

SHOULDER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Three-year functional outcome of transosseousequivalent double-row vs. single-row repair of small and large rotator cuff tears: a double-blinded randomized controlled trial



Mohamed Imam, MD, PhD, FRCS(Tr and Orth)^{a,b}, Asser Sallam, MD, PhD^{b,*}, Lukas Ernstbrunner, MD^c, Glenn Boyce, MBBS, FRACS^d, Nikolaos Bardakos, MBBS^e, Ashraf Abdelkafy, MD^b, Moussa Moussa, MD^b, Mohamed-Adel Ghazal, MD^b

^aNorfolk and Norwich University Hospitals, Norfolk, England

^bDepartment of Orthopaedic Surgery and Trauma, Suez Canal University Hospitals, Ismailia, Egypt

^cDepartment of Orthopaedics, Balgrist University Hospital, University of Zürich, Zürich, Switzerland

^dBendigo Orthopaedic and Sports Medicine, and University Hospital Geelong, Ryrie and Bellarine Street Geelong,

Geelong, VIC, Australia

^eSouth West London Elective Orthopaedic Centre, Epsom, UK

Background: The trial aimed to prospectively compare the functional outcomes of patients undergoing arthroscopic rotator cuff repair using transosseous-equivalent double-row (TEDR) or single-row (SR) suture anchor techniques at 3 years postoperatively for both large (>3 cm) and small (<3 cm) tears.

Methods: Eighty patients with a symptomatic and magnetic resonance imaging (MRI)–proven full-thickness rotator cuff tear, who had failed conservative management of at least 6 months' duration and who had a complete passive range of motion of the affected shoulder, were enrolled in the trial. Patients were randomized to TEDR repair (n = 40) or SR repair (n = 40). Subgroup analysis was conducted for tears <3 cm (TEDR n = 17, SR n = 19) and tears >3 cm (TEDR n = 23, SR n = 21). Primary outcomes included the Oxford Shoulder Score (OSS), the University of California, Los Angeles (UCLA) score, and the Constant-Murley score (CMS). The secondary outcomes included a 0-100-mm visual analog scale (VAS) score for pain, range of motion (ROM), and EQ-5D scores. All patients completed a follow-up of 3 years.

Results: There was a significant difference in the mean OSS postoperative score for tears >3 cm (P = .01) and mean improvement from baseline in the TEDR group (P = .001). For tears >3 cm, mean postoperative scores were also significantly higher in the TEDR group for UCLA (P = .015) and CMS (P = .001). Post hoc testing showed that the differences between these groups was statistically significant (P < .05). For tears <3 cm, a significant postoperative difference in favor of SR repair was seen in the mean CMSs (P = .011), and post hoc testing showed that the difference was statistically significant (P = .015). No significant difference was seen with mean postoperative OSS or UCLA, and post hoc testing did not show a statistically significant difference between groups.

This study was approved by the Suez Canal University Institutional Research Board (IRB) and registered in the national registry (ORT/1059-2008).

*Reprint requests: Asser Sallam, MD, PhD, Department of Orthopedic Surgery and Trauma, Suez Canal University Hospitals, Kilo 4.5 Ring Road, 41111 Ismailia, Egypt.

E-mail address: assersallam@hotmail.com (A. Sallam).

1058-2746/\$ - see front matter © 2020 Journal of Shoulder and Elbow Surgery Board of Trustees. All rights reserved. https://doi.org/10.1016/j.jse.2020.05.005 **Conclusions:** TEDR repair showed improved functional outcomes for tears >3 cm compared with SR repair. For tears <3 cm, no clear benefit was seen with either technique.

Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

 $\ensuremath{\mathbb{C}}$ 2020 Journal of Shoulder and Elbow Surgery Board of Trustees. All rights reserved.

Keywords: Double row; single row; transosseous equivalent; rotator cuff; arthroscopy; tear; shoulder

Rotator cuff repair techniques have shifted away from open repair to arthroscopic repair after equivalent or even improved results of published arthroscopic methods.^{9-13,19,27,40} There are multiple factors influencing success after cuff repair, including surgeon experience, appropriate suture configuration, careful patient selection, and adequate postoperative rehabilitation.²⁷ A gold standard repair technique has not yet been identified, but an ideal repair would optimize suture-to-bene fixation, suture-to-tendon fixation, abrasion resistance of the suture, suture strength, knot security, and loop security.^{1-6,17,18}

Despite our improved understanding and the advances in repair techniques, the reported retear occurrence rate is still 25%-40%.^{3,11,17,18,31} Risk of retear has been attributed to various factors, such as patient's age, tear size, repair technique, and tendon quality.^{16,20,33,38,40} However, retear does not always correlate to poor patient outcome.²⁹

Transosseous-equivalent double-row (TEDR) repair, as reported by Park et al,⁴⁴ is based on suture bridges and combines medially placed anchors for a horizontal mattress suture with laterally placed anchors as the base of a suture bridge. This provides compression of the restored cuff over a wider tendon bone interface than single-row repair,^{30,34,36,41,45,46,50} leading to enhanced healing between tendon and bone.⁵³ Although biomechanically superior to single-row repairs, double-row repair has not clearly translated to improved functional outcome in studies to date despite the postoperative radiologic evidence of decreased retear rates.^{8,14,15,24}

Thus, the purpose of the current clinical trial was to prospectively compare the functional outcome as well as pain and range of motion after arthroscopic TEDR repair vs. single-row (SR) rotator cuff repair for both smaller (<3 cm) and larger (>3 cm) tears. We hypothesized that transequivalent double-row arthroscopic rotator cuff repair would show better functional outcome than single-row repair.

Materials and methods

Institutional ethics approval was gained prior to this study, and the trial was registered in our national registry. A power calculation was undertaken to calculate the optimal study size based on a difference of 18 points in the Constant-Murley score (CMS) between subgroups.²⁶ Thirty patients would be needed in each group to reach significance.

The study was conducted as a prospective randomized controlled trial between April 2009 and February 2016. Eighty patients undergoing arthroscopic rotator cuff repair in our institution were enrolled and randomized into 2 groups with 40 in each arm (TEDR vs. SR techniques).

