Anterior Cruciate Ligament Reconstruction Autograft Choice: Bone-Tendon-Bone Versus Hamstring

Does It Really Matter? A Systematic Review

Kurt P. Spindler,^{*†} MD, John E. Kuhn,[†] MD, Kevin Blake Freedman,[‡] MD, Charles E. Matthews,[†] PhD, Robert S. Dittus,[†] MD, MPH, and Frank E. Harrell, Jr,[†] PhD *From [†]Vanderbilt University Medical Center, Nashville, Tennessee, and [‡]Loyola University Medical Center, Maywood, Illinois*

Anterior cruciate ligament graft choice is controversial, with no evidence-based consensus available to guide decision making. The study design was evidence-based medicine systematic review of randomized controlled trials evaluating patellar tendon versus hamstring tendon autografts. A literature review identified 9 randomized controlled trials comparing patellar tendon and hamstring tendon autografts. An evidence-based systematic review was performed. Objective and subjective outcomes of interest included surgical technique, rehabilitation, instrumented laxity, isokinetic strength, patellofemoral pain, return to preinjury activity, and Tegner, Lysholm, Cincinnati, and International Knee Documentation Committee-1991 scores. Additional surgery, graft failure, and complications were reviewed. Slight increased laxity on arthrometer testing was seen in the hamstring population in 3 of 7 studies. Pain with kneeling was greater for the patellar tendon population in 4 of 4 studies. Only 1 of 9 studies showed increased anterior knee pain in the patellar tendon group. Frequency of additional surgery seemed to be related to the fixation method and not graft type. No study reported a significant difference in graft failure between patellar tendon and hamstring tendon autografts. Objective differences (range of motion, isokinetic strength, arthrometer testing) were not detected between groups in the majority of studies, suggesting that their sensitivity to detect clinical outcomes may be limited. Increased kneeling pain in the patellar tendon group was seen consistently in the studies evaluated. Subjective differences in anterior knee pain or return-to-activity level were not consistently observed in these studies. With numbers available, failure rates were not significantly different between groups. These findings suggest that graft type may not be the primary determinant for successful outcomes after anterior cruciate ligament surgery.

Keywords: anterior cruciate ligament (ACL); bone-tendon-bone; hamstring; outcomes; evidence-based medicine (EBM)

The orthopaedic surgeon contemplating the operative choice for ACL grafts and technique is confronted with a myriad of choices and several hundred articles expressing different opinions. The overwhelming majority of these studies are case series evaluating a single graft, lacking an adequate comparison group. In addition, many of these studies are retrospective, with several sources of bias affecting the results and conclusions. In an evidence-based

medicine hierarchy, a surgeon should ideally base decisions on randomized controlled trials (RCTs) or controlled prospective comparative studies. 15,17,21,35 Evidence-based medicine requires weighting and ranking the available data by the validity and design of the individual studies so that clinicians can make decisions that affect their practices based on the strength of the evidence, not on opinion. Systematic reviews collect and present data using an evidencebased medicine approach. An earlier systematic review of the science of ACL reconstruction using prospective comparative studies suggested that only subtle objective differences exist in the outcomes of patients who differ by autograft choice.¹³ In 1996, O'Neill²⁵ published one of the early RCTs evaluating differences between the patellar tendon autograft (PT) and the hamstring tendon autograft (HG) for ACL reconstruction. Since 2000, 8 additional RCTs have been published.^{2,3,7,10-12,20,31} This article is a systemat-ic review of these 9 RCTs^{2,3,7,10-12,20,25,31} designed to compare autograft types (PT vs HG). The purpose of this sys-

^{*}Address correspondence to Kurt P. Spindler, MD, Vanderbilt Sports Medicine Center, 2601 Jess Neely Drive, Nashville, TN 37212 (e-mail: kurt.spindler@vanderbilt.edu).

Presented at the 30th annual meeting of the AOSSM, Quebec City, Quebec, Canada, June 2004.

One or more of the authors have declared a potential conflict of interest as specified in the AJSM Conflict of Interest statement.

The American Journal of Sports Medicine, Vol. 32, No. 8

DOI: 10.1177/0363546504271211

^{© 2004} American Orthopaedic Society for Sports Medicine

tematic review is to identify reproducible, clinically significant differences in objective (stability, range of motion [ROM], strength) and subjective (questionnaire results) measures to determine if autograft choice is an important variable in the outcome after ACL reconstruction.

The results of this review, including primary outcome variable (instrumented laxity) and secondary outcome variables (objective and subjective scales), are presented in a series of tables. As a result, each orthopaedic surgeon can easily evaluate the series of studies for a trend in each outcome. In addition, the absolute differences between outcome measures for the 2 different graft types can be evaluated, leaving the reader to interpret the clinical significance of the results. This approach should be deemed complementary to and not a substitute for formal statistical combining of data in a meta-analysis.

Our hypothesis is that few reproducible, clinically significant differences would be observed in objective (stability, ROM, strength) or subjective (questionnaire results) measures, suggesting that graft choice may not be the most important variable in the outcomes after ACL reconstruction. Furthermore, we believe systematic reviews of major clinical choices in treatment not only foster evidencebased decision making in orthopaedics by orthopaedic surgeons but stimulate the reader's critical thinking in choosing a technique on solid scientific ground (evidence-based medicine criteria).

