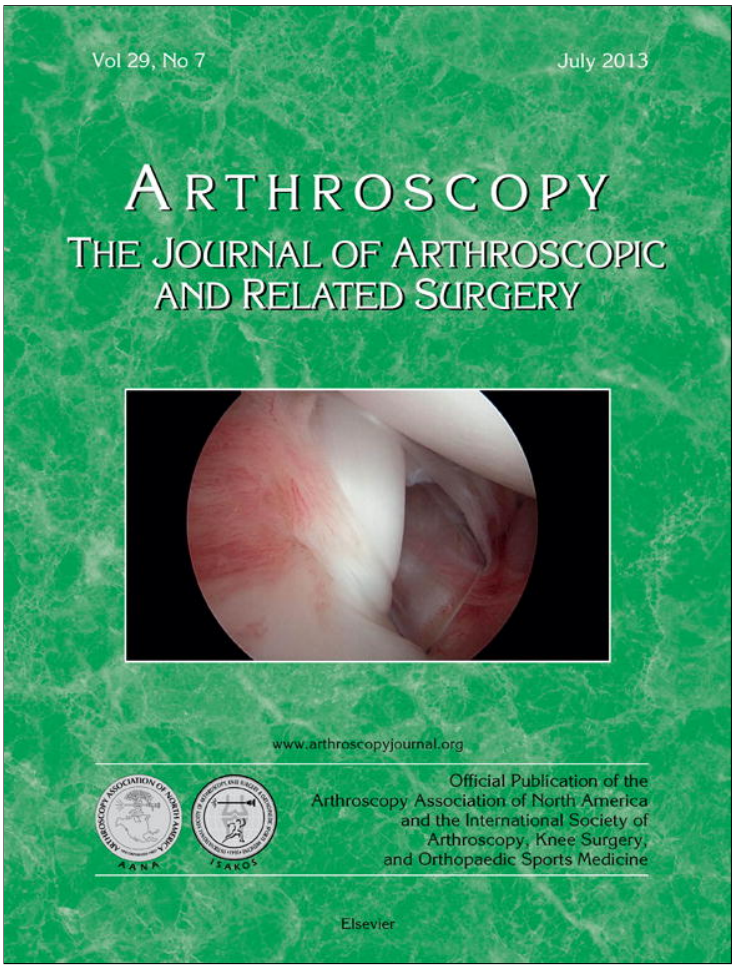

Randomized Controlled Trial Comparing All-Inside Anterior Cruciate Ligament Reconstruction Technique With Anterior Cruciate Ligament Reconstruction With a Full Tibial Tunnel

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Purpose: The purpose of this investigation was to compare the clinical effectiveness of full-tunnel anterior cruciate ligament (ACL) reconstructive surgery with all-inside ACL reconstruction. **Methods:** After statistical power analysis was performed and institutional review board approval and patient informed consent were obtained, 150 patients having ACL reconstruction were prospectively randomized to an all-inside or full—tibial tunnel technique. Outcome (International Knee Documentation Committee [IKDC] Knee Examination Form, IKDC Subjective Knee Evaluation Form, Knee Society Score [KSS], Short Form 12 [SF-12] score, femoral or tibial tunnel or socket widening, narcotic consumption, and visual analog scale [VAS] pain score compared with baseline) was measured and recorded preoperatively and at various postoperative time points with a minimum follow-up of 2 years. **Results:** There were no differences between groups with regard to IKDC Knee Examination Form, IKDC Subjective Knee Evaluation Form, KSS score, SF-12 score, or femoral socket or tibial tunnel or socket widening, or narcotic consumption. The VAS pain score compared with baseline was significantly lower for the all-inside technique on day 1, on day 7, at 1.5 weeks, and at 24 months. **Conclusions:** The null hypothesis (no difference between all-inside ACL reconstruction and ACL reconstruction with a full tibial tunnel) is supported for IKDC scores, KSS score, SF-12 score, narcotic consumption, and tibial and femoral widening, whereas all-inside ACL reconstruction results in a lower VAS pain score compared with baseline. **Level of Evidence:** Level I, randomized controlled clinical trial with greater than 80% patient follow-up 2 years postoperatively.

