REVIEW

Biological augmentation strategies in rotator cuff repair

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ABSTRACT

Rotator cuff tears (RCT) are a common problem encountered by orthopaedic surgeons. The incidence of re-tears (up to 94%) following surgical repair of RCTs renders the management of RCTs challenging. This higher re-tear rate has been attributed to the failure of healing at the tendon-bone junction. Biological augmentation methods such as growth factors, stem cell therapies, and biomaterials have been developed to promote the healing at the tendon-bone junction. Growth factors and stem cell therapies have been intensively studied in mid to large RCTs. Biomaterials have been generally utilized for large or massive RCTs. However, these newly generated biological augmentation strategies are mostly studied in animal models. The efficacy and safety of the biological augmentation methods in humans need further investigation. In this review, we aimed to highlight the most recent advancements in RCT surgical repair with biological augmentation.

Key words: platelet-rich plasma, rotator cuff injuries, stem cells, tissue engineering

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INTRODUCTION

Rotator cuff tears (RCT) are a frequent problem encountered in daily orthopaedics practice. There has been an increase in the incidence of patients undergoing surgery due to RCT since 2001 (1). It has been reported that more than 16000 RCT repairs were performed only in New York State in 2009, and the incidence of surgical procedures for RCTs has an upward trend (2).

Patients with RCT often complain of shoulder pain and disability. Thus, surgical repair of RCTs aims to alleviate the shoulder pain (3). Although surgical repair of RCTs commonly resolves the shoulder pain, re-tear following RCT repair is a major concern for orthopaedic surgeons. Re-tear rate after RCT repair has been reported to range up to 40% for small to medium tears and up to 94% for large and chronic tears (4). The etiology of re-tears has been investigated and it has been reported that initial biomechanical strength of the repair, tear size, tissue quality of the tendon were strongly associated with re-tear rates (5).

The tendon to bone healing following RCT repair is quite different than the original structure of tendon-bone junction. The native tissue of tendon insertion to the bone is composed of mostly type I collagen fibres. On the other hand, repaired RCT does not regenerate and tendon-bone interface is made up of a fibro vascular scar tissue containing predominantly type III collagen fibres (6). In addition, these type III collagen fibres are less organized and have reduced tensile strength than the original structure of tendon insertion (7).

As the biology of tendon to bone healing in the surgical repair of RCT has been enlightened in more detail (6,7), biological augmentation became an encouraging method to improve the healing of repaired RCT (5). Current literature has focused on the biological solutions for decreasing the re-tear rate following the surgical repair of RCT (8-11).

In this review, we will discuss the current biological augmentation strategies in the treatment of RCT.

GROWTH FACTORS

Platelet-rich plasma (PRP)

Platelet-rich plasma (PRP) is an autologous concentration of the patients' blood to enrich the platelet level. The platelet concentration of PRP has been reported to be three or five folds of the normal concentration. Some growth factors such as platelet-derived growth factor (PDGF), insulin-like growth factor-1 (IGF-1), transforming growth factor-β (TGF-β), and vascular endothelial growth factor (VEGF) could be released by platelets and these growth factors have been shown to enhance tendon healing (11). Owing to the potential effects of PRP on soft tissue regeneration, PRP has gained popularity during the surgical repair of soft tissues (11,12).

The augmentation of RCT with PRP has been intensively studied in the last decade with animal studies as well as clinical trials (12,13). There are controversial results regarding the effect of PRP on RCT repairs. Dolkart et al. reported that a single dose of PRP during surgical repair of a rat's supraspinatus tendon enhanced the histological parameters of tendon healing, resistive strength to load and tendon stiffness (13). Despite the promising effect of PRP on RCT repair in animal models, many clinical trials failed to demonstrate its positive effect in the re-tear rate following RCT repair (12,14,15). On the other hand, in a recent systematic review with meta-analysis Cavendish et al. reported that perioperative augmentation of RCTs with PRP reduces the re-tear risk; however, the authors were unable to make a specific recommendation due to variable PRP preparation procedures (11).

Other growth factors

Growth factors were up-regulated in the injury site during tendon healing until the establishment of the tissue repair (16). In contrast to the high data volume regarding PRP on tendon healing, several studies have investigated a single growth factor or a mixture of growth factors mostly in animal models (17-19). Bone morphogenetic protein (BMP)-7 has been reported to improve enthesis matrix production in a rat RCT model (20). Lamplot et al. demonstrated that BMP-13 yielded higher mechanical strength than PRP in rat supraspinatus tendon insertion model (17). During the revascularization of the injured tendon, VEGF expression in the endothelial cells increases. In addition, VEGF has been reported to improve tendon healing via inhibiting microRNA-205-5p expression in a rat model (18). The VEGF is a major growth factor in tendon healing by promoting vascularization; however, excessive vascularization could lead to proteolysis of the extracellular matrix (21). Rodeo et al. investigated a mixture of growth fac-

tors including TGF-β1, TGF-β2, and TGF-β3; fibroblast growth factor (FGF); and BMP-2 through 7 utilizing a type I collagen sponge in a sheep infraspinatus tear model. The experimental group had higher fibrocartilage formation, better mechanical strength than the control group (19).