MATERIALS AND METHODS

For this systematic review, only prospective RCT studies were included, as this type of study has the greatest validity in an evidence-based medicine approach. A MEDLINE literature search was performed to identify all Englishlanguage comparative studies evaluating autograft ACL reconstruction choice from January 1, 1966, to December 31, 2003. Studies were required to have a minimum of 2year follow-up. Fifteen studies were identified. To reduce the possibility of selection bias, we limited this review to studies using strict randomization techniques (random numbers $^{2,3,7,10-12}$ or birth date 20,25,31). We excluded studies that assigned patients to treatment groups by criteria such as surgeon, site, alternating sequence,^{1,23} consecutive series (2 points in time),⁹ or surgeon or patient choice,^{4,26,27} as these methods have greater potential for selection bias.^{15,17,21,35} Assigning patients to treatment methods by random number or birth date cannot be manipulated consciously or unconsciously by surgeons or teams, thus minimizing selection bias and better preserving equality of groups before graft choice. Using these strict criteria for entry, we were left with 9 prospective RCT studies for the systematic review.

A worksheet adapted from evidence-based guides^{15,21} was developed by the authors to assist in the systematic review of each article. This worksheet included title, author, journal, year, reference, primary and secondary hypotheses, and type of study. Next, details or methods used by the authors to control major confounding variables were recorded.

The 4 major sources of bias were evaluated for each study: selection, performance, transfer, and detection. Selection bias occurs when patients are selected for the treatment group (PT or HG) based on factors that could influence the results. Performance bias (confounding) is the inability to control for interventions performed on one group that are not identical to the other group. These factors could then lead to a difference in result that should not be attributed to choice of graft. Examples could be one population having more meniscus tears, or different prevalence or treatment of articular cartilage injuries between groups. Furthermore, the skill and experience of a set of surgeons, method of fixation, immediate postoperative bracing or immobilization, and postoperative rehabilitation could be major sources of performance bias, if not distributed equally between groups.

Transfer or exclusion bias may occur with inadequate follow-up in each group. The minimal accepted follow-up has been defined as 70% of the study population, although greater than 80% of the study population is preferred.^{15,34}

Detection bias occurs when outcomes or methods of assessing results are performed differently for one group of patients compared with the other. In other words, the same results should be assessed identically for each treatment group. Independent examiners for physical examination and instrumented laxity or validated patient-relevant outcome questionnaires minimize detection bias.

Each study was individually analyzed by a worksheet, and the data were collected (Tables 1-7). Demographic data were collected, including data such as total number of subjects, final number of subjects evaluated, percentage of subjects at final follow-up, mean age, mean follow-up interval, gender, and previous knee surgery. The surgical protocol was evaluated, describing the technique of the surgical approach and the femoral and tibial fixation methods. The rehabilitation protocol in each study was evaluated for weightbearing status and postoperative immobilization, the use of continuous passive motion, and the time to return to unrestricted sports activity. The outcome measurements evaluated from each study included total graft failure, KT-1000 arthrometer (MedMetric Corp, San Diego, Calif) side-to-side differences in laxity, pivotshift examination, loss of motion, subjective patient satisfaction, return to previous level of sports, and knee scores. Complications evaluated in each study included total reoperation rate, lysis of adhesions or manipulation under anesthesia, subsequent meniscectomy or meniscal repair, graft failure, infection, subsequent hardware removal, and anterior knee pain. Additional information was collected from each study when appropriate, such as preoperative and postoperative knee scores.

Statistical evaluation methods were reviewed for appropriate use of parametric or nonparametric methods. In this review, we report the sample sizes when available from each study to help the reader interpret both statistical significance (P < .05) and power ($\beta = .80$).

The data for each study were collected and are presented in Tables 1 through 7. Trends between studies were evaluated to look for results that were observed consistently among the 9 studies. By presenting the data in this form, the reader has the opportunity to review the reproducibility and clinical significance of the data and then make informed decisions using evidence-based guidelines with regard to altering his or her clinical practice. The study data are presented in a series of tables to provide an easily understandable format for each reader to draw his or her own analysis of data. Table 1 provides details of inclusion criteria, follow-up, and surgical technique. Table 2 describes the major components of the postoperative rehabilitation protocols. Note that each study comparing grafts subjected the 2 groups to identical rehabilitation protocols. Table 3 evaluates the results of instrumented laxity measurements at final follow-up. Table 4 includes isokinetic strength, and Table 5 reviews patellofemoral pain. Activity and functional assessment at final follow-up are presented in Table 6. Table 7 evaluates the frequency of additional surgical procedures, graft failure, and complications such as infection, deep venous thrombosis, and nerve injury.

Demographics

The gender, age, sport, and time from injury to surgery were equal between graft choices in all studies. However, no study identified the number of professional or National Collegiate Athletic Association Division I athletes.

Surgical Technique

With regard to the surgical technique (Table 1), the approach was more consistent among PT constructs than among HG constructs. Within the PT technique, 3 studies used a rear-entry/2-incision approach, and 6 used an endoscopic or single-incision approach. Except for 2 studies, all fixation of bone blocks was by interference fit screws. In contrast, the HG populations demonstrated much more variety with regard to surgical technique. Three studies from the early 1990s^{7,20,25} used a rear-entry/2-incision approach with staple or suture fixation. Other studies^{2,3,10-12,25,31} used an endoscopic approach with predominantly 4-stranded constructs secured with EndoButtons (Acufex Microsurgical Inc, Mansfield, Mass), interference screws, or posts.

Outcomes

The results displayed in Tables 3 through 7 demonstrate an obvious lack of consistent evaluation tools except for instrumented laxity, ROM (not shown), and anterior knee pain (reported in 100% [9/9] of the studies). Instrumented laxity in millimeters (not by grouping <3 mm) (Table 3) and isokinetic strength evaluation (Table 4) were reported in 78% (7/9) of the studies. All studies reporting instrumented laxity had sufficient sample sizes to prevent type II errors for this measure. The ROM was significantly reduced for PT in 46% (4/9) of the studies. Differences in ROM, instrumented laxity, or isokinetic strength between the graft choices were not seen consistently. Less than 50% of studies demonstrated a difference between grafts in ROM (4 of 9 studies showed loss of motion for PT), instrumented laxity (3 of 7 studies showed less translation with PT), and isokinetic strength (3 of 7 studies showed hamstring weakness in HG). When the observed differences were seen in a minority of studies, they were consistent between studies with PT having a few degrees less of total ROM ($0.7^{\circ}-3.0^{\circ}$ less) and less instrumented laxity (1-3.4 mm less) (Table 3), and all the HG being weaker on isokinetic evaluation (mean 11% loss of flexion strength) (Table 4). However, the absolute differences seen were relatively small.

