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Biomechanical Evaluation of a New Technique for Rotator Cuff Repair*

Charles J. Petit, MD, Robert Boswell, MD, Andrew Mahar, MS, James Tasto, MD, and Robert A. Pedowitz,† MD, PhD

From the Orthopaedic Biomechanics Research Center, Children's Hospital, San Diego, California

Background: In recent studies, investigators have used a cyclic loading model to investigate the efficacy of rotator cuff fixation modalities.
Hypothesis: A bioabsorbable poly-D-lactic acid screw and toothed washer implant will provide more stable fixation of rotator cuff repairs than standard suture anchor techniques.
Study Design: Controlled laboratory study.
Methods: Forty bovine shoulders (ages 3 to 6 months) had 1 × 2 cm defects created in the infraspinatus tendon. There were five repair groups (eight specimens per group) consisting of either two screw and washer implants or two suture anchors. Four suture techniques were tested: single-loaded anchors with simple sutures, double-loaded anchors with simple sutures, single-loaded anchors with horizontal mattress sutures, or single-loaded anchors with modified Mason-Allen sutures. Repairs were loaded at 5-second cycles from 10 to 180 N with use of a hydraulic testing machine. The number of cycles to gap formation of 5 and 10 mm was recorded.
Results: Gap formation of 5 and 10 mm occurred significantly later for the screw repair group than for any of the suture anchor groups. There was no significant difference between suture groups.
Conclusions: The bioabsorbable screw and washer provided more stable fixation than suture anchor techniques under isometric cyclic loading conditions.
Clinical Relevance: This is a time-zero study of implant performance. The results indicate that the implant may decrease clinical failures in the early postoperative period under standard rehabilitation protocols.

The most secure method of rotator cuff fixation continues to be a topic of investigation. In several clinical studies, the use of ultrasonography or arthrography has shown residual defects in surgically repaired rotator cuffs, with an incidence as high as 50% in some reports.[9,14,17] The use of suture anchors or the transosseous technique requires arthroscopic or mini-open tying of suture knots, which is a difficult and time-consuming procedure. Failure by the surgeon to tie tight and precise knots can lead to inadequate fixation at the tendon-bone interface, which may result in a poor outcome. The ideal fixation device would consist of an anchor that could be placed easily with mini-open or arthroscopic techniques and would provide sufficient fixation over a long period, thereby allowing for healing and early rehabilitation exercises, with minimal impingement and postoperative morbidity. A better understanding of which devices or techniques are the most stable under cyclic, submaximal loads would aid in clinical decision-making regarding rotator cuff repairs and postoperative rehabilitation.

Earlier biomechanical studies investigating rotator cuff fixation failures have employed an ultimate load-to-failure model.[1–4,15] However, this model does not represent physiologic loading conditions in vivo. In recent biomechanical studies, investigators have used more physiologic methods, including cyclic loading, to evaluate the efficacy of different suture techniques for rotator cuff fixation.[6–8,10,13,18,21] These methods more accurately represent the physiologic forces placed on repairs in vivo. To our knowledge, no published studies have compared standard suture anchor techniques with a bioabsorbable

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† Address correspondence and reprint requests to Robert A. Pedowitz, MD, University of California, San Diego, Department of Orthopaedics 8894, 350 Dickinson Street, San Diego, CA 92103-8894.

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screw and toothed washer device under cyclic loading conditions.

The purpose of this study was to compare the performance of a new bioabsorbable poly-D-lactic acid (PDLA) screw and toothed washer (Bionx, Inc., Blue Bell, Pennsylvania) with that of four commonly used suture anchor fixation methods under physiologically representative loads and directions.

MATERIALS AND METHODS

Forty fresh-frozen bovine shoulders (specimen age, 3 to 6 months) were obtained from a local food supply warehouse and stored at –20°C. Shoulders were divided equally among five repair groups. Right and left shoulders were randomly assigned among groups.

The shoulders were dissected so that the infraspinatus muscle and tendon insertion were left intact, with all other soft tissues removed. The distal humerus was sectioned, leaving approximately 15 cm of proximal humerus that was then fixed in two-part epoxy resin (Fig. 1). A 1 × 2 cm defect was created at the tendon insertion (1 cm in line with the fibers of the tendon and 2 cm in width), as described by Burkhart et al.[6,7] Each defect was repaired under direct vision by using one of five repair techniques. One surgeon (RB) performed all repairs using standard techniques for the Bionx BioCuff screw and washer and Mitek Super QuickAnchor Plus (G4) suture anchors (Mitek Products, Inc., Norwood, Massachusetts).