Our inclusion criteria were all patients with a symptomatic and magnetic resonance imaging (MRI)–proven full-thickness rotator cuff tear who had failed conservative management of at least 6 months' duration and who had a complete passive range of abduction in the scapular plane, forward flexion, and internal and external rotation of the affected shoulder. Symptoms included pain, weakness, and loss of active range of movements (Table I). The conservative therapy varied from nonsteroidal antiinflammatory drugs and physical therapy to subacromial steroid injection.

The patients had to be willing to undergo a standardized postoperative rehabilitation and able to provide an informed consent. Exclusion criteria included smoking, prior shoulder surgery, prior infection, instability, adhesive capsulitis, or loss of passive range of motion prior to surgery and inflammatory arthropathy. All potential participants were screened for eligibility by the surgical team. Initially, 107 patients presented a symptomatic and MRI-proven full-thickness rotator cuff tear. Twelve patients were excluded from the study as they failed to meet the inclusion criteria. Ten patients declined to participate. In addition, 5 patients were not amenable to repair and thus excluded. This left a total of 80 patients (40 per group) available for analysis (CONSORT flow⁴⁹; Fig. 1).

Randomization of patients was conducted with the use of a sealed envelope containing the group allocation for each case, produced by an independent epidemiology department not directly involved in the study. The blinded surgeon opened the envelope on the day of surgery. Based on MRI findings with intraoperative measurement and confirmation of tear size, patients were further categorized as having a tear <3 cm or >3 cm.

A patient information sheet was included together with the informed consent form. A trained member of the team explained the study verbally to all participants. All foreseeable risks and potential benefits, which might occur during and after arthroscopic rotator cuff repairs, were discussed with all patients. Basic demographic and operative data were collected and included age, gender, operative side, dominant arm, duration of symptoms, operative time, length of stay, pattern of tear, active and passive ranges of movement, and complications. Data collection occurred preoperatively, at 24 hours postoperatively, and at 6, 24, and 36 months postoperatively. The visual analog scale (VAS) scores were collected at 24 hours and 6 weeks postsurgery.

Primary outcome measures included the Oxford Shoulder Score (OSS),⁴² the University of California, Los Angeles (UCLA) score,³² and the CMS.⁴⁷ Secondary outcome measures included a 0-100-mm VAS for pain at different time points,⁷ range of motion,

Variable, mean (range)	Overall	Single row	Double row	P value
Age, yr	60.8 (55-70)	61.6 (55-70)	60.0 (55-70)	.39
Symptom duration, d	22 (18-25)	21 (18-24)	23 (19-25)	.39
Symptoms, n (%)				
Pain	78 (97.5)	39	39	>.99
Weakness	77 (96.25)	38	39	.56
Limited active movement	79 (98.75)	39	40	—
Degenerative/traumatic tears	73/7	37/3	36/4	.69
Operative time, min	100 (50-140)	60 (50-80)	120 (90-140)	<.001
Length of stay, h	26 (20-30)	22 (20-25)	29.5 (27-30)	<.001
Number of anchors	3	2	4	<.001
Preoperative scores				
Active flexion, degrees	100 (80-115)	99 (90-115)	88 (80-110)	.073
Abduction, degrees	45 (40-48)	43 (41-47)	42 (40-48)	.475
Active IR, degrees	25 (22-28)	26 (24-28)	25 (22-27)	.593
Active ER, degrees	30 (25-34)	30 (25-32)	30 (27-34)	.680
CMS	49.2 (45-52)	50.6 (47-52)	47.8 (45-50)	.456
OSS	23.6	24.7	22.5	.147
UCLA	16.0	16.0	15.0	.465
EQ-5D	0.36	0.43	0.36	.641
Tear size, n (%)				
<3 cm	36 (45)	17 (42.5)	19 (47.5)	.074
>3 cm	44 (55)	23 (57.5)	21 (52.5)	

Table I	Basic demographic	and operative dat	a for the SR andTEDR	R patient groups, a	as well as preoperative scores
---------	-------------------	-------------------	----------------------	---------------------	--------------------------------

SR, single-row; TEDR, transosseous-equivalent double-row; IR, internal rotation; ER, external rotation; CMS, Constant-Murley score; OSS, Oxford Shoulder Score; UCLA, University of California, Los Angeles.

Unless otherwise noted, values are mean (range).

and EQ-5D (visual analog method of calculation).²⁵ All participants were enrolled and randomized before surgery, and no participant was recruited after surgery.

Preoperative assessment

Demographic data and all functional scores were recorded preoperatively. Range of motion was measured by well-trained orthopedic fellows using a standard goniometer.

imaging included Preoperative a shoulder plain radiograph series (anteroposterior with neutral, external, and internal rotation and an axillary view) and MRI scans without gadolinium enhancement.

Tear size measurement

An experienced musculoskeletal radiologist read all MR scans and assessed the size of each rotator cuff tear in the coronal and sagittal planes. The tear was categorized in the sagittal plane in 2 groups: tears less than 3 cm and those equal to or more than 3 cm. The validity of the MRI measurements was assessed intraoperatively using the arthroscopic probe before débridement of the tear. There were no cases of disagreement between the 2 techniques, and no patient changed group once assigned.

Surgical technique

All operations were performed with the patient in the lateral decubitus position under general anesthesia supplemented by an interscalene block. An arthroscopic pump, set at 50 mm Hg of inflow pressure, and a 30° arthroscope was used in all cases. Standard viewing and working portals were established. Subtotal bursectomy and acromioplasty was performed to create working space in all cases. Standard preparation included clearance of the rotator interval and mobilization of the superior capsule from the superior labrum.

Both groups

We have standardized the same medial-row technique for both groups. Two medial 5-mm double-loaded fully threaded suture anchors (Corkscrew II Suture Anchor; Arthrex, Naples, FL, USA) were inserted in the medial footprint through the superolateral accessory portal.

Single-row group

The limbs of the no. 2 FiberWire (Arthrex) were passed 10-15 mm medial to the margin of the torn tendon using a suture-passing device (Multifire Scorpion Suture Passer; Arthrex). Duncan Loop knots were used in all cases (Fig. 2, a).

