

From the Department of Orthopaedics, University of British Columbia, Vancouver, British Columbia, Canada.

The authors report no conflicts of interest.

Address correspondence and reprint requests to Shalinder Arneja, M.D., M.H.Sc.(Epi), Department of Orthopaedics, University of British Columbia, Room 3114, 910 W 10th Ave, Vancouver, BC V5Z 4E3, Canada. E-mail: shal.arneja@hotmail.com

© 2009 by the Arthroscopy Association of North America 0749-8063/09/2502-8243\$36.00/0 doi:10.1016/j.arthro.2008.07.010

flexion angle at the time of fixation,⁶⁻⁸ the amount of tibial internal rotation during graft tensioning,⁸ the method of graft fixation,⁹ and the initial graft tension at the time of fixation.¹⁰ Of these variables, it has been hypothesized that an important determinant of successful ACL reconstruction is the amount of tension applied during graft fixation.^{2,11-14}

Various authors have recommended that "strong tension"¹³ should be applied, that the graft should be pulled through the tunnels "as far as it would go,"⁷ or that "5 mm of anterior–posterior translation should be preserved"² during graft tensioning. In a biomechanical study using hamstring grafts, Easom et al.¹⁵ con-

cluded that 80 N of tension provided the greatest knee stability immediately after reconstruction when compared with 40 N or 20 N.15 In biomechanical studies using bone-patellar tendon-bone (BPTB) models, findings have suggested that 20 N to 67 N should be applied during graft fixation.^{16,17} Finally, in a review of basic science and clinical outcomes related to graft tensioning, Tohyama and Yasuda¹⁴ reiterated that initial tension is one of the most significant factors affecting the results of ACL reconstruction. They concluded, however, that it is still necessary to establish quantitative guidelines for optimal tension for each graft used in ACL reconstruction.¹⁴ This question remains unanswered: What is the most effective amount of tension applied to an ACL graft during graft fixation?

Because the amount of tension applied to the ACL graft is a technically important aspect in the overall success of the reconstruction, the amount of tension to apply during graft fixation must be supported by highquality, Level I research evidence. Therefore, the purpose of our study was 2-fold: (1) to conduct a systematic review of all of the randomized controlled trials (RCTs) that assessed the effect of initial graft tensioning during graft fixation on the outcomes of ACL reconstruction, and (2) to determine the scientific quality of published RCTs evaluating graft tensioning in ACL reconstruction using the Detsky score.¹⁸ Our hypothesis was that the most effective amount of tension to apply during graft fixation is 80 N of force for both hamstring tendon and patellar tendon graft sources.

METHODS

Study Identification

Studies to be included in this systematic review were selected by 2 investigators. The investigators independently conducted a computer-based literature search on 5 databases: Medline (1966 to July 1st, 2008), Embase (1980 to July 1st, 2008), PubMed (July 1st, 2008), the Cochrane central register of controlled trials (2nd quarter, 2008) and the Cochrane database of systematic reviews (2nd quarter, 2008). The recommended optimal Medline search strategy¹⁹ was used in the searches as follows: (1) "ACL reconstruction" or "Anterior cruciate ligament reconstruction"; (2) "initial graft tension" or "graft tension"; and (3) both 1 and 2.

To ensure that there were no RCTs missed during the computer-based literature search, 2 investigators

TABLE 1. Manual Searches of Journal and Meeting Abstracts (1998-2007)

Key Journals

Journal of Orthopaedic Research Journal of Bone and Joint Surgery—American Volume Clinical Orthopaedics and Related Research Journal of Bone and Joint Surgery—British Volume

Clinical Journal of Sports Medicine

American Journal of Sports Medicine

Arthroscopy: The Journal of Arthroscopic and Related Surgery Knee Surgery, Sports Traumatology, Arthroscopy

British Journal of Sports Medicine

International Journal of Sports Medicine

Key Meeting Abstracts

American Academy of Orthopaedic Surgeons Annual Meeting International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine Biennial Congress

American Orthopaedic Society for Sports Medicine Annual Meeting

American Orthopaedic Society for Sports Medicine Specialty Day

Arthroscopy Association of North America Annual Meeting Canadian Orthopaedic Association Annual Meeting European Society for Sports Traumatology, Knee Surgery and Arthroscopy Biennial Congress

conducted a manual review of the 10 highest impact factor journals related to orthopaedic sports medicine and 7 highly attended orthopaedic sports medicine conferences from 1998 to 2007 (Table 1). Any discrepancy in regard to the selection of studies was resolved by the study committee consisting of 2 investigators (S.A., M.M.) and the senior author (J.L.).

