

SECTION II

ORIGINAL ARTICLES

A Novel Double-row Rotator Cuff Repair Exceeds Strengths of Conventional Repairs

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Double-row rotator cuff repairs are becoming popular because of their ability to improve initial ultimate failure load for full-thickness rotator cuff tears, especially in middle-aged to elderly patients. We hypothesized a quasi-double-row repair using a combination of transosseous sutures, anchors, and double knots (TOAK technique) would exceed the clinically relevant 250-N load threshold and the initial mean ultimate failure loads of anchor-only and transosseous suture-only fixation. In simulated full-thickness supraspinatus tears in cadavers (mean age, 62 years; range, 50–77 years), failure loads of two repair techniques were compared with a TOAK repair using sutures and bioabsorbable anchors. Radiographic densitometry was conducted on all humeral heads. Testing was performed at 6 mm per minute in 18 bones in the following three groups (n = 6 per group): (1) transosseous suture-only with weave-type stitch and single-knot fixation; (2) anchor-only with horizontal mattress stitch and single-knot fixation; and (3) TOAK. The mean ultimate failure load was 238 N for the transosseous suture-only group and 215 N for the anchor-only group. Although the bones had lower density, TOAK specimens failed at 55% to 67% higher loads (mean, 404 N) than the other groups. These data support further evaluation of the TOAK technique for full-thickness supraspinatus tears in middle-aged to elderly patients.

Double-row rotator cuff repairs are becoming popular because of their ability to improve initial ultimate failure load of repaired full-thickness tears.^{13,24–26,38} Because it takes many weeks to achieve mechanically strong tendon-to-bone healing,²³ the initial ultimate failure load of the surgical repair is important in determining when active motion can be started.^{6,11,15,17,36,39} Commonly used methods for repairing a full-thickness rotator cuff tear include using suture anchors to reattach a tendon into a bony trough^{2,19,22,27,28} or the more conventional technique of using sutures through transosseous tunnels.^{14,16–19,21,30,34,40} Although all of the techniques can provide adequate tissue alignment, their initial mechanical integrity varies.^{18,19,27,28,30,34}

To improve the initial ultimate failure load of rotator cuff repairs, Gerber et al¹⁹ compared ultimate failure loads of several augmented and nonaugmented cuff repairs in a cadaveric model. The ultimate failure load of augmented double transosseous suture fixation (mean, 329 N) was 2.3 times greater than that of nonaugmented double transosseous fixation (mean, 146 N) and 2.3 times greater than that of double anchor-only fixation (mean, 142 N). However, augmented repairs have undesirable features (eg, nonabsorbable augmentation devices) and/or do not consistently provide ultimate failure loads that exceed the mean ultimate failure load of 329 ± 44 N that they reported for augmented double transosseous suture fixation.

Burkhead et al recently described a quasi-double-row technique for full-thickness supraspinatus tendon repairs, the transosseous anchor double-knot (TOAK) technique,¹⁰ that proved to have a greater mean ultimate failure load than that of repairs using permanent augmented devices reported by Gerber et al.¹⁹ However, a metal anchor, commonly used in this repair, can be associated with complications, such as progressive injury to the articular surface

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should migration and pullout occur.⁴² Additionally, evaluation of cuff integrity using MRI can be obscured by metal anchors.³² For these reasons, bioabsorbable anchors are becoming more commonly used in rotator cuff repairs. We therefore asked whether the TOAK technique using a bioabsorbable anchor, instead of the metal anchor, would withstand a mean ultimate failure load similar to that with the TOAK technique using the metal anchor and would thus have a greater mean ultimate failure load than current single-row rotator cuff repair techniques.

We hypothesized the initial ultimate failure load of the bioabsorbable-anchor TOAK construct would (1) consistently exceed 250 N, which corresponds to a clinically important ultimate failure load threshold (see description in Materials and Methods), and (2) substantially exceed the mean ultimate loads of transosseous suture-only fixation and anchor-only fixation. We also present additional findings of the failure modes of the TOAK construct.