Growth factor levels have a fluctuating concentration during rotator cuff healing. It has been demonstrated in rat and rabbit studies, their levels rise and fall in two weeks starting from the injury time (22). Thus, a single bolus of injection during the surgical repair of RCT may not be the optimal method for RCT augmentation. A protocol mimicking the natural healing period by augmentation with growth factors needs further investigations.

STEM CELLS

Considering the importance of the biological environment during tendon healing, stem cell therapies have gained popularity in recent years (9). Mesenchymal stem cells (MSC) are commonly used for the biological augmentation of soft tissue repairs due to their secretory capability of trophic factors in wound healing, inflammation and fibrocartilage formation (23). Promising results have been reported with the utility of MSCs in animal RCT models. Omi et al. reported that bone marrow-derived MSCs increased the healing strength and stiffness following RCT repair in a rat model (24). Kaizawa et al. augmented the RCT repair with adipose-derived MSCs in a rat chronic supraspinatus tear model: at the eighth week, adipose-derived stem cell augmentation group revealed better bone morphometry at the supraspinatus insertion on the humerus than the non-augmented control group (8). Morton-Gonzaba et al. recently conducted meta-analysis on the application of MSCs to rotator cuff pathologies including 18 pre-clinical studies. Their analysis revealed that biologic augmentation with MSCs improved biomechanical failure loads, bone mineral densities, and stimulated fibrocartilage formation. Despite the promising outcomes with MSC augmentation, the authors emphasized the requirement for optimizing MSCs for standard protocols (9).

Owing to the encouraging results with the utility of MSCs in RCT surgical repairs in animals, MSCs have started to be used for biological augmentation in humans as well (25). Different sources of MSCs such as bone marrow, adipose, muscle, tendon, bursa derived have been used in pre-clinical studies for the augmentation of RCT repairs (26). However, two autologous sources of MSCs, bone marrow-derived and adipose-derived, are currently available for commercial use (5).

The first study reporting the results of biologic augmentation with bone marrow-derived MSCs during RCT surgery was conducted by Ellera Gomez et al. in 2011. The authors repaired 14 patients' RCT with trans osseous stitches through mini-open incision and injected bone marrow-derived MSCs to the tendon borders which were obtained from iliac crests. MRI was obtained from each patient after 12 months and revealed tendon integrity in all patients. At a minimum 12 months of follow-up, patients had significant improvements in the UCLA scores except for one patient (27). Since then only one study has reported utilizing bone marrow-derived MSC for the biological augmentation for RCT. Hernigou et al. compared the outcomes of 90 patients who underwent arthroscopic single-row RCT repair with (n=45) or without augmentation (n=45) with bone marrow-derived MSCs aspirated from anterior iliac crest. Injection of MSCs was performed to the tendon-bone junction and to the footprint. The most important finding was that the augmentation of RCT surgical repair with MSCs reduced re-tear rate. At the most recent follow up, 87% of the augmented group had intact rotator cuff while the non-augmented group had 44% (28).

In the two published studies regarding augmentation of RCT with bone marrow-derived MSCs, cells were obtained from ilium before the surgery (27, 28). However, Otto et al. reported that proximal humerus is a reliable source for bone marrow-derived MSCs as ilium during arthroscopic surgery (29). Considering the positive effect of bone marrow-derived MSCs on RCT repair and easy access through proximal humerus during shoulder arthroscopy, biological augmentation may turn to be a routine procedure. On the other hand, the presence of limited data with only two reported studies with bone marrow-derived MSC augmentation does not allow strong recommendation.

Administration of adipose-derived MSCs on RCT is mostly centred around intratendinous injections in the literature. The first human trial was conducted by Jo et al. in 2018 with adipose-derived MSCs on RCT. The authors investigated three different

injection doses of adipose-derived MSCs, the low dose (1.0×10^7 cells), mid dose (5.0×10^7 cells), and high dose (1.0×10^8 cells). Arthroscopic examination at sixth month revealed that the size of RCT defects decreased 83% in mid doses and 90% in high doses (30). The authors also followed the same patients for 2 years and MRIs of the patients in high dose group at first-year demonstrated that bursal side tears almost disappeared and did not recur in the second year (31). Only a single study by Kim et al. has reported the biologic augmentation of RCT repair with adipose-derived MSCs in humans. The authors compared arthroscopic double-row repair technique with or without augmentation with adipose-derived MSCs and reported that re-tear rate with MRI evaluation at minimum 12 months after surgery was 28.5% in the non-augmented group and 14.3% in the augmented group. Further studies are warranted evaluating the biologic augmentation of RCT repair with adipose-derived MSCs because of limited evidence in the literature.

