HSS Journal®: The Musculoskeletal Journal of Hospital for Special Surgery
2023, Vol. 19(1) 44–52

DOI: 10.1177/15563316221114135
journals.sagepub.com/home/hss
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Biomechanical Comparison of Synthetic Polytetrafluoroethylene (PTFE) vs Human Dermal Allograft (HDA), 2 vs 3 Glenoid Anchors, and Suture vs Minitape in Superior Capsule Reconstruction

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Abstract

Background: Superior capsule reconstruction (SCR) is an option for the treatment of massive, irreparable rotator cuff tears. However, which materials yield the strongest constructs remains undetermined. *Purposes*: We sought to investigate whether SCR with polytetrafluoroethylene (PTFE) or human dermal allograft (HDA), 2 or 3 glenoid anchors, and suture or minitape resulted in better failure load properties at the patch-glenoid interface. *Methods*: We conducted a biomechanical study in 30 glenoid-sided SCR repairs in Sawbones models divided into 5 groups. Each was pulled to failure to assess mode of failure, peak load (N), stiffness (N/mm), yield load (N), peak energy (N m), and ultimate energy (N m). The 5 groups were as follows: group 1—PTFE, 2 anchors, and suture; group 2—PTFE, 2 anchors, and minitape; group 3—HDA, 2 anchors, and suture; group 4—HDA, 2 anchors, and minitape; group 5—PTFE, 3 anchors, and minitape. *Results*: Repairs failed by buttonholing of suture/minitape. Group 5 had greater peak load, stiffness, yield load, and peak energy (384 ± 62 N; 24 ± 3 N/mm; 343 ± 42 N; 4 ± 2 N m) than group 3 (226 ± 67 N; 16 ± 4 N/mm; 194 ± 74 N; 2 ± 1 N m) or group 4 (274 ± 62 N; 17 ± 4 N/mm; 244 ± 50 N; 2 ± 1 N m) and greater ultimate energy (8 ± 3 N m) than all other groups. *Conclusions*: This biomechanical study of SCR repairs in Sawbones models found that yield load was greater in PTFE than HDA, 3 anchors were better than 2, and minitape was no better than suture.

Keywords
biomechanics, superior capsular reconstruction, synthetic, arthroscopy, irreparable rotator cuff tear

Received April 12, 2022. Accepted June 24, 2022.

Massive, irreparable rotator cuff tears are difficult injuries to treat, and there are various approaches to their management. These have included debridement, tendon transfers [8,11,16,29], interposition grafts [2,4,5,13–15,22,24,31,32,34, 41–43,45,47,48], shoulder arthroplasty [17,23,30,35,40,49], and superior capsule reconstruction (SCR). Mihata et al [28] pioneered SCR in 2012, using autologous fascia lata graft anchored to the glenoid medially and to greater tuberosity laterally in a biomechanical study of 8 human cadaveric shoulders. This study compared the superior stability of cadaveric shoulders in 5 conditions, using intact and torn supraspinatus groups as controls. Fascia lata SCR was effective in restoring superior humeral head stability, reducing subacromial contact pressure, and improving the range of motion at the glenohumeral joint.

Clinically, however, human dermal allograft (HDR) has become popular in SCR [21]. The main advantage of using HDR is it circumvents harvesting of autologous fascia lata and the associated donor site morbidity. Ex vivo biomechanical studies that compared fascia lata with HDR found

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that when grafts were of similar thickness, HDR was equally as effective as fascia lata in increasing the acromiohumeral distance and reducing subacromial contact pressures [10,46].

Synthetic patches also circumvent autologous harvest. In a clinical study of 35 patients treated with Teflon (polytetrafluoroethylene [PTFE]) SCR, Okamura et al [33] compared single-layer PTFE with triple-layer PTFE in 15 and 20 patients, respectively, with a minimum 2-year follow-up. Both groups experienced improvements in American Shoulder and Elbow Surgeons Shoulder (ASES) scores, visual analog scale score for motion pain, and strength in abduction. However, those in the triple-layer group experienced greater acromiohumeral distance (6 mm vs 9 mm) at 1-year post-operation and active elevation (107° vs 142°) at final follow-up than those in the single-layer group. Although synthetic patch SCR has shown promising results, how synthetic PTFE patches compare with HDR with respect to failure properties in SCR remains undetermined.

