Cyclic Loading of Anchor-Based Rotator Cuff Repairs: Confirmation of the Tension Overload Phenomenon and Comparison of Suture Anchor Fixation With Transosseous Fixation

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Summary: Previous experimental studies of failure of rotator cuff repair have involved single pull to ultimate load. Such an experimental design does not represent the cyclic loading conditions experienced in vivo. We created 1 x 2 cm rotator cuff defects in 16 cadaver shoulders, repaired each defect with three Mitek-RC suture anchors (Mitek Surgical Products, Inc, Westwood, MA) using simple sutures of No. 2 Ethibond, and cyclically loaded the repairs by a servohydraulic materials test system actuator at physiological rates and loads (rate of 33 mm/s, load 180 N). A progressive gap was noted in each specimen, for a 100% rate of failure of the repairs. The central suture always failed first and by the largest magnitude, confirming tension overload centrally. One specimen exhibited combined bone and tendon failure, but the other 15 specimens failed through the tendon. Overall, the repairs failed to 5 mm and 10 mm at an average of 61 cycles and 285 cycles, respectively. Half the specimens were less than 45 years of age and had a 5-mm and 10-mm failure at an average of 107 and 478 cycles, respectively. The other half were over 45 years of age and failed to 5 mm and 10 mm at an average of 17 and 91 cycles, respectively, indicating more rapid failure of the rotator cuff tendons in the older group, and this was statistically significant (P = .02). Comparison of suture anchor fixation in this study with transosseous bone tunnel fixation in a previous cyclic loading study at this institution indicates that bone fixation by suture anchors is significantly less prone to failure than bone fixation through bone tunnels (P = .0008). Changing the bone fixation from bone tunnels to suture anchors effectively transferred the weak link from bone to tendon.

Key Words: Rotator cuff—Rotator cuff tear—Biomechanical testing—Cyclic loading—Suture anchor.

The ideal means of securely repairing the torn rotator cuff to bone has obviously not been identified, as evidenced by recent clinical studies that show a high rate of residual defects in surgically repaired rotator cuffs. Failure can occur through bone, tendon, and/or suture.

Our inability to reliably identify and overcome the weak link in rotator cuff repair may be more a problem with experimental methodology than with surgical technique. In reviewing the literature on experimental investigations of rotator cuff fixation, we found that all previous experimental designs took the rotator cuff repair to failure by a single pull to the ultimate load.

We did not feel that such a model adequately represented the conditions to which a repaired rotator cuff
was subjected in vivo, so we elected to study failure modes of cuff repairs by means of cyclic loading.

The present study represents the second in a series of cyclic loading experiments from our laboratory designed to investigate the weak link in rotator cuff fixation. Our first experimental study investigated cyclic loading of transosseous rotator cuff repairs through bone tunnels and showed that the predominant mode of failure was through bone, with the suture cyclically sawing through the bone bridge. Comparing this cyclic loading experiment with a previous experiment conducted by the senior author (S.S.B.), in which transosseous rotator cuff repairs were taken to failure by a single pull, one realizes that the mode of failure is different under the two loading modes: under cyclic loading, bone failure predominates, whereas under continuous single pull, suture failure predominates. To understand what happens in vivo, we must be sure that our experimental design simulates physiological conditions. The present study used the same repair technique as the earlier cyclic loading experiment except that suture anchors were used for bone fixation rather than transosseous bone tunnels. In this way, we were able to isolate bone fixation as our primary variable and analyze the differences between suture anchor fixation to bone versus bone-tunnel fixation.