TEDR repair group

The FiberWire suture tails of the medial anchors were passed through the tendon with the Multifire Scorpion Suture Passer. The FibreWire from the medial sutures were then fixed with 5-mm Bio-Corkscrew anchors (Arthrex) laterally to form a transosseousequivalent repair (Fig. 2, b and c). Tensioning of the FiberWire

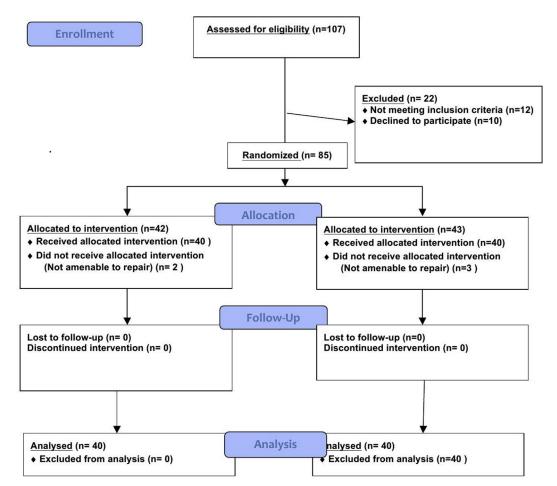


Figure 1 CONSORT flow diagram.

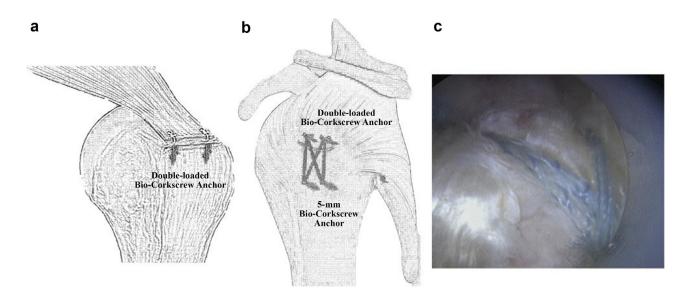


Figure 2 Rotator cuff repair constructs using double-loaded Bio-Corkscrew anchors and No. 2 FiberWire. (a) Single-row anchored construct using 2 sutures, 2 suture limbs, 2 tendon passes, 2 mattress stitches, 2 anchors, and 0 suture bridges. (b) Transosseous equivalent construct using 2 sutures, 4 suture limbs, 4 tendon passes, 2 mattress stitches, 4 anchors, and 4 suture bridges. (c) Final arthroscopic view of the TEDR Rotator cuff repair in one of the TEDR group. *TEDR*, transosseous equivalent double row.

during the second screw insertion maximized tendon compression and fixation of the tendon footprint on the tuberosity.

Postoperative care and rehabilitation

On the day of surgery, all patients were given information regarding use of a sling, activities of daily living, axillary hygiene, and education on movements and functional activities to be avoided. Advice was given regarding recovery of sensation from plexus nerve block if still active.

Postoperatively, all patients used an abduction sling for 4 weeks and started an identical rehabilitation program. Patients were assessed every 2 weeks for the first month and then at 6 months after surgery, and finally at 36 months postoperatively.

Follow-up

No patients were lost to follow-up and all completed the 36month evaluation. VAS score was obtained at 24 hours and recorded in a pain diary given to each patient. Complications were recorded at each time point until 36 months postsurgery. The following outcome assessments were used at 6, 24, and 36 months postoperatively: OSS, CMS, and UCLA scores. The second and sixth authors, both experienced orthopedic surgeons, assessed the patients postoperatively and they were unaware of the assigned treatment.

Statistical analysis

Data management was performed using SPSS, version 16.0 (Chicago, IL, USA). Statistical analyses were conducted by an independent member after deidentification of results and performed according to the intention-to-treat principle. Data were initially assessed for normality by the Shapiro-Wilk test and variances were shown to be equal by the Levene statistic. Normally distributed data were compared by the Student *t* test and the 1-tailed analysis of variance. Post hoc analysis was performed by the Bonferroni multiple comparison test to confirm statistically significant results between groups. For subgroup analysis, the Mann-Whitney *U* test and Kruskal-Wallis test were used to compare between proportions. A *P* value <.05 was considered statistically significant.

Discriminant function analysis showing the distribution of individual observations and of the group centroids was also performed.

Results

Demographic data and preoperative scores (Table I) showed no statistically significant differences between groups. A significant difference (irrespective of the tear size) was seen in operative time (P < .001), number of anchors (P < .001), and length of stay (P < .001) in favor of SR repair (Table I).

Both groups were similar (Table II) regarding the postoperative OSS, UCLA, CMS, and VAS scores (P = .0596, .409, .706, and .679, respectively), as well as the mean postoperative improvement of OSS, UCLA, CMS, and VAS scores (P = .751, .317, .319,and .726, respectively).

Subgroup analysis revealed a significant difference in both postoperative mean OSS, UCLA, and CMS (P = .010, .015, and .001, respectively) for tears >3 cm. A significant difference also existed in the mean postoperative CMS score for tears <3 cm (P = .011) in favor of SR (Table II).

For tears >3 cm, the postoperative mean improvement from baseline preoperative values of OSS (P = .001) was significant and in favor of TEDR at 2 years postsurgery (Fig. 3). In contrast, the mean improvement from preoperative CMS and UCLA scores did not reach significance between groups (Table II). For tears <3 cm, the subgroups were similar regarding the mean improvement in all scores.

Post hoc testing showed that differences in OSS and UCLA scores in the TEDR and SR groups for tears >3 cm were statistically significant (P = .020 and .041, respectively) in favor of TEDR. But for tears <3 cm, the groups were not significantly different. Although post hoc testing of CMS showed significant differences between the SR and TEDR groups for tears <3 cm (P = .015) and tears >3 cm (P = .023) (Fig. 4).

A discriminant function analysis scatter plot is shown in Figure 5 for individual observations and of the group centroids. The SR >3-cm group is best discriminated through function 1 (mostly dependent on OSS) from 2 patient groups and through function 2 (mostly dependent on CMS) from the fourth group.

There was an initial significant difference at 24 hours in VAS scores between the TEDR and SR groups for tears <3 cm (P = .019) and tears >3 cm (P < .01) in favor of SR repair. At 6 weeks postoperation, no significant difference was seen in the mean VAS scores between the TEDR and SR groups (Table II). Post hoc testing did not show the groups to be statistically different at the 6-week time point (Fig. 6).