MATERIALS AND METHODS

Eighteen fresh-frozen cadaver shoulders (10 female shoulders, eight male shoulders; mean age, 62 years; range, 50–77 years) were separated into three groups of six each for mechanical testing: Group 1, transosseous suture single-knot fixation; Group 2, metal-anchor single-knot fixation; and Group 3, transosseous bioabsorbable PANALOK[®] anchor (DePuy Mitek Corp, Norwood, MA) double-knot (TOAK) fixation, which combined the techniques in Groups 1 and 2. Results of a power analysis using previously published failure data from conventional and TOAK repairs¹⁰ showed a minimum of six specimens would be required in each group. Assuming an initial load of 230 ± 70 N (mean ± standard deviation) for each nonTOAK group (Groups 1 and 2) and a 60% greater load for the TOAK group (Group 3), or 368 ± 70 N, six specimens per group provided 83% power to detect this difference. Likewise, six specimens in the TOAK group provided 90% power to detect a mean load greater than a constant 250 N, assuming the population load was 368 ± 70 N. Both of these calculations are based on an alpha less than 0.05 (Type I error) and a two-sided comparison. A load of 250 N was selected as the minimum clinically relevant ultimate failure load based on previous biomechanical investigations of rotator cuff repairs.^{9,10,19,26} Twelve of the 18 bones used in our study (Groups 1 and 2) had been used in a previous study. Six of those 12 shoulders were from left-right pairs, leaving six unpaired

bones. The remaining six of the 18 bones used in our study (Group 3) were obtained subsequently; of these six bones, there were two left-right pairs, leaving two unpaired bones. We found no age differences in the specimens in the three experimental groups (Table 1).

Each shoulder was dissected to expose the rotator cuff muscles and tendons. The supraspinatus muscle was dissected subperiosteally from the supraspinous fossa, and the glenohumeral joint was disarticulated. None of the specimens exhibited gross evidence of rotator cuff disease. However, one specimen showed minor arthritic changes but without deformity of the humeral head. With the exception of the supraspinatus muscle and its humeral insertion, all soft tissues from the proximal 25 cm of the humerus were removed. The supraspinatus tendon was detached from its insertion into the greater tuberosity; this represented a full-thickness rotator cuff tear measuring 3 to 3.5 cm in anteroposterior (AP) breadth. Specimens were stored frozen in towels moistened with normal saline.

A simple radiographic densitometry method was used to help detect density differences between the test groups and allowed for comparisons with Gerber et al.¹⁹ The rationale for this method was derived from Gerber et al,¹⁹ and our use of it in this context also was based on a method for determining bone quality and load-carrying capacity of the proximal femur.⁵

Anteroposterior radiographs were obtained of each specimen oriented with neutral version³⁵ with an aluminum step-wedge for standardizing the densitometric measurements. The wedge consisted of 1-mm (± 0.001 mm) steps ranging from 6 to 14 mm. Densitometry measurements using a digital optical densitometer with a 2-mm-diameter aperture (TBX Densitometer, Tobias Associates Inc, Ivyland, PA) were made in five mutually exclusive locations of a 12- × 12-mm area in the central portion of the humeral head. The mean of these measurements was converted to millimeters of aluminum using a linear regression analysis from data of all aluminum steps in which, in all cases, r² values were greater than 0.995 and p values were less than 0.001. Average densitometric-determined millimeters of aluminum for each bone were normalized by dividing this number by the AP diameter of the humeral head. These normalized values provided a relative bone density score.

Using this radiographic bone density scoring method, the bones from the two nonTOAK groups had been sorted in a previous study so that they had similar bone density scores.¹⁰ However, the mean density score of the TOAK group was lower (p < 0.05) than those of the nonTOAK groups (Table 1).

To secure the humerus, a 6-cm-long and 0.47-mm-diameter threaded Steinmann pin was drilled transversely across the distal

TABLE 1. Intergroup Comparisons

Comparison	Age		Relative Bone Density		Maximum Load	
	% Difference	p Value	% Difference	p Value	% Difference	p Value
Suture-only versus anchor-only	-3%	> 0.1	5%	> 0.1	10%	> 0.1
TOAK-PANALOK [®] versus suture-only	-5%	> 0.1	-30%	< 0.05	55%	= 0.02
TOAK-PANALOK [®] versus anchor-only	-7%	> 0.1	-27%	< 0.05	67%	= 0.01

% difference = percent difference between group means; the signs of the comparisons (negative or positive) in the first row are made with respect to the suture-only group, whereas the signs in the second and third rows are made with respect to the TOAK-PANALOK[®] group; TOAK = transosseous anchor double knot

end of each bone, which had been cut transversely at midshaft. The cut end then was potted into a block of polymethylmethacrylate (Buehler Inc, Lake Bluff, IL). Using a 6-mm burr, a shallow, broad trough was made by an orthopaedic surgeon in the area of the supraspinatus insertion. The trough extended from 2 mm medial to the articular margin, laterally across the sulcus, to the medial edge of the proximal greater tuberosity (Fig 1). The medial-lateral breadth of the trough was approximately 12 to 14 mm. The trough extended across the AP breadth of the sulcus from the proximal aspect of the bicipital groove to 30 mm in the posterior direction. The trough also was deepened to slightly expose cancellous bone. The detached supraspinatus tendon of each bone then was reattached using one of three techniques.

