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The biomechanical role of scaffolds in augmented rotator cuff tendon repairs

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Background: Scaffolds continue to be developed and used for rotator cuff repair augmentation; however, the appropriate scaffold material properties and/or surgical application techniques for achieving optimal biomechanical performance remains unknown. The objectives of the study were to simulate a previously validated spring-network model for clinically relevant scenarios to predict: (1) the manner in which changes to components of the repair influence the biomechanical performance of the repair and (2) the percent load carried by the scaffold augmentation component.

Materials and methods: The models were parametrically varied to simulate clinically relevant scenarios, namely, changes in tendon quality, altered surgical technique(s), and different scaffold designs. The biomechanical performance of the repair constructs and the percent load carried by the scaffold component were evaluated for each of the simulated scenarios.

Results: The model predicts that the biomechanical performance of a rotator cuff repair can be modestly increased by augmenting the repair with a scaffold that has tendon-like properties. However, engineering a scaffold with supraphysiologic stiffness may not translate into yet stiffer or stronger repairs. Importantly, the mechanical properties of a repair construct appear to be most influenced by the properties of the tendon-to-bone repair. The model suggests that in the clinical setting of a weak tendon-to-bone repair, scaffold augmentation may significantly off-load the repair and largely mitigate the poor construct properties.

Conclusions: The model suggests that future efforts in the field of rotator cuff repair augmentation may be directed toward strategies that strengthen the tendon-to-bone repair and/or toward engineering scaffolds with tendon-like mechanical properties.

Level of evidence: Basic Science Study.

Keywords: Rotator cuff; shoulder; scaffolds; biomechanics; model

An estimated 75,000 rotator cuff surgeries are performed annually in the United States.[24] Although surgical treatment and rehabilitation strategies continue to evolve, the surgical management of these tears still poses a significant challenge to the orthopedic community, as evidenced by the 20% to

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90% repair failure rates reported after rotator cuff repair surgery.[1,6,7,12-14,16] High surgical failure rates can be attributed to a number of biologic, anatomic, and mechanical factors, which include inferior tissue quality, tendon retraction, muscle atrophy and fatty infiltration, undue tension at the repair site in the early postoperative period, and the synovial fluid environment.[5,8,15,22,23] Although different repair strategies and hardware, immobilization protocols, and postoperative rehabilitation approaches have been used to reduce rotator cuff repair failure rates,[11,17-19,21] structural repair failure remains a problem. Hence, there is a critical need to develop mechanical and/or biologic augmentation repair strategies to increase the clinical success of these repairs.

During the last decade, natural and synthetic biomaterials have been developed as scaffolds for tendon repair augmentation. Currently, scaffolds derived from various natural and synthetic biomaterials are being marketed as augmentation devices for rotator cuff repairs at the time of surgery.[3,9,10] The US Food and Drug Administration (FDA) has cleared these devices "to support soft tissues where weakness exists" but not "to provide the full mechanical strength for the tendon repair." The mechanical connotation of their intended use leads to the common belief that when applied appropriately, these devices may provide some degree of load-sharing of forces across the tendon repair site and thus decrease the likelihood of tendon retear.

Although significant advances have been made in the development of scaffolds for rotator cuff repair augmentation, there are limited experimental data to support the notion that scaffold augmentation of a tendon repair will actually improve the biomechanical performance of the repair construct. McCarron et al[20] recently showed that augmentation with a polylactic acid scaffold device (X-Repair, Synthasome Inc, San Diego, CA, USA) significantly increased the yield load (56%-92%) and ultimate load (56%-76%) of rotator cuff repairs in a human cadaver model.[20] X-Repair augmentation also altered the mode of repair failure: failure by sutures cutting through the tendon was reduced, occurring in 17 of 20 nonaugmented repairs but in only 7 of 20 augmented repairs. In another study, Barber et al[4] demonstrated a 19% increase in failure load and fewer failures at the suture−tissue interface for supraspinatus repairs augmented with GraftJacket (Human Acellular Dermis, Wright Medical, Arlington, VA, USA) compared with nonaugmented repairs.

Although these studies demonstrate the potential for scaffold augmentation to improve the initial biomechanical properties of a rotator cuff repair construct, the appropriate scaffold material properties and/or surgical application techniques for achieving optimal biomechanical performance in the setting of rotator cuff repairs are unknown. Furthermore, no studies to date have investigated the percent load carried by a scaffold when used for rotator cuff repair augmentation.

To address these questions and enhance our understanding of the basic mechanics of scaffold augmentation, we recently developed and validated a spring-network model for nonaugmented and augmented human rotator cuff repairs.[2] The objectives of the current study are now to use this model to predict (1) the manner in which simulated changes to components of the tendon repair, such as reduced tendon quality, altered surgical technique, and different scaffold designs, influence the biomechanical performance (yield load and stiffness) of the repair construct and (2) the percent load carried by the scaffold augmentation component of the repair construct in each of these simulated clinical scenarios.

Materials and methods

We previously developed and validated a spring-network model for simplified nonaugmented and augmented human rotator cuff repairs, based on the physics of springs in series and in parallel.[2] For the cadaveric rotator cuff repairs, a strip of the superior infraspinatus tendon (12 mm wide) was released and repaired to the greater tuberosity using a double-row transosseous technique with 2 Mason Allen sutures per row.[20] The prototypical augmentation graft used for the augmented repairs was a poly-L-lactic acid (PLLA) scaffold (X-Repair, Synthasome Inc, San Diego, CA, USA). The nonaugmented repair was modeled as 2 springs in series (Fig.1, *A* and *B*), and the augmented repair was modeled as a combination of 5 springs in series and parallel (Fig. 1, *C* and *D*). The individual spring components, representing the points of compliance of the repair constructs, were modeled as nonlinear springs (Table I). The springs representing the tendon (spring #2), scaffold augmentation component (spring #3) and scaffold-tendon attachment (spring #4) were modeled using a single phase nonlinear equation, $F = F^o + Ax^b$, and the spring representing the tendon-to-bone repair (spring #1) was modeled using a biphasic nonlinear equation, $F = F^o + \frac{Ax^b}{1 + Bx^c}$. In these equations, force (F) is a function of the displacement (x) of the individual spring component. The parameters F^o, A, B, b, and c were estimated using nonlinear least-squares analysis of experimental data from each individual component. The aggregate spring-network models were validated by comparing the model predictions to in vitro experimental data in the failure-loading region of repair constructs that were preconditioned for 100 cycles from 50 to 150 N at 0.25 Hz and subsequently distracted to failure with uniaxial loading in tension at 30 mm/min.[20] Further details of the model and its validation have previously been described.[2]

In the current study, the validated models were varied parametrically to simulate clinically relevant scenarios, namely, changes in tendon quality, altered surgical technique(s) and different scaffold designs. More specifically, parameter A of the tendon-to-bone repair (spring #1), the scaffold augmentation component (spring #3), and the scaffold-tendon attachment (spring #4) was varied from its respective baseline value, while keeping other parameters at their respective baseline values. (The baseline values are those derived from the actual experimental data). Although the parameter A itself does not have any particular physical significance, it is a proportionality constant associated with changes in load-displacement characteristics of a given spring component and hence can be varied to simulate different clinical scenarios, such as weak and/or strong tendon-to-bone fixation, degenerative tendon tissue, or compliant/stiff scaffolds.