Combined results for all patients showed significant improvement in postoperative range of motion (all P < .001), with increase in median forward flexion (100° vs. 150°), abduction (90° vs. 145°), internal rotation (25° vs. 34°), and external rotation (30° vs. 79°). The differences among the 4 subgroups in ROM were statistically significant with respect to forward flexion (P < .001) and external rotation (P = .010) in favor of TEDR but not for abduction (P = .12) and internal rotation (P = .014). Patients with a tear >3 cm undergoing TEDR repair had the least mean postoperative forward flexion (146°); those with tears >3 cm and SR repairs had the least external rotation (60°). In discriminant analysis (Fig. 7), forward flexion was the main discriminator among patient groups (Wilks lambda: 0.45, P < .001).

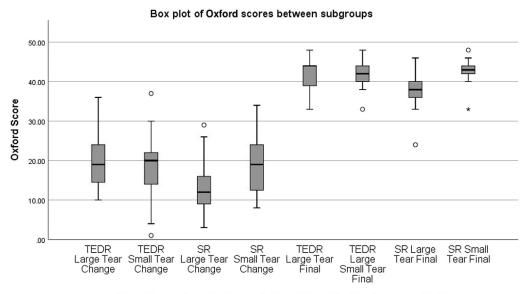
A significant overall improvement was observed in the EQ-5D in the whole cohort (P < .001). At 3 years postrepair, EQ-5D scores were significantly improved in patients with tears >3 cm who underwent TEDR repair than those who underwent SR repair. This was in contrast to

	SR			TEDR		
	Tear <3 cm	Tear $>$ 3 cm	Total	Tear <3 cm	Tear $>$ 3 cm	Total
Postoperative functional score						
OSS	$\textbf{42.8}\pm\textbf{3.0}$	$\textbf{38.05} \pm \textbf{4.5}$	40.5 \pm 3.8	$\textbf{41.5} \pm \textbf{3.6}$	$\textbf{41.7} \pm \textbf{4.4}$	$\textbf{41.6} \pm \textbf{4.0}$
UCLA	$\textbf{32.1} \pm \textbf{2.2}$	$\textbf{29.76} \pm \textbf{2.4}$	$\textbf{31.0} \pm \textbf{2.3}$	$\textbf{31.1} \pm \textbf{1.9}$	$\textbf{31.7} \pm \textbf{2.5}$	$\textbf{31.3} \pm \textbf{2.2}$
CMS	$\textbf{84.5} \pm \textbf{11.0}$	74.2 \pm 5.7	79.4 \pm 8.3	$\textbf{72.8} \pm \textbf{10.1}$	$\textbf{82.3} \pm \textbf{8.8}$	$\textbf{77.6} \pm \textbf{9.4}$
VAS (100-mm scale)	$\textbf{13.7} \pm \textbf{16.9}$	$\textbf{13.1} \pm \textbf{7.4}$	$\textbf{13.4} \pm \textbf{12.2}$	$\textbf{12.1} \pm \textbf{14.6}$	$\textbf{12.7} \pm \textbf{12.5}$	$\textbf{12.2} \pm \textbf{13.6}$
Mean improvement from the						
preoperative score						
OSS	$\textbf{18.11} \pm \textbf{7.24}$	$\textbf{12.85} \pm \textbf{6.11}$	$\textbf{15.48} \pm \textbf{6.68}$	$\textbf{18.35} \pm \textbf{8.75}$	19.7 \pm 6.89	$\textbf{19.03} \pm \textbf{7.82}$
UCLA	$\textbf{13.47} \pm \textbf{5.27}$	$\textbf{14.90} \pm \textbf{4.29}$	$\textbf{14.19} \pm \textbf{4.78}$	$\textbf{15.24} \pm \textbf{5.01}$	$\textbf{15.83} \pm \textbf{3.55}$	$\textbf{15.54} \pm \textbf{4.28}$
CMS	$\textbf{25.84} \pm \textbf{19.89}$	$\textbf{28.76} \pm \textbf{14.79}$	$\textbf{27.3} \pm \textbf{17.34}$	$\textbf{26.06} \pm \textbf{15.85}$	$\textbf{33.78} \pm \textbf{17.25}$	$\textbf{29.92} \pm \textbf{15.55}$
VAS (100-mm scale)	$\textbf{49.42} \pm \textbf{22.6}$	$\textbf{58.33} \pm \textbf{17.94}$	$\textbf{53.88} \pm \textbf{20.27}$	$\textbf{55.13} \pm \textbf{23.77}$	$\textbf{57.76} \pm \textbf{22.85}$	$\textbf{56.45} \pm \textbf{23.31}$

Table II The mean postoperative functional and pain scores and their mean improvement from the preoperative scores

SR, single-row; TEDR, transosseous-equivalent double-row; CMS, Constant-Murley score; OSS, Oxford Shoulder Score; UCLA, University of California, Los Angeles.

Values are mean \pm standard deviation.



Mean Change in Oxford score (left) and Mean Final Review score (right)

Figure 3 Box and whiskers summary of OSS change in the 2 groups. *Circles* and *stars* represent outliers. *TEDR*, transosseous equivalent double row; *SR*, single row.

patients with tears <3 cm, among whom the EQ-5D scores were significantly improved those who underwent SR repair compared with TEDR repair (P = .005) (Fig. 8).

Complications

There were 2 cases (1 in the TEDR group and 1 in the SR group) of superficial infection, both of which were successfully treated with oral antibiotics. One male patient aged 55 years had a recurrent full-thickness tear at 12 months postoperatively, following an SR repair of a large

supraspinatus tear >3 cm in length. He underwent a revision arthroscopy and augmented revision repair with the use of an extracellular dermal matrix allograft.³⁹ We did not routinely perform MRI scans in asymptomatic patients to confirm repair integrity.

Discussion

In the current trial, combined results for all patients showed significant improvement in postoperative range of motion.

