Autologous Platelet Concentrate (APC+); an exciting and effective new modality for Foot and Ankle surgeons

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Overview

The regenerative proteins in Autologous Platelet Concentrate (APC+) have improved clinical outcomes in our practice for patients with Plantar Fasciosis, Tibial Dysfunction, Achilles Tenosynovitis, Neuroma and Stump Neuromas, Neuropathic Ulcers, and Trophic Ulcers. In addition, by utilizing APC+, we have significantly increased our revenue stream while maintaining a low-cost alternative to other therapies.

While it is not our intention to provide detailed scientific, controlled evidence regarding the efficacy of APC+ (there are literally hundreds of articles and papers already published on autologous platelet concentrates), it is our hope that the following information will be useful in helping you understand the many benefits it offers to patients, doctors, and practice management in the office setting.

With a 90% clinical success rate, simple preparation and use in the office setting and favorable reimbursement, we believe that APC+ is an essential therapeutic tool for clinicians treating a wide variety of foot and ankle conditions.

The New Paradigm

Overuse tendinopathies are common in primary care. Numerous clinicians have shown that the pathology underlying these conditions is Tendinosis or collagen degeneration. When examined under a light microscope, abnormal tendon from patients with chronic tendinopathies differs from normal tendon in several key ways. It has a loss of collagen continuity and an increase in ground substance, vascularity and cellularity. Cellularity results from the presence of fibroblasts and myofibroblasts - not inflammatory cells. Thus, in patients who have chronic overuse tendinopathies, inflammatory cells are absent.

At the American Academy of Orthopaedic Surgeons, 2005 Annual Meeting (Feb. 23-27), a podium presentation on "Treatment of Chronic Severe Elbow Tendinosis with Platelet Rich Plasma" demonstrated an 81% improvement in visual analog pain scores with APC+, versus only a 60% improvement in the control group.

This applies equally in the Achilles, patellar, medial and lateral elbow and rotator cuff tendons.

It may equally apply to Plantar Fasciitis. Latest studies show that in many cases of plantar fasciitis there really is no inflammation, but rather an avasuclarity and collagen degeneration.

Because there is a growing body of evidence to suggest that recalcitrant plantar fasciitis (fasciosis) in not an inflammatory disorder, it calls into question the current practice of treatment with non-steroidal anti-inflammatory agents and corticosteroid injections. A controlled study published in Reumatology, 1991 demonstrated that an NSAID was no better than a single analgesic or placebo in the treatment of Achilles tendinopathy. Researchers have also demonstrated that corticosteroid injections do not change the pathological process.

Advances in understanding of tendon pathology indicate that traditional approaches to treating tendinopathies as an inflammatory "tendonitis" is likely flawed. Clinicians should consider that the cause is most often due to tendinosis, rather than tendonitis, and treat the problem using a fundamentally different paradigm.

Autologous Platelet Concentrate (APC+)

The use of autologous platelet concentrate (APC+) is not a new treatment. The healing cascade, which is the physiological response to any injury or surgical intervention, is well documented and relies on proteins that are delivered to the damaged site by Platelets, Growth Factors and White Cells.

The role of an APC in tissue repair and regeneration has been presented in several studies. Platelets are carriers of proteins specifically involved in regeneration of injured tissue. These proteins are called Growth Factors (GF).

Platelet alpha granules contain a multiplicity of potent GF. Upon activation, the platelet alpha granules release these GF in specific ratios to one another. These GF act locally to: (1) recruit undifferentiated cells to the site of injury and (2) trigger mitosis in these cells.

Platelet growth factors are active signals for attracting stem cells into the site of injury and triggering proliferation of these cells once they are at the site. In order for an APC to have the potential to enhance healing, it is important that the process for producing an APC is capable of extracting as many platelets from the blood sample as possible and that these platelets can release the desired GF levels. The scientific proof of bone and soft tissue healing has been shown using APC with viable platelet levels increased 4-6 times above baseline levels. The more GF that can be delivered to the injury site, the greater the potential to enhance the healing process.