While various morphological patterns of graft failure exist [6], several clinical studies have identified through postoperative magnetic resonance imaging that graft failures most commonly failed at the glenoid interface, followed in frequency by intrasubstance tearing [3,9,12,18,39]. A number of authors used 2 glenoid anchors as described in both clinical and biomechanical studies by Mihata et al [26,28], whereas others used 3 glenoid anchors [7,19,36,44]. Pogorzelski et al [38] found that SCR with 3 glenoid anchors had greater pull-out strength than SCR with 4 anchors in 36 cadaveric shoulders. However, to our knowledge, there has been no study to determine whether there is any biomechanical advantage of using 3 versus 2 anchors at the glenoid.

A previous study by our institution found that tape had higher peak failure loads compared with suture rotator cuff repairs in ovine shoulders [20]. However, the potential benefits of minitape versus suture have not been investigated with respect to SCR.

We hypothesized that with respect to mode of failure and peak failure load, that synthetic PTFE patches would be superior to HDR, 3 glenoid anchors would be superior to 2 glenoid anchors, and minitape would be superior to suture. The aims of this study, therefore, were to determine whether using (1) PTFE or HDR, (2) suture or minitape, and (3) 2 or 3 glenoid-sided anchors would result in different mode of failure, peak failure load, and stiffness properties in SCR.

Methods

We conducted a biomechanical study in 30 glenoid-sided SCR repairs in Sawbones models (#1050, large left scapula, foam cortical shell with cancellous material, with vise attachment block). We sought to determine mode of failure, peak load (N), stiffness (N/mm), yield load (N), peak energy (N m), and ultimate energy (N m) in 3 comparisons: 2.87-mm-thick synthetic PTFE patches (PTFE Felt) versus 1.27- to 1.78-mm thick HDR (GraftJacket, MaxForce Extreme; 1.9–2.5 mm thickness, 40 mm × 70 mm); 2 versus 3 anchors (SwiveLock; Arthrex; 4.75 mm); and suture (No. 2 FiberWire) versus minitape (MINITAPE).

We divided the 30 glenoid-sided SCR repairs into 5 groups: group 1—PTFE, 2 anchors, and suture; group 2—PTFE, 2 anchors, and minitape; group 3—HDA, 2 anchors, and suture; group 4—HDA, 2 anchors, and minitape; group 5—PTFE, 3 anchors, and minitape (Fig. 1). Sawbones models were chosen as they provided controlled bone density in the context of this load-to-failure study. Polytetrafluoroethylene was selected as it is an accessible material that has shown promising 2-year outcomes in both functional tests and patient-reported outcome measures [33]. Human dermal allograft was selected because it has become the most commonly used graft in SCR [21]. Suture was selected as it is the conventional fixation used in SCR, and minitape was selected to investigate for a biomechanical difference between the 2.

A total of 18 PTFE and 12 HDR grafts were cut to 30 mm × 50 mm patches for surgical repair method testing. The strips of human dermal allografts were rehydrated according to the manufacturer's instructions by soaking in 0.9% normal saline for at least 1 hour before being cut, fabricated, and repaired for testing on the same day. The scapular part of 15 Sawbones scapulae was sawn off, leaving rectangular blocks that accommodated 2 SCR repairs each.

A template (Fig. 2a) was created for the standardization of 24 patches for 2-glenoid anchor SCR repairs (groups 1–4). Four guide holes were made with a 3-0 tapered needle, with 2 holes for each inverted mattress suture/minitape. Another template (Fig. 2b) was created for the standardization of 6 patches for the 3-glenoid anchor SCR group (group 5). Six guide holes were made with a 3-0 tapered needle for 3 inverted mattress sutures/minitapes.