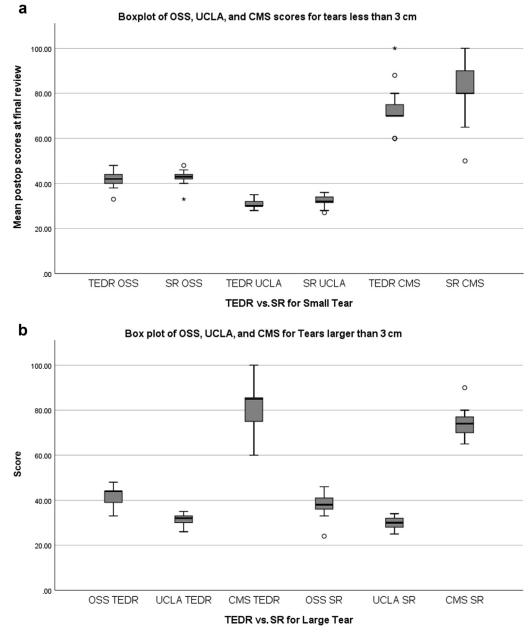


Figure 4 Box and whiskers summary of functional scores change in the 2 groups. (a) Scores for small tears. (b) Scores for large tears. *Circles* and *stars* represent outliers. *OSS*, Oxford Shoulder Score; *UCLA*, University of California, Los Angeles; *CMS*, Constant-Murley score; *postop*, postoperation; *TEDR*, transosseous equivalent double row; *SR*, single-row.

Smaller tears did not appear to be influenced significantly by SR or TEDR techniques and only showed a statistically significant difference when comparing mean postoperative Constant scores. When comparing the mean improvement in functional scores rather than the mean score itself, no significant difference was seen for tears less than 3 cm. TEDR only yielded superior improvement in clinical outcomes when compared with SR in large tears of 3 cm or larger.

The mean number of anchors used was significantly higher in TEDR repairs compared with SR repairs. There was also a significant difference in the length of hospital stay and operative time. SR was favorable in terms of immediate postoperative pain, although a significant difference in VAS scores was not seen at 6 weeks between groups. Without a clear advantage for TEDR for smaller tears, SR could be considered based on initial postoperative pain and resource use, but a recommendation based on optimizing functional outcome cannot be made from our study.

For tears larger than 3 cm, TEDR yielded a significantly better outcome, reflected most by the significant difference in improvement from pre- to postoperative functional

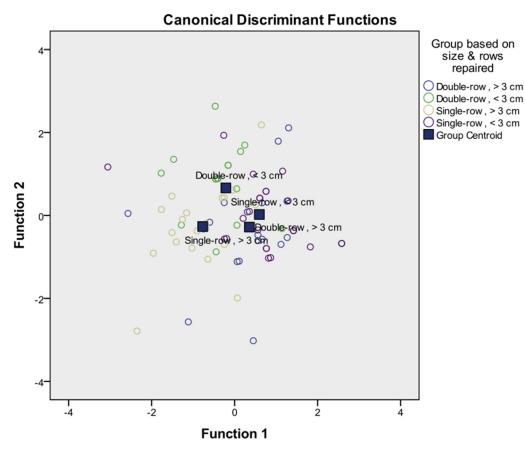


Figure 5 Scatter plot of the results of discriminant function analysis, showing the distribution of individual observations and of the group centroids. The single-row, >3-cm group is best discriminated through function 1 (mostly dependent on OSS) from 2 patient groups and through function 2 (mostly dependent on CMS) from the fourth group. *OSS*, Oxford Shoulder Score; *CMS*, Constant-Murley score.

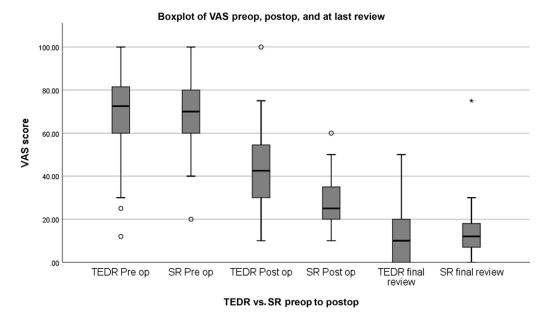


Figure 6 Box and whiskers summary of VAS scores in different subgroups preoperatively compared to those postoperatively and at final follow-up. *Circles* and *stars* represent outliers. *VAS*, visual analog scale; *preop*, preoperation; *postop*, postoperation; *TEDR*, transosseous equivalent double row; *SR*, single-row.

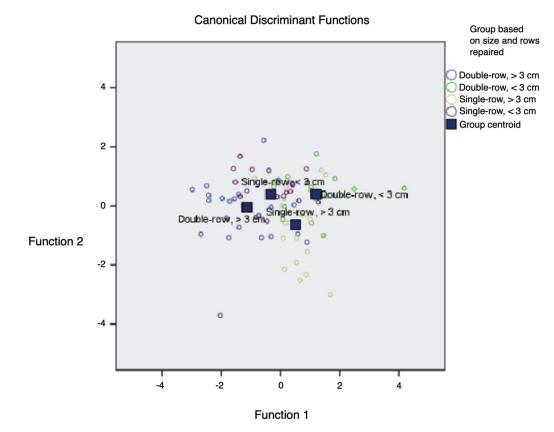


Figure 7 Scatter plot of the results of discriminant function analysis, showing the distribution of individual observations and of the group centroids. The TEDR, >3-cm group is best discriminated through function 1 (mostly dependent on forward flexion) from the remaining patient groups. Function 2 (dependent on external rotation) discriminates the groups to a lesser extent. *TEDR*, transosseous equivalent double row.

scores. All functional scores were in agreement for a significant improvement in mean score for the TEDR group and we recommend, in agreement of Samitier and Calvo,⁴⁸ a TEDR repair for large tears over SR repair.

Hantes et al²⁶ prospectively compared the radiologic and clinical midterm results between SR and DR suture bridge fixation techniques for arthroscopic rotator cuff repair in patients younger than 55 years and concluded, in agreement of our study, that the double-row repair technique potentially provides superior tendon healing. Gartsman et al²³ reported a significantly higher tendon healing rate (as determined by ultrasonographic examination) when using an arthroscopic transosseous equivalent double-row repair of an isolated supraspinatus rotator cuff tear compared with arthroscopic single-row repair. Similarly, Toussaint et al⁵² demonstrated significant improvement in CMS, pain score, and forward elevation for patients with small, large, and massive tears.