Eligibility Criteria

To qualify for inclusion for this systematic review, a study had to be described as a prospective RCT in patients with isolated, unilateral ACL insufficiency undergoing ACL reconstruction. The study had to assess patients both preoperatively and for at least 1 year postoperatively. The study had to use an objective knee ligament testing device as an objective assessment tool. Finally, a measured tensioning device had to be used during graft fixation. There were no restrictions in terms of graft source used in the studies (i.e., allograft, BPTB autograft, or hamstring grafts).

Study Selection

The titles and abstracts of all studies were assessed for study eligibility criteria. If it was clear from the information provided in the title or abstract that the study was not relevant, it was excluded. If it was unclear from the title or abstract, then the full text was reviewed. If the title suggested that the study was relevant but there was no abstract, then the full text was reviewed. There was no blinding to study author, place of publication, or study results. The final decision regarding inclusion of studies was made by the study committee.

Assessment of Methodologic Quality

Each eligible study was independently reviewed by 2 blinded raters for methodologic quality; these raters were not part of the study committee. They were blinded to specific study information including the authors, the study institution(s), and hospital or industry affiliations. All discrepancies were resolved by consensus with a third independent rater. The Detsky quality index was used to score the methodologic quality of the RCT.¹⁸ The Detsky quality index is a 14-item scoring system that contains items in the following domains: (1) randomization, (2) outcome measures, (3) patient eligibility criteria, (4) interventions in the study arms, and (5) statistics. Each of the 5 domains is given equal weight (4 points), and the total score is 20 for positive trials. A positive trial is one that reports statistically significant differences in outcome. The total score for negative trials is 21. A negative trial is one that did not report statistically significant differences. The extra point for negative trials is given for trials that provide confidence intervals or performed post hoc power calculations. The scores were standardized to a maximum score of 100 as described by Bhandari et al.20 The 2 raters were experienced in the use of the Detsky quality index. The standardized Detsky score was established for each article. The mean Detsky percentage score was then calculated for each article. A precedent exists that establishes the standard of acceptability for the Detsky quality index at $\geq 75\%$.^{20,21}

Data Extraction

The primary investigator (S.A.) extracted all study characteristics and data into summary tables. The primary outcome measure in this study was overall side-to-side differences (STSD) in knee laxity as measured by an objective knee laxity testing device. Secondary outcome measures that were extracted included quality of life or subjective questionnaires. Other information that was extracted included characteristics of the surgical technique, characteristics of the study parameters, and patient demographic information. Characteristics of the surgical technique included the type of graft used in the reconstruction and whether it was autograft or allograft, the type of fixation used to

secure the graft, whether the graft was preconditioned, the tensioning device used during graft fixation, the amount of tension applied during graft fixation in the study groups, and the position of the extremity during tibial fixation.

Characteristics of the study parameters included the device used in knee laxity testing, the timing of knee laxity testing, whether secondary outcome measures were used and, if so, what they were and the timing of administration.

Patient demographic information included, age, sex, and associated meniscal injury. Adverse events were also extracted which included knee stiffness, residual symptoms of instability, effusions, infection, or graft failure.

RESULTS

Study Identification

From the initial review of the citations found during the literature search, 55 studies were identified. Twentynine articles were rejected based on information available in the title that made it clear that the article did not meet the eligibility criteria. Twenty-six abstracts were reviewed and 17 articles were rejected based on the information available in the abstracts. Nine full text articles were reviewed, of which 4 were rejected. The reasons for exclusion of the full-text articles were as follows: 2 studies involved animal models, 1 study was a basic science review, and 1 study was a biomechanical study. Five studies²²⁻²⁶ met the inclusion criteria and were included in the systematic review (Table 2).