Group 1 repairs were made with two PDLA acid screw and toothed washer implants (Fig. 2) placed 1 cm apart in the defect. After the defect was created, the tendon was mobilized and the screw-washer devices were inserted into predrilled holes in the region between the greater tuberosity and the lateral edge of the articular surface of the humeral head (according to the manufacturer's guidelines). Insertional torque did not exceed 5 pound-inches when placing the screws. Screws were placed with approximately 5 mm of tendon between the insertion site and the free edge.

Suture anchors were inserted 45° to the surface of the bone, in predrilled holes, in the same region where the screws were placed (according to manufacturer's guidelines). Sutures were then tied over the tendon by using one of the following techniques. Group 2 repairs consisted of two single-loaded suture anchors placed 1 cm apart in the defect and a simple suture technique (Fig. 3). Group 3 repairs were made with two double-loaded suture anchors and a simple suture technique consisting of a total of four suture limbs in the repair (Fig. 4). Group 4 repairs consisted of two single-loaded suture anchors and a horizontal suture repair technique (Fig. 5). Group 5 repairs consisted of two single-loaded suture anchors and a repair employing the modified Mason-Allen technique described by Gerber et al.[11] (Fig. 6).

The muscle-tendon complex was secured in a serrated clamp that held approximately 4 cm of tissue with another 10 cm between the clamp and the tendon insertion. The specimens were loaded in the physiologic direction of the rotator cuff tendon perpendicular to the longitudinal axis

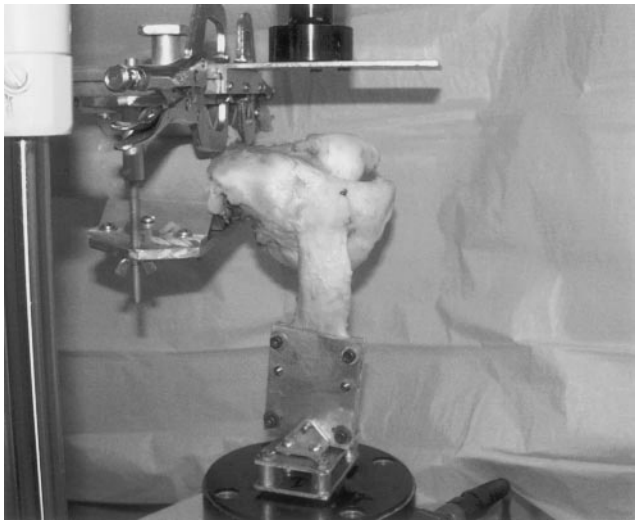

Figure 1. Specimen fixed in materials testing machine before repair.

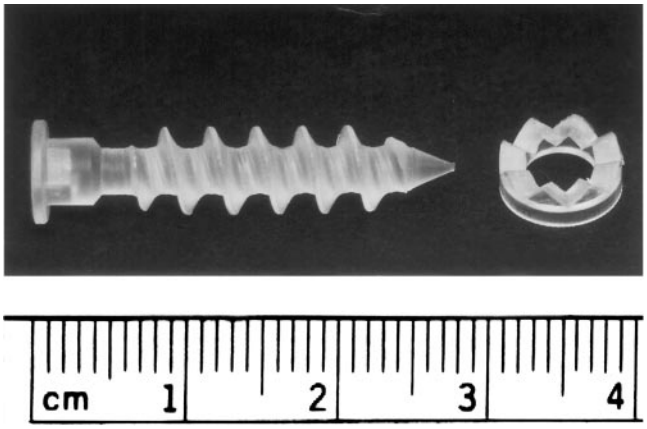

Figure 2. Poly-D-lactic acid screw and washer device (group 1).

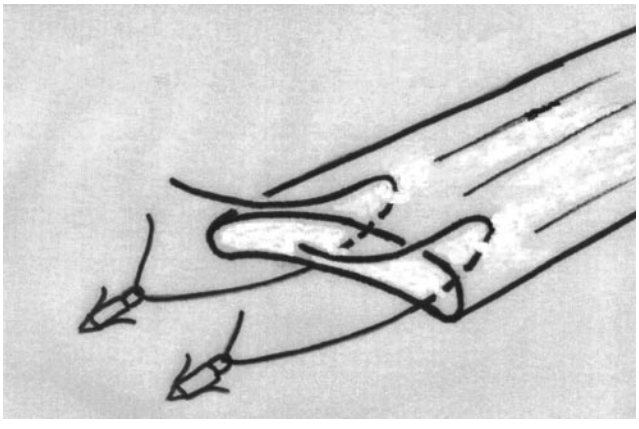

Figure 3. Single-loaded suture anchors with simple technique (group 2).