MATERIALS AND METHODS

Sixteen fresh-frozen human cadaveric shoulders were used in this study. The average age was 41 years, and the range was 18 to 63 years. Half the specimens were from cadavers that were less than 45 years of age at the time of death, and half were from cadavers that were over 45 years of age at death. Each specimen consisted of a humeral head and an intact rotator cuff. There were no pre-existing rotator cuff tears in these specimens. With the exception of bone fixation, the same experimental protocol was followed as in our previous cyclic loading study. A rotator cuff defect was created at the insertion of the supraspinatus and a portion of the infraspinatus. This defect measured 1 × 2 cm (1 cm in the medial-to-lateral dimension and 2 cm in the anterior-to-posterior dimension) and comprised a portion of the rotator crescent. An actual defect was made rather than a simple detachment because the authors have observed that most rotator cuff tears involve degeneration at the tendon insertion, with actual loss of tendon substance. This experimental configuration was considered to best simulate what occurs in vivo. Three Mitek-RC suture anchors (Mitek Surgical Products, Inc, Westwood, MA) were used for each repair. The anchors were inserted at 45° to the surface of the bone, and were placed 8 mm apart in a shallow bone trough adjacent to the articular surface. Each anchor had a No. 2 Ethibond suture through its eyelet that was used to repair the rotator cuff by means of a simple suture. One limb of each suture was passed through the rotator cuff tendon 1 cm from its free margin to effect a repair of the defect by three simple sutures attached to three Mitek-RC suture anchors. The proximal end of the rotator cuff tendon was affixed to a looped nylon strap by means of multiple mattress sutures as a means of applying load to the repaired tendon (Fig 1).

The humerus was fixed by means of an adjustable vise so that the repaired tendon could be longitudinally loaded in the anatomic direction of the repaired muscle-tendon unit. The nylon strap that had been sutured to the tendon was affixed over a horizontal bar that was connected to a servohydraulic materials test system (MTS Model 858 Bionix; MTS Corp, Minneapolis, MN). The bar and strap configuration assured a distributed load across the repaired rotator cuff tendon. Each specimen was then cyclically loaded to 180 N at a rate of 33 mm/s. The duration of each cycle was 5 seconds. The load of 180 N represented approximately two thirds the load that could be delivered by a maximal contraction of the muscles that subtended the cuff defect, so the load was considered to be well within the physiological range. The rate of 33 mm/s has been previously reported as a loading rate that occurs in normal daily activities.

Each specimen was cyclically loaded and observed for failure of the cuff repair. Calipers were used to measure gap formation at the repair site. The repair was deemed to have reached 50% of complete failure when a 5-mm gap developed (the original defect had a width of 10 mm) and complete failure when a 10-mm gap developed. The extent to which failure occurred through bone or tendon was observed and measured.

In our original cyclic loading study, three control specimens without rotator cuff defects or repairs were cyclically loaded with an arbitrary cut off at 3,500 cycles. We considered that failure would be unlikely to occur with further cycling, and we stopped loading that specimen. In these controls, no failure of rotator cuff attachments occurred after 3,500 cycles.

Donor variability on the number of cycles for 5-mm gap creation and 10-mm gap creation were examined using analysis of variance (ANOVA). Fisher’s Least Significant Difference (FLSD) multiple comparisons test of the means was applied when the F-test in ANOVA was significant (P < .05). Unpaired Student’s t
The purposes of this study were fourfold. First, to determine whether progressive fixation failure of the repaired rotator cuff occurred with cyclic loading. Second, to measure the number of cycles required to reach 50% failure (a 5-mm gap) and 100% failure (a 10-mm gap). Third, to observe the location of the failure (bone, tendon, suture). Fourth, to compare the mode of failure and location of failure with our previous cyclic loading study in which the rotator cuff was repaired to bone through bone tunnels. All specimens eventually failed to a 10-mm gap. The specimens reached 50% failure (5-mm gap) at an average of 61 cycles. The specimens reached 100% failure (10-mm gap) at an average of 285 cycles.

Progressive gap formation was noted in each repaired specimen, for a 100% rate of failure of the repairs. The portion of the tendon that was secured by the central suture always failed first and by the largest magnitude. One specimen showed combined bone and tendon failure, but the other 15 specimens failed through the tendon. The one instance of bone failure (combined with tendon failure) occurred when the central Mitek-RC anchor pulled partially out of the bone. Close examination of this anchor revealed that one of the Nitinol tines had not deployed so that the normal resistance to pull-out by this anchor was defective. No other anchors showed evidence of pull-out from bone or contiguous bone failure by compression of adjacent bone.