Study Characteristics: The study population, treatment interventions, follow-up time frame, and reported results of the 5 trials were extracted and tabulated (Table 3). The sample size ranged from 38 to 70, with a total sample of 147 men and 101 women for a total of 248 subjects. Only one study²⁶ performed an a priori power analysis and sample size calculation. Four of the studies^{22-24,26} reported that there was no difference in the treatment groups in regard to associated meniscal injury at the time of surgery; however, none commented on the specific treatments of the associated pathology. The remaining study²⁵ did not report on the incidence or treatment of meniscal pathology. One study²² reported a statistically significant difference in gender distribution between treatment arms. In this study, 1 group had 10 women compared with 1 in the other group. Within each study, there were no other differences between treatment groups in terms of age,

		Detsky Score		
Author	Title	Raw	Standardized	
van Kampen et al. ²²	The effect of different graft tensioning in anterior cruciate ligament reconstruction: A prospective randomized study	8/21	38.1	
Nicholas et al. ²⁶	A prospectively randomized double-blind study on the effect of initial graft tension on knee stability after anterior cruciate ligament reconstruction	16/20	80	
Yoshiya et al.23	Graft tension and knee stability after anterior cruciate ligament reconstruction	13/21	61.9	
Yasuda et al. ²⁵	Anterior cruciate ligament reconstruction: Autogenous doubled hamstring tendons connected in series with polyester tapes	15/20	75	
Kim et al. ²⁴	The effect of initial graft tension on postoperative clinical outcome in anterior cruciate ligament reconstruction with semitendinosus tendon	14/21	66.7	

 TABLE 2.
 Studies Included in Systematic Review With Detsky Scores

NOTE. The maximum raw Detsky score is 21 for trials that did not show statistically significant differences and 20 for trials that did show statistically significant differences. The maximum standardized Detsky score is 100.

sex, or number of subjects or in any other demographic information preoperatively. The duration of follow-up assessment ranged from 12 to 30 months.

Surgical Technique

Graft Source: For ACL reconstruction, 3 of the studies^{22,23,26} used an autogenous BPTB, 1 study²⁴ used a 5-strand autogenous semitendinosus–polyester graft (5STP), and 1 study used a 4-strand autogenous semitendinosus–gracilis–polyester graft (STGP).²⁵

Tensioning Protocol: Before placing the graft in situ, 3 studies²³⁻²⁵ reported that the grafts were preconditioned, 1 study²⁶ reported that the grafts were not preconditioned, and 1 study²² did not report whether the graft was or was not preconditioned. The tensioning device used during graft fixation was reported in all studies. Four of the studies used a custom-designed tensioner,^{22-24,26} and 1 study used a commercially available tensiometer.²⁵ During graft fixation, 2 studies^{23,26} reported that the knee was placed in full extension, 1 study²² reported that the knee was placed at 20° of knee flexion, and 2 studies^{24,25} reported that the knee was placed at 30° of knee flexion.

The amount of tension applied during graft fixation was different among all of the studies. In the study by van Kampen et al.,²² the treatment arms received 20 N or 40 N of tension. In the study by Nicholas et al.,²⁶ the treatment arms received 45 N or 90 N of tension. In the study by Yoshiya et al.,²³ the treatment arms received 25 N or 50 N of tension. All of these studies used BPTB as the graft source. In the study by Yasuda et al.,²⁵ the 3 treatment arms received 20 N, 40 N, or 80 N of force, respectively. Finally, in the study by Kim et al.,²⁴ the 3 treatment arms received 78.5 N, 117.7 N, or 147.1 N of tension, respectively. These 2

studies used hamstrings as the graft source with polyester augmentation.

Technical Considerations: Graft fixation was achieved with interference screws for both tibial and femoral fixation in 2 studies.^{23,26} In 2 studies, the grafts were secured using staples for both tibial and femoral fixation.^{24,25} One study²² did not report the form of fixation used for graft fixation. The location of the tibial and femoral tunnels was described in 3 of the studies^{23,25,26}; however, the location was not reported in 2 studies.^{22,24}