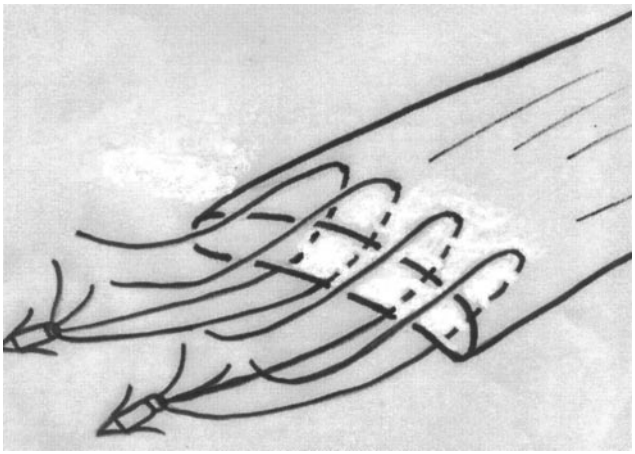

Figure 4. Double-loaded suture anchors with simple technique (group 3).

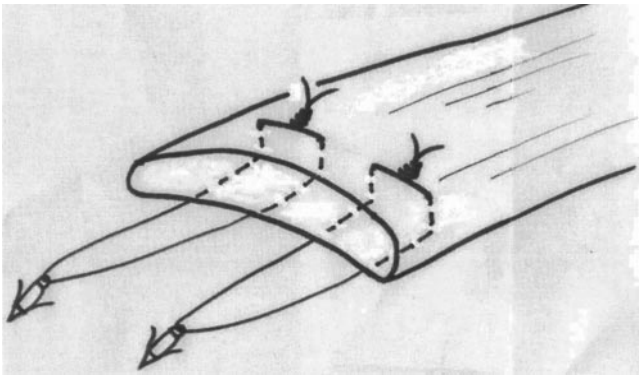

Figure 5. Single-loaded suture anchors with mattress technique (group 4).

of the humerus. After preconditioning, a materials testing machine (MTS Corp., Eden Prairie, Minnesota) was used to cycle specimens between 10 and 180 N over 5 seconds; this testing technique was similar to that described by Burkhart et al.[6,7] The loading force was applied to the humerus, with the humerus maintained in a constant angle relative to the tendon, resulting in simulated isometric muscle contraction. This was continued for a maximum of 2500 cycles or until achievement of 100% failure, which was defined as formation of a 10-mm gap or the point at which the original defect length was reached. Gap formations of 5 and 10 mm were measured directly with digital calipers and the number of cycles was recorded.

Cycles to failure at 5 and 10 mm were averaged and compared between treatment groups with a one-way analysis of variance ($P < 0.05$), and Tukey's post hoc comparison was used when significant differences were found. The mode of failure was identified and recorded.

RESULTS

The performance for each repair technique is shown in Table 1. The shoulders repaired with two PDLA screws and toothed washers (group 1) demonstrated a significantly greater number of cycles to 50% failure (5 mm) during submaximal cyclic loading ($P < 0.05$). There was no significant difference between repair types for the suture anchors at 5 mm. The PDLA screws (group 1) were associated with a significantly greater number of cycles to 100% failure (10 mm) than the suture repairs ($P < 0.05$). In five of eight specimens repaired with PDLA screws, the maximum number of cycles (2500) was attained before formation of a 10-mm gap, whereas no specimens with suture repairs reached this level. There were no significant differences between suture repair types for number of cycles to 10-mm gap.

Table 2 shows the failure mode of each group. Failures were noted to occur by tendon pullout past the screw, suture pullout through the tendon, or by suture breakage. All eight specimens in the screw and washer group (group 1) demonstrated failure through the tendon. Failure involved the screw cutting a path through the tendon in line with the fibers; no screws broke or pulled out of bone.