Sutures/minitapes were passed using the inverted mattress technique (4 mm apart, 16 mm from medial end of the graft) using a suture passer (Scorpion; Arthrex) through the premarked patches (Fig. 1). Two holes were tapped 15 mm apart for groups 1 to 4, and 3 holes were tapped 10 mm apart for group 5 in Sawbones blocks using a 4.7-mm SwiveLock punch. Each free end of the suture/minitape was cut to 25 mm and then passed through a SwiveLock anchor. The anchor was tapped into the premade holes and screwed into the Sawbones block.

This study used a custom testing apparatus that incorporated 2 clamps: 1 stationary vice to hold the Sawbones block and 1 clamp for the graft, which was connected to a loadcell (HFG 110, Transducer Techniques) mounted on a separate vice. A digital caliper (RS193-252, Mitutoyo) was attached to the mobile vice for linear position measurements. Modes of failure were recorded by video for each repair.

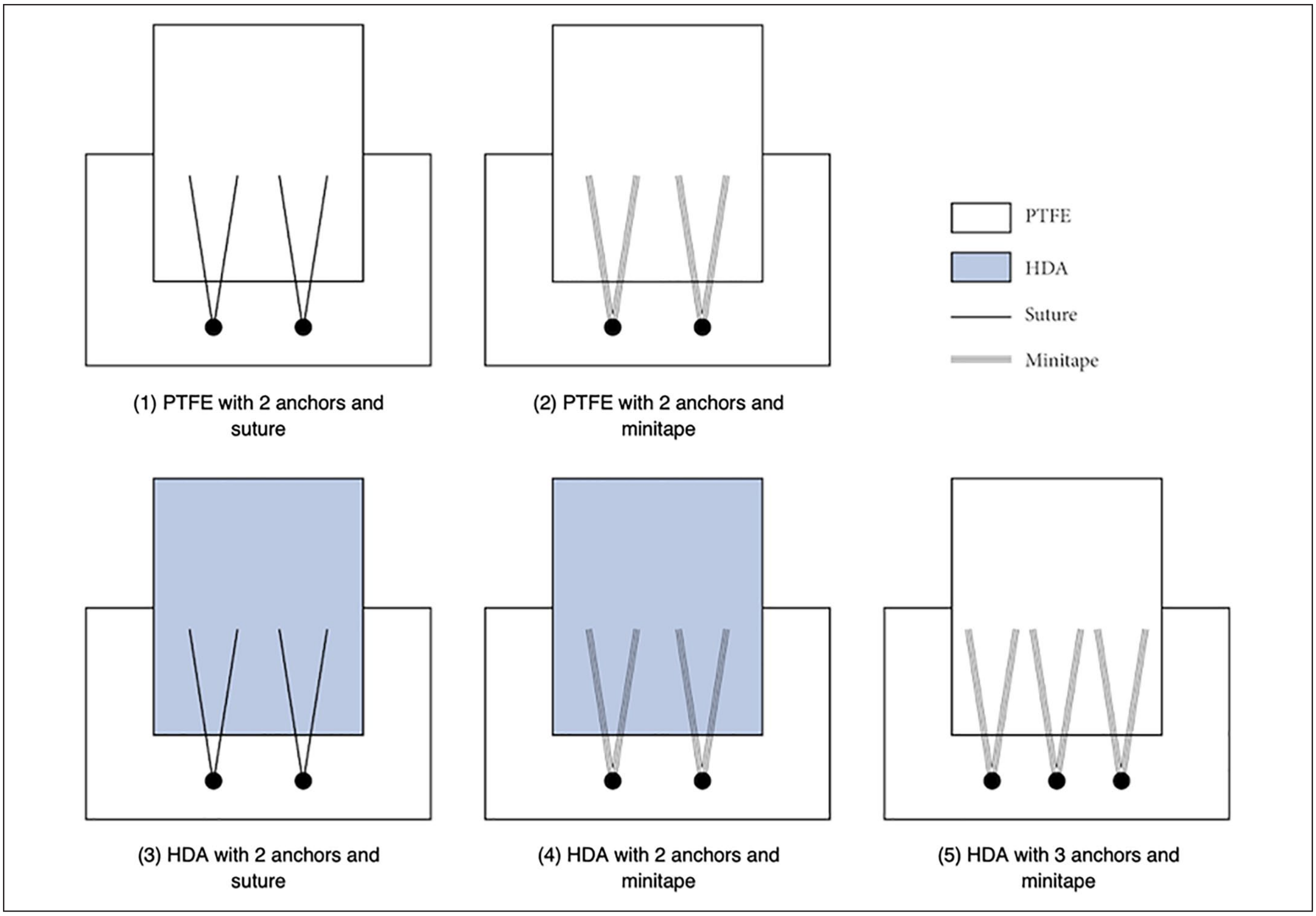

Fig. 1. Schema of superior capsule reconstruction repair groups 1–5; n = 6 for each group. *PTFE* polytetrafluoroethylene, *HDA* human dermal allograft.

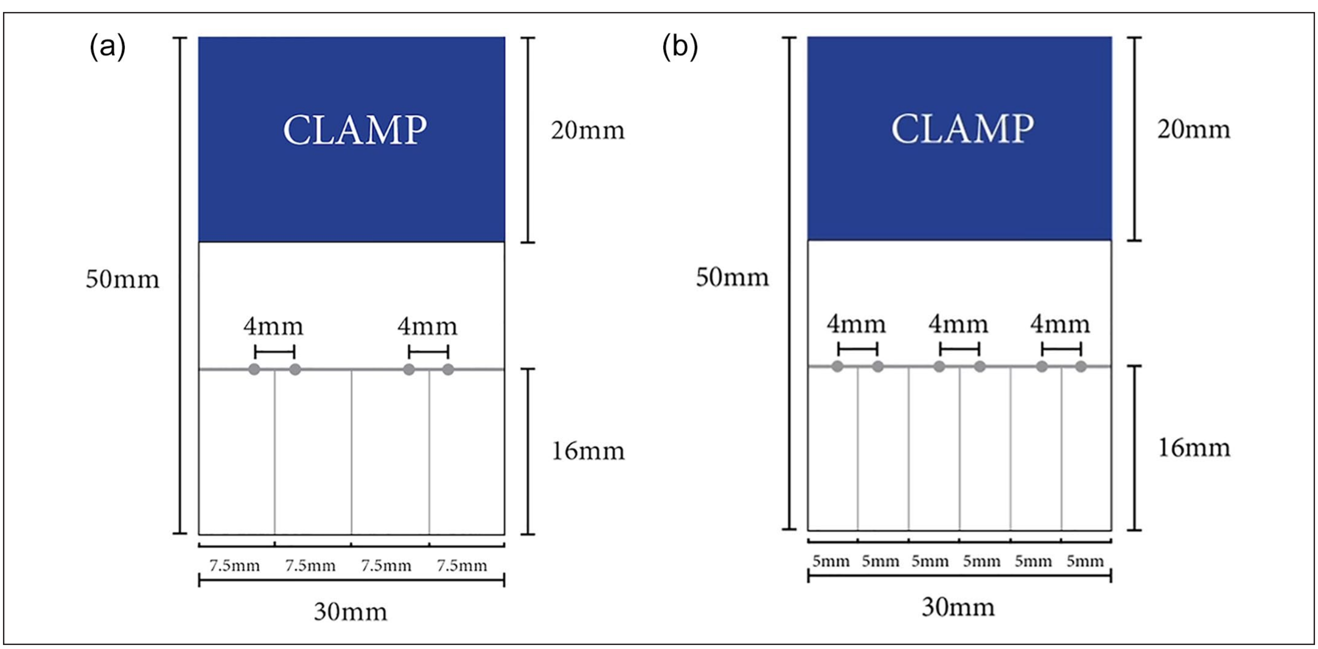

Fig. 2. Template used for the preparation of (a) 2-anchor and (b) 3-anchor repairs.