Patellofemoral pain either anteriorly or while kneeling is shown in Table 5. All studies that assessed pain with kneeling (4/4) demonstrated PT had more kneeling pain. In contrast, anterior knee pain was equal in 8 of 9 studies. Radiographic imaging was only obtained at follow-up in 33% (3/9) of the studies. No differences were observed between graft choices.

Activity and functional assessment is shown in Table 6. No consistent activity level or composite knee scoring scales were used between studies. Furthermore, no patient-relevant outcome measures were used. The measurements of activity by return to preinjury or Tegner score failed to demonstrate any significant differences between groups. No differences were detected in the Lysholm or composite subjective and objective scales (Cincinnati and 1991 International Knee Documentation Committee [IKDC]) in 88% (7/8) of the studies.

COMPLICATIONS

Graft failure, additional surgical procedures, and complications such as infection can be devastating psychologically and can influence short-term and long-term outcomes. Table 7 reports data for the requirement of additional procedures in total and arthroscopic-only procedures, graft failure, contralateral ACL tear, and the complications of infection, deep venous thrombosis, and nerve injury. Graft failure (as defined by clinical failure, MRI, or the need for revision surgery) was reported in 8 of the 9 studies. The incidence of graft failure ranged from 1.5% to 5.7% (Table 7). Twenty-four failures at short-term follow-up of 664 patients produced an overall incidence of 3.6% (95% confidence interval [CI], 2.3%-5.3%). No individual study reported a difference in graft failure when comparing HG to PT. When the populations from these 9 studies were combined, a failure rate of 3.1% (10/325; 95% CI, 1.2%-5.0%) was noted for the PT and 4.1% (14/339; 95% CI, 2.0%-6.2%) for HG (P = .47).

Infections were found to occur between 0% and 2.9% on the individual studies. When averaging the studies reporting on infection, the frequency was 0.8% (5/608). Reported additional surgical procedures were varied and included arthroscopic removal of scar, treatment of meniscal tears or arthritis, and open removal of painful hardware. The frequency covered a wide range from 1.8% to 36%. If extraarticular procedures for removal of the painful tibial post are excluded, the upper limit on frequency is 24%. The mean reoperation rate for the 5 studies that reported these data was 14.7% (72/491), and the majority of these procedures were performed arthroscopically.

						Pa	Patellar Tendon	uc		Hamstring		
Authors	Journal, Year	Country	Surgeons	Number at Follow-up $(\%)^a$ Groups Approach b	Groups	$\operatorname{Approach}^{b}$	${\rm Femoral} \\ {\rm Fixation}^{c}$	Tibial Fixation d	Tibial Femoral Fixation ^{d} Approach ^{b} Fixation ^{c}	${\rm Femoral} \\ {\rm Fixation}^c$	$\begin{array}{c} \text{Tibial} \\ \text{Fixation}^d \end{array}$	$\operatorname{Strands}^e$
Anderson et al ²	American Journal of Sports Medicine. 2001	United States	0	102/105(97%)	3 ^f	Endo	Screw	Staple	Rear	Staple	Suture	2
Aune et al ³	American Journal of Sports Medicine 2001	Norwav	-	65/72 (90%)	6	Endo	Screw	Screw	Endo	Button	Screw	4
Beynnon et al^7	Journal of Bone and		4		I							4
	Joint Surgery, American volume. 2002	United States	ŝ	44/56 (79%)	2	Rear	Screw	Screw	Rear	Staple	Staple	2
Ejerhed et al ¹⁰	American Journal of)		I							I
2	Sports Medicine, 2003	Sweden	1	71/71 (100%)	2	Endo	Screw	Screw	Endo	Screw	Screw	3 or 4
Eriksson et al ¹¹	Journal of Bone and											
	Joint Surgery, British											
	volume, 2001	Sweden	8	154/164 (94%)	2	Endo	Screw	Screw	Endo	Button	Screw	4
Feller and Webster ¹²	A											
	Sports Medicine, 2003	Australia	1	57/64 (89%)	7	Endo	Button	Screw	Endo	Button	Post	4
Jansson et al 20	American Journal of											
ac	Sports Medicine, 2003	Finland	2	(%)06)66/68	2	Rear	Screw	Screw	Endo	Button	Post	4
0'Neill ²⁵	Journal of Bone and											
	Joint Surgery, American											
	volume, 1996	United States	1	113/129 (88%)	သို့	Endo	Screw	Screw	Rear	Staples	Staples	7
Shaieb et al ³¹	American Journal of											
	Sports Medicine, 2002	United States	1	70/80 (88%)	2	Endo	Screw	Screw	Endo	Screw	Screw	4
Total		5	21	765/840 (91%)								

TABLE 1

"Strands, number of hamstring tendons in reconstruction. "frintd group with extra-articular Losee in addition to identical hamstrings reconstruction. "Third group rear-entry patellar tendon identical to endoscopic except for approach.

^dTibial fixation (method): screw, interference screw; post, tie hamstring over screw (post).

^bApproach: endo, endoscopic or single incision; rear, rear entry/2 incision. ^cFemoral fixation (method): screw, interference screw; button, EndoButton.