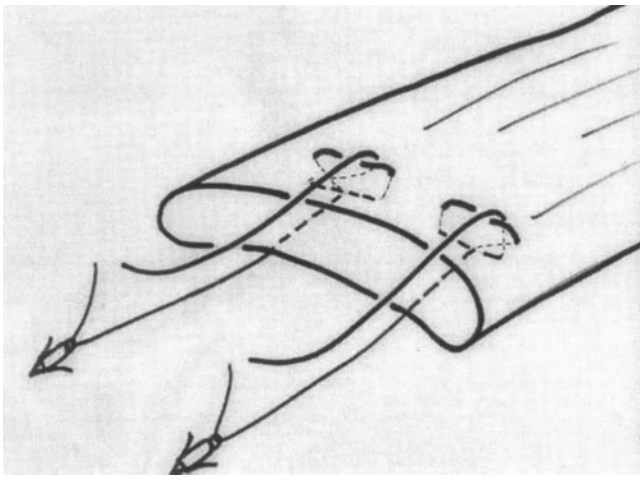

Figure 6. Single-loaded suture anchors with modified Mason-Allen technique (group 5).

TABLE 1
Performance (Cycles to Failure) for Each Repair Technique

Group	5 mm (Mean ± SE)	10 mm (Mean ± SE)
1	787.5 ± 313.0	1665.3 ± 407.6
2	25.6 ± 13.4	166.1 ± 55.2
3	32.0 ± 11.3	703.9 ± 179.5
4	109.6 ± 81.5	802.5 ± 212.3
5	6.1 ± 2.3	352.0 ± 178.5

TABLE 2
Failure Mode for Each Group

Group	Tendon	Suture
1	8	N/A
2	3	5
3	5	3
4	1	7
5	2	6

In the suture groups, failure occurred at the tendon or by suture breakage. Suture breakage occurred in 21 of 32 specimens. Suture breakage was noted to occur most commonly in groups 2, 4, and 5, where they occurred in 63%, 88%, and 75% of specimens, respectively. In group 3, suture breakage was less common, occurring in 38% of specimens. In all suture failures, breakage occurred away from the knot, with suture failure at either the suture-bone interface or at the angle of the eyelet.

DISCUSSION

The purpose of our study was to test, using cyclic loading methods, the biomechanical performance of a new bioabsorbable screw and toothed washer against standard suture anchor techniques for rotator cuff tendon repair. The results demonstrate that the PDLA screw and washer performed significantly better than standard suture anchor techniques in resisting gap formation in a cyclic isometric contraction model.

The performance of suture anchors in this study was similar to that found in prior studies employing cyclic loading protocols. Using three single-loaded Mitek G4 anchors and simple suture knots, Burkhart et al.[6] found cycles to failure of 5 and 10 mm to be 61 and 285, respectively, at the same loads used in this study (10 to 180 N). Their study was performed on cadaveric specimens with an average age of 41 years. In another cyclic loading study (involving loads of 10 to 180 N), Goradia et al.[13] used two single-loaded Mitek G4 anchors and simple suture knots and reported cycles to failure of 5 and 10 mm to be 8 and 101, respectively. Their study was performed using cadaveric specimens with an average age of 77 years. In the most comparable group of our study, group 2, the average cycles to failure of 5 and 10 mm were 26 and 166, respectively. As expected, our results fall between those of Burkhart et al.,[6] who used three suture anchors and relatively young cadaveric specimens, and those of Goradia et al.,[13] who used two suture anchors, but much older cadaveric specimens.

We selected immature bovine shoulders for use in this study because we found the consistency of the tissue to be superior to that of human cadaveric shoulders. The infraspinatus tendon was found to be the closest match in size to normal human supraspinatus tendon during preliminary studies. The average bone density of immature bovine bone has been shown to be 0.8 g/cm^3, which is similar to that of young human bone.[12] The anatomy of the bovine shoulder varies slightly from the human shoulder. It contains no clavicle, and the scapula is oriented from superior to inferior rather than medial to lateral. However, these differences should not interfere with testing various fixation modalities.

A study by Upasani and coworkers (unpublished data, 2002) compared 14 bovine shoulders, of the same age and from the same source as those used in this study, with human shoulders. Measurements across several clinically relevant structural parameters were compared with published data on the human supraspinatus tendon. No significant difference was found between the bovine shoulder and the human shoulder for the clinically relevant parameters. The relevant anatomic sites consisted of, for bovine and human specimens (respectively), the average tendon thickness across the first 30 mm (2.99 versus 3.10 mm), the average tendon width (36.08 versus 35.40 mm), and the pennation angle of the inferior muscle insertion (15.14° versus 14.00°). The pennation angle is the angle formed between the central axis of the tendon and the orientation of the muscle fibers and indicates loading direction. Additionally, the bovine specimens had less variability in these anatomic parameters, making it a useful and consistent model for experimentation.