BIOMATERIALS

High failure rates especially following large RCT have promoted seeking new strategies to reduce re-tear rates. Improvements in tissue engineering studies have allowed the use of scaffolds that maintain cellular ingrowth while providing mechanical support until healing. Various types of biomaterials including xenografts, allografts, and synthetic grafts have been used to augment healing after RCT repair (10).

Xenografts

Xenografts originating from different species of different tissues have been developed in recent years. Using an acellular sheet of cross-linked porcine dermis for the augmentation of massive RCTs Cho et al. found that the MRI of the patients at eight months follow-up demonstrated 80% integrity of rotator cuff (32). However, Soler et al. reported 100% inflammatory reaction in their small case series including four patients with using the same acellular sheet of cross-linked porcine dermis (33). Gupta et al. used porcine dermal tissue matrix xenograft in 27 shoulders with massive or two-tendon RCT: a total of 73% of the patients had visible intact rotator cuff on ultrasonography at the most recent follow-up and only one patient had complained of re-tear (34). Arnocky et al. investigated the histological behaviour of highly porous reconstituted bovine collagen implants in seven patients at an average of 3 months (5 weeks to 6 months) after surgery; histology sections revealed aligned linear orientation of the cells within the collagen implant structure (35). Due to the small number of studies with small patient population, further human studies are needed before the wide use of xenografts.

Allografts

Allografts that are harvested from tensor *fascia lata* or skin tissue have been used for the biological augmentation of the RCT repairs. Agraval et al. used acellular human dermal graft in patients with large, massive and re-teared RCT; MRIs of the patients demonstrated 85.7% intact rotator cuff in addition to the favourable functional outcomes (36). Barber et al. investigated the effect of dermal grafts prepared from epidermal and dermal layers of human skin in a prospective, randomized controlled trial including patients with massive and two-tendon RCT and found that MRI scans showed 85% intact rotator cuffs in the augmented group but 40% in the non-augmented group (37). In the Hohn et al. study with the minimum 2 years follow-up, 69% of patients who underwent revision RCT repair surgery with the use of acellular human dermal matrix allograft showed intact repair constructs in MRI or ultrasonography (38). Further research is required with larger patient populations to confirm the findings of existing literature regarding the allografts.

Synthetic grafts

Synthetic grafts could be synthesized from variable polymers such as polyester, polyacrylamide, polypropylene, dacron, silicon, carbon, or nylon. Synthetic grafts have drawbacks mainly due to foreign body reactions although they are biomechanically superior to the biologic grafts (39).

Investigating polycarbonate polyurethane scaffold in the open repair of full thickness RCTs of ten patients, Escalada-Diaz et al. reported 10% failure rate at first-year follow-up (40). Proctor reported the long-term outcomes of 18 patients with large to massive RCT with augmentation via poly-l-lactic acid synthetic patch; 83% of the patients had intact rotator cuff at the annual follow-up and 78% had intact rotator cuff at a mean 42 months after surgery (41). Ciampi et al. conducted a controlled study on massive RCT and compared the conven-

tional repair with polypropylene patch augmentation: the polypropylene patch group had 17% re-tear rate at 3 years follow-up while control group had 41% (42). Renebo et al. reported long-term results of a synthetic graft made of Dacron; nine of 12 patients had rotator cuff arthropathy after a mean 17-year follow-up (43). Biologic augmentation with synthetic grafts appears to reduce the re-tear rate, however, a study by Renebo et al.(43) raised questions regarding the success in long-term.

In conclusion, the surgical repair of RCTs has successful outcomes. On the other hand, re-tear of the repaired RCT is a disappointing complication which could be observed up to 94%. Re-tear of the repaired RCT may occur due to a mechanical failure at suture-tendon site at the short term or it can occur later because of insufficient healing at the tendon-bone junction. Biological augmentation strategies aim to promote the repair site located at tendon-bone junction. Most of the studies were performed on animal models in addition to the few human studies without control groups. As the results of biologic augmentation of RCT are promising, further controlled studies with large patient population would be beneficial to translate previous literature to routine clinical use.

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Conflicts of interest: None to declare

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