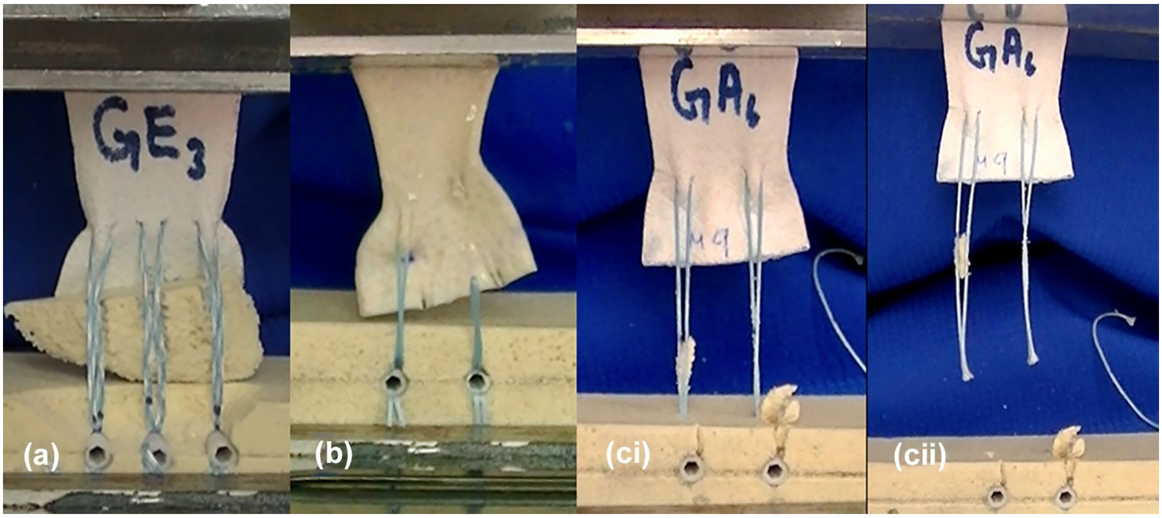

Fig. 3. Modes of failure: (a) avulsion of Sawbones, (b) button-holing at the right suture human dermal allograft interface, (ci) suture cutout through Sawbones and (cii) eventual suture pullout from anchors.

The protocol used was as per previous investigations [1,20,24,37,42,48]. In brief, the Sawbones block was secured in the stationary vice, and the patch graft was secured by a 20-mm bite of the clamp in the dynamic component of the testing apparatus (Fig. 2). The repairs were tested with the direction of pull through the longitudinal axis of the graft, perpendicular to the anchors. Each repair was preloaded with 10 N for 30 seconds as previously established [1,20,24,37,42,48] and then progressively pulled to failure at a rate of 1 mm/second. This protocol was repeated for all 5 groups.

Modes of failure were recorded by video for each repair. Peak load was the maximum load value recorded during testing (N). Stiffness was the resistance to deformation (N/mm). Yield load was the load at which elastic deformation became permanent or "plastic" deformation (N). Peak energy was the area under the load-displacement curve up to the yield load (N m). Ultimate energy was the entire area under the load-displacement curve.

Sample size was set at 6 in accordance with a power calculation ($\alpha = 0.05$, power = 0.80) that determined a minimum of 4 samples were required. Differences in peak load (N), stiffness (N/mm), yield load (N), peak energy (N m), and ultimate energy (N m) were analyzed by 1-way analysis of variance with correction for multiple comparisons using the Tukey method. $P < .05$ was considered statistically significant.

The reliability of using this setup was evaluated in an unpublished biomechanical study. The reliability of using ImageJ (Ver. 1.51, National Institutes of Health) to measure the predefined parameters was assessed using 12 measurements for the length on superior and lateral views between 2 markings on a patch, which was preloaded at 10 N for 30 seconds. Rater 1 and Rater 2 measured the lengths independently using ImageJ. Two-way random-effects intraclass correlation coefficients (ICCs) were calculated using SPSS. The reliability of using ImageJ for measurement was excellent, with inter-rater reliability ICC = 0.93 and intra-rater reliability ICC = 0.99.