Basic Scientific References to Support Clinical Effect of APC+

Slater et al has shown that there was a "marked increase in proliferative activity and the continued differential activities, including matrix formation and mineral deposition of osteoblast like cells in the platelet supplemented cultures" and that this "provide(s) some in vitro evidence to support the proposal that the substances released by platelets may play a role in fracture repair and potentially may have clinical applications in fracture healing". The effect is not limited to osteoblasts.

Gfatter et al "demonstrated the efficacy of activated platelets bound in fibrinogen in the mitosis of fibroblasts, which (effect) is a response to growth factors secreted by platelets". Taylor et al demonstrated in rabbit

patellar tendons that injecting whole blood was safe and that the injected tendons were stronger biomechanically than control tendons at 12 weeks.

Kevy et al, and other researchers have documented that APC+ has four to six times the normal level of GF which results in fibrocyte migration and induction of neurovascular growth.

Sclafani et al demonstrated in New Zealand white rabbits that APC + (5 times baseline platelet concentration) significantly improved wound healing and soft tissue in-growth in surgically implanted grafts. Statistically significant increases over the control group were observed in fibroblast and endothelial cell counts at 7 days.

Marx et al demonstrated in a controlled human study (88 patients) that the addition of APC with autologous cancellous bone grafts for mandibular continuity defects 5 cm and greater resulted in a radiographic maturation rate of 2 times that of grafts without APC. Also, as assessed by histomorphometry, there was a significantly greater bone density in grafts in which APC was added.

Barrett et al demonstrated in a series of 9 plantar fascia patients that APC, with ultrasound guidance, could be safely injected into the medial and central bands of the most affected fascia with promising results. Seven out of nine patients had complete resolution of their plantar fascial pain and all the patients in the study had improvement that was noted on diagnostic ultrasound. One of the patients was considered a failure because of a subsequent steroid injection even though all pain had resolved.

In addition, there are currently on-going "tendinosis" studies being conducted using APC+ for rotator cuff tears, tennis elbow, and patellar tendon applications.

PLANTAR FASCIITIS (FASCIOSIS) IS A COMMON CAUSE OF HEEL PAIN.

Plantar fasciitis / Heel spur syndrome is the most common cause of inferior heel pain for which a patient will seek treatment. It has been estimated that in a typical Podiatric practice, approximately 40% of patients complain of heel pain.

PROTOCOL

The mainstay of our protocol for treating plantar fasciosis is Conservative Care. Biomechanical control, physical therapy and durable medical equipment are our first treatment options. Since tendinosis results from collagen degeneration and generally, mechanical overload, it is vital that the clinician establishes why this occurred and assesses any equipment being used (shoes, running shoes, orthotics, etc.). If these therapies fail, we find that APC+ is a better choice than either ESWT or surgical intervention.

ESWT is not indicated in patients with neuropathy. Moreover, in our patient population we find that patients with both peripheral neuropathy and a concomitant diagnosis of Plantar Fasciitis have benefited from APC+ injection.

EPF treatment is utilized infrequently in our practice because this procedure is limited to treatment of the medial band.

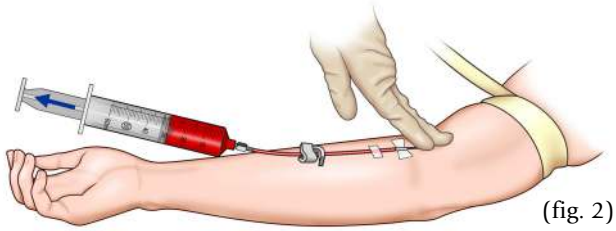
The diagnosis for plantar fasciosis is easily made in our office. The utilization of ultrasound has proven to be an invaluable tool. We first take ultrasound measurements of the medial, central and lateral bands prior to injection of APC+. After measurement of the plantar band, we often find patients with plantar bands measuring approximately 5 mm or greater. We find that these patients will benefit from APC+.

The patient is prepped in the usual manner. Each patient is anesthetized with a block of the posterior tibial peripheral nerve and sural nerve. Subsequently, the foot is prepared with a skin antiseptic.