In Group 1, the detached supraspinatus tendon was reattached using transosseous suture single-knot fixation. Using a power drill and a 2-mm-diameter drill bit, three holes were drilled in the sagittal plane formed by the long axis of the central portion of the trough. Three corresponding drill holes then were made in the proximolateral aspect of the greater tuberosity 1.0 to 1.5 cm lateral to the lateral edge of the trough. In each location (ie, trough and greater tuberosity), the centers of adjacent holes were separated by 1 cm. A curved grasping clamp (ie, a surgical towel clip) was used to make a transosseous tunnel between each pair

of holes. Three Number 2 Ethibond sutures (Ethicon Inc, Somerville, NJ) were inserted into the tendon 1 cm from its distal-most edge. The sutures were separated so that each could be tied over its corresponding pair of drill holes. These sutures then were weaved through the tendon using a modified Mason-Allen stitch (Fig 2) in accordance with Gerber et al.¹⁹ For each pair of holes, the suture strand from the deep surface of the tendon was passed through the transosseous tunnel and tied to the suture strand, which was passed over the superficial surface of the tendon. The strands were tied with a consistent series of knots (2 + 1 + 1 + 1).¹⁹

In Group 2, the detached supraspinatus tendon was reattached using metal-anchor single-knot fixation. Three Mitek Rotator Cuff suture anchors (Depuy Mitek) with Number 2 Ethibond (Ethicon) sutures were placed near the medial edge of the trough (near the anatomic location of the cartilage-bone junction) (Fig 3). The centers of adjacent anchors were separated 1 cm apart. The anchors were inserted into bone using predrilled holes as recommended by the manufacturer. The holes were drilled 45° to the long axis of the humeral shaft. These anchors were 2.9 mm in diameter with a 10.2-mm arch span after being set into bone. After insertion, the anchor was set by firmly pulling on its suture, which forced the anchor against the cortical bone by impacting