Results

The most common mode of failure in 2-anchor repairs (groups 1–4) was button-holing of the suture/minitape through the graft (Fig. 3a), whereas the most common mode of failure in 3-anchor repairs (group 5) was avulsion of the Sawbones by the suture/minitape (Fig. 3b). Suture/minitape cutout through the Sawbones (Fig. 3ci) and eventual pullout from the anchors (Fig. 3cii) were the remaining modes of failure that were observed. The peak load (N), stiffness (N/mm), yield load (N), and peak energy (N m) values were significantly greater in group 5 (PTFE, 3 anchors, and minitape) than in either group 3 (HDA, 2 anchors, and suture) or group 4 (HDA, 2 anchors, and minitape). The ultimate energy (N m) was significantly greater in group 5 than in groups 1 to 4, respectively (Table 1).

In group 1, 4/6 repairs failed by button-holing, and 2/6 repairs failed by suture cut-out. In group 2, 6/6 repairs failed by button-holing. In group 3, 6/6 repairs failed by button-holing. In group 4, 6/6 repairs failed by button-holing. In group 5, 3/6 repairs failed by avulsion of the Sawbones, 2/6 repairs failed by button-holing, and 1/6 repairs failed by consecutive cutting out of each of the minitapes.

Group 5 had a significantly greater peak load (384 ± 62 N) than group 3 (226 ± 67 N; $P = .037$) or group 4 (274 ± 62 N; $P = .006$) (Fig. 4). Group 5 had a significantly greater stiffness (24 ± 3 N/mm) than group 3 (16 ± 4 N/mm; $P = .004$) or group 4 (17 ± 3 N/mm; $P = .044$) (Fig. 5). Group

Table 1. Most common mode of failure (number of samples that failed in stated mechanism/number of samples), peak load (N), stiffness (N/mm), yield load (N), peak energy (N m), and ultimate energy (N m).

	(1) PTFE, 2 anchors, suture	(2) PTFE, 2 anchors, minitape	(3) HDA, 2 anchors, suture	(4) HDA, 2 anchors, minitape	(5) PTFE, 3 anchors, minitape	Significant differences between groups ($P < .05$)
Most common mode of failure	Button-holing (4/6)	Button-holing (6/6)	Button-holing (6/6)	Button-holing (6/6)	Avulsion (3/6)	Statistical analysis was not performed.
Peak load (N)	293 ± 65	291 ± 36	226 ± 67	274 ± 62	384 ± 62	(3) vs (5) (4) vs (5)
Stiffness (N/mm)	22 ± 3	22 ± 3	16 ± 4	17 ± 4	24 ± 3	(3) vs (5) (4) vs (5)
Yield load (N)	268 ± 70	264 ± 33	194 ± 74	244 ± 50	343 ± 42	(3) vs (5) (4) vs (5)
Peak energy (N m)	3 ± 1	3 ± 1	2 ± 1	2 ± 1	4 ± 2	(3) vs (5) (4) vs (5)
Ultimate energy (N m)	4 ± 1	4 ± 1	2 ± 1	3 ± 1	8 ± 3	(1) vs (5) (2) vs (5) (3) vs (5) (4) vs (5)

Data are mean ± SD. *PTFE* polytetrafluoroethylene, *HDA* human dermal allograft.

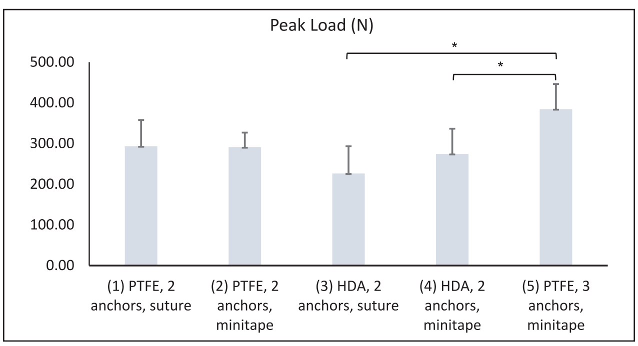

Fig. 4. Peak failure load (N) for groups 1–5. *PTFE* polytetrafluoroethylene, *HDA* human dermal allograft.
*$P < .05$ calculated with 1-way analysis of variance using the Tukey multiple comparisons test.