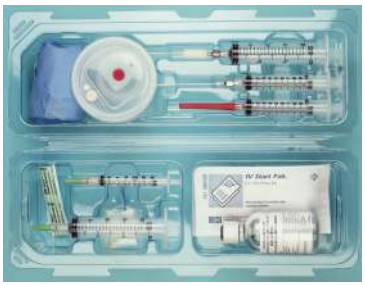
(fig.1)

APC+ PREPARATION

Using the SmartPReP® system (fig.1) (Harvest Technologies Corp., Plymouth, MA), we perform a simple antecubital phlebotomy and withdraw 20 cc of whole blood from the patient (fig. 2), point of care. The company packages all of the blood draw and blood processing accessories (fig. 3) required for the APC+ injection. It has been documented that the platelets prepared with the SmartPReP® system are viable, concentrated to a 4-6 times baseline level and that there is a linear increase in the number of GF



(fig. 2)



with each increase over baseline of platelets. Furthermore, it has been documented that the more GF delivered to the injury site, the greater the potential to enhance the healing process.

(fig. 3)

(fig. 4)

The SmartPReP® process (fig. 4) to harvest and concentrate the platelets does not damage or change the platelets in any way. After processing the 20 cc blood sample (fig. 5), 3 cc of highly concentrated platelet rich plasma, which we call APC+, is obtained.

The system is easy to operate and use in the office setting. The SmartPReP® system is fully automated which means that the system automatically separates blood components and concentrates the platelets for you.

(fig. 5)

Using diagnostic ultrasound for guidance, we inject 3 cc of APC+ into the most hypoechoic areas within the medial and central bands of the affected fascia with a large bore – 16 gauge needle. In order to facilitate and enhance effectiveness of the placement of the APC+, we perforate the fascia approximately five (5) times. Other foot and ankle surgeons applying this technique have used up to a 25 gauge needle, however, we feel the use of a larger bore needle is more effective.

Follow up ultrasounds are taken six (6) months post injection.

CLINICAL RESULTS

We have treated approximately 200 patients in our office with excellent results. The overall success rate for APC+ injection for patients with Plantar Fasciosis is 90%.

The injection of Autologous Platelet Concentrate (APC+) is safe and none of our patients have experienced any significant complications from their plantar fascia injection. APC+ revascularizes tissues, reduces pain, and decreases edema. Follow up ultrasound at six months post injection almost always shows a significant reduction in the thickness of the fascial bands.

POSTERIOR TIBIAL DYSFUNCTION (PTD)

Biomechanical control including AFO is mandatory for long-term successful treatment for patients with Posterior Tibial Dysfunction (PTD). But before this can be achieved, the tissue must be healthy.

While Biomechanical control including AFO is often successful in controlling these patients and provides relief, often times the pain continues. At this point, MRI usually confirms multiple tears, usually longitudinal along the course of the posterior tibial tendon. Before the use of APC+, these repairs were usually performed surgically through an open procedure. With the surgical treatment, the patient was taken to the Operating Room, the tendon prepared and rolled on itself. Patients would normally heal in 4 months.

Now, using ultrasound guidance, we are successfully able to inject APC+ into multiple locations along the posterior tibial tendon and specifically in the area of injury. We use a 27.5 gauge needle in this procedure to avoid trauma to the tendon. In our practice, APC+ clearly stands out as the best treatment modality for chronic pain to the posterior tibial tendon. It appears that revascularization is achieved in these fibrotic areas.

Many patients diagnosed with PTD are elderly. As a result, surgery is often not a good option. APC+ provides these patients relief without the complications associated with surgical intervention.

TENOSYNOVITIS

Achilles Tenosynovitis is often difficult to treat. Injection into the area with a steroid is often not considered to be prudent. Utilizing APC+ injection into this area can be performed without concern of weakening the tendon. As in PTD, we utilize a 27.5 gauge needle to avoid trauma to the tendon.

