Tissue Engineering Strategies for Rotator Cuff Repair

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Healing of full thickness rotator cuff tears, after either open or arthroscopic repair, varies from 5% to 95%.[1-4] Factors that affect healing include the size of the tear; the quality of the tendon and muscle tissue; the method of repair; postoperative rehabilitation and patient medical comorbidities; and environmental factors, such as tobacco use.[1-9] Over the past 20 years, we have learned that supraspinatus tears involving the anterior cable,[10] as well as larger chronic tears involving 2 tendons, result in (1) muscle atrophy and fatty infiltration that change the material properties of the tendon muscle unit, (2) difficulty with tendon mobilization,[11] and (3) increased strain on the rotator cuff.[12,13] Most tendon tears occur through diseased tendon tissue, resulting in decreased ability for suture retention.[14-17] The most common mechanism of rotator cuff repair failure is believed to be suture cutting through tendon secondary to excessive tension at the repair site. We believe that, generally, this occurs as a gradual elongation or gap formation associated with cycle loading. When tendon tissue is formed between the muscle and greater tuberosity, the tendon is considered, according to magnetic resonance imaging or ultrasound criteria, to have healed, but in follow-up studies the atrophy or fatty changes in the muscle do not improve, and in some cases, increase in severity.[18]

The goal of most tissue engineering (TE) strategies is to improve the percentage of repairs that heal and recovery of the muscle atrophy and fatty changes. The TE strategies have, for the most part, concentrated on the repair of full thickness tears, using the most current knowledge to optimize the surgical procedure and the postoperative rehabilitation. These TE strategies have considered the mechanical and biologic factors associated with the healing process and have used natural or synthetic patches to mechanically augment the repair site.[14,16,19-26] Some TE strategies that have been applied clinically, including platelet rich plasma (PRP) as a source of growth factors, increase the biologic potential of the healing tissues.[27] Other strategies consider both the biologic potential of the healing tissues and the matrix graft materials. To date, there are no level 1 studies published in the peer review literature that demonstrate a positive clinical effect of any currently FDA-approved graft material or preparation of PRP. In fact, results of one level 1[23] and one level 2[26] study show an adverse effect of one of the extracellular matrix patches currently on the market for augmentation of rotator cuff repair.

Despite the growing clinical use of scaffold devices for rotator cuff repair, there are numerous questions related to their indication, surgical application, safety, mechanism of action, and efficacy that remain to be clarified or addressed. Some of these issues can be evaluated in a laboratory setting. For instance, several recent studies have evaluated robust mechanical and suture properties, the ability to limit gap formation in a human rotator cuff repair model, and biocompatibility and ability to enhance tendon repair in an animal model. Their results demonstrate that some of the grafts currently on the

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market are able to meet most of these criteria. What are lacking, however, are the carefully designed and executed clinical studies to provide the necessary data to define how and when these scaffold devices are effective.

In summary, there is an important clinical need to improve the healing of rotator cuff repairs. A successful strategy likely will involve a scaffold-based approach that provides both mechanical and biologic augmentation, with the goal of minimizing gap formation, restoring muscle–tendon length, and enhancing tendon–bone repair. Some scaffold devices currently available on the market have sufficient preclinical data to support their investigation in a clinical trial. The obligation of the orthopedic community is to execute carefully designed level 1 studies to define what, how, and when these devices are effective.

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