The purported advantage of the TEDR technique over the standard DR is the capability to provide compression through the footprint by increasing the contact area.^{34,35,44-46} This is achieved by connecting the medial and lateral rows, thus wielding compression throughout the repair, instead of only at the anchor insertion points.²⁸ The advantages of the TEDR

technique may explain the significant results found in our study compared with SR.

Only 2 previous Level I studies^{15,24} have examined patient satisfaction after arthroscopic rotator cuff repair. Both showed no statistically significant difference between the groups, with no significant differences in the rate of return to work. Similarly, Franceschi et al²¹ reported, in agreement of our study, that the operative time was significantly longer with the DR repair than the SR repair.

We report 1 case of superficial infection in each of the 2 groups, who were managed with antibiotic therapy alone. Park et al⁴³ reported 2 patients with wound infection in the single-row repair group. They also detected 1 case of suture anchor pullout in the SR group.

Toussaint et al⁵² demonstrated 14% failure of their rotator cuff repair. Mihata et al³⁷ documented 10.8%, 26.1%, and 4.7% retear rates after SR, DR, and compression DR techniques, respectively, indicating that the TEDR technique decreased the retear rate for large and massive tears above SR and DR techniques. The combination of the double-row and suture-bridge techniques had the lowest rate of postoperative retear and led to superior clinical outcomes. Only 1 patient with a recurrent tear after repair of a massive tear with single-row technique underwent a

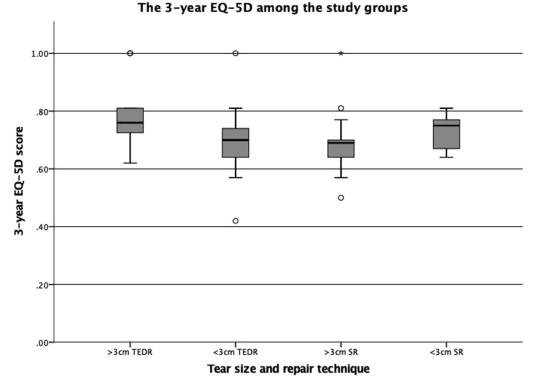


Figure 8 Box and whiskers summary of EQ-5D scores in different subgroups. *Circles* and *stars* represent outliers. *TEDR*, transosseous equivalent double row; *SR*, single-row.

revision surgery after 1 year and, correspondingly, we established clinical superiority of the TEDR technique in repair of large tears.

Bishop et al¹¹ reported that large tears have twice the retear rate after arthroscopic repair. Similarly, a 40% retear rate in their group of patients with massive tear was reported by Sugaya et al,⁵¹ compared with a 5% retear rate in the patients with small to medium tears. Galatz et al²² demonstrated a high percentage of 89% retear rate in patients with massive rotator cuff tears.

Strength and limitations of the current study

The strength of our study includes the fact that we had 100% follow-up in an adequately powered prospective randomized clinical trial. We also applied 3 different shoulder-scoring systems and 1 validated score for quality of life assessment to evaluate the study population.

There are limitations to this study; first, we did not obtain follow-up MRI scans to assess the integrity of the rotator cuff repairs. This was not possible because of the associated costs and the high demand for this imaging study at our institution. We only undertook MRI scans in symptomatic patients.

A comparison of patients who were nonoperatively managed or who had a standard DR technique would add value to compare the natural history with surgical therapy and to show if TEDR is clearly superior to DR, or if the significant results were achieved through adequate power.

It is possible that longer follow-up would have been of value; however, as soft tissue healing can be considered to be complete by 12 months,⁴⁰ 36 months would be a sufficient follow-up period.

Although a power analysis was performed to determine the size of the overall study, it was underpowered to account for the difference between the subgroups based on tear size and type of repair. However, we achieved an evidence of superiority of TEDR repair in large tears.

Finally, we recommend further larger, multicenter, welldesigned randomized clinical trials to verify our findings.

Conclusions

Our hypothesis that double-row fixation yields superior functional and quality-of-life outcomes compared with single-row lateral fixation was not supported. However, the transosseous-equivalent double-row cuff repair showed superior functional outcomes in repair of large rotator cuff tears >3 cm. TEDR is associated with increased postoperative pain, prosthetic and time-related costs, and longer hospital admissions.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

References

- Abdelshahed M, Mahure SA, Kaplan DJ, Mollon B, Zuckerman JD, Kwon YW, et al. Arthroscopic rotator cuff repair: double-row transosseous equivalent suture bridge technique. Arthrosc Tech 2016;5: e1297-304. https://doi.org/10.1016/j.eats.2016.07.022
- Abtahi AM, Granger EK, Tashjian RZ. Factors affecting healing after arthroscopic rotator cuff repair. World J Orthop 2015;6:211-20. https:// doi.org/10.5312/wjo.v6.i2.211
- Accousti KJ, Flatow EL. Technical pearls on how to maximize healing of the rotator cuff. Instr Course Lect 2007;56:3-12.
- Ahmad CS, Levine WN, Bigliani LU. Arthroscopic rotator cuff repair. Orthopedics 2004;27:570-4.
- Aleem AW, Syed UA, Wascher J, Zoga AC, Close K, Abboud JA, et al. Functional outcomes after bilateral arthroscopic rotator cuff repair. J Shoulder Elbow Surg 2016;25:1668-73. https://doi.org/10.1016/j.jse. 2016.01.027
- Almazan A, Nieves J, Patino P, Ruiz M, Cruz F, Perez FX, et al. Engaging needles: a simple technique for arthroscopic side-to-side rotator cuff repair. Arthroscopy 2006;22:456.e1-3. https://doi.org/10. 1016/j.arthro.2005.11.005
- American Academy of Orthopaedic Surgeons. Joint motion: method of measuring and recording. Chicago, IL: American Academy of Orthopaedic Surgeons; 1965.
- Aydin N, Kocaoglu B, Guven O. Single-row versus double-row arthroscopic rotator cuff repair in small- to medium-sized tears. J Shoulder Elbow Surg 2010;19:722-5. https://doi.org/10.1016/j.jse. 2009.11.053
- Barnes LA, Kim HM, Caldwell JM, Buza J, Ahmad CS, Bigliani LU, et al. Satisfaction, function and repair integrity after arthroscopic versus mini-open rotator cuff repair. Bone Joint J 2017;99-B:245-9. https://doi.org/10.1302/0301-620X.99B2.BJJ-2016-0055.R1
- Bhatia S, Piasecki DP, Nho SJ, Romeo AA, Cole BJ, Nicholson GP, et al. Early return to work in workers' compensation patients after arthroscopic full-thickness rotator cuff repair. Arthroscopy 2010;26: 1027-34. https://doi.org/10.1016/j.arthro.2009.12.016
- Bishop J, Klepps S, Lo IK, Bird J, Gladstone JN, Flatow EL. Cuff integrity after arthroscopic versus open rotator cuff repair: a prospective study. J Shoulder Elbow Surg 2006;15:290-9. https://doi.org/ 10.1016/j.jse.2005.09.017
- Buess E, Steuber KU, Waibl B. Open versus arthroscopic rotator cuff repair: a comparative view of 96 cases. Arthroscopy 2005;21:597-604. https://doi.org/10.1016/j.arthro.2005.01.002
- Burkhart SS, Lo IK. Arthroscopic rotator cuff repair. J Am Acad Orthop Surg 2006;14:333-46. https://doi.org/10.5435/00124635-200606000-00003
- Carbonel I, Martinez AA, Calvo A, Ripalda J, Herrera A. Single-row versus double-row arthroscopic repair in the treatment of rotator cuff tears: a prospective randomized clinical study. Int Orthop 2012;36: 1877-83. https://doi.org/10.1007/s00264-012-1559-9
- 15. Charousset C, Grimberg J, Duranthon LD, Bellaiche L, Petrover D. Can a double-row anchorage technique improve tendon healing in arthroscopic rotator cuff repair?: A prospective, nonrandomized, comparative study of double-row and single-row anchorage techniques