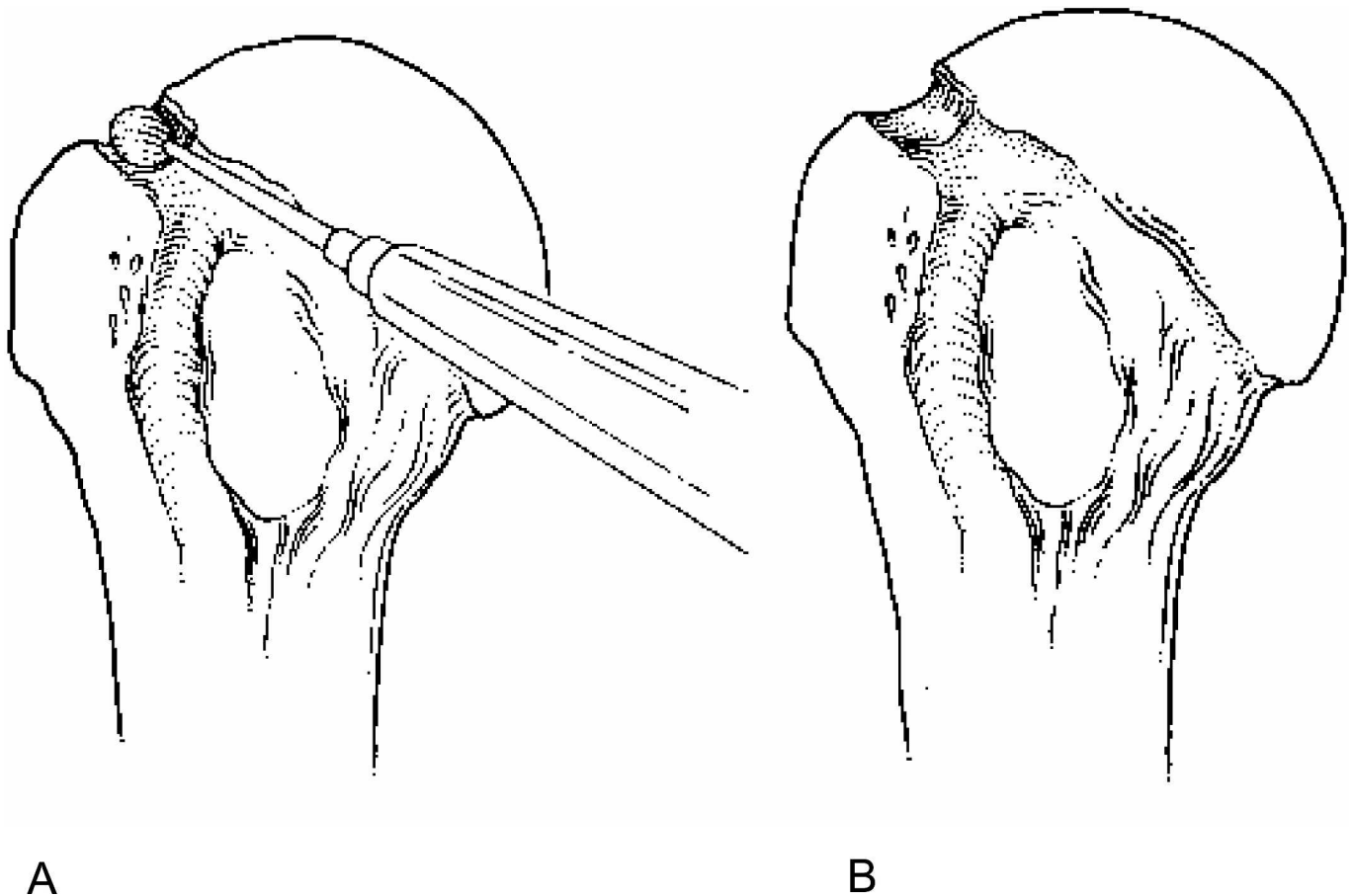


Fig 1A–B. The diagrams illustrate trough preparation in a proximal humerus. (A) A broad, shallow trough is prepared with a burr. (B) The medial edge of the trough extends beyond the cartilage-bone junction.

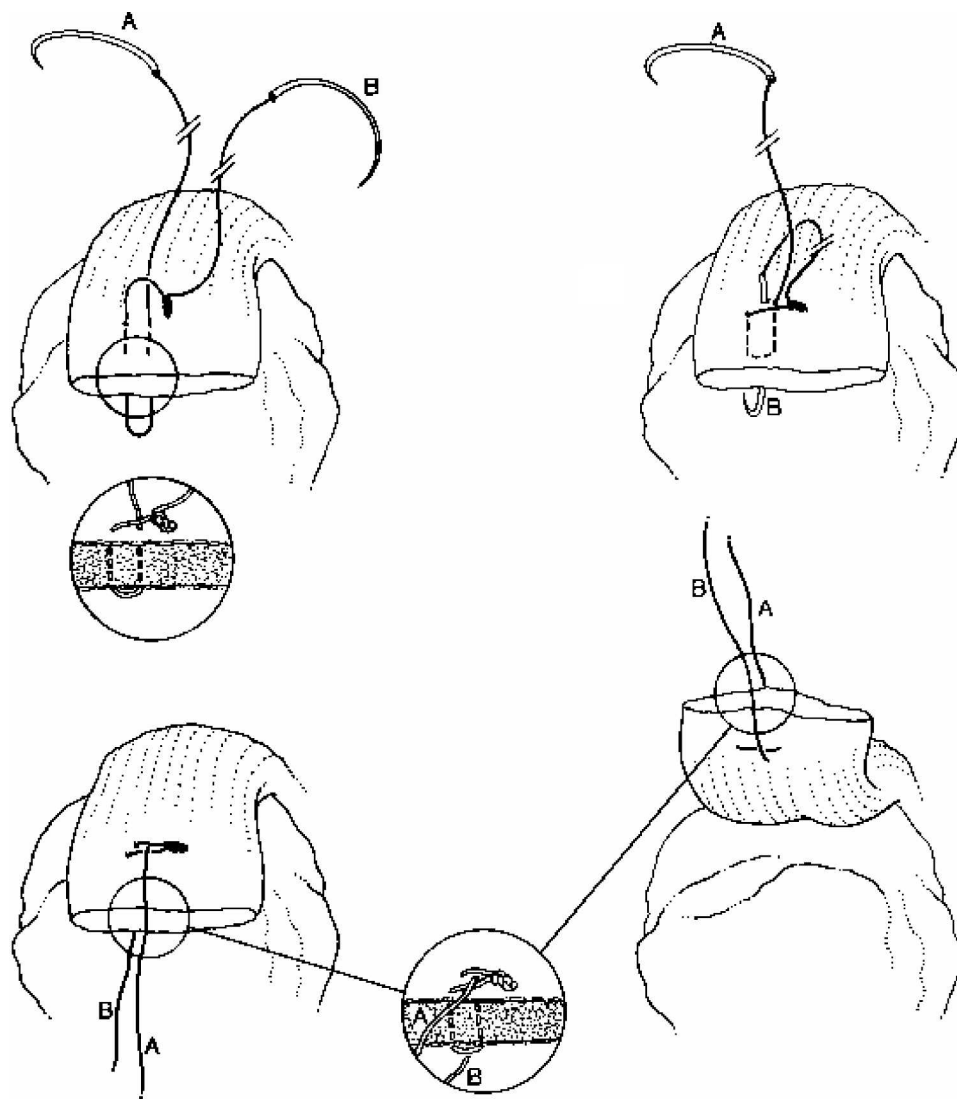


Fig 2. A modified Mason-Allen stitch used in the transosseous suture technique and in the TOAK technique is shown. For practical use in the applications used in our study, this stitch was modified from the Mason-Allen stitch described by Ellman and Gartsman.¹⁶