Anterior cruciate ligament (ACL) reconstruction with full tibial tunnels is a common orthopaedic surgery technique.[1] The all-inside ACL reconstruction technique is a modification of the full—tibial tunnel technique whereby the tibial bone tunnel is eliminated in favor of a tibial socket. The all-inside technique has been hypothesized to result in less pain compared with full-tunnel ACL reconstruction[2,3] and has been biomechanically evaluated,[4,5] but the results of all-inside ACL surgery have never been reported.

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The purpose of this investigation was to compare the clinical effectiveness of ACL reconstructive surgery in patients having full-tunnel versus all-inside ACL reconstruction. The null hypothesis was that there is no difference between all-inside ACL reconstruction and ACL reconstruction with a full tibial tunnel.

Methods

After study institutional review board approval, patient informed consent, and Health Insurance Portability and Accountability Act consent were obtained, we included patients aged 18 to 64 years with an ACL-deficient knee who chose to have ACL reconstructive surgery with allograft tissue. Patients having associated meniscal and chondral debridement or meniscal repair were included. Excluded were patients with grade II or grade III tears of the knee medial collateral ligament, posterior cruciate ligament, lateral collateral ligament, posteromedial corner, or posterolateral corner or previous ACL reconstructive surgery.

Patients meeting the study criteria were prospectively randomized to the treatment (all-inside) or control (full-tunnel) group by use of sealed-envelope, computer-generated block randomization among 3 centers. Patients

Table 1. Demographics

	All Inside	Endoscopic	Statistics	Procedure
Age (yr)	39.3 ± 12.1	41.1 ± 10.8	No difference, $P = .335$	Mann-Whitney rank sum
Sex	38 male and 37 female	39 male and 34 female	No difference, $P = .746$	2-Proportion test
Surgery time (min)	67.8 ± 15.3, n = 76	62.7, n = 72	No difference, $P = .114$	Mann-Whitney test

Table 2. IKDC Subjective Knee Score

	All Inside	Endoscopic	Statistics	Procedure
Preoperative	47.4 ± 15.0, n = 76	49.6 ± 16.4, n = 73	No difference, $P = .353$	2-Way repeated-measures ANOVA
6 wk	60.0 ± 11.8*, n = 77	59.6 ± 13.1*, n = 70	No difference, $P = .712$	
12 mo	83.3 ± 13.7*, n = 55	80.8 ± 16.2*, n = 49	No difference, $P = .379$	
24 mo	86.5 ± 11.6*, n = 63	84.0 ± 12.1*, n = 55	No difference, $P = .481$	

ANOVA, analysis of variance.
*Statistical difference from preoperative within treatments.

were not blinded to the surgical technique. All patients had outpatient ACL allograft reconstruction under general anesthesia and with a tourniquet, without nerve block, by use of 2-strand tibialis tendon grafts with an identical surgical technique with the exception of the independent variable (i.e., tibial technique) described later.

In both groups femoral sockets were created through an anteromedial portal technique at the 10-o'clock (right knee) or 2-o'clock (left knee) position with the knee in hyperflexion.[6] Femoral fixation in both groups was achieved with a bioabsorbable femoral interference screw (Arthrex, Naples, FL) measuring 1 mm in diameter smaller than the femoral tunnel diameter and 23 mm in length. The portion of the graft in the femoral tunnel was whip-stitched.

A postoperative ACL accelerated rehabilitation protocol was standardized for both groups, with a focus on achieving immediate full knee extension equal to the normal, contralateral knee; return to running at 3 months; and return to cutting and pivoting sports at 6 months.

