

AUGMENTATION DEVICES FOR ROTATOR CUFF REPAIR

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Rotator cuff tears affect 40% or more of those over age 60 and are a common cause of pain and disability. Surgical repairs have high failure rates that range from 20 to 90%. Currently, scaffolds derived from various natural and synthetic biomaterials are being marketed as augmentation devices for rotator cuff repairs at the time of surgery¹⁻³. 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”. Based on the mechanical connotation of their intended use, it is commonly believed 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 re-tear.

However, there is limited experimental data to support the notion that scaffold augmentation of a tendon repair will actually improve the biomechanical performance of the repair construct^{4,5}. Furthermore, the appropriate scaffold material properties and/or surgical application techniques for achieving optimal biomechanical performance in the setting of rotator cuff repairs are unknown, and no studies to date have investigated the percent load carried by a scaffold when used for rotator cuff repair augmentation.

The purpose of this paper is to review the current basic science and clinical understanding of augmentation scaffold devices for rotator cuff repair. Our review will emphasize the host immune response and scaffold remodeling, the mechanical and suture retention properties of devices, human cadaver models, and clinical studies on the use of augmentation devices for rotator cuff repair.

Further we have recently developed and validated an analytical model for non-augmented and augmented human rotator cuff repairs⁶. We will describe how we used 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.

Finally, we will discuss the implications of these data on the future directions for use of these scaffolds in tendon repair procedures.

Reference List

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