Primary Outcome Measure

All of the studies used an objective knee ligament testing device as an outcome measurement instrument. Two studies^{23,26} used the KT-1000 knee ligament arthrometer (MEDmetric, San Diego, CA), 1 study²⁴ used the KT-2000 knee ligament arthrometer (MEDmetric), 1 study²⁵ used the Stryker Tensiometer (Stryker, Kalamazoo, MI), and 1 study²² used a custom-designed knee ligament arthrometer. The results of the knee laxity testing are shown in Table 3. In all of the studies, there was no statistical difference in the preoperative knee laxity testing between groups within each study. Two of the studies reported a statistically significant difference between treatment groups at the final postoperative knee laxity testing.^{25,26} In the study by Nicholas et al., 26 there was a statistically significant overall decrease mean laxity in the 90 N group (2.2 \pm 1.6 mm) compared with the 45 N group (3.0 \pm 2.2 mm). In the study by Yasuda et al.,25 there was a statistically significant overall decrease in mean laxity in the 80-N group (0.6 \pm 1.7 mm) compared with the 20-N group $(2.2 \pm 1.4 \text{ mm})$. In the study by Kim et al.,²⁴ there was

 TABLE 3.
 Data Extraction Table

	Study											
	van Kamp	en et al. ²⁴	Nichola	s et al. ²⁶	Yoshiy	a et al. ²³	•	Yasuda et al.	25		Kim et al.24	
Patient demographics												
No. of patients	19*	19*	22*	27*	22*	21*	23*	23*	24*	16*	16*	16*
Females	10^{\dagger}	1 [†]	8*	8*	12*	10*	11*	11*	11*	5*	5*	9*
Mean age, y	NR	NR	33 ± 8*	$30 \pm 7*$	23*	23*	$22.7 \pm 6.7*$	$23.0 \pm 5.7*$	$25.5 \pm 8.1*$	27.1*	22.6*	23.7*
Study characteristics												
Tension applied	20 N	40 N	45 N	90 N	25 N	50 N	20 N	40 N	80 N	78.5 N	117.7 N	147.1 N
Graft source [‡]	BPTB	BPTB	BPTB	BPTB	BPTB	BPTB	STGP	STGP	STGP	5STP	5STP	5STP
Tensioning device	CT	CT	CT	CT	CT	CT	STR	STR	STR	CT	CT	CT
Pretensioned (Y/N)	NR	NR	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Knee flexion during tensioning	20°	20°	0°	0°	0°	0°	30°	30°	30°	30°	30°	30°
Knee ligament testing device	CKLA	CKLA	KT1	KT1	KT1	KT1	SKLA	SKLA	SKLA	KT2	KT2	KT2
Secondary outcome measure	LS	LS	KOS	KOS	IKDC-SF	IKDC-SF	NSS	NSS	NSS	VAS	VAS	VAS
Knee laxity testing												
Preoperative STSD (mm)	5.7 ± 2.4*	$6.1 \pm 2.9*$	5.3 ± 2.4	$5.7 \pm 2.7*$	$5.2 \pm 2.0*$	$5.4 \pm 1.5*$	5.1 ± 1.9*	$6.3 \pm 2.1*$	$5.9 \pm 1.8*$	5.6 ± 1.9*	$5.0 \pm 2.0 *$	$6.3 \pm 2.6*$
Postoperative STSD (mm)	$2.6 \pm 1.4*$	$2.5 \pm 1.8*$	$3.0 \pm 2.2^{\dagger}$	$2.2 \pm 1.6^{\dagger}$	$1.4 \pm 2.6*^{\P}$	$1.9 \pm 4.0^{*,\P}$	2.2 ± 2.4 §	$1.4 \pm 1.8*$	$0.6 \pm 1.7^{\S}$	$1.3 \pm 1.4*$	$2.1 \pm 1.9*$	$2.4 \pm 2.2*$
No. of negative STSD scores	1	0	0	1	NR	NR	3	3	4	0	1	0
Minimum and maximum STSD												
scores	(-0.9, 5.2)	(0.2, 5.8)	(0, 7.5)	(-1, 4.5)	NR	NR	(-2, 7.5)	(-2, 5)	(-3, 4)	(0.4, 5.5)	(-1, 6.5)	(0.2, 7.5)
Quality of life subjective measure										` ` ` ′		
Preoperative score	66*	66*	ND	ND	ND	ND	28 ± 6.1*	$29.4 \pm 5.7*$	$27.4 \pm 6.5*$	30 ± 25*	$36 \pm 24*$	$37 \pm 17*$
Postoperative score	94*	94*	92 ± 4*	$90 \pm 7*$	ND	ND	42.2 ± 7.5*	$44.6 \pm 8.8*$	$44.9 \pm 7.9*$	84*	83*	79*
Length of follow-up (mos)	12	12	20	20	—	_	30	30	30	16.3	15.8	18.8