Table 3. IKDC Knee Examination Score

	Normal	Nearly Normal	Abnormal	Severely Abnormal
All inside				
Preoperative (n = 63)	2%	13%	51%	35%
6 wk (n = 67)	48%	39%	9%	4%
12 mo (n = 56)	71%	27%	2%	0%
24 mo (n = 63)	83%	17%	0%	0%
Endoscopic				
Preoperative (n = 65)	6%	8%	55%	31%
6 wk (n = 65)	49%	37%	11%	3%
12 mo (n = 47)	70%	26%	4%	0%
24 mo (n = 57)	84%	16%	0%	0%

NOTE. A 2-proportion test was used to compare the percent of normal of the all-inside and endoscopic groups at each respective time point. There was no statistical difference at any time point ($P = .365$ preoperatively, $P > .999$ at 6 weeks, $P > .999$ at 12 months, and $P > .999$ at 24 months).

Independent Variable: Tibial Technique

Full Tunnel. The standard tibial technique included tunnel creation with an antegrade, cannulated drilling technique, and fixation in the full-tunnel group was achieved with a bioabsorbable tibial interference screw (Delta tapered screw; Arthrex) measuring 2 mm in diameter larger than the tibial tunnel diameter and 35 mm in length. In cases in which screw insertion torque was less than 15 ft-lb, as measured with the QuickConnect Ratcheting Screwdriver with Torque Measuring Device (Arthrex), the screw was exchanged for a screw measuring 3 mm in diameter larger than the tibial tunnel diameter. The portion of the graft in the tunnel was whip-stitched.

All Inside. All-inside tibial socket creation was performed with a retrograde drilling technique (RetroDrill; Arthrex), and tibial fixation in the all-inside group was achieved with a bioabsorbable tibial interference screw (RetroScrew; Arthrex) measuring 1 mm in diameter smaller than the tibial socket diameter (as recommended by the manufacturer for aperture fixation in the dense, cortical bone of the proximal tibial plateau). The portion of the graft in the tunnel was whip-stitched.

Evaluation

We measure and report patient demographic data using the International Knee Documentation Committee (IKDC) Knee History Form, on which age, sex, and operative time are reported. Also recorded are the IKDC Knee Examination Form, IKDC Subjective Knee Evaluation Form, Knee Society Score (KSS) for pain and function, and Short Form 12 (SF-12) score preoperatively and at 1.5 weeks, 6 weeks, and 12 and 24 months postoperatively, as well as femoral socket or tibial tunnel or socket widening as measured by use of orthogonal radiographs at 24 months postoperatively. Clinical research assistants collected the data in a blinded manner.

Table 4. Knee Society Score

	All Inside	Endoscopic	Statistics	Procedure
Pain score				2-Way repeated-measures ANOVA
Preoperative	68.9 ± 17.2, n = 76	73.2 ± 16.3, n = 73	No difference, $P = .063$	
1.5 wk	75 ± 17.4, n = 76	76.7 ± 18.3, n = 69	No difference, $P = .447$	
6 wk	90.5 ± 11.4*, n = 75	93.1 ± 8.2*, n = 69	No difference, $P = .271$	
12 mo	97.5 ± 3.5*, n = 50	95.3 ± 10.7*, n = 47	No difference, $P = .930$	
24 mo	93.3 ± 15.1*, n = 62	95.9 ± 7.4*, n = 57	No difference, $P = .187$	
Function score				2-Way repeated-measures ANOVA
Preoperative	61.3 ± 30.1, n = 76	60.3 ± 30.4, n = 73	No difference, $P = .781$	
1.5 wk	33.5 ± 23.4*, n = 76	34.6 ± 26.9*, n = 69	No difference, $P = .602$	
6 wk	82.5 ± 19.8*, n = 75	83.0 ± 18.5*, n = 69	No difference, $P = .906$	
12 mo	97.4 ± 6.3*, n = 50	96.2 ± 10.5*, n = 47	No difference, $P = .923$	
24 mo	97.6 ± 6.7*, n = 62	98.8 ± 5.0*, n = 57	No difference, $P = .581$	

ANOVA, analysis of variance.
*Statistical differences from preoperative within treatments.

