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Biological Augmentation in Repair and Reconstruction of the Rotator Cuff

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Rotator cuff tears are among the most common causes of pain and disability in the upper extremity. Despite significant advances in repair techniques and instrumentation, retear rates after surgery remain high. Numerous avenues of structural and biological augmentation have been explored to increase healing potential and achieve successful outcomes particularly in patients with massive cuff tears and those undergoing revision surgery. The purpose of this article is to present and discuss various techniques currently published that are designed to augment this process through variable methodologies. A common methodology is the use of graft tissue to "load share" with the repair or facilitate placement of pluripotential stem cell or growth factors at the site of needed healing or both. Although this field remains in development, this article attempts to explain the concepts currently employed and summarize the current Food and Drug Administration–approved options.
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Introduction

Rotator cuff tears are among the most common causes of pain and disability in the upper extremity. A recent analysis reported an increase in the number of rotator cuff repairs performed annually with a 2010 estimate of 200,000 surgeries performed.[1] Moreover, the cost-benefit analysis of rotator cuff surgery has been established with a reported age-weighted mean total societal savings of $13,771 with rotator cuff repair compared to nonoperative treatment.[2] It is clear that these injuries represent a common problem for which repair has a clear patient and societal benefit despite, in many situations, the lack of a reproducible treatment, particularly in the treatment of large to massive cuff tears.

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Evermore emphasis in recent years has been placed on optimizing the biological processes involved in healing. Biologics in orthopaedic surgery refers to harvested natural products used to augment a surgical repair or reconstruction to enhance or optimize healing potential. Basic science and biomechanical research of the tendon-to-bone interface, enthesis, has shown that biomechanically inferior fibrovascular tissue forms at the repair site subsequently making repairs prone to failure.[3-7] This tissue is biomechanically weaker than the native calcified fibrocartilage secondary to its more organized, linear collagen alignment and its calcified basement membranous attachment, both are absent in a naïve repair (Fig. 1). In an attempt to circumvent such obstacles to healing, numerous autograft and allograft tendon sources have been described, and different methods of biological augmentation have been employed including various growth factor and cell- and tissue-based products. Interestingly, within the field of regenerative medicine, the concepts remain the same, namely that all 3 factors are ultimately needed—a scaffold on which to work, cells that can be directed to differentiate to specific tissue types, and exogenous or endogenous chemical modulators that can initiate, enhance, and direct tissue development (Fig. 2). One

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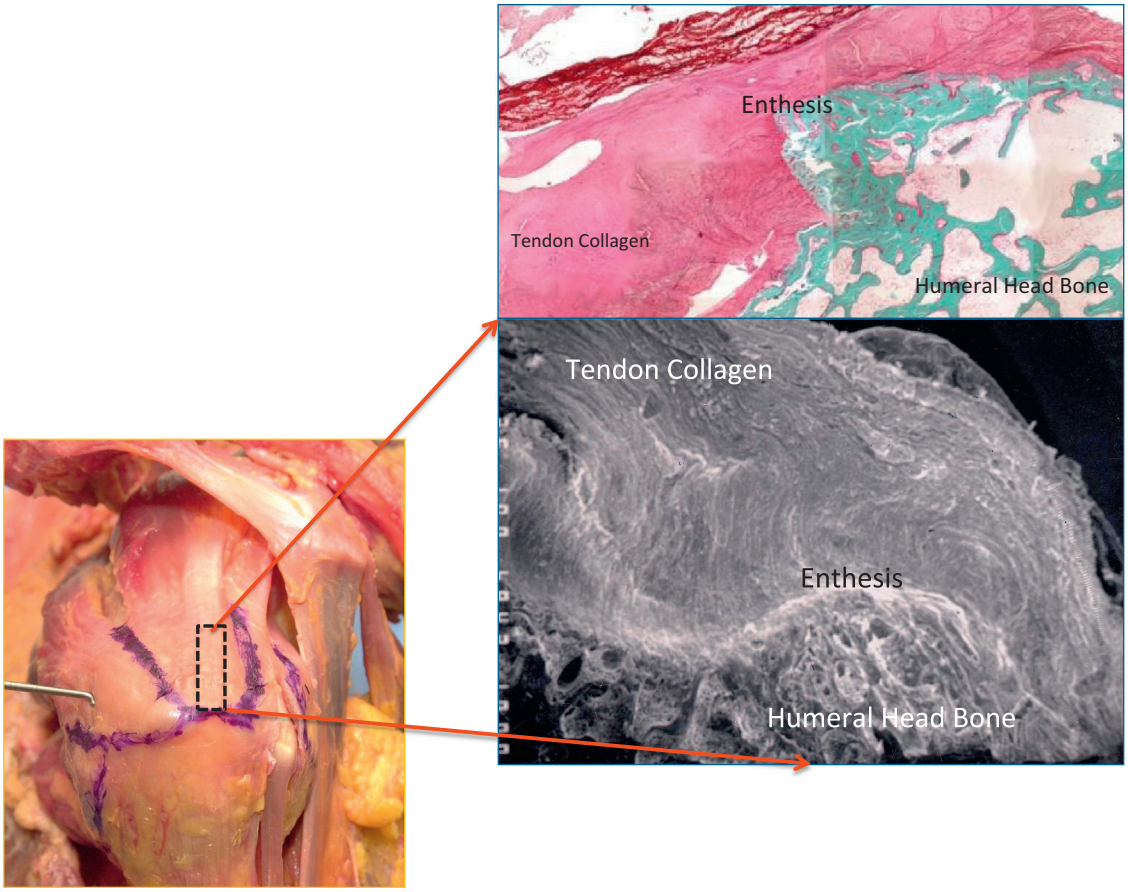