subcortical cancellous bone. The two suture strands from each anchor then were passed directly superiorly through the supraspinatus tendon 12 mm from its distal-most edge. The tendon was secured into the trough using a horizontal mattress stitch over each anchor using a consistent series of knots (2 + 1 + 1 + 1).

In Group 3, the detached supraspinatus tendon was reattached using the TOAK-PANALOK[®] technique. The tendons were secured into the trough using a combination of the techniques described previously for Groups 1 and 2. We drilled holes for suture anchors and corresponding pairs of holes for transosseous tunnels. As in Group 2, the suture strands from the anchors were passed directly in the superior direction through the tendon and tied securely using a horizontal mattress stitch (first knot). The suture strands then were weaved from this knot progressively

toward the distal edge of the tendon using a modified Mason-Allen stitch (Fig 2). The suture strand from the deep surface of the tendon then was passed through the transosseous tunnel and tied to the other suture strand (second knot), which had been passed over the superficial surface of the tendon (Fig 4). Both knots were tied with a consistent configuration (2 + 1 + 1 + 1).

Each specimen was tested to failure in tension using a servohydraulic test machine (Bionix 858, MTS Inc, Minneapolis, MN) with a 227.3-kg (2224-N) load cell. After fixing the muscle belly into the aluminum clamp, the clamp was attached to the crosshead of the machine (Fig 5). The potted end of the specimen was attached firmly to the base of the machine. Before testing, each specimen was preloaded in tension to 0.5 kg. Each specimen then was loaded in tension to failure by pulling the tendon

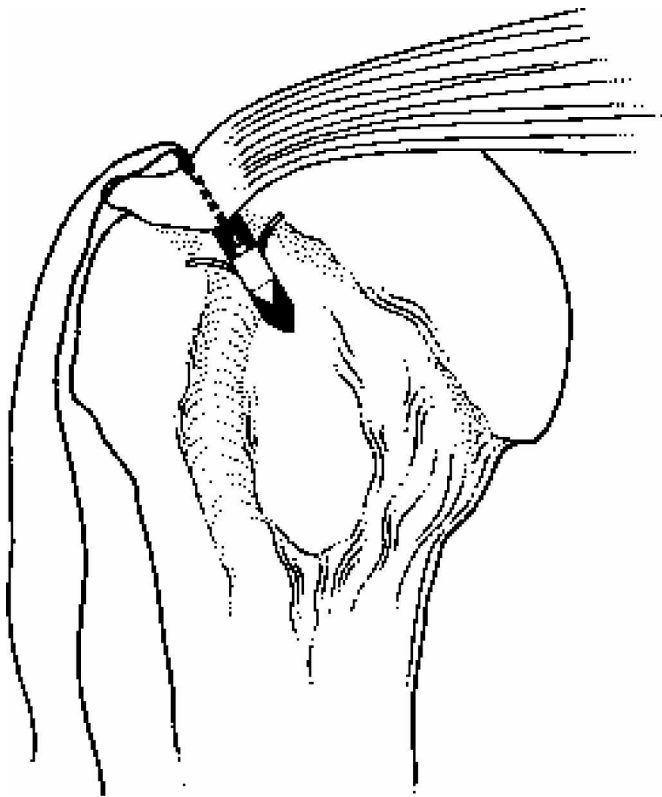


Fig 3. Anchor placement near the anatomic location of the cartilage-bone junction for fixation in the anchor-only technique and in the TOAK technique is shown. A metal anchor is shown in this illustration.

using stroke control at a rate of 6 mm per minute, which was at the upper end of the range of loading rates used by Gerber et al¹⁹ to test ultimate failure loads of sutures and cuff repairs.