Other procedures (that benefit from use of APC+)

- Excisional Neuroma and Stump Neuromas
- Osseous defects; repair and regeneration
- Chronic Wounds

REIMBURSEMENT

APC+ is a low cost autologous hemocyte tissue matrix, which provides an autologous, "biologically active" tissue scaffold for implantation with tendon, allograft or autograft bone. In addition, APC+ helps to control bleeding, seal surgical wounds, reduce or eliminate post-operative oozing at the site and reduces swelling and bruising.

The utilization of APC+ is not a new modality to most insurance companies. Other clinical providers have successfully used APC+ for years. Insurance reimbursement in the "Chicago-land" has been favorable. The overall return on investment is significant.

LETTER TO INSURER

It is suggested that practitioners send a letter to their insurer medical review staff disclosing a description of autologous platelet concentrate treatment.

EXAMPLE LETTER TO INSURER

Dear Insurer,

This letter is being sent to disclose my use of the autologous hemocyte tissue matrix in my surgical treatment plans to seal, fill and help repair wound damaged tissues encountered in my practice. This treatment uses specific machine harvested autologous hemocytes which are then applied to the surgical wound.

It is important to note that the hemocyte tissue components are not manufactured substances, packaged or sold commercially. They are the patient's own sequestered hemocyte tissues crafted by the practitioner into a cellular matrix or coagulum. This natural prosthetic has structural integrity, functions as a bioactive sealant, and is implanted into the patient's wound(s) or incisions.

This letter serves to introduce my medically necessary use of this procedure as needed to treat my patients. All my claims for this service will include similar procedures and protocols, and will be documented with a care plan of treatment and appropriate clinical summaries.

Thank you for your help in reviewing and covering of this efficacious, medically necessary, established procedure and my claims for related benefits.

Signed…

CODES

It is important to note that ALL PROCEDURES AND CODING SHOULD BE PRECERTIFIED FOR FULL DISCLOSURE TO PAYERS.

Since coding advice must be tailored to the specific circumstances of each claim for benefits, nothing provided herein should be used as a substitute for advice of competent legal counsel. We are not certified as "expert" or "specialist" pursuant to any authority governing the submission of claims for benefits in the United States.

We have used the following codes in our practice for **injecting APC+** (private insurance). The quoted amounts reflect our average and are not a guarantee of payment. Our experience with payment varies widely. Your experience will vary widely as well. We do not assume any responsibility or liability for your reimbursement decisions or claims denials you believe related to your use of any of this information. The mentioned codes are examples only. Many other codes are not presented here and may be more descriptive and appropriate to the specific medical need and plan of treatment.

Code	$ Bill Amount	$ Average Recovered Amount
20926 Tissue Graft	836	757
76942 Ultrasound	250	209
Total	$ 1,036	$ 966

We have used the following codes for **topically applying APC+** (excision of mass).

Code	$ Bill Amount	$ Average Recovered Amount
20926 Tissue Graft	836	757
11422 Excision of Mass	214.50	214.50
76942 Ultrasound	250	209
Total	$ 1,250.50	$ 1,180.50

CONCLUSION

We have over 18 months of experience using APC+ in our practice and have concluded that APC+ is a "win-win" solution for a number of clinical conditions including Plantar Fasciosis, Posterior Tibial Dysfunction, Tenosynovitis, Excisional Neuromas and Stump Neruomas, Osseous defect repair and regeneration, and chronic wounds.

The patient benefits, because APC+ is a biologically active tissue graft that provides an alternative to surgery, accelerates healing, reduces edema and ecchymosis, reduces pain and results in faster recovery time. In addition, patients appreciate the "high-tech" way in which they are being treated.

The doctor benefits from the utilization of APC+ in several ways; 1) Patients are happy with the clinical results including faster healing time and less pain, 2) APC+ produces a significantly increased revenue stream while at the same time, maintaining a low-cost alternative to other therapies, 3) Reimbursement for the performance of the procedure is attractive, 4) APC+ is perceived by the community as the "latest technology" and therefore presents a good marketing opportunity and excellent word of mouth publicity, 5) The incorporation of APC+ into the Office Practice is seamless. The APC+ system is automated and simple to operate and use.

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