COMPOSITIONS AND MINIMALLY INVASIVE METHODS FOR TREATING INCOMPLETE TISSUE REPAIR

RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 10/941,124, filed Sep. 15, 2004 which is a continuation of Ser. No. 10/412,821, filed Apr. 11, 2003, now U.S. Pat. No. 6,811,777 which claims the priority of Provisional Application No. 60/372,682, filed Apr. 13, 2002 which are all incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

In one embodiment, the present invention is directed to a method for the treatment of damaged tissue with a composition that includes platelet-rich plasma. The treated tissue may be connective tissue, cardiac muscle, skeletal muscle, disc material, vertebral bodies, pancreas and other internal organs, brain tissue or spinal cord tissue, or vascular tissue. In a preferred embodiment, the tissue is connective tissue. The described compositions and methods are also useful in wound healing and infections.

2. Description of the Related Art

There is a need for treatment protocols for connective tissue injuries which are refractory to standard treatments such as anti-inflammatory medication, bracing, rest and physical therapy. Injuries or other damage to flexible, relatively avascular connective tissues (hereafter "connective tissue" or "connective tissues") are known to take a very long time to heal (months or even years). In many cases, injuries to connective tissues may never heal properly, necessitating surgical intervention. Connective tissue injuries and disorders have a significant impact on society. The overall prevalence of these problems is approximately 140 per 1000 persons in the United States, according to a 1995 survey by the National Center for Health Statistics. The same survey estimated the direct costs to be $88.7 billion and the indirect costs estimated to be up to $111.9 billion for lost productivity.

One example of a connective tissue disorder is lateral epicondylitis. Lateral epicondylitis or "tennis elbow" is a well-known sports medicine and orthopedic disorder. The pathology underlying the disorder is related to overuse injury and microtearing of the extensor carpi radialis brevis tendon at the elbow. The body attempts to repair these microtears but the healing process is incomplete in many cases. Pathologic specimens of patients undergoing surgery for chronic lateral epicondylitis reveal a disorganized angiofibroblastic dysplasia. This incomplete attempt at repair results in degenerative, immature and avascular tissue. Incompletely repaired tissue is weaker than normal tendon tissue and lacks the strength to function normally. This tissue also limits the patient by causing pain and negatively impacting the patient's quality of life.

Similar incomplete repair may be present in other types of connective tissue injuries or damage, such as patellar tendonitis (Jumper's Knee), Achilles tendonitis (common in runners), and rotator cuff tendonitis (commonly seen in "overhead" athletes such as baseball pitchers), chronic injuries of the ankle ligaments ("ankle sprains"), or ligament tears.

The pathophysiology of the above-mentioned conditions have been studied. Presently, many different non-operative and operative treatments exist. The non-operative measures include rest, activity modification, oral anti-inflammatory medication and cortisone injections. Rest and activity modification may help patients with some of these conditions, but

there remains a significant clinical population that are not reachable with these therapies. Despite widespread use, oral anti-inflammatory medications have not proven to be useful in controlled studies. Some studies further suggest that non-steroidal medication may actually have an adverse effect on the healing process for ligament injuries. Also, no acute inflammatory cells have been found in pathologic samples of cases of lateral epicondylitis. Cortisone injections are frankly controversial in the treatment of tendinoses and are contraindicated in acute ligament injuries. Several studies note an improvement in patients treated with cortisone in short term follow up. Results beyond one year, however, reveal a high symptom recurrence rate and only an equivocal efficacy rate. These injections also carry the risk of tendon rupture, infection, skin depigmentation, subdermal atrophy and hyperglycemia in diabetic patients. The operative measures include debridement and repair of the associated pathologic tendons. However, open or arthroscopic surgery has many potential complications such as deep infection, damage to neurovascular structures, and scar formation. The surgery is also expensive and carries the additional risks associated with regional or general anesthesia.

What is needed are compositions and methods for solving the problems noted above. Platelet-rich plasma (PRP) is an enriched platelet-containing mixture, isolated from whole blood, which is resuspended in a small volume of plasma. While whole blood may contain about 95% red blood cells, about 5% platelets and less than 1% white blood cells, PRP may contain 95% platelets with 4% red blood cells and 1% white blood cells. PRP can be combined with activating agents such as thrombin or calcium which activate the platelets to release their contents such as cytokinins and other growth factors. PRP has been used in medicine, primarily in bone grafting and dental implant applications and as part of a composition to use as a surgical adhesive. For example, Landesberg et al (U.S. Pat. No. 6,322,785) disclose an autologous platelet gel that includes PRP for bone grafts and dental implants. The PRP is activated by collagen and is applied topically to promote wound healing.

Antanavich et al. (U.S. Pat. No. 5,585,007) disclose preparation of PRP and use as a tissue sealant. Cochrum (U.S. Pat. No. 5,614,214) discloses a biopolymer that optionally includes PRP and its use to temporarily block arteries and veins. Gordinier et al. (U.S. Pat. No. 5,599,558) disclose a platelet releasate product, which includes platelets buffered to approximately pH 6.5, for use in a topical application to wounds.

None of the prior art teach treatment of connective tissue with PRP to promote tissue repair. Furthermore, Applicant has discovered that PRP has even broader application in treating a wide range of tissue injury and/or damage.

SUMMARY OF THE INVENTION

In one embodiment, the present invention is drawn to a method of treating an injured tissue in an individual including the steps of determining a site of tissue injury in the individual; and introducing a platelet-rich plasma composition into and around the site of tissue injury. In preferred embodiments, the tissue is selected from the group consisting of connective tissue, cardiac muscle, skeletal muscle, disc material, a vertebral body, brain, spinal cord, and vascular tissue. In a preferred embodiment, the tissue is a part of an internal organ. In a more preferred embodiment, the internal organ is the pancreas. In a particularly preferred embodiment, the tissue is a connective tissue.