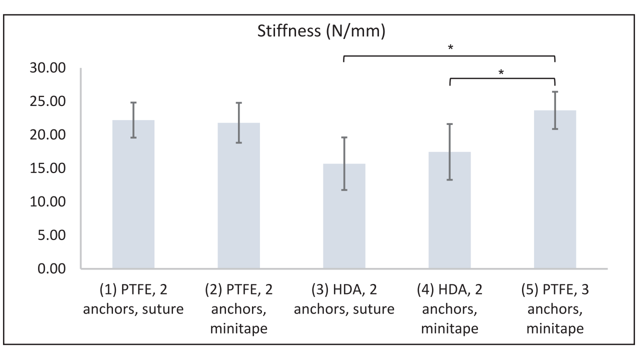

Fig. 5. Stiffness (N/mm) for groups 1–5. *PTFE* polytetrafluoroethylene, *HDA* human dermal allograft.
*$P < .05$ calculated with 1-way analysis of variance using the Tukey multiple comparisons test.

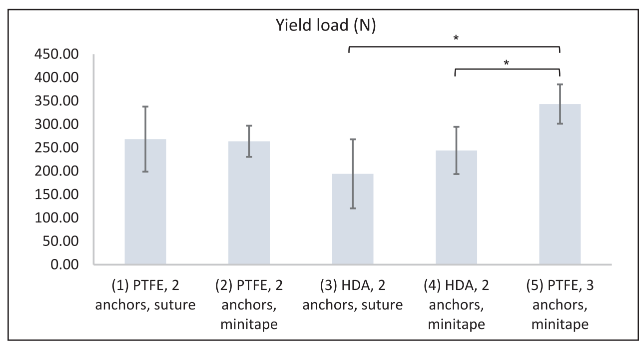

Fig. 6. Yield load (N) for groups 1–5. *PTFE* polytetrafluoroethylene, *HDA* human dermal allograft.
*$P < .05$ calculated with 1-way analysis of variance using the Tukey multiple comparisons test.

5 had a significantly greater yield load (343 ± 42 N) than group 3 (194 ± 74 N; $P = .001$) or group 4 (244 ± 50 N; $P = .038$) (Fig. 6). Group 5 had a significantly greater peak energy (4 ± 2 N m) than group 3 (2 ± 1; $P = .006$) or group 4 (2 ± 1 N m; $P = .044$) (Fig. 7a). Group 5 had a significantly greater ultimate energy (8 ± 3 N m) than group 1 (4 ± 1 N m; $P = .041$), group 2 (4 ± 1 N m; $P = .028$), group 3 (2 ± 1 N m; $P = .001$), or group 4 (3 ± 1 N m; $P = .002$) (Fig. 7b).

Discussion

Our major finding in this biomechanical study was that SCR with PTFE, 3 anchors, and minitape demonstrated a significantly greater peak load, ultimate energy, stiffness,