We used a monotonic loading regime that was designed to simulate a low loading rate that occurs during passive and active-assisted motion allowed during the first 8 postoperative weeks of the rehabilitation program that we use for large full-thickness rotator cuff tears.³ The rationale for the relatively slow loading rate is as follows. First, the force exerted by the rotator cuff is an estimated 9.6 times the weight of the upper extremity.⁴¹ Assuming an average individual weighs approximately 80 kg and the supraspinatus represents $\frac{1}{4}$ of the maximum rotator cuff force of contraction, then application of a 100-N load will simulate passive elevation of the arm that occurs in an early motion rehabilitation program.²⁶ Second, others have used a force of 180 N based on an estimated $\frac{2}{3}$ of the load of a maximum contraction of the rotator cuff.^{9,39} Third, this range of loads in cyclically tested full-thickness rotator cuff repairs in cadavers results in complete failure when gap formation approaches 10 mm (eg, 3000 cycles at one cycle per second with a 100-N load approaches a 4-mm gap; 235 cycles at one cycle per 5.0 second with a 180-N load gaps 5–10 mm).^{8,26,31} (These in vitro estimates are required because there are no data yet available from in vivo animal or human clinical studies.) Finally, the average

rate of gap formation to rupture caused by 100- to 180-N loads is less than 1 mm per minute. Active-assisted motion rehabilitation programs would be expected to produce rates several times faster, consistent with the upper end of the 1 to 6 mm per minute range used by Gerber et al,¹⁹ but not the higher rates used to estimate active motion (greater than 30 mm per minute).^{9,12,26,31}

During testing, the direction of pull was in line with the long axis of the humeral shaft to simulate loading in 90° of abduction, which produces high stress in the supraspinatus tendon and represents a compromise between loading in a low arc of motion (less than 60° humeral abduction) and loading in a high arc of motion (greater than 120° humeral abduction).²⁹

Outputs of the load cell and crosshead were plotted on a chart recorder as load displacement curves. The point of failure was defined as the first peak or major deviation from linearity in the load displacement curve. Invariably, these failure loads were also peak failure loads. We did not analyze the displacement data because loosening, suture and tendon elongation, and pullout contributed to the total displacement. Failure modes were determined by three observers (JGS, PJO, WAP) who independently viewed a video of the repair constructs during testing and directly examined the repair constructs after testing. Each observer could describe the failure modes for each construct as the following: suture failure (breakage), anchor failure, suture pullout (suture cutting through bone in transosseous tunnel or in tendon), anchor pullout, failure at musculotendinous junction, and fracture.

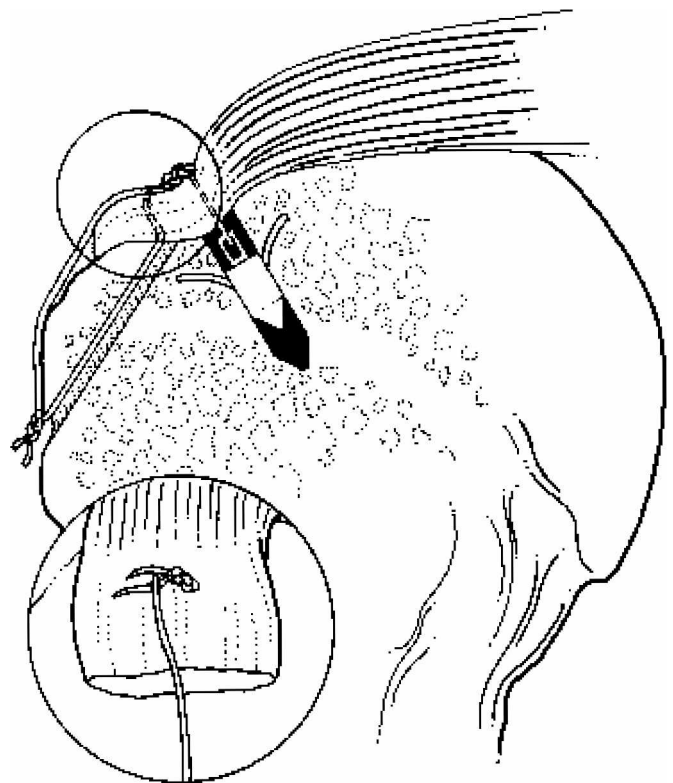


Fig 4. A diagram illustrates the TOAK fixation. The inset shows superficial suture of the transosseous component of the TOAK construct. A metal anchor is shown in this illustration.