Donor height, weight, and age showed no statistically significant differences between repair groups and control groups. However, within the repair group, there was a statistically significant difference between the cycles to failure in the older specimens (>45 years of age) compared with the younger specimens (<45 years of age). Half the specimens were less than 45 years of age and had a 5-mm and 10-mm failure at 107 and 478 cycles, respectively. The other half were over 45 years of age and had a 5-mm and 10-mm failure at 17 and 91 cycles, respectively, indicating more rapid failure of the rotator cuff repair in the older group. This difference in cycles to failure was statistically significant ($P \leq .02$).
A previous cyclic loading study at this institution\textsuperscript{11} examined the mode of failure of rotator cuff repairs done by transosseous bone tunnel fixation. In that study, 9 of 16 rotator cuff repairs had bone failure, compared with 1 of 16 instances of bone failure in the present study with suture anchors. Using the Test of Proportions ($\chi^2$-Square), this difference in bone fixation security was statistically significant at $P \leq .0008$. This comparison indicates that bone fixation by suture anchors is significantly stronger than bone fixation through transosseous bone tunnels.

**DISCUSSION**

If we are to identify the optimal means of repair of rotator cuff tears, we must first be certain that we have an in vitro model that accurately represents the loading conditions in vivo, and then we must use that model to identify the weak link in various repair constructs. This study represents the second in a series designed to identify the weak link in a particular repair construct. By comparing the modes of failure of the various constructs, we hope to be able to identify the optimal means of rotator cuff fixation.

Most previous studies of rotator cuff fixation have used a single-pull load to failure.\textsuperscript{4-10} Such loads are not physiological. Furthermore, the mode of failure under nonidentical loading conditions may be different for the same repair construct, depending on whether it was loaded cyclically or by a single pull. For example, the senior author (S.S.B.) conducted a previous experiment comparing transosseous mattress sutures to simple sutures in which failure of the construct was accomplished by a single pull at a fixed rate of elongation.\textsuperscript{9} In that study, the predominant failure mode was suture breakage at the knot. However, when transosseous rotator cuff repair was investigated at this institution by means of cyclic loading, the predominant failure mode was bone failure. The inescapable conclusion is that physiological loading conditions (in this case, cyclic loading) must be reproduced to give meaningful, accurate data about the failure.

We have previously postulated a tension overload phenomenon in which the central portion of the cuff, which was repaired under the greatest tension, would...
fail to the greatest extent until the resting tension of its muscle-tendon units was equal to that of the remainder of the construct (Fig 2). This would necessitate a failure of the central portion of the cuff to a 10-mm gap and, indeed, this occurred in every specimen. The results of this study reinforce those of our previous cyclic loading study, which supported tension overload as a mechanism of failure in rotator cuff repair. We have previously suggested that in view of this tension overload concept, some of our successful repairs might better be described as controlled failures.

First-generation suture anchors often did not provide adequate fixation in the cancellous bone of the greater tuberosity. However, the current generation of anchors designed specifically for rotator cuff fixation has been shown to possess excellent pullout characteristics.14 Because anchor failure provided rather spectacular radiographic proof of failure, and since bone tunnel failure was radiographically silent, fixation by bone tunnels was generally assumed to be superior to anchors until recently. However, now that anchor pullout is rare, it is time to revisit the issue of bone fixation and objectively compare suture anchors with bone tunnels.

Our previous cyclic loading study showed that 9 of 16 specimens with transosseous bone tunnel repairs had failure through bone. In the present study with suture anchor fixation, only one specimen failed through bone (anchor pullout). Comparing the two studies indicates that bone fixation through bone tunnels fails more frequently than bone fixation by present-generation suture anchors (Mitek-RC), and this difference is statistically significant at $P = .0008$.

The repair constructs of our two cyclic loading experiments differed only in the means of bone fixation (bone tunnels vs suture anchors). The suture anchor construct effectively transferred the weak link of the construct to the tendon, since tendon failure was the predominant mode of failure in the suture anchor construct. This weak-link transfer to the tendon necessarily will lead us to investigate the most secure means of fixation of suture to tendon under cyclic loads.

In examining the tendon failures, we found that the tendons failed at significantly lower numbers of cycles in specimens over 45 years of age than in those under 45 years of age. Because clinically significant rotator cuff tears usually occur in the older age group, security of tendon fixation will become an even more important issue, and is the subject of a forthcoming study from this institution.

Acknowledgement: The authors wish to thank Dan Lancot, M.S., for his technical assistance with this project.

REFERENCES