Abbreviations: 5STP, 5-strand hamstring-polyester autograft; BPTB, bone-patellar tendon-bone autograft; CK, LA, custom knee ligament arthrometer; CT, custom tensiomoter; IKDC-SF, International Knee Document Committee-subjective form; KOS, Knee Outcome Survey; KT1, KT-1000 Arthrometer; KT2, KT-2000 Arthrometer; LS, Lysholm score; N, Newton; ND, reported in the study only as "no differences found"; NR, not reported; NSS, Noves Scoring System; STGP, semitendinosus-gracilis-polyester autograft; STR, Stryker Tensiometer; STSD, side-to-side difference in instrumented knee laxity testing; VAS, visual analogue scale.

^{*}Not statistically significant result between groups within trial (P > .05).

[†]Statistically significant result between groups within trial (P < .05). *Autogenous graft sources were used in every trial.

[§]Statistically significant result (P = .046).

Results approach significance (P = .11).

The authors were contacted and numeric values were not published nor were available; therefore, data are derived from a graph.

no statistically significant difference shown; however, the differences between the 78.5-N group $(1.3 \pm 1.4 \text{ mm})$ and the 147.1-N group $(2.4 \pm 2.2 \text{ mm})$ approaches significance (P=.11). Finally, 4 of the studies^{22,24-26} reported on the proportion of subjects who had negative STSD scores. There were no statistically significant differences found when the proportion of subjects who had negative STSD scores was analyzed.

Secondary Outcome Measure

All the studies used a secondary outcome measure; however, they differed among studies. The questionnaires used in these studies included the Lysholm scale,²² the Knee Outcome Survey,²⁶ the International Knee Document Committee Subjective Form,²³ the Noyes Scoring System,²⁵ and a generic 100-mm visual analogue scale.²⁴ None of these questionnaires has been validated for use in subjects with an ACL-deficient knee (Table 3). There were no statistically significant differences found within each trial between treatment groups preoperatively or at the final postoperative assessment.

Finally, the amount of tension applied during graft fixation is quite heterogeneous among the trials. For example, in the 2 trials using hamstring grafts, the treatment arms in 1 trial²⁵ applied 20 N, 40 N, and 80 N of tension. The treatment arms in the second trial²⁴ applied 78.5 N, 117.7 N, and 147.1 N of tension. In the trials using BPTB grafts, the treatment arms in the first trial²² applied 20 N and 40 N of tension; in the second trial,²⁶ 45 N and 90 N of tension was applied; and in the third trial,²³ 25 N and 50 N of tension was applied.

Other sources of heterogeneity among the trials include the type of knee laxity testing device used in the trials, the secondary outcome measures used in the trials, the type of tensioning device used in the trials, the degree of knee flexion during graft fixation and tensioning, and whether or not the grafts were preconditioned (Table 3).

Adverse Events

In terms of stiffness, there was no difference between treatment groups within each study at the final follow-up; however, only 3 studies²⁴⁻²⁶ reported the range of motion numeric values. All of the studies reported the incidence of infection, which only occurred in 1 patient in 1 study.²⁶ There were 4 cases of reoperation all occurring in 1 study,²⁶ 2 in the 90-N group and 2 in the 45-N group. Both cases in the 90-N group were caused by arthrofibrosis. In the 45-N group, 1 case was caused by infection and 1 case was caused by arthrofibrosis. Three studies²³⁻²⁵ did not have any

cases of repeat arthroscopy, and 1 study²² did not report whether there were any cases of repeat arthroscopy. None of the studies reported on whether there were any graft failures or revision ACL surgery during the study period.

Scientific Quality

The mean standardized score (and standard deviation) for the overall quality of the 5 studies was $61.3 \pm 15.2\%$. One study²² scored below 50%; 2 studies^{23,24} scored between 50% and 75%; and 2 studies^{25,26} scored at or above 75%. The proportion of studies meeting the selected standard of acceptability (\geq 75%) was 0.40. The Detsky scores of the 5 articles are presented in Table 2.

