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METHOD FOR TREATMENT OF TENDINOSIS USING PLATELET RICH PLASMA

RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119(e) to provisional application No. 60/655,668 filed Feb. 23, 2005 and is a continuation-in-part of U.S. Application No. 10/941,124, filed Sep. 15, 2004, now U.S. Pat. No. 7,314,617, which is a continuation of U.S. Application No. 10/412,821, filed Apr. 11, 2003, now U.S. Pat. No. 6,811,777, which claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Application No. 60/372,682, filed Apr. 13, 2002. All of the above are incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

Embodiments of the invention are directed to methods and kits for the treatment of damaged tissue in a human or non-human animal using autologous platelet-rich plasma. In a preferred embodiment, methods and kits are described for the treatment of lateral epicondylitis, plantar fasciitis, and rotator cuff injury.

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 tendinosis. Unlike tendonitis, tendinosis is not primarily an inflammatory condition. Tendinosis is an accumulation over time of small-scale injuries that don't heal properly; it is a chronic injury of failed healing. Tendinosis can occur in any tendon, with some of the most common areas being the hand, wrist, forearm, elbow, shoulder, knee, and heel. Tendinosis can result from repetitive activities such as playing sports, using computers, playing musical instruments, or doing manual labor. Some occupations that have increased risk for chronic tendon injuries include assembly line workers, mail sorters, computer programmers, writers, court recorders, data entry processors, sign language interpreters, cashiers, professional athletes, and musicians.

One specific type of tendinosis is lateral epicondylitis. Lateral Tendinosis (tennis elbow) is a common disorder which is seen in about 5 per 1000 patients in general practice. Although the etiology is not fully understood, it is typically seen in patients over the age of 35 as a result of some repetitive activity. 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

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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.

Another common tendinosis is Plantar fasciitis. While "plantar" means the bottom of the foot, "fascia" is a type of connective tissue, and "itis" means "inflammation", it is now thought that plantar fasciitis is not an inflammatory disorder. Furthermore, the plantar fascia is really a tendonous aponeurosis, not a fascial layer (Barrett, et al. (November 2004) Podiatry Today, pages 37-42).

The plantar fascia encapsulates muscles in the sole of the foot. It supports the arch of the foot by acting as a bowstring to connect the ball of the foot to the heel. When walking and at the moment the heel of the trailing leg begins to lift off the ground, the plantar fascia endures tension that is approximately two times body weight. This moment of maximum tension is increased if there is lack of flexibility in the calf muscles. A percentage increase in body weight causes the same percentage increase in tension in the fascia. Due to the repetitive nature of walking, plantar fasciitis may be a repetitive stress disorder similar to tennis elbow. It is common in several sub-groups of people, including runners and other athletes, people who have jobs that require a fair amount of walking or standing (especially if it is done on a hard surface), and in some cases it is seen in people who have put on weight—either by dietary indiscretion or pregnancy. Unfortunately, plantar fasciitis usually takes many months to resolve. According to statistics from the Southern California Orthopedic Institute, it takes approximately 6 months for 75% of people to recover from this problem.

The classic sign of plantar fasciitis is heel pain with the first few steps in the morning. The pain is usually in the front and bottom of the heel, but it can be over any portion of the bottom of the foot where the fascia is located. The pain can be mild or debilitating. It can last a few months, become permanent, or come and go every few months or years for the rest of a patient's life with no obvious explanation. Every year, about 1% of the population seeks medical help for this condition.

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. What is needed are compositions and methods for solving the problems noted above.

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 or plantar fasciitis. Cortisone injections are frankly controversial in the treatment of tendinosis 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