Patients were provided only 1 oral analgesic postsurgically (acetaminophen–oxycodone hydrochloride, 5 mg). Total acetaminophen–oxycodone hydrochloride intake over each previously specified interval was recorded. Patients' requests for alternative narcotic pain medications were accommodated, with data normalized and reported as acetaminophen–oxycodone hydrochloride equivalents.[7] Pain is compared with baseline by use of a 10-cm visual analog scale (VAS) pain score[8] at 24 hours postoperatively (day 1). In addition to the VAS score at 24 hours, the VAS score was recorded daily for postoperative days 2 through 7, 1.5 weeks postoperatively, 6 weeks postoperatively, and 12 and 24 months postoperatively.

Statistical Analysis

With regard to the cohort size, sample size analysis showed that a minimum of 128 patients (64 per group) were required to detect a 20% difference in VAS pain levels between the 2 groups assuming an SD of 40. For the power analysis, the α value was set at .05 and the β value at .8. Computerized block randomization was performed, with equal division of study group and control group patients among 3 study sites.

Results

After we performed the power analysis as described earlier, to allow for loss of patients to follow-up, 150 patients were block randomized among 3 sites. Two patients were randomized and then excluded because of cancellation of surgery. We included 148 patients (76 all-inside and 72 endoscopic patients). We achieved follow-up on 120 patients (81%) at 24 months. No major complications were recorded.

Preoperatively, demographics were similar with regard to age. The operative time was 5 minutes greater for the all-inside group, with no statistically significant difference detected ($P = .114$) (Table 1).

There were no differences between groups with regard to outcome measures (Tables 2-7) including narcotic consumption, IKDC Knee Examination Form, IKDC Subjective Knee Evaluation Form, KSS for pain and function, SF-12 score, and femoral socket or tibial tunnel or socket widening at 24 months postoperatively. The VAS pain score compared with baseline (preoperative pain) was significantly lower for the all-inside technique on day 1, on day 7, at 1.5 weeks, and at 24 months (Table 8, Fig 1).

Table 5. SF-12 Score

	All Inside	Endoscopic	Statistics	Procedure
Physical score				2-Way repeated-measures ANOVA
Preoperative	37.5 ± 9.6, n = 76	38.9 ± 9.4, n = 73	No difference, $P = .303$	
1.5 wk	32.4 ± 5.4, n = 76	33.7 ± 6.7, n = 70	No difference, $P = .215$	
6 wk	39.5 ± 8.5, n = 76	40.5 ± 8.4, n = 70	No difference, $P = .449$	
12 mo	52.6 ± 8.6*, n = 53	52.2 ± 9.3*, n = 50	No difference, $P = .613$	
24 mo	53.3 ± 6.6*, n = 64	52.5 ± 6.9*, n = 56	No difference, $P = .888$	
Mental score				2-Way repeated-measures ANOVA
Preoperative	54.6 ± 9.6, n = 76	53.3 ± 10.6, n = 73	No difference, $P = .982$	
1.5 wk	54.6 ± 10.5, n = 76	52.5 ± 10.2, n = 70		
6 wk	55.8 ± 8.1, n = 76	55.2 ± 9.2, n = 70		
12 mo	56.4 ± 4.9, n = 50	53.7 ± 9.1, n = 50		
24 mo	56.8 ± 3.8, n = 64	55.3 ± 6.7, n = 56		

ANOVA, analysis of variance.
*Statistical differences from preoperative within treatments.

Table 6. Radiographic Results

	All Inside	Endoscopic	Statistics	Procedure
2-yr radiographs obtained	62	56		
Subjective tibial widening	Present in 14	Present in 22	No difference, $P = .071$	2-Proportion test
Tibial tunnel width (mm)	10.3 ± 1.8	11.4 ± 2.8	No difference, $P = .073$	Mann-Whitney *t* test
Subjective femoral widening	Present in 13	Present in 17	No difference, $P = .292$	2-Proportion test
Femoral tunnel width (mm)	10.1 ± 3.8	9.9 ± 3.0	No difference, $P = .869$	Mann-Whitney *t* test

Table 7. Acetaminophen—Oxycodone Hydrochloride Consumption (Number of Tablets During Each 24-Hour Period and in Total)