DISCUSSION

The primary purpose of this study was to perform a systematic review of the RCTs evaluating graft tensioning in ACL reconstruction. We identified 5 studies that met the eligibility criteria. Applying tension to the ACL graft is a technically important aspect of ACL reconstruction. Closely related to the amount of tension applied to the graft is the amount of preconditioning applied graft and the position the leg is put in during graft fixation. It has been suggested that grafts should be preconditioned before implantation to prevent postimplantation graft creep.²⁷ In addition, it has been suggested that grafts should be secured with the knee in 20° to 30° of knee flexion unless the graft shortens during isometric testing.²⁸ In this systematic review, 3 of the studies²³⁻²⁵ preconditioned the graft before being placed in vivo, 1 study²⁶ did not, and 1 did not report whether or not the grafts were preconditioned.²² There was a large degree of heterogeneity in the degree of knee flexion during graft fixation, with 3 studies placing the knee between 20° to 30° of knee flexion, and 2 studies placing the knee in full extension. Finally, the amount of tension applied to the grafts during graft fixation was entirely different among the 5 studies. The heterogeneity of these studies is the fundamental reason that the data extracted cannot be combined to perform statistical testing on the aggregate data. Despite this, there seems to be a trend in the results that suggests that the ideal amount of tension to place for ACL reconstruction using hamstring-polyester graft sources is 80 N of tension. For ACL reconstruction using patellar tendon graft sources or hamstring grafts without polyester augmentation, there is no clear trend in terms of statistically significant or clinically relevant differences in the amount of applied tension to apply to the graft during graft fixation.

It is intriguing to discover there has not been one RCT that has sought to determine the most appropriate amount of tension to apply to a 4-strand STG autograft without polyester augmentation. This graft source is one of the most commonly used grafts in ACL reconstructive procedures and it is certainly necessary for there to be Level I evidence to provide evidence-based guidelines as to the most appropriate tension to apply.

The decision to perform a qualitative systematic review or a quantitative meta-analysis is based on a number of variables, including the quality of the trials, the quality of the data, and the degree of heterogeneity among the trials. Cook et al.29 stated that a qualitative systematic review should be performed when data are too sparse, of too low quality, or too heterogeneous to proceed with statistical aggregation. We have decided to perform a qualitative systematic review for the following reasons. First, the quality of the RCTs as determined by the Detsky scores is below the acceptable standard in 3 of the 5 studies in this analysis. Second, 3 of the trials involve the use of BPTB autografts, and 2 of the trials involve the use of hamstring autografts. There is evidence to suggest that the tissue properties of the 2 different graft sources are inherently different and that the amount of tension that is required to apply to hamstring graft sources is different than that for BPTB graft sources.30 Finally, there is a significant amount of methodologic heterogeneity among the trials. Unfortunately, because we were not able to perform a quantitative meta-analysis, we are unable to perform statistical testing of our hypothesis.

The secondary purpose of this study was to determine the scientific quality of published RCTs evaluating graft tensioning in ACL reconstruction. The quality of the studies involved in this analysis was assessed using the Detsky Quality Index. As shown, only 2 of the 5 studies met the accepted standard of quality (≥75%). Substandard quality of RCTs has been shown to be prevalent in the orthopedic literature.^{20,21}

More robust methodology would significantly improve the internal validity of the studies. Of the 3 studies that failed to show a difference in the primary outcome of knee laxity testing, none of the studies presented confidence intervals or post hoc power analyses. We have preformed post hoc power analyses for these studies (Table 4). Our analysis suggests that these studies were grossly underpowered. In the study by Kim et al.,²⁴ there were 6 patients per group. Based on our analysis, a minimum of 47 subjects would be required in each group to show superiority. For the

 TABLE 4. Post Hoc Power Analysis for Negative Trials^a

Study	α	β	σ	n
Van Kampen et al. ²²	0.05	0.2	1.4	2,424
Yoshiya et al. ²³	0.05	0.2	2.6	335
Kim et al. ²⁴				
78.5 N v 147.1 N	0.05	0.2	1.9	47
78.5 N v 147.1 N	0.05	0.2	1.9	89
117.7 N v 147.1 N	0.05	0.2	1.9	496

Abbreviations: α , alpha; β , beta; σ , standard deviation; n, no. of patients per group.