			Reha	abilitation					
					Authors	5			
	$\begin{array}{c} \text{Anderson} \\ \text{et al}^2 \end{array}$	Aune et al ³	Beynnon et al ⁷	Ejerhed et al ¹⁰	Eriksson et al ¹¹	Feller and Webster ¹²	Jansson et al ²⁰	O'Neill ²⁵	Shaieb et al ³¹
Rehabilitation equal	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Postoperative brace	Yes	No	Yes	No	Yes	No	No	No	No
Full range of motion	6 wk	Day 1	8 wk	Day 1	Day 1	Day 1	Day 1	Day 1	Day 1
Full weightbearing	3 wk	Day 1	3 wk	Day 1	Day 14	Day 1	Day 14	Day 1	Day 1
Closed chain	No	Day 14	No	Day 1	Day 14	Day 42	Day 14	Day 42	Day 21
Run	12 wk	Approxi- mately 8 wk	16 wk	12 wk	Not re- corded	10 wk	Not re- corded	12 wk	8 wk
Sport specific	4-6 mo	2.5 mo	Not re- corded	Not re- corded	Not re- corded	4 mo	Not re- corded	4 mo	Not re- corded
Full sports	6-7 mo	6 mo	6-8 mo	6 mo	6-12 mo	9 mo	6-12 mo	6 mo	5-6 mo
Functional brace	No	No	No	No	No	No	No	No	No
Continuous passive motion	No	No	No	No	No	No	No	No	No
Surgery date	1991-1993	Not re- corded	1990-1991	Not re- corded	1995-1997	1996-1998	Not re- corded	1989-1992	1994- 1996

TABLE 2 Rehabilitation

 TABLE 3

 Instrumented Laxity at Final Follow-up^a

			Patellar Te	ndon Graft	Hamstrin	ng Graft	
Authors	Instrument	Force (<3 mm)	Laxity, mm $(variation)^b$	%	Laxity, mm $(variation)^b$	%	Р
Anderson et al ²	KT-1000 arthrometer	Manmax	2.1 (2.0)	71	3.1 (2.3)	50	$.05^{c}$
Aune et al ³	KT-1000 arthrometer	Manmax	2.7(2.2)	Not reported	2.7(2.1)	Not reported	NS
Beynnon et al ⁷	KT-1000 arthrometer	133 N	1.1 (0.9)	77	4.4 (1.0)	45	$.004^{c}$
Ejerhed et al ¹⁰	KT-1000 arthrometer	89 N	2.0	Not reported	2.25	Not reported	NS
Eriksson et al ¹¹	Stryker	18.2 kg	Not reported	49	Not reported	43	NS
Feller and Webster ¹² Jansson et al ²⁰	KT-1000 arthrometer CA 4000 (OSI,	134 N	0.5 (1.5)	95	1.6 (1.3)	85	$.05^{c}$
	Hayward, Calif)	Not reported	1.7	Not reported	1.2	Not reported	NS
O'Neill ²⁵	KT-2000 arthrometer	Manmax	Not reported	87	Not reported	83	NS
Shaieb et al ³¹	KT-1000 arthrometer	134 N	1.5	79	2.5	45	.13

^aManmax, manual maximum; NS, not significant.

^bVariation, individual study variation.

^cStatistically significant.

Evidence-Based Evaluation of Bias

Selection bias (method of allocation of patients as described earlier) was minimized by study inclusion criteria of randomized control to be either random numbers or birth date. The inclusion criteria (RCT) and excellent follow-up (range, 79%-100%; mean, 91% [765/840]) minimized selection (allocation of patients) and transfer bias (adequate follow-up) in all studies (Table 1).

When evaluating these studies for performance bias (identical technique except primary variable, ie, graft) using strict criteria, only 2 studies had identical approaches and fixation methods for both grafts^{10,31} (Table 1). Nevertheless, we believe all 9 studies minimized performance bias, as we assume that tunnel position and fixation

were both appropriate and adequate. Thus, we believe all 9 RCTs adequately minimized selection, performance, and transfer bias.

Detection bias is minimized by having an unbiased evaluation of ACL reconstruction results by an independent examiner blinded to the graft type or by using validated patient-relevant outcome questionnaires (eg, 36-item Short Form Health Survey [SF-36],^{33,34} the Western Ontario and McMaster Universities Arthritis Index [WOMAC],^{5,6} Knee Injury and Osteoarthritis Outcome Score [KOOS],²⁸⁻³⁰ and IKDC^{18,19}). Unfortunately, no validated patient-relevant outcome questionnaires were used in the reviewed studies (Table 6). The return to preinjury activity, Tegner activity level,³² and Lysholm assessment²¹ are interviewer-based assessments and as such may be

			Quadric	eps Extension		Ha	mstrings Flexio	n
Authors	Instrument	Speed, %	PT, %	HG, %	Р	РТ, %	HG, %	Р
And erson et al^2	Cybex II (Cybex International Inc,							
	Medway, Mass)	60	86	96	NS	96	96	NS
		180	91	99	NS	100	96	NS
Aune et al ³	Cybex 6000	60	90	90	NS	94	90	NS
		240	90	92	NS	100	85^b	$.01^b$
Beynnon et al ⁷	Cybex	60	95	88	NS	99	96	
·	U	180	96	92	NS	96	91	
		240	97	93	NS	100	89^b	$.04^b$
Ejerhed et al ¹⁰	Cybex	60	210	215	NS	100	190	NS (injured
Feller and	Cybex II	60	77	89	NS	98	91^b	.05 ^b
Webster ¹²	Cybex II	240	85	91	NS	106	99	.00
Jansson et al ²⁰	Dynamometer	60 and 180	Not reported	Not reported	NS	Not reported	Not reported	NS
O'Neill ²⁵	Biodex (Biodex Medical Systems, Shirley, NY)	60, 180, and 240	Not reported	Not reported	NS	Not reported	Not reported	NS

TABLE 4 Isokinetic Strength at Final Follow-Up a

^aPT, patellar tendon autograft; HG, hamstring autograft; NS, not significant.