	All Inside (n = 75)	Endoscopic (n = 70)	Statistics	Procedure
Day 1	5.0 ± 3.7	5.8 ± 3.8	No difference, $P = .133$	2-Way repeated-measures ANOVA
Day 2	6.3 ± 3.5	7.2 ± 3.2	No difference, $P = .084$	
Day 3	4.8 ± 3.3	5.7 ± 3.3	No difference, $P = .078$	
Day 4	3.5 ± 3.1	4.3 ± 3.1	No difference, $P = .112$	
Day 5	2.9 ± 2.8	3.8 ± 3.1	No difference, $P = .085$	
Day 6	2.8 ± 2.5	2.9 ± 2.3	No difference, $P = .870$	
Day 7	2.5 ± 2.7	2.5 ± 2.3	No difference, $P = .914$	
Total	27.8 ± 16.7	32.2 ± 15.9	No difference, $P = .106$	*t* Test

ANOVA, analysis of variance.

Discussion

Our results show almost identical knee stability results as determined by the IKDC Knee Examination score ($P > .999$) at 24 months. All other outcomes were equal except VAS pain score, which was lower for the all-inside technique. We are unaware of previous publications reporting the results of all-inside ACL reconstruction.

Measuring orthopaedic outcome is challenging and requires "clinician-reported and patient-reported measures. Patient-reported measures include measures of symptoms (such as pain), measures of activity and function (such as work ability or sports participation), and measures of general health status (such as quality of life). Measures of symptoms and measures of activity and function may be specified as joint or region, and disease or injury, specific…[C]linical outcome studies [should] include a combination of these measures. In addition, clinical outcome measures should be practical, widely accepted, reliable, valid and responsive. Finally, the evidence for reliability, validity and responsiveness should be specific to the disease and/or population of interest."[9]

Limitations

In this study we measure outcome using the IKDC Knee Examination Form, IKDC Subjective Knee Evaluation Form, KSS for pain and function, SF-12 score, femoral socket and tibial tunnel or socket widening as measured using orthogonal radiographs, acetaminophen—oxycodone hydrochloride (or equivalent) intake, and VAS pain score compared with baseline pain. The IKDC Knee Examination Form is commonly used to assess ACL outcome, and the IKDC Subjective Knee Evaluation Form

Table 8. VAS Pain Score

	All Inside	Endoscopic	Statistics	Procedure
Preoperative	2.6 ± 2.1	1.6 ± 2.0	Difference, $P = .003$	2-Way repeated-measures ANOVA
Day 1	2.5 ± 3.2, n = 75	3.8 ± 3.4, n = 70	Difference, $P = .002$	
Day 2	3.4 ± 2.8, n = 75	4.0 ± 2.9, n = 70	No difference, $P = .160$	
Day 3	2.1 ± 2.4, n = 75	2.6 ± 2.9, n = 70	No difference, $P = .203$	
Day 4	1.4 ± 2.4, n = 75	1.7 ± 2.6, n = 70	No difference, $P = .460$	
Day 5	0.8 ± 2.5, n = 75	1.6 ± 2.6, n = 70	No difference, $P = .081$	
Day 6	0.5 ± 2.6, n = 75	1.2 ± 2.6, n = 70	No difference, $P = .084$	
Day 7	−0.1 ± 2.3, n = 75	0.9 ± 2.5, n = 70	Difference, $P = .033$	
1.5 wk	−1.1 ± 2.4, n = 76	0.0 ± 2.7, n = 69	Difference, $P = .015$	
6 wk	−1.8 ± 2.3, n = 75	−1.2 ± 2.0, n = 69	No difference, $P = .106$	
12 mo	−2.3 ± 2.0, n = 50	−1.2 ± 1.5, n = 47	No difference, $P = .109$	
24 mo	−2.5 ± 2.0, n = 63	−1.7 ± 2.1, n = 55	Difference, $P = .026$	

NOTE. Pain scores were compared with baseline values (a negative value represents less pain).
ANOVA, analysis of variance.