with computed tomographic arthrography tendon healing asses. Am J Sports Med 2007;35:1247-53. https://doi.org/10.1177/0363546507301661

- Chillemi C, Petrozza V, Garro L, Sardella B, Diotallevi R, Ferrara A, et al. Rotator cuff re-tear or non-healing: histopathological aspects and predictive factors. Knee Surg Sports. Traumatol Arthrosc 2011;19: 1588-96. https://doi.org/10.1007/s00167-011-1521-1
- Cho NS, Yi JW, Lee BG, Rhee YG. Retear patterns after arthroscopic rotator cuff repair: single-row versus suture bridge technique. Am J Sports Med 2010;38:664-71. https://doi.org/10.1177/ 0363546509350081
- Choi S, Kim MK, Kim GM, Roh YH, Hwang IK, Kang H. Factors associated with clinical and structural outcomes after arthroscopic rotator cuff repair with a suture bridge technique in medium, large, and massive tears. J Shoulder Elbow Surg 2014;23:1675-81. https://doi. org/10.1016/j.jse.2014.02.021
- Colvin AC, Egorova N, Harrison AK, Moskowitz A, Flatow EL. National trends in rotator cuff repair. J Bone Joint Surg Am 2012;94: 227-33. https://doi.org/10.2106/JBJS.J.00739
- Duquin T, Buyea C, Bisson L. Which method of rotator cuff repair leads to the highest rate of structural healing? A systematic review. Am J Sports Med 2010;38:835-41. https://doi.org/10.1177/ 0363546509359679
- Franceschi F, Ruzzini L, Longo UG, Martina FM, Zobel BB, Maffulli N, et al. Equivalent clinical results of arthroscopic single-row and double-row suture anchor repair for rotator cuff tears: a randomized controlled trial. Am J Sports Med 2007;35:1254-60. https:// doi.org/10.1177/0363546507302218
- 22. Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. J Bone Joint Surg Am 2004;86:219-24. https://doi.org/10.2106/00004623-200402000-00002
- Gartsman GM, Drake G, Edwards TB, Elkousy HA, Hammerman SM, O'Connor DP, et al. Ultrasound evaluation of arthroscopic fullthickness supraspinatus rotator cuff repair: single-row versus doublerow suture bridge (transosseous equivalent) fixation. Results of a prospective, randomized study. J Shoulder Elbow Surg 2013;22:1480-7. https://doi.org/10.1016/j.jse.2013.06.020
- Grasso A, Milano G, Salvatore M, Falcone G, Deriu L, Fabbriciani C. Single-row versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy 2009;25:4-12. https:// doi.org/10.1016/j.arthro.2008.09.018
- 25. Gudex C. The descriptive system of the EuroQOL instrument. In: Kind P, Brooks R, Rabin R, editors. EQ-5D concepts and methods: a developmental history. Berlin: Springer; 2005. p. 19-27.
- Hantes ME, Ono Y, Raoulis VA, Doxariotis N, Venouziou A, Zibis A, et al. Arthroscopic single-row versus double-row suture bridge technique for rotator cuff tears in patients younger than 55 years: a prospective comparative study. Am J Sports Med 2018;46:116-21. https:// doi.org/10.1177/0363546517728718
- Ide J, Maeda S, Takagi K. A comparison of arthroscopic and open rotator cuff repair. Arthroscopy 2005;21:1090-8. https://doi.org/10. 1016/j.arthro.2005.05.010
- Imam MA, Abdelkafy A. Outcomes following arthroscopic transosseous equivalent suture bridge double row rotator cuff repair: a prospective study and short-term results. SICOT J 2016;2:7. https:// doi.org/10.1051/sicotj/2015041
- Jost B, Zumstein M, Pfirrmann CW, Gerber C. Long-term outcome after structural failure of rotator cuff repairs. J Bone Joint Surg Am 2006;88:472-9. https://doi.org/10.2106/JBJS.E.00003
- Kim DH, Elattrache NS, Tibone JE, Jun BJ, DeLaMora SN, Kvitne RS, et al. Biomechanical comparison of a single-row versus double-row suture anchor technique for rotator cuff repair. Am J Sports Med 2006;34:407-14. https://doi.org/10.1177/ 0363546505281238