^bSignificant P < .05 weakness in knee flexion or hamstring strength.

 TABLE 5

 Patellofemoral Pain at Final Follow-up^a

	Ant	erior Knee Pai	n		Kı	neeling	Pain		
Authors	Scale	PT	HG	P	Scale	\mathbf{PT}	HG	Р	Comment
Anderson et al ²	Patellofemoral crepitus								Equal IKDC criteria
Aune et al ³	Pain, Cincinnati	16%	13%	NS	VAS	36%	19%	$.05^b$	
Beynnon et al ⁷	None	32%	23%	NS					
Ejerhed et al ¹⁰	Define test	19%	21%	NS	"Knee walk"	53%	23%	$.01^b$	
Eriksson et al ¹¹	Werner	43	43	NS	Werner	2	4	$.0001^b$	
Feller and Webster ¹²	VAS	43%	33%	NS	VAS	67%	26%	$.01^b$	
Jansson et al ²⁰	Kujala	Not reported	Not reported	NS					
O'Neill ²⁵	Patellofemoral crepitus	-	-						Equal IKDC criteria
Shaieb et al ³¹	None	42%	20%	$.05^b$					Asked single question

^aPT, patellar tendon autograft; HG, hamstring autograft; IKDC, International Knee Documentation Committee; NS, not significant; VAS, visual analog scale.

^cStatistically significant.

subject to detection bias. Of these 9 studies, 5 used independent examiners for patient evaluations.^{3,10-12,31} In addition, objective measures such as instrumented laxity, ROM, and isokinetic strength may be less likely to produce detection bias.

DISCUSSION

In this systematic review using principles of evidence-based medicine 15,17,21,35 to compare PT and HG for ACL

reconstruction, we found few reproducible clinically significant differences in the objective parameters of instrumented stability, ROM, and isokinetic strength. Objective differences were reported in less than half of the studies reviewed. In addition, the differences reported were quite small and likely of little clinical importance. For example, a loss of 0.7° to 3.0° of the total ROM may not be enough to influence a surgeon's decision on which graft to use. Likewise, instrumented laxity differences of approximately 1.0 mm (reported in 3 studies) are likely of little clinical

	Activi	ty Level			Composite	Scale Scor	re		
Author	Scale	\mathbf{PT}	HG	Р	Scale	\mathbf{PT}	HG	P	Comment
Anderson et al^2 Aune et al^3	IKDC	83%	85%	NS	IKDC 1991 Cincinnati	97% 88 (13)	79% 86 (12)	.02 NS	
Beynnon et al ⁷	Tegner IKDC	459%	$4 \\ 45\%$	NS NS					
Ejerhed et al ¹⁰	Tegner	6	6.5	NS	Lysholm IKDC 1991	95 53%	90 59%	NS NS	
Eriksson et al ¹¹	Tegner	6	6	NS	Lysholm IKDC 1991	85 60%	$\frac{86}{55\%}$	NS NS	
Feller and Webster ¹²	IKDC	27%	36%	NS	Cincinnati	93 (8)	94 (9)	NS	Tunnel widening >25% 94% HG vs 11% PT
Jansson et al ²⁰	Tegner	6.1	6.0	NS	IKDC 1991 Lysholm (excellent + good results)	$71\% \\ 84\%$	93% 87%	NS NS	
O'Neill ²⁵	Return to pre- injury activity	$95\%^b$	89%	$.02^b$	IKDC 1991 Lysholm (>90)	79% 90%	84% 93%	NS NS	Two-incision tech- nique, endoscopic = 88
Shaieb et al ³¹	Activity reduction	45%	37%	NS	IKDC 1991 Lysholm	88% 91	95% 92	NS NS	- •

TABLE 6 Activity and Functional Assessment at Final Follow-up^a

^aPT, patellar tendon autograft; HG, hamstring autograft; IKDC, International Knee Documentation Committee final level I activities; NS, not significant; IKDC 1991, IKDC 1991 final rating normal and nearly normal. Numbers in parentheses represent SDs.

^cStatistically significant.

Authors	No. at Follow-up	Total (%)	Simple (%)	Graft Failure $(\%)^a$	Contra- lateral ACL Tear	Deep Intra- articular Infection	Deep Venous Thrombosis	Nerve Injury ^b
Anderson et al^2	102	13 (12.7)	11 (10.8)	2 (1.8)	Not reported	0	0	0
Aune et al ³	65	5 (7.7)	2(1.8)	3 (4.6)	3	0	0	1
Beynnon et al ⁷	44	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Ejerhed et al ¹⁰	71	Not reported	Not reported	3(4.2)	Not reported	2 (2.9)	Not reported	Not reported
Eriksson et al ¹¹	154	40 (26)	37 (24)	5(3.2)	Not reported	2(1.3)	Not reported	Not reported
Feller and					_		_	_
$Webster^{12}$	57	10 (15.4)	10 (15.4)	1(1.5)	Not reported	0	Not reported	Not reported
Jansson et al ²⁰	89	34 (38.2)	32^{c} (36.0)	2(2.2)	Not reported	1 (1.1)	0	0
O'Neill ²⁵	113	16 (14.2)	12 (10.6)	4 (3.5)	Not reported	Not reported	Not reported	Not reported
Shaieb et al^{31}	70	Not reported	Not reported	4 (5.7)	Not reported	0	Not reported	Not reported

TABLE 7 Additional Surgical Procedures, Graft Failure, Infections

^aArthroscopic only or hardware removal (ie, tibial post).

^bIncludes saphenous, tibial, and peroneal nerves.