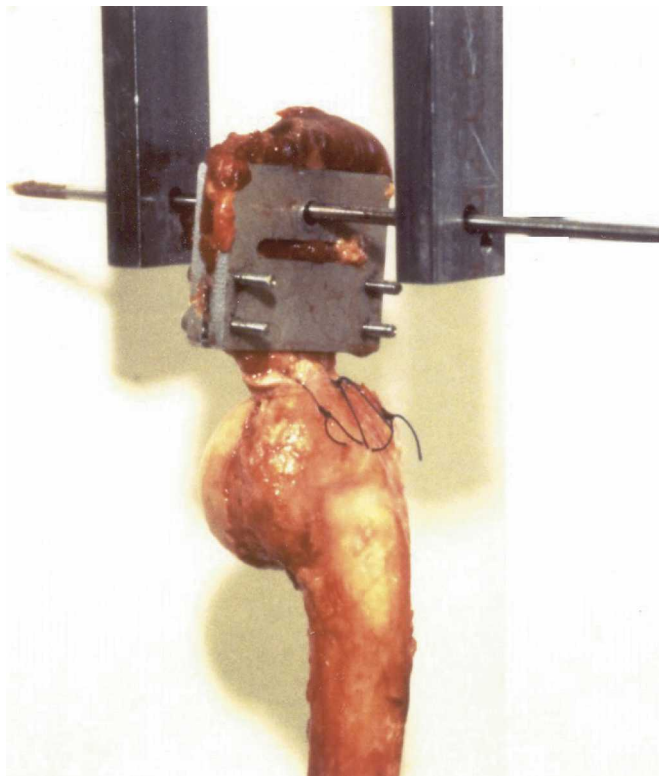


Fig 5. A photograph shows the clamp used for grasping the muscle belly near the musculotendinous junction.

Using a commercially available microcomputer statistical program (NCSS 6.0, Number Cruncher Statistical Systems, Kaysville, UT), data were tested for normality using several tests.³³ Differences between mean failure loads of the three groups were evaluated using the nonparametric Kruskal-Wallis multiple comparison z value test. Results are expressed as means \pm standard deviation.

RESULTS

The TOAK-PANALOK[®] technique failed at 404 ± 184 N, which exceeded the clinically important load threshold of 250 N (Fig 6). However, one of the TOAK specimens showed a failure load of 111 N, whereas the remaining TOAK specimens failed at loads exceeding 290 N. The ultimate failure loads of the transosseous suture-only fixation group (mean, 238 ± 68 N; range, 140–345 N) and the anchor-only fixation group (mean, 215 ± 82 N; range, 117–334 N) did not exceed the clinically important load threshold of 250 N.

The TOAK-PANALOK[®] technique exceeded the loads of the transosseous suture-only fixation group ($p = 0.02$) and the anchor-only fixation group ($p = 0.01$) (Fig 6; Table 1). The mean ultimate failure loads of the two non-TOAK groups were not substantially different ($p > 0.1$).

The TOAK group showed greater ultimate failure load even though the bones in this group had a lower mean bone density score than the two nonTOAK groups.

There was 100% agreement among the three observers regarding the failure modes of each of the specimens. One of the TOAK specimens failed at the musculotendinous junction (295 N), whereas the remaining five failed at the repair construct in the following specific ways: one suture cutting through the bone (613 N), one mechanical failure at the eyelet (518 N), one suture breakage (522 N), and one anchor pullout (361 N). The final TOAK specimen failed at 111 N, which was approximately 24% of the mean of the other five specimens ($111 \text{ N}/462 \text{ N}$). This low failure load was in the specimen that had mild arthritic changes. Retrospective qualitative gross examination of this specimen's radiograph also revealed it had relatively greater osteopenia in the greater tuberosity region than the other TOAK specimens. Excluding this specimen, the mean failure load of TOAK specimens was 462 ± 130 N.

DISCUSSION

Although increasing initial load is a primary goal of rotator cuff repair, minimizing complications from permanent devices is also important. Despite having a lower mean bone density score, the TOAK-PANALOK[®] repair had greater ultimate failure load than the other groups. In contrast to the nonTOAK repairs, the TOAK-PANALOK[®] repair usually, but not consistently (one exception), exceeded the clinically relevant failure threshold of 250 N and was 19% greater than the initial failure load of 329 ± 44 N reported by Gerber et al¹⁹ for augmented transosseous fixation tested at a similar slow rate of loading. These results pave the way for continuing investigation of TOAK techniques for enhancing fixation load when compromised bone density warrants double-row fixation.

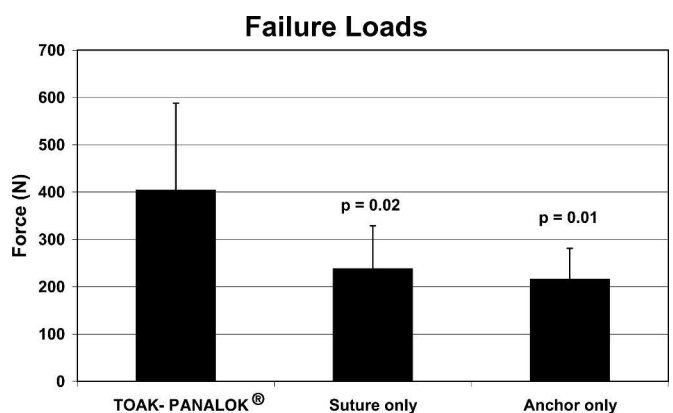


Fig 6. Maximum failure loads of each group are reported as means and standard deviations (bars). The p values indicate comparisons to the TOAK-PANALOK[®] group.