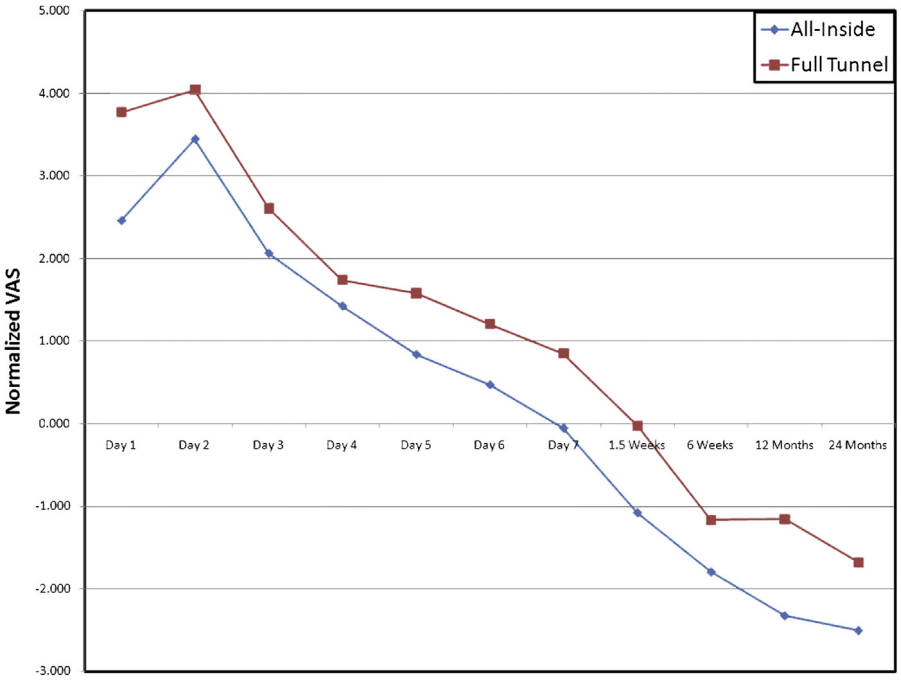

Fig 1. VAS pain score compared with baseline for all-inside ACL reconstruction patients versus full-tunnel reconstruction patients.

is validated for "knee-specific patient-reported health status."[9] The KSS is validated for knee arthroplasty, as opposed to ACL reconstruction; socket widening using radiographs is reported but not validated; and the SF-12 is valid for general health status. With regard to evaluation of pain, narcotic intake is commonly assessed, and the VAS score compared with baseline is recommended because individual variations with regard to perception of pain may be vast and comparison with baseline achieves normalization, which minimizes selection bias.[8] A study limitation is that there is no consensus outcome measure for ACL reconstruction; however, the custom of evaluation using diverse outcome measures provides a broad understanding of the similarities and differences with regard to the comparative effectiveness of all-inside versus full–tibial tunnel ACL reconstruction and allows readers and future researchers to determine the clinical significance, or lack thereof, of the objectively reported data (Tables 1-8).

Additional limitations are that only allograft ACL reconstruction is investigated, with or without meniscal partial meniscectomy or repair. Inclusion of patients with different meniscal pathology or treatment is a confounding variable but was required for robust patient recruitment. Patients were not blinded to the surgical technique. An additional limitation of the study is that ACL techniques have evolved since the initiation of our clinical trial, and future research is required to determine outcomes of all-inside graft-link techniques.[10] A further limitation is that the study is statistically powered to evaluate VAS pain score, but we are unable to rule out β error with regard to other outcome measures. Finally, statistical significance does not signify clinical significance. Narcotic consumption was similar between groups, and differences in pain were small. We find it clinically significant that at the first post-operative visit (1.5 weeks), the all-inside group showed less pain than preoperative.

Conclusions

The null hypothesis (no difference between all-inside ACL reconstruction and ACL reconstruction with a full tibial tunnel) is supported for IKDC scores, KSS, SF-12 score, narcotic consumption, and tibial and femoral widening, whereas all-inside ACL reconstruction results in a lower VAS pain score compared with baseline.

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