Figure 1 Microscopic view of tendon enthesis.

can appreciate the complexity of this task and realize that optimal results are multifactorial, which we are only beginning to understand.

Despite evolving surgical techniques, a significant percentage of rotator cuff tears fail to heal, and retear after surgery remains a common complication. Several factors contribute to repair failure including patient age, tear chronicity, tear size, fatty infiltration, and muscle atrophy. Therefore, evolving augmentation products are of particular interest in the setting of revision rotator cuff surgery where standard repair measures have failed and risks of poor outcome and retear are increased. Likewise, massive cuff tears represent a particularly difficult subset of patients with reported retear rates as high as 96%.[8-10] These situations necessitate increased measures to facilitate enhanced healing potential. The purpose of this review is to provide an overview of autograft, xenograft, and allograft tendon augmentation options; summarize the regulation of biologics; and examine the current body of literature regarding biologics in rotator cuff repair surgery to effectively help surgeons direct optimal healing and achieve successful results in their patients.

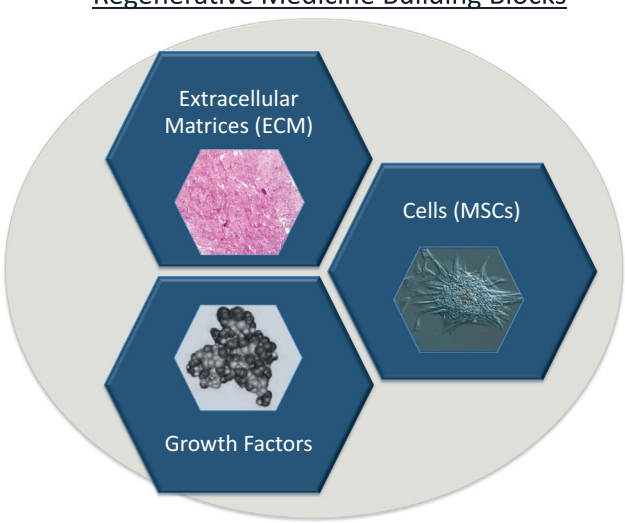

Figure 2 Regenerative medicine building blocks.

Regulation of Biologics

The use of biologics in the United States is regulated by a branch of the US Food and Drug Administration (FDA) known as the Center for Biologics Evaluation and Research.[11] Some of the biologics used in rotator cuff repair are under the purview of the FDA. These include allografts, which are regulated under Title 21, Part 1270, of the Code of Federal Regulations (CFR). These regulations require that the FDA's good tissue practices be followed. The term "HCT/Ps" is used to describe human cells, tissues, and cellular- and tissue-based products. Most of

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