^aNegative trials did not show statistically significant differences.

same effect, in the study by Yoshiya et al.,²³ 335 patients would have been required in each group and in the study by van Kampen et al.,²² 2,424 subjects would have been required per group.

Study Limitations

The power of a systematic review is correlated to the quality of the studies that meet the eligibility criteria. We have shown that only 2 of the 5 studies included meet the Detsky standard of acceptability. Furthermore, the ability to form meaningful conclusions in this systematic review is limited by the significant heterogeneity that exists between the trials. Specifically, there is significant heterogeneity between the studies in terms of the amount of tension applied, the angle of knee flexion during tensioning, the graft source used for reconstruction, the different fixation devices used, and in the outcome measures used. These limitations collectively resulted in an inability to perform a quantitative meta-analysis; instead, we were only able to perform a qualitative systematic review.

CONCLUSIONS

Based on the evidence in this systematic review, there is a trend that suggests that 80 N of tension is the most effective amount of tension to apply during ACL reconstruction using hamstring-polyester graft sources. For ACL reconstruction using semitendinosus-gracilis or patellar tendon graft sources, there is no clear trend in terms of statistically significant or clinically relevant differences in the amount of applied tension to apply to the graft during graft fixation. We are unable to provide recommendations as to the amount of tension to apply to 4-strand semitendinosus-gracilis autografts without polyester augmentation because there has been no randomized clinical trial conducted to

determine the most effective amount of tension to apply when using this graft source.

REFERENCES

- Noyes FR, Butler DL, Grood ES, Zernicke RF, Hefzy MS. Biomechanical analysis of human ligament grafts used in knee-ligament repairs and reconstructions. *J Bone Joint Surg Am* 1984;66:344-352.
- 2. Noyes FR, Butler DL, Paulos LE, Grood ES. Intra-articular cruciate reconstruction. I: Perspectives on graft strength, vascularization, and immediate motion after replacement. *Clin Orthop Relat Res* 1983;172:71-77.
- Noyes FR, Grood ES. The strength of the anterior cruciate ligament in humans and rhesus monkeys. Age-related and species-related changes. J Bone Joint Surg Am 1976;58A: 1074-1082.
- Penner DA, Daniel DM, Wood P, Mishra D. An in vitro study of anterior cruciate ligament graft placement and isometry. Am J Sports Med 1988;16:238-243.
- Sidles JA, Larson RV, Garbini JL, Downey DJ, Matsen FA III. Ligament length relationships in the moving knee. *J Orthop Res* 1988;6:593-610.
- Bylski-Austrow DI, Grood ES, Hefzy MS, Holden JP, Butler DL. Anterior cruciate ligament replacements: A mechanical study of femoral attachment location, flexion angle at tensioning, and initial tension. J Orthop Res 1990;8:522-531.
- Clancy WG Jr, Nelson DA, Reider B, Narechania RG. Anterior cruciate ligament reconstruction using one-third of the patellar ligament, augmented by extra-articular tendon transfers. J Bone Joint Surg Am 1982;64:352-359.
- Yasuda K, Ichiyama H, Kondo E, Miyatake S, Masayuki I, Tanabe Y. An in vivo biomechanical study on the tensionversus-knee flexion angle curves of 2 grafts in anatomic double bundle anterior cruciate ligament reconstruction: Effects of initial tension and internal tibial rotation. *Arthroscopy* 2008; 24:276-284.
- 9. Robertson DB, Daniel DM, Biden E. Soft tissue fixation to bone. *Am J Sports Med* 1986;14:398-403.
- Mae T, Shino K, Nakata K, Toritsuka Y, Otsubo H, Fujie H. Optimization of graft fixation at the time of anterior cruciate ligament reconstruction: Part 1: Effect of initial tension. Am J Sports Med 2008;36:1087-1093.
- Fu FH, Bennett CH, Ma CB, Menetry J, Lattermann C. Current trends in anterior cruciate ligament reconstruction: Part II. Operative procedures and clinical correlations. Am J Sports Med 2000;28:124-130.
- Fu FH, Bennett CH, Lattermann C, Ma CB. Current trends in anterior cruciate ligament reconstruction: Part I: Biology and biomechanics of reconstruction. Am *J Sports Med* 1999;27: 821-830.
- 13. Zarins B, Rowe CR. Combined anterior cruciate-ligament reconstruction using semitendinosus tendon and iliotibial tract. *J Bone Joint Surg Am* 1986;68:160-177.
- Tohyama H, Yasuda K. Significance of graft tension in anterior cruciate ligament reconstruction: Basic background and clinical outcome. *Knee Surg Sports Traumatol Arthrosc* 1998; 6(Suppl 1):S30-S37.

