Platelet Rich Plasma for the Treatment of Foot and Ankle Pathologies

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Abbreviations:

AOFAS – American Orthopedic Foot and Ankle Society

PRP – Platelet Rich Plasma

UCSD – University of California, San Diego

ABSTRACT

Introduction: Platelet rich plasma (PRP) is a concentrate of platelets and their bioactive factors derived from the peripheral venous blood of patients. Platelets contain factors that improve healing and tissue regeneration. PRP may offer an excellent means of non-operatively treating foot and ankle pathology.

Objectives: To determine whether PRP injections improve outcomes for foot and ankle pathologies.

Methods: A retrospective cohort study of patients aged ≥ 18 years diagnosed with foot or ankle pathology at University of California San Diego between January 2011 and September 2016 was performed. Patients treated with an intra-articular injection using platelet-rich plasma were categorized into the PRP group. Age and gender matching were used to select active comparator group (triamcinolone injection), and a control group (conservative treatment). Primary outcomes were patient-reported pain and function before treatment and at 12 weeks post-treatment. Pain ranged from 0-10 with higher scores corresponding to higher perception of pain. Function was determined by patient-reported activity limitations and scored according to the American Orthopedic Society Foot and Society (AOFAS) ankle hindfoot scale. High scores corresponded to better function.

Results: We identified four patients that met inclusion criteria for the PRP group (n=4), with age and gender matching for triamcinolone (n=4), and control (n=4). Patients averaged 41 years old, (range 26-61), were 75% female, and had an average BMI of 28.9 (range 19.7-44.3). The median pain score before and after treatment did not change significantly after 12 weeks in the PRP group (95% CI -1,8; P = 0.19), triamcinolone group (95% CI-7,5; P =.88), or the control group ((95% CI -1,7; P = .08). Functional scores before and after treatment did not significantly change

after 12 weeks in the PRP group (95% CI -3,0; P =.058), triamcinolone group (95% CI -6,3; P = .74), or the control group (95% CI -6,6; P = 1). There was no significant difference in change of pain or change of function between PRP, triamcinolone, and conservative therapy (P = .31, P = .09, respectively).

Conclusion: Among patients with foot ankle pathologies at UCSD, PRP did not result in greater improvement in pain or function at 12 weeks post-treatment compared to triamcinolone or conservative treatment.

INTRODUCTION

Musculoskeletal injuries of the foot and ankle are among the most common orthopaedic ailments impacting considerable a proportion of the population in the USA. Foot and ankle injuries account for 15-25% of sports injuries in collegiate athletes, and 40% of high school athletes. [1–5]. Furthermore, 20% of middle aged and older people have pain due to foot and ankle disease. [6] The more common athletic injuries include: foot and ankle sprains, ankle fractures, turf toe, Lisfranc injuries, and overuse injuries ranging from plantar fasciitis and Achilles tendinopathy.

Non-surgical treatment of foot and ankle pathologies typically involves activity reduction, cryotherapy, and anti-inflammatory medication. However, non-surgical treatment is often insufficient, and the pathology may evolve into a chronic injury and/or require surgical intervention. For instance, in an eight year follow up study, Pavaalo et al 2012, determined that 30% of patients failed conservative treatment of Achilles tendinopathy and required operative management.[7] In another study, Buchbinder et al 2004, observed that approximately 20% percent of patients with plantar fasciitis have symptoms lasting longer than 12 months, with approximately 5% requiring surgical management.[8]

Surgical treatment for foot and ankle disease not only increases morbidity in patients but is also costly and can result in long-term consequences. Surgery for foot and ankle disease contributed to an estimated economic burden of $11billion in the Medicare population in 2011, up 38.2% since 2000.[9]. Arthroscopic foot and ankle surgeries have the highest rates of

complications, and can be associated with damage to articular cartilage, wound complications, instrument breakage, infection, injuries to nerves, tendons, and ligaments, and long-term neurologic injury. [10–14]

Biologic treatments have gained popularity as a means of treating refractory cases without the need for surgery. Platelet rich plasma (PRP) has risen to the forefront of consideration due to the ease of extracting and processing peripheral blood in an outpatient setting and the potential for restorative and regenerative mechanism to promote healing inherent in it. [15,16] PRP is a concentrate of peripheral venous blood obtained from the patient and it is theorized to promote wound healing by delivering growth factors, cytokines, and chemokines. Furthermore, its use by professional athletes, and coverage in the media has led to increased public awareness and demand.[17] In fact, the global market for PRP has seen a large rise in its valuation, and researchers predict that the opportunity for PRP will rise from $160 million 2015 to 451.9 million in 2024.[18] Despite these strides, the mechanism by which PRP influences healing is poorly understood, with no consensus among the scientific community regarding its efficacy and impact.

