INTRODUCTION:
Scaffolds used for repair and augmentation of rotator cuff tendons should possess appropriate mechanical properties and be applied in a surgically appropriate manner [1,2]. This study aimed to evaluate the failure and fatigue biomechanics of acellular dermis constructs tested in a surgically relevant size and loading condition (loaded via sutures). The effect of two surgical variables: (i) the fixation of grafts under varying magnitudes of pretension, and (ii) the use of reverse-cutting versus tapered needles for suturing the grafts were also investigated. We hypothesized that application of increasing in situ pretension would reduce elongation and increase stiffness of dermis patches during fatigue testing. Secondly, we hypothesized that dermis constructs prepared with reverse-cutting needles would have reduced fatigue behavior compared to constructs prepared with tapered needles.

METHODS:
Hydrated acellular human dermis patches (4×4 cm; AlloPatch HD™, Musculoskeletal Transplant Foundation, Edison, NJ) were affixed to a custom tension-with-side-constraint test apparatus using 16 peripheral, simple, interrupted sutures applied with tapered needles (Fig 1). All testing was performed in a saline bath at 37°C using a materials testing machine. Failure mechanics of dermis constructs were assessed with the constructs subjected to 10N of static side pretension at the onset of the test, preloaded to 5N in the vertical axis, preconditioned for 10 cycles from 5−15N at 6 mm/min, and loaded to failure at 30 mm/min (n = 6). Fatigue mechanics of dermis constructs were studied by cyclic loading from 5 to 150N for 2500 cycles at 0.25Hz, after application of varying magnitudes of circumferential pretension (0, 10 or 20N) at the onset of the test (n = 6/group). To determine the effect of needle type on fatigue mechanics of dermis constructs, an additional group of constructs (n = 6) were prepared by applying the sutures using a reverse-cutting needle and similarly fatigue tested after application of 10N circumferential pretension. The results were compared with the corresponding constructs sutured using tapered needles.

RESULTS:
In failure tests, dermis patches showed a bilinear load-displacement profile and stretched ~25% (~11 mm: 6mm from preconditioning and 5mm in toe region) before bearing significant loads in the high stiffness region (Fig 2). While 91% (21/24) of the patches withstood 2500 cycles of loading to 150N, suggesting their robustness for use in soft tissue repair, the patches underwent significant elongation and accumulated 13−19mm of (presumably) non-recoverable elongation after fatigue loading (Figs 3-4). This elongation could be reduced by 20−32% when reverse-cutting needles were used to prepare constructs (Fig 3) or by applying 20N of initial circumferential tension to the constructs before loading (Fig 4).

DISCUSSION:
This study indicates that use of reverse-cutting needles for suture passage, preconditioning (cyclically stretching several times) and/or surgical fixation under at least 20N (5lb) of circumferential pretension could be developed as strategies to remove at least some of the compliance of dermis in order to optimize its use for rotator cuff repair.

Figure 1. Tension-with-side-constraint test apparatus

Figure 2. Average load-displacement curve from failure tests (n=6)

Figure 3. Fatigue testing showed that dermis sutured using reverse-cutting needles (10N-CT group) had lower cyclic elongation compared to dermis sutured using tapered needles (10N group) (* p < 0.01).

Figure 4. Fatigue testing after application of varying magnitudes of circumferential pretension (0, 10 or 20N) showed that pretensioning to 20N lowered cyclic elongation (* p < 0.05)

SIGNIFICANCE:
This study evaluated the biomechanical performance of acellular dermis as a surgically relevant construct and suggests surgical strategies that could be used to improve the outcome of rotator cuff repair and augmentation.

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