- Easom JC, Goradia VK, Pearson SE, Wiley WB. Anterior cruciate ligament tensioning: KT-1000 measurements after anterior cruciate ligament reconstruction and tensioning (SS-68). Arthroscopy 2004;20;e32.
- Gertel TH, Lew WD, Lewis JL, Steward NJ, Hunter RE. Effect of anterior cruciate ligament graft tensioning direction, magnitude and flexion angle on knee biomechanics. *Am J Sports Med* 1993;21:572-581.
- 17. Blankevoort L. *Passive motion characteristics of the human knee joint experiments and computer simulations.* Nijmegen, the Netherlands: University of Nijmegen, 1991 (thesis).
- Detsky AS, Naylor CD, O'Rourke K, McGeer AJ, L'Abbe K. Incorporating variations in the quality of individual randomized trials into metaanalysis. *J Clin Epidemiol* 1992;45:255-265
- Clarke M, Oxman AD, eds. Optimal search strategy for RCTs. *Cochrane Reviewers Handbook*. Version 4.1.4 [updated October 2001]. Oxford: The Cochrane Library, Issue 4, 2001.
- Bhandari M, Richards RR, Sprague S, Schemitsch EH. The quality of reporting of randomized trials in *The Journal of Bone and Joint Surgery* from 1988 through 2000. *J Bone Joint Surg Am* 2002;84:388-396.
- Dulai SK, Slobogean BL, Beauchamp RD, Mulpuri K. A quality assessment of randomized clinical trials in pediatric orthopaedics. *J Pediatr Orthop* 2007;27:573-581.
- van Kampen A, Wymenga AB, Huub JL, van der Heide HJL, Bakens HJAM. The effect of different graft tensioning in anterior cruciate ligament reconstruction: A prospective randomized study. *Arthroscopy* 1998;14:845-850.
- Yoshiya S, Kurosaka M, Ouchi K, Kuroda R, Mizuno K. Graft tension and knee stability after anterior cruciate ligament reconstruction. *Clin Orthop Relat Res* 2002;394:154-160.
- 24. Kim SG, Kurosawa H, Sakuraba K, Ikeda H, Takazawa S. The effect of initial graft tension on postoperative clinical outcome in anterior cruciate ligament reconstruction with semitendinosus tendon. Arch Orthop Trauma Surg 2006;126:260-264.
- Yasuda K, Tsujino J, Tanabe Y, Kaneda K. Effects of initial graft tension on clinical outcome after anterior cruciate ligament reconstruction: Autogenous doubled hamstring tendons connected in series with polyester tapes. Am J Sports Med 1997;25:99-106.
- Nicholas SJ, D'Amato MJ, Mullaney MJ, Tyler TF, Kolstad K, McHugh MP. A prospective randomized double-blind study on the effect of initial graft tension on knee stability after anterior cruciate ligament reconstruction. Am J Sports Med 2004;32:1881-1886.
- Howard ME, Cawly PW, Lossee GM, Johnston RB III. Bonepatellar tendon bone grafts for anterior cruciate ligament reconstruction: The effects of graft pretensioning. *Arthroscopy* 1996;12:287-292.
- 28. Heis FT, Paulos LE. Tensioning of the anterior cruciate ligament graft. *Orthop Clin North Am* 2002;33:697-700.
- Cook DJ, Sackett DL, Spitzer Wo. Methodologic guidelines for systematic reviews of randomized control trials in health care from the Potsdam Consultation on Meta-Analysis. *J Clin Epidemiol* 1995;48:167-171.
- Burks RT, Leland BSR. Determination of graft tension before fixation in anterior cruciate ligament reconstruction. *Arthros*copy 1988;4:260-266.