One study limitation is our use of radiographic densitometry to estimate humeral head density. Advanced techniques such as dual-energy xray absorptiometry (DEXA) scanning are finding increased use in this research. Although we did not perform DEXA analyses, clear benefits have been reported for using this or related technologies to determine regional osteopenia in the proximal humerus.^{20,37} Osteopenia in the region of the repair may be one reason why one TOAK specimen failed by anchor pullout at 24% lower load than the mean of the other five specimens. Additional studies that determine the influence of localized osteopenia on the mechanical competence of these cuff repairs are needed. Some investigators suggest simple abrasion of the bony surface is sufficient for preparing the footprint for cuff repair and a shallow trough for increasing blood flow at the cuff repair site is not necessary.^{1,12,31} Consequently, the shallow trough used in our study might be one reason why the anchor-only fixation showed lower failure loads.

Comparisons between our data and those of some previous investigations are limited by our use of a relatively slow loading rate (6 mm per minute). One reason for using this rate was to draw comparisons with results of Gerber et al¹⁹ who simulated clinically relevant slipping or creeping of the suture materials through the tendon fibers; they did not observe this behavior with rapid loading (Drs. Christian Gerber and Alberto Schneeberger, personal written communication). Slow loading rates, therefore, simulate failures that, when compared with rapid loading, would more likely occur during the first several postoperative weeks when passive or passive-assisted motion is emphasized.^{13,26} Although we also couched our study in this context, relatively faster loading rates (often greater than 30 mm per minute) have become popular in cadaveric testing of cuff repairs.^{13,24–26,38} In fact, some investigators who have emphasized the importance of cyclic regimes in testing cuff repairs in cadaver models consider monotonic loading a method that is not physiologic for testing the integrity of cuff repairs.⁹ We disagree with this opinion because relatively slower load rates probably are produced by the quasi-isometric muscle contractions that occur spontaneously and/or the passive or gentle active-assisted exercises that we allow during the phase of rehabilitation before substantial healing of the repair. Rapid loading in early rehabilitation, therefore, occurs in our patients as a result of accidents (eg, a fall) or noncompliance (eg, active lifting). For these reasons, we view slow and rapid monotonic testing as important considerations in research programs that focus on the comprehensive testing of a repair construct for the demands of early rehabilitation. Studies of cuff repairs in cadaveric models have similarly initiated biomechanical analyses of cuff repairs using monotonic load tests^{7,12,18,19,28,34} before they were tested with more

advanced loading protocols such as cyclic loading. We recognize relatively slow loading rates are less common in rehabilitation protocols that, unlike the one that we follow,³ include active and much earlier active-assisted motion.³⁰ Therefore, in the perspective of our rehabilitation program, testing at faster rates would be more clinically relevant 8 to 10 weeks postoperatively when we allow active motion. To evaluate the mechanical integrity of TOAK repairs during cyclic and a myriad of other accidental or physiologic loads, including accelerated active motion programs used by some surgeons that these repairs must endure before they heal, studies using rapid monotonic and various cyclic loading regimes are needed. Favorable results of our study pave the way for these future studies.

Some surgeons may view the fact that our TOAK technique is an open repair as an important limitation of our study because we state our technique is a quasi-double-row repair, which generally is performed arthroscopically. However, although TOAK repairs can be performed arthroscopically if a stitching device could place the Mason-Allen stitch distal to the mattress suture, one recent study showed open cuff repairs are more favored than arthroscopic repairs for tears greater than 3.0 cm,⁴ which is the size we simulated.

Another advantage of the TOAK technique is the compression of the distal-most tendon. In addition to enhancing load, this supplemental compression reduces the possibility that a flap of tendon could impinge beneath the acromion. Enhancing distal tendon apposition is referred to as edge stability and is considered important for achieving a mechanically competent repair.⁷ However, additional compression over the distal tendon might reduce blood flow required for timely and/or adequate healing. However, this seems unlikely in view of a recent cadaver study of contact pressures that showed single-row anchor and double-row anchor repairs were only 18% and 16% greater, respectively, than a transosseous repair, and there was no difference between these techniques.³⁸ The relatively broad surface provided by the TOAK technique for healing also more closely restores the footprint of the native tendon, which is the rationale for the increased interest in using double-row anchor repair techniques.^{13,24–26,38}

Our data obtained using a relatively slow load rate show the TOAK technique using bioabsorbable anchors has greater initial ultimate failure load than fixation using only metal anchors or only transosseous sutures.

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