PRP is considered an important and easy way to improve tissue healing, delay or even eliminate the need for surgery, and, in surgical cases, improve surgical outcomes. However, not much evidence regarding the extent of this efficacy is available and the Thus, the objective of this study is to mine existing patient data at UCSD and elucidate the effect of PRP injections compared to other standard of care therapies including triamcinolone injections and conservative management.

METHODS

Data and study population

A patient search in UCSD Electronic Medical Record (EMR) system was performed to obtain a list of patients who received care for foot and ankle pathologies between January 2011 and September 2016. Criteria for inclusion were: (i) a diagnosis of plantar fasciitis, osteochondral talar lesions, surgical adjuvant, or Achilles tendonitis; (ii) a follow up visit at least 12 weeks post-treatment; (iii) 18 years or older. Once patients in the PRP group were identified, age and gender matched controls were selected for triamcinolone and conservative treatment groups.

Interventions

Interventions included PRP injection, triamcinolone injection, or conservative therapy. Injections were administered by physicians at UCSD. PRP was prepared according to the Arthrex Angel 7% protocol. Blood was drawn aseptically from right and/or left arms. Approximately 100-120cc of blood were aspirated and centrifuged with Arthrex Angel for an output of 4-6cc of PRP available for injection. Injections were performed under aseptic conditions under ultrasound guidance without any complications. Patients were placed in a CAM boot immediately after injection for approximately 1 week and performed a supervised physical therapy program.

Triamcinolone injections were performed under aseptic conditions with ½-1 cc 40mg triamcinolone, depending on the condition. There were no complications.

Conservatively managed patients were instructed to complete a home exercise program or formal physical therapy. They were advised to use ice, and NSAIDs as needed.

Outcome Measures

Data mining of patient charts was performed to elicit pain and function data at the initial pre-treatment visit and at 12 weeks post-treatment. Pain was patient-reported on a scale from 1-10, with 0 being no pain and 10 being maximal pain. Patient-reported activity limitations were used to determine function. Function was scored according to the AOFAS ankle and hindfoot score. The AOFAS ankle and hindfoot score allows for a valid, reliable, and objective measure of patient function.[19]

Statistical Analysis

Pre-injection pain scores were compared against post-injection scores at approximately 12 weeks using Wilcoxon signed ranks test with an alpha level of $p < .05$. Pre-injection function scores were compared at 12 weeks using Wilcoxon signed ranks test with an alpha of $p <.05$. Kruskal-Wallis tests were used to determine differences between groups in change of pain and function with an alpha of $p<.05$.

The following variables were analyzed and were not found to correlate with post-treatment reductions in pain, or improvements in function: BMI, age, gender, pre-treatment pain, or pre-treatment function (Table 3).

RESULTS

Patient and clinical characteristics

Between January 2011 and September 2016, 7 patients were treated with PRP for foot and ankle disease. Four patients met inclusion criteria. Four age and gender matched controls were determined for the triamcinolone and control groups (n=12) (see METHODS). Table 1 displays descriptive statistics of the demographic variables. The mean age was 41 years old, with a range of 26 to 61. Females were significantly predominant (75%). There were no significant differences between groups for age, gender, BMI, pre-treatment pain, or pre-treatment function.

Outcome Measures

Table 2 summarizes the scores obtained for pain and function before and after treatment. In the PRP group pain and function scores improved with treatment, but not significantly (p =.19 and .06, respectively). Pain and function scores did not significantly change in triamcinolone (p= .88 and .74) or the control group (p= .08 and 1). There was no significant difference in change of pain or change of function between groups (P = .31, P = .09, respectively) (Figure 1, Figure 2).

DISCUSSION

Platelet-rich plasma (PRP) is an autologous concentrate of peripheral blood that is posited to promote wound healing by delivering growth factors, cytokines, and chemokines (stored in the alpha granules, dense granules, and lysosomal granules of platelets). [15,16] Alpha granules secrete various growth factors including: platelet-derived growth factor (PDGF), transforming growth factor (TGF-b), platelet-derived epidermal growth factor (PDEGF), vascular endothelial growth factor (VEGF), insulin-like growth factor 1 (IGF-1), fibroblastic growth factor (FGF), and

epidermal growth factor (EGF).[20] These factors initiate growth, morphogenesis, and differentiation by exerting effects on osteoblasts, fibroblasts, endothelial cells, epidermal cells, and mesenchymal stem cells.[21] Alpha granules also contain chemokines and proteins that stimulate chemotaxis, cell proliferation and maturation, attract leukocytes, and modulate inflammation.[22] Dense granules contain ADP, ATP, calcium ions, histamine, serotonin, and dopamine. Lastly, lysosomal granules secrete cathepsin D and E, acid hydrolases, elastases, and lysozyme.[23] PRP injections allow increased platelet delivery to sites of injury. In an acute setting, this allows for a higher platelet concentration than baseline to help with healing. In a chronic context, PRP injections increase autologous platelets, stimulate tissue injury and inflammation in areas that have ceased the inflammatory healing phase. [24–26]