^cThere were 32 tibial post screw removals in hamstring group.

relevance. Finally, one may ask if a mean difference of 11% in hamstring muscle strength is of clinical significance. Thus, differences in objective outcome data were not consistently identified among 9 studies, and the differences that were reported in the minority of the studies were small and thus may not be clinically significant.

Anterior knee pain has been debated as the major reason to choose the HG over PT for ACL reconstruction. This opinion, however, is based on retrospective studies without a comparison group. Anterior knee pain may occur after ACL reconstruction regardless of graft choice. In Table 5, the incidence ranged from 13% to 43%. In the 9 RCTs in this systematic review, the majority of studies (8/9) could not detect a difference in anterior knee pain between HG and PT groups. The one study that did detect a difference demonstrated more pain in PT, but it also revealed the greatest loss of flexion in the PT group at 3.4°. In addition, anterior knee pain after ACL reconstruction may be related to the injury itself. Bynum et al⁸ demonstrated that up to 40% of patients with a torn ACL will have anterior knee pain before they undergo surgery. This study was an RCT designed to compare closed versus open chain physical therapy ACL reconstruction rehabilitation protocols and was the only prospective study to document anterior knee pain before ACL reconstruction. Bynum et al reported that both techniques significantly decreased anterior knee pain from before surgery (40%) to after surgery (20%-25%),⁸ with no significant differences detected between rehabilitation techniques.

This systematic review demonstrates that there is no reproducible difference between graft types in anterior knee pain, but there is a reproducible difference for pain with kneeling for patients in the PT group. Pain with kneeling data were reported in 4 studies, and all 4 studies demonstrated that the PT group had more pain with kneeling than did the HG group (Table 5). Therefore, using evidence-based medicine, a surgeon should not choose a graft based on trying to limit anterior knee pain. He or she may be justified in choosing the HG to avoid pain with kneeling.

The correlation between small objective differences in graft choice, such as anterior knee or kneeling pain, and patient-relevant outcomes is unknown. Return to preinjury activity, the Tegner activity assessment,³² and the Lysholm²² assessment were initial attempts to measure patient outcomes. The current validated patient-relevant outcome questionnaires (SF-36,^{33,34} WOMAC,^{5,6} KOOS,²⁸⁻³⁰ and 1999 IKDC^{18,19}) were not used in any of the studies. Based on the infrequent use of earlier outcome measures, only a single study observed a difference between the PT group and the HG group (return to preinjury [3/4], Tegner [2/2], Lysholm [4/4]). However, because less than half the studies used these measures, reproducibility in these outcome measures cannot be judged with a reasonable degree of certainty. We suggest that future RCTs use a validated patient-relevant outcome questionnaire. The deficiency of validated patient-relevant outcome questionnaires is obvious, and the advent of the 1999 IKDC questionnaire and KOOS should provide a common scale for evaluation of ACL reconstruction results in the future.

In 1991, the IKDC developed a "composite" form to evaluate ACL reconstruction results.¹⁶ Like the Cincinnati assessment tool,²⁴ the IKDC is a composite form combining patient questions on pain and function with physical examination findings, instrumented laxity, and imaging to produce a single score. Including the Lysholm, 8 of 9 studies (89%) used one of these measures, 5 used both, and another used neither. Interestingly, regardless of the outcome assessment used, the majority of studies (87%, 7/8)did not detect differences between the PT and HG groups. A total of 13 functional assessments (by Lysholm, IKDC 1991, and Cincinnati) were used, with 92% (12/13) demonstrating no differences between autografts. The only study that did report a difference used a 2-stranded HG construct, which is not commonly used today. Thus, this systematic review demonstrates that graft type does not seem to affect these results as reported by these outcome assessments.

Additional surgical procedures after ACL reconstruction have a widely reported range in the literature. In this review, 6 studies reported these data. In the early 1990s, a large tibial post was commonly used to fix the HG. This produced pain and required removal in many patients, as described by Jansson et al.²⁰ Newer techniques for HG fixation are less likely to require hardware removal. In the 5 other RCTs that did not use this post, additional procedures were required for 17% of 491 patients. The association of the need for additional procedures and the effect on outcomes at long-term follow-up are currently unknown.

Graft failure was reported in 8 of the studies. None of the studies demonstrated a difference in graft failure when comparing PT to HG. Because graft failure is relatively rare, these studies may not have had adequate numbers to detect a difference.

Seven studies disclosed data on postoperative infection. Four of these 7 studies reported no infection. Three studies reported a total of 5 infections. The range within studies was 0% to 2.9%. The mean for 7 studies was 0.8% (5/608). Only 1 study reported contralateral ACL failure of 3, or 4.6%.³ In summary, infection, contralateral ACL tear, and graft failure are relatively rare. However, the incidence of additional procedures, primarily arthroscopic procedures on meniscus, arthritis, and scar tissue, is almost 1 in 5 patients. Furthermore, the influence of these factors on later outcomes and the predictors of risk are unknown. Future investigation is clearly warranted.

This systematic review demonstrates that the objective measures used to evaluate the outcomes in RCTs comparing PT to HG could not detect a reproducible difference in the graft type used. Based on the best available evidence, a surgeon could rationally choose a PT because he or she values the small decrease in laxity or the small increase in hamstring strength demonstrated in the minority of studies. Conversely, one could with sound rationale choose HG because he or she values the small improvement in ROM. However, given lack of reproducibility and the small differences observed, which were below our threshold for clinical significance and likely fall within the range of measurement error, we view these grafts as equivalent based on objective measures.

When evaluating subjective anterior knee pain or kneeling pain, the results are reproducible and clear-cut. Choosing a graft based on perceived differences in anterior knee pain is not justified. However, choosing an HG to decrease kneeling pain is supported by the consistent data in these RCTs. How these objective and subjective knee pain scales relate to validated patient-relevant outcome questionnaires is unknown and requires investigation. It is hoped that the outcome instruments based on patientrelevant questionnaires (the 1999 IKDC and KOOS) can be adopted to facilitate comparison between studies on a validated measure.