- Kim JH, Hong IT, Ryu KJ, Bong ST, Lee YS, Kim JH. Retear rate in the late postoperative period after arthroscopic rotator cuff repair. Am J Sports Med 2014;42:2606-13. https://doi.org/10.1177/ 0363546514547177
- Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. Arthroscopy 2003;19:1109-20. https://doi. org/10.1016/j.arthro.2003.10.030
- Le BTN, Wu XL, Lam PH, Murrell GAC. Factors predicting rotator cuff retears: an analysis of 1000 consecutive rotator cuff repairs. Am J Sports Med 2014;42:1134-42. https://doi.org/10.1177/ 0363546514525336
- Lee TQ. Current biomechanical concepts for rotator cuff repair. Clin Orthop Surg 2013;5:89-97. https://doi.org/10.4055/cios.2013.5.2.89
- Longo UG, Franceschi F, Berton A, Maffulli N, Denaro V. Arthroscopic transosseous rotator cuff repair. Med Sport Sci 2012;57:142-52. https://doi.org/10.1159/000328900
- Ma CB, Comerford L, Wilson J, Puttlitz CM. Biomechanical evaluation of arthroscopic rotator cuff repairs: double-row compared with single-row fixation. J Bone Joint Surg Am 2006;88:403-10. https://doi. org/10.2106/JBJS.D.02887
- 37. Mihata T, Watanabe C, Fukunishi K, Ohue M, Tsujimura T, Fujiwara K, et al. Functional and structural outcomes of single-row versus double-row versus combined double-row and suture-bridge repair for rotator cuff tears. Am J Sports Med 2011;39:2091-8. https://doi.org/10.1177/0363546511415660
- Millett PJ, Warth RJ, Dornan GJ, Lee JT, Spiegl UJ. Clinical and structural outcomes after arthroscopic single-row versus double-row rotator cuff repair: a systematic review and meta-analysis of level I randomized clinical trials. J Shoulder Elbow Surg 2014;23:586-97. https://doi.org/10.1016/j.jse.2013.10.006
- Narvani AA, Imam MA, Polyzois I, Sarkhel T, Gupta R, Levy O, et al. The "pull-over" technique for all arthroscopic rotator cuff repair with extracellular matrix augmentation. Arthrosc Tech 2017;6:e679-87. https://doi.org/10.1016/j.eats.2016.11.007
- Nho SJ, Adler RS, Tomlinson DP, Allen AA, Cordasco FA, Warren RF, et al. Arthroscopic rotator cuff repair: prospective evaluation with sequential ultrasonography. Am J Sports Med 2009;37: 1938-45. https://doi.org/10.1177/0363546509335764
- Nho SJ, Yadav H, Pensak M, Dodson CC, Good CR, MacGillivray JD. Biomechanical fixation in arthroscopic rotator cuff repair. Arthroscopy 2007;23:94-102, 102.e1. https://doi.org/10.1016/j.arthro.2006.10.010
- 42. Olley LM, Carr AJ. The use of a patient-based questionnaire (the Oxford Shoulder Score) to assess outcome after rotator cuff repair. Ann R Coll Surg Engl 2008;90:326-31. https://doi.org/10.1308/ 003588408X285964

- Park JY, Lhee SH, Choi JH, Park HK, Yu JW, Seo JB. Comparison of the clinical outcomes of single- and double-row repairs in rotator cuff tears. Am J Sports Med 2008;36:1310-6. https://doi.org/10.1177/ 0363546508315039
- 44. Park MC, Elattrache NS, Ahmad CS, Tibone JE. "Transosseousequivalent" rotator cuff repair technique. Arthroscopy 2006;22:1360. e1-5. https://doi/org/10.1016/j.arthro.2006.07.017
- 45. Park MC, ElAttrache NS, Tibone JE, Ahmad CS, Jun BJ, Lee TQ. Part I: Footprint contact characteristics for a transosseous-equivalent rotator cuff repair technique compared with a double-row repair technique. J Shoulder Elbow Surg 2007;16:461-8. https://doi.org/10.1016/ j.jse.2006.09.010
- 46. Park MC, Tibone JE, ElAttrache NS, Ahmad CS, Jun BJ, Lee TQ. Part II: Biomechanical assessment for a footprint-restoring transosseousequivalent rotator cuff repair technique compared with a double-row repair technique. J Shoulder Elbow Surg 2007;16:469-76. https://doi. org/10.1016/j.jse.2006.09.011
- 47. Rocourt MH, Radlinger L, Kalberer F, Sanavi S, Schmid NS, Leunig M, et al. Evaluation of intratester and intertester reliability of the Constant-Murley shoulder assessment. J Shoulder Elbow Surg 2008;17:364-9. https://doi.org/10.1016/j.jse.2007.06.024
- 48. Samitier G, Calvo E. Double row rotator cuff transosseous equivalent repair. In: Imhoff AB, Savoie FH III, editors. Rotator cuff across the life span. Berlin: Springer; 2019. p. 165-74.
- Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials (Chinese version). Zhong Xi Yi Jie He Xue Bao 2010;8:604-12 [in Chinese]. https://doi.org/10.3736/jcim201007025
- Smith CD, Alexander S, Hill AM, Huijsmans PE, Bull AM, Amis AA, et al. A biomechanical comparison of single and double-row fixation in arthroscopic rotator cuff repair. J Bone Joint Surg Am 2006;88: 2425-31. https://doi.org/10.2106/JBJS.E.00697
- Sugaya H, Maeda K, Matsuki K, Moriishi J. Repair integrity and functional outcome after arthroscopic double-row rotator cuff repair. A prospective outcome study. J Bone Joint Surg Am 2007;89:953-60. https://doi.org/10.2106/JBJS.F.00512
- Toussaint B, Schnaser E, Bosley J, Lefebvre Y, Gobezie R. Early structural and functional outcomes for arthroscopic double-row transosseous-equivalent rotator cuff repair. Am J Sports Med 2011; 39:1217-25. https://doi.org/10.1177/0363546510397725
- 53. Weiler A, Hoffmann RF, Bail HJ, Rehm O, Sudkamp NP. Tendon healing in a bone tunnel. Part II: Histologic analysis after biodegradable interference fit fixation in a model of anterior cruciate ligament reconstruction in sheep. Arthroscopy 2002;18:124-35. https:// doi.org/10.1053/jars.2002.30657