PRP is growing in popularity and recent literature has supported its use for foot and ankle injuries. In vivo models have shown that PRP increases PDGF and TGF, circulatory inflammatory cells, angiogenesis, and tenocyte proliferation, all of which are beneficial in the recovery of acute and chronic injuries to tendons and ligaments. [27] Furthermore, PRP has been shown to directly influence chondrocyte proliferation, and modulate collagen synthesis through its effects on TGFb1. Lastly, PRP modulates the inflammatory response, initially increasing the presence of inflammatory cells and their growth factors, and later decreasing the presence of inflammatory molecules, and limiting monocyte infiltration. [28] This overall down-regulation of inflammation leads to well-documented pain reduction and may influence the progression of osteoarthritis.

This retrospective cohort study did not show any statistical difference in outcomes 12 weeks following PRP injection. Our findings regarding PRP's effect on pain and function fit into current literature that has shown conflicting results. Several case series and small randomized

control trials have shown benefits with PRP administration. These include: better outcomes, faster recovery, and quicker return to sport for Achilles tendon rupture; pain reduction and functional recovery in Achilles tendinopathy; clinical improvement in plantar fasciitis; clinical improvement in osteochondral talar lesions; and better fusion rates for tibiotalar fusions. [29,30,39,31–38] A recent meta-analysis determined that although PRP has been shown to be beneficial for foot and ankle disease, the evidence is from low level studies, making it difficult to draw clinical conclusions.[26] Additionally, this study did not show any significant improvement of pain or function with triamcinolone injections after 12 weeks. Our triamcinolone group consisted mainly of participants with plantar fasciitis. This finding fits current literature which shows that triamcinolone injections reduce pain in plantar fasciitis patients better than placebo for 1 month with decreasing efficacy afterward. [40,41] Patients in the control group did not improve after 12 weeks of conservative therapy, a trend consistent with plantar fasciitis prognosis. The course of plantar fasciitis is often indolent with 80% of patients requiring 10-12 months for full recovery.[42]

It is difficult to draw any conclusions from this retrospective study due to small sample size. Seven patients received PRP injections for foot and ankle diseases at UCSD between January 2011 and September 2016. Three of those patients did not follow up at all after their injection and were therefore excluded from this study. Poor follow up may have contributed to selection bias in which symptomatic patients continued follow up visits while improved patients did not; thus, decreasing effect size of treatment. Another variable to consider is time of follow up. This study was also limited to 12 weeks of follow up, because only two of four PRP patients were seen past that time. This may not have allowed enough time for PRP to truly impact the underlying pathology being treated. Most studies demonstrating the benefits of PRP allow at least 6 months for follow up.

Moving forward, this study seeks to find more patients that received PRP injections at UCSD, and to find patients with follow up of at least 6 months. Increasing the number of participants will better power the study for significance. Appropriate length of follow up will potentially give the treatments time to exert their effects. Prospective studies would allow for more regimented follow up, and patient questionnaires that acquire more information. Future areas of interest are PRPs effect for specific indications, and the rapidity and length of benefits.

CONCLUSION

This ongoing retrospective cohort study did not find any significant effect of PRP on pain or function after 12 weeks but was limited by small sample size and short follow up. More subjects and longer follow up are needed to draw clinical conclusions.

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There are no financial conflicts of interest to disclose.

DISCLOSURES

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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TABLES

Table 1. Baseline Characteristics of PRP, Triamcinolone, and Control Groups

Characteristics	**PRP** (n=4)	**Triamcinolone** (n=4)	**Control** (n=4)	**P- value[a]**
Age, mean (SD), y	41 (14.12)	40.75 (15.71)	40.25 (14.56)	.9973
Sex, female	3	3	3	1
Function, mean (SD)	4.8 (1.5)	6.3 (1.5)	7 (2.5)	.2740
Pain, mean (SD)	5.25 (2.217)	5.75 (2.630)	4.75 (5.00)	.8196
BMI (SD)	23.2 (4.6)	34.4 (10.2)	29.2 (1.71)	.1144
Indication				
Achilles tendinopathy	1	0	0	
Plantar Fasciitis	1	2	4	
OLT	1	0	0	
Surgical Adjuvant	1	0	0	
Ankle sprain	0	1	0	
Sinus tarsi	0	1	0	

AOFAS, Ankle Orthopedic Foot and Ankle Society; BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; PRP, platelet-rich plasma.