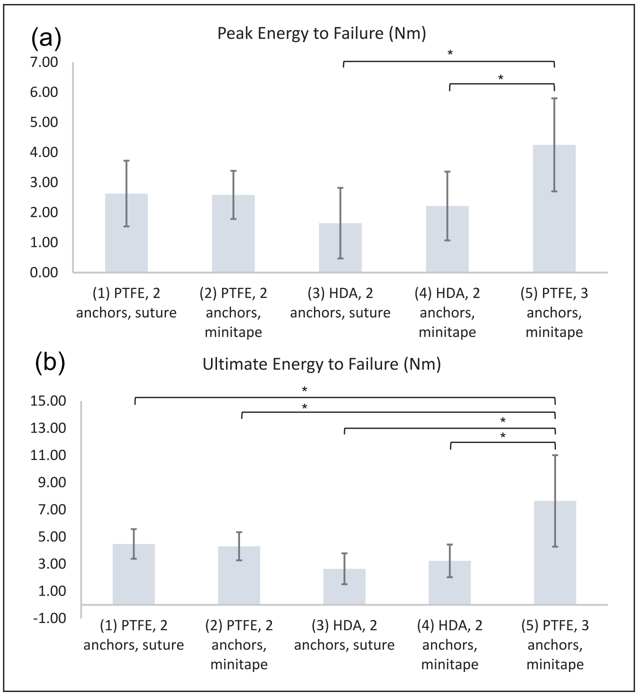

Fig. 7. (a) Peak energy (N m) and (b) ultimate energy for groups 1–5. *PTFE* polytetrafluoroethylene, *HDA* human dermal allograft. *$P < .05$ calculated with 1-way analysis of variance using the Tukey multiple comparisons test.

and yield load than HDA with 2 anchors and suture or HDA with 2 anchors and minitape at the glenoid interface. Polytetrafluoroethylene with 3 anchors and minitape also demonstrated a significantly greater ultimate energy than all other groups. Our hypotheses, that PTFE would be superior to HDA and that 3 anchors would be superior to 2 anchors, were affirmed, whereas our hypothesis that suture would be superior to minitape was refuted.

This study has some limitations. First, we focused on one side of the repair and did not analyze the patch-greater tuberosity interface. However, we focused on the glenoid interface because of the tendency for SCR to fail at the glenoid in the clinical setting [3,9,12,18,39]. Second, we used Sawbones instead of cadaveric models, and as with any ex vivo biomechanical study, we were unable to account for any biological changes that would occur clinically. The focus of this study was on the material properties of the graft itself. Finally, a larger sample size may have revealed more subtle differences between groups.

Peak load was the greatest load before failure, peak energy was the energy absorbed by the repair up to the yield point, and ultimate energy was the energy that was absorbed by the repair until it failed completely. While these are important material properties, stiffness, the resistance to elastic deformation, and yield load, the load at which elastic deformation becomes plastic deformation, are more clinically relevant properties when one considers the repetitive, low-grade stresses that occur in vivo. Because superior capsule reconstruction is a static stabilizer, its efficacy is diminished as it loses tension at higher angles of abduction [27]. Stiffer grafts with higher yield loads are less susceptible to plastic deformation, thereby preserving the graft's ability to buttress the humeral head and reduce superior translation and subacromial contact pressure [25].

Among 2-anchor repairs, the most common mode of failure was by button-holing of the suture or minitape through the patch, which occurred in 6/6 samples for all 2-anchor groups except for the PTFE, 2 anchors, and suture group, in which suture cutout occurred in 2/4 samples. This demonstrated that 2 anchor repairs failed at the patch-suture interface in preference to bony damage. The most common mode of failure in the PTFE with 3 anchors and minitape group was by avulsion of Sawbones, which occurred in 3/6 samples, followed by button-holing. A potential clinical implication of glenoid avulsion would be destruction of bone stock, resulting in increased difficulty if revision arthroplasty is needed.

Among the groups that used 2 anchors, there were no significant differences in peak load, ultimate energy, peak energy, stiffness, or yield load between PTFE and HDR, or between suture and minitape.

In conclusion, glenoid-sided superior capsule reconstruction with PTFE, 3 anchors, and minitape demonstrated greater peak load, peak energy, stiffness, and yield load than either HDR with 2 anchors and suture or minitape, and greater ultimate energy than all other groups. The most common mode of failure was button-holing of suture/minitape through the graft. There were no differences between suture and minitape in 2-anchor repairs.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: George A.C. Murrell, MD, DPhil, reports relationships with Smith & Nephew, the *Journal of Shoulder and Elbow Surgery*, and *Shoulder and Elbow*. The other authors declare no potential conflicts of interest.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Human/Animal Rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

Informed Consent

Informed consent was not required for this biomechanical study.

Level of Evidence

Level V, Biomechanical Study.

Required Author Forms

Disclosure forms provided by the authors are available with the online version of this article as supplemental material.

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