The individual orthopaedic surgeon usually lacks either time or expertise to systematically review the literature. However, each is capable of interpreting clearly presented, clinically relevant results in tables or figures in a systematic review to judge individually how to incorporate this information into practice or to verify the authors' interpretations of the data. Thus, in the future, well-informed readers will demand well-designed, prospective, randomized, controlled clinical studies before they consider adopting fundamental shifts in treatment or emerging biotechnology. The ultimate result will be the incorporation of evidence-based medicine principles to foster the best care of our patients by orthopaedic surgeons performing ACL reconstructions. We are indebted to all of the authors of these 9 studies for their contribution to orthopaedic and sports medicine science.

This study evaluated each of the 9 RCTs on evidencebased criteria. Critical review of these studies revealed that they were well designed and minimized many potential sources of bias. Selection bias was eliminated by performing well-designed randomization techniques in all studies. Transfer bias (ensuring adequate follow-up) was acceptable, with follow-up ranging from 79% to 100%. The authors of each trial also minimized the introduction of performance bias (or confounding) by using identical surgical and rehabilitation techniques for both autograft groups. In addition, data were well collected on other potential confounders, such as meniscal or articular cartilage injuries in each group.

Our evidence-based review demonstrated that future studies should focus on limiting detection bias—the equal evaluation of outcomes in each group. This feature would be improved by using blinded observers, as well as using validated, patient-relevant outcomes for evaluation of the results.

This study has several strengths. By presenting a systematic review of the literature using evidence-based med-icine criteria, 15,17,21,35 these 9 studies $^{2,3,7,10-12,20,25,31}$ provide the most valid data in the English literature on comparisons of 2 autograft choices (PT vs HG) for ACL reconstruction. In this systematic review, only prospective studies that used strict randomization methods were included. Sources of bias, such as selection bias, performance bias, transfer bias, and detection bias, were assessed and reported. By limiting this review to truly randomized controlled prospective studies, discussing the sources of bias, and presenting the common findings in these studies, we have enabled each orthopaedic surgeon to intelligently evaluate the reproducibility and absolute differences between outcome measures for the 2 different ACL graft types and thereby interpret the clinical significance of the results.

There are several potential weaknesses to this study. The data were (purposely) not combined in a formal metaanalysis. The combination of the data could provide more quantitative summary measures of any differences between grafts. Because of differences in reporting between studies and possible methodological flaws in data combination, it was decided to present the data in tabular form only. This approach should be deemed complementary to, and not a replacement for, a formal statistical combining of data as in a meta-analysis, which does not allow the reader to evaluate how the results were derived. Furthermore, the past 2 meta-analyses on graft choice 14,36 did not include the 8 RCTs that have been published since 2000.

Another potential weakness of the study is the generalizability of the results. There may be certain subpopulations who do better or worse with a particular graft choice, and these were not evaluated. For example, few Division I or professional athletes were enrolled in each study, so these data may not reflect results in these populations. In addition, other differences that may affect results, such as gender, were not evaluated.

This systematic review does not recommend a particular graft choice, as each has slight, albeit small, differences. Rather, we believe the improvement in HG fixation and constructs (4 vs 2 strands) and improved rehabilitation vield equivalent results in the short term for the majority of our patients. How these grafts differ on patient-relevant outcomes or at longer follow-up (5-10 years) is unknown. The data from this systematic review suggest that graft choice may not be the primary determinant of successful results after ACL surgery. We hypothesize that given improvements in surgical technique, the injury to the meniscus and articular cartilage and their treatment, as well as the requirement for additional surgical procedures, may have a more profound influence on ACL reconstruction results and patient-relevant outcomes than will the graft type selected.

ACKNOWLEDGMENT

The authors thank the Orthopaedic Research and Education Foundation and Vanderbilt Sports Medicine Research Fund for funding; Aircast Inc, and Smith & Nephew Inc, for educational gifts; the late Dr Alexandra Kirkley for her inspiring mentorship; Lynn S. Cain for editorial assistance; and MOON for collaboration and the goal to promote evidence-based medicine evaluation of ACL outcomes. We thank Trisha Greenhalgh and recommend her text, *How to Read a Paper: The Basics of Evidence Based Medicine.*¹⁵ Finally, we appreciate the dedication and excellence of the authors of these RCTs on autograft choice.

REFERENCES

- Aglietti P, Buzzi R, Zaccherotti G, De Biase P. Patellar tendon versus doubled semitendinosus and gracilis tendons for anterior cruciate ligament reconstruction. *Am J Sports Med.* 1994;22:211-217; discussion 217-218.
- Anderson AF, Snyder RB, Lipscomb AB Jr. Anterior cruciate ligament reconstruction: a prospective randomized study of three surgical methods. *Am J Sports Med.* 2001;29:272-279.
- Aune AK, Holm I, Risberg MA, Jensen HK, Steen H. Four-strand hamstring tendon autograft compared with patellar tendon–bone autograft for anterior cruciate ligament reconstruction: a randomized study with two-year follow-up. *Am J Sports Med.* 2001;29:722-728.
- Barrett GR, Noojin FK, Hartzog CW, Nash CR. Reconstruction of the anterior cruciate ligament in females: a comparison of hamstring versus patellar tendon autograft. *Arthroscopy*. 2002;18:46-54.
- 5. Bellamy N, Buchanan W, Goldsmith C. Validation study of WOMAC: a health status instrument for measuring clinically important patient-

relevant outcomes following total hip or knee arthroplasty in osteoarthritis. *Orthop Rheumatol.* 1988;1:95-108.

- Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol. 1988:15:1833-1840.
- Beynnon BD, Johnson RJ, Fleming BC, et al. Anterior cruciate ligament replacement: comparison of bone-patellar tendon-bone grafts with two-strand hamstring grafts: a prospective, randomized study. J Bone Joint Surg Am. 2002;84:1503-1513.
- Bynum EB, Barrack RL, Alexander AH. Open versus closed kinetic chain exercises after anterior cruciate ligament reconstruction. *Am J Sports Med.* 1995;23:401-406.
- Corry IS, Webb JM, Clingeleffer AJ, Pinczewski LA. Arthroscopic reconstruction of the anterior cruciate ligament: a comparison of patellar tendon autograft and four-strand hamstring tendon autograft. *Am J Sports Med.* 1999;27:444-454.
- Ejerhed L, Kartus J, Sernert N, Kohler K, Karlsson J. Patellar tendon or semitendinosus tendon autografts for anterior cruciate ligament reconstruction? A prospective randomized study with a two-year followup. *Am J Sports Med.* 2003;31:19-25.
- Eriksson K, Anderberg P, Hamberg P, et al. A comparison of quadruple semitendinosus and patellar tendon grafts in reconstruction of the anterior cruciate ligament. *J Bone Joint Surg Br.* 2001;83:348-354.
- Feller JA, Webster KE. A randomized comparison of patellar tendon and hamstring tendon anterior cruciate ligament reconstruction. *Am J Sports Med.* 2003;31:564-573.
- Fox JA, Nedeff DD, Bach BR Jr, Spindler KP. Anterior cruciate ligament reconstruction with patellar autograft tendon. *Clin Orthop.* 2002;402:53-63.
- 14. Freedman KB, D'Amato M, Nedeff DD, Kaz A, Bach BR Jr. Arthroscopic anterior cruciate ligament reconstruction: a metaanalysis comparing patellar tendon and hamstring tendon autografts. Am J Sports Med. 2003;31:2-11.
- Greenhalgh T. How to Read a Paper: The Basics of Evidence Based Medicine. 2nd ed. London, England: BMJ Publishing Group; 2001.
- Hefti F, Muller W, Jakob RP, Staubli HU. Evaluation of knee ligament injuries with the IKDC form. *Knee Surg Sports Traumatol Arthrosc.* 1993;1:226-234.
- Hurwitz SR, Slawson D, Shaughnessey A. Orthopaedic information mastery: apply evidence-based information to improve patient outcomes while saving orthopaedists' time. J Bone Joint Surg Am. 2000;82:888-894.
- Irrgang JJ, Anderson AF. Development and validation of health-related quality of life measures for the knee. *Clin Orthop.* 2002;402:95-109.
- Irrgang JJ, Anderson AF, Boland AL, et al. Development and validation of the International Knee Documentation Committee subjective knee form. *Am J Sports Med.* 2001;29:600-613.
- Jansson KA, Linko E, Sandelin J, Harilainen A. A prospective randomized study of patellar versus hamstring tendon autografts for anterior cruciate ligament reconstruction. *Am J Sports Med.* 2003;31:12-18.

- Lang TA, Secic M. How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers. Philadelphia, Pa: American College of Physicians; 1997.
- Lysholm J, Gillquist J. Evaluation of knee ligament surgery results with special emphasis on use of a scoring scale. Am J Sports Med. 1982;10:150-154.
- Marder RA, Raskin JR, Carroll M. Prospective evaluation of arthroscopically assisted anterior cruciate ligament reconstruction: patellar tendon versus semitendinosus and gracilis tendons. *Am J Sports Med.* 1991;19:478-484.
- 24. Noyes FR, Barber SD, Mooar LA. A rationale for assessing sports activity levels and limitations in knee disorders. *Clin Orthop.* 1989;246:238-249.
- 25. O'Neill DB. Arthroscopically assisted reconstruction of the anterior cruciate ligament: a prospective randomized analysis of three techniques. J Bone Joint Surg Am. 1996;78:803-813.
- Otero AL, Hutcheson L. A comparison of the doubled semitendinosus/gracilis and central third of the patellar tendon autografts in arthroscopic anterior cruciate ligament reconstruction. *Arthroscopy*. 1993;9:143-148.
- Pinczewski LA, Deehan DJ, Salmon LJ, Russell VJ, Clingeleffer A. A five-year comparison of patellar tendon versus four-strand hamstring tendon autograft for arthroscopic reconstruction of the anterior cruciate ligament. *Am J Sports Med.* 2002;30:523-536.
- 28. Roos EM, Lohmander LS. The Knee Injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes.* 2003;1:64.
- 29. Roos EM, Roos HP, Lohmander LS. WOMAC Osteoarthritis Index: additional dimensions for use in subjects with post-traumatic osteoarthritis of the knee. Western Ontario and McMaster Universities. Osteoarthritis Cartilage. 1999;7:216-221.
- Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS): development of a self-administered outcome measure. J Orthop Sports Phys Ther. 1998;28:88-96.
- 31. Shaieb MD, Kan DM, Chang SK, Marumoto JM, Richardson AB. A prospective randomized comparison of patellar tendon versus semitendinosus and gracilis tendon autografts for anterior cruciate ligament reconstruction. *Am J Sports Med.* 2002;30:214-220.
- Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. *Clin Orthop.* 1985;198:43-49.
- 33. Ware J. The Health Institute. New Eng Med Center Hospital; 1988.
- Ware J, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36), I: conceptual framework and item selection. *Med Care*. 1992;30:473-483.
- Wright JR, Swintkowski MF, Heckman JD. Editorial: introducing levels of evidence into the journal. J Bone Joint Surg Am. 2003;85:1-3.
- Yunes M, Richmond JC, Engels EA, Pinczewski LA. Patellar versus hamstring tendons in anterior cruciate ligament reconstruction: a meta-analysis. *Arthroscopy.* 2001;17:248-257.