Our data raise concerns about suture anchor techniques. As shown in Table 2, more than half of the specimens repaired with a suture configuration failed by suture breakage. We believe that this failure occurred at the suture-bone interface. This identifies an additional point of weakness in the suture anchor repair apparatus that, to our knowledge, has not been discussed in the literature. If the anchor eyelet is inserted well below the surface, the suture hinges on the bone outlet and may be more susceptible to breakage under cyclic loading. No failures occurred at the knot in this series. Furthermore, suture failure through tendon occurs earlier because of the relative ease with which the suture can cut through the tendon in line with its fibers, especially in simple suture techniques. Only one previous study has shown suture breakage to be a significant mode of failure in rotator cuff repair.[20]

The results of this study also raise concern about techniques used with multiple loops, as in the modified Mason-Allen technique. Gerber et al.[11] reported impressive data on the ultimate tensile strength of this technique. With multiple loops, this grasping suture helps to prevent pullout through the tendon, thus transferring the weak link to the suture. Under cyclic loading conditions, however, we found that an early 5-mm gap occurred. We believe that settling of the multiple loops in the first cycles creates this early gap in the repair. The suture did relatively well in holding on to the tendon and ultimately failed by suture breakage in most specimens.

This study implies superior performance of the PDLA screw and washer device during cyclic loading. This anchor is composed of a biodegradable material, poly-D-lactic acid. This material is one of the most common biodegradable substances used to construct implants and has a wet-strength half-life of over 6 months.[22] The exact composition of the screw and washer device is 96%L and 4%D polylactic acid. The screw is designed to be low profile when fully engaged so that impingement is avoided. Clinical studies, currently underway, will assist in showing whether the design successfully avoids impingement in clinical use.

Other common bioabsorbable materials used in orthopaedics include polyglycolic acid (PGA), polydioxanone (PDS), and other mixtures of polylactic acid (PLA) such as poly-L-lactic acid (PLLA). The degradation of these copolymers generally occurs by hydrolysis and nonspecific enzymatic action. Breakdown rates vary between polymers—for PGA, it is on the order of months, whereas PLA

derivatives generally take several years to completely breakdown.[19]

None of the copolymers have been shown to have any teratogenic or toxic properties. The primary complication reported for PGA, PDS, and PLA implants placed intraarticularly is aseptic synovitis.[5] The implants create an indistinct foreign body reaction within the tissue. Histologic studies have shown polymetric birefringent particles surrounded by mononuclear phagocytes and multinucleated foreign body giant cells.[5,19] A large review of patients who underwent repair with PGA or PLA implants showed a 5.3% (107 of 2037) and 0.2% (1 of 491) rate of adverse reactions for PGA and PLA implants, respectively.[5] Since PDLA degrades over a long period, a theoretical complication of using the implant would be a loose body in the articular cavity causing impingement if the implant were to fail. However, this has not been reported in the literature.

A weakness of this study is that it is an in vitro, time-zero study. We are unable to determine the effects of biologic processes on the PDLA implant over time in an in vivo model. It can only be assumed that the reaction rate is as low as is reported in the literature, and that it is limited to aseptic synovitis. This should be addressed in further clinical trials.

Two additional weaknesses of this study are the use of a new animal model and the use of very high loads on the repaired rotator cuffs in an isometric fashion. The bovine model is anatomically similar to the human rotator cuff but is composed of very strong young tissue. Most rotator cuff repairs are performed in elderly patients, who often have osteoporotic bone and weaker tendons and muscles. The maximum load of 180 N was chosen because it has been described in the literature to represent two-thirds of the force that could be transmitted across the rotator cuff under maximal muscle contraction.[6,16] In the immediate postoperative period, passive rehabilitation does not induce loads of 180 N on the rotator cuff repair. However, much higher isometric loads are probably induced with noncompliant patients or with accidental overuse. Therefore, stronger fixation should provide additional confidence for early rehabilitation.

Although it may be assumed that decreased gap formation may result in improved clinical results, this has not been demonstrated in the literature. Additional clinical investigation is needed to answer this question.

In the majority of cases, fixation of rotator cuff defects with suture anchor techniques is adequate. However, this study suggests that bioabsorbable screws with toothed washers may provide decreased gap formation, which may lead to more stable fixation during the immediate postoperative period than is provided by standard suture anchor techniques employing simple, horizontal mattress, or modified Mason-Allen knots. This could translate into fewer failures of rotator cuff repairs under standard rehabilitation protocols.

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