[a]P-value determined by one-way ANOVA with alpha level of p <.05. No significant differences between groups.

Function scored according to AOFAS hindfoot score questionnaire – 10 points for no activity limitations; 7 points for no limitations of daily, limitations of recreational, no support; 4 points for limitations of daily and recreational activity, cane; 0 points for severe limitations, crutches, wheelchair, brace. Higher function score is more favorable.

Table 2. Pain and function scores before and after treatment for PRP, Triamcinolone, and Control

	Pre	Post	Estimation for Difference [a] (CI; P-value)
PRP			
Pain, median	5	3.01	2.98 (95% CI -1,8; P = 0.19)
Function, median	4	7	-3 (95% CI -3,0; P =.058)
Triamcinolone			
Pain, median	6.5	5	1 (95% CI-7,5; P =.88)
Function, median	7	7	0 (95% CI -6,3; P = .74)
Control			
Pain, mean	4.5	1.5	3 (95% CI -1,7; P = .08)
Function, median	7	7	0 (95% CI -6,6; P = 1)

CI, confidence interval

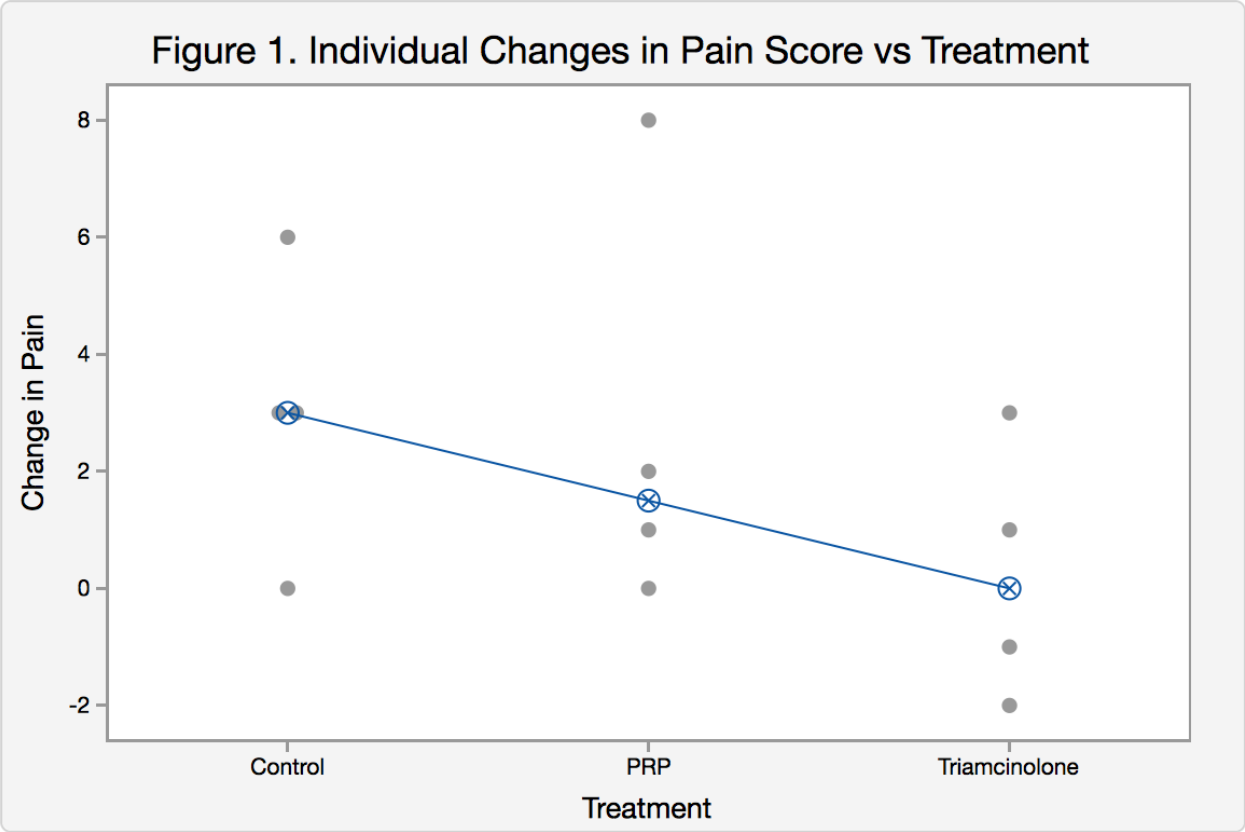
[a] *Determined by Wilcoxon signed ranks test. No significant change in pain or function before and after treatment with PRP, triamcinolone, or control.*

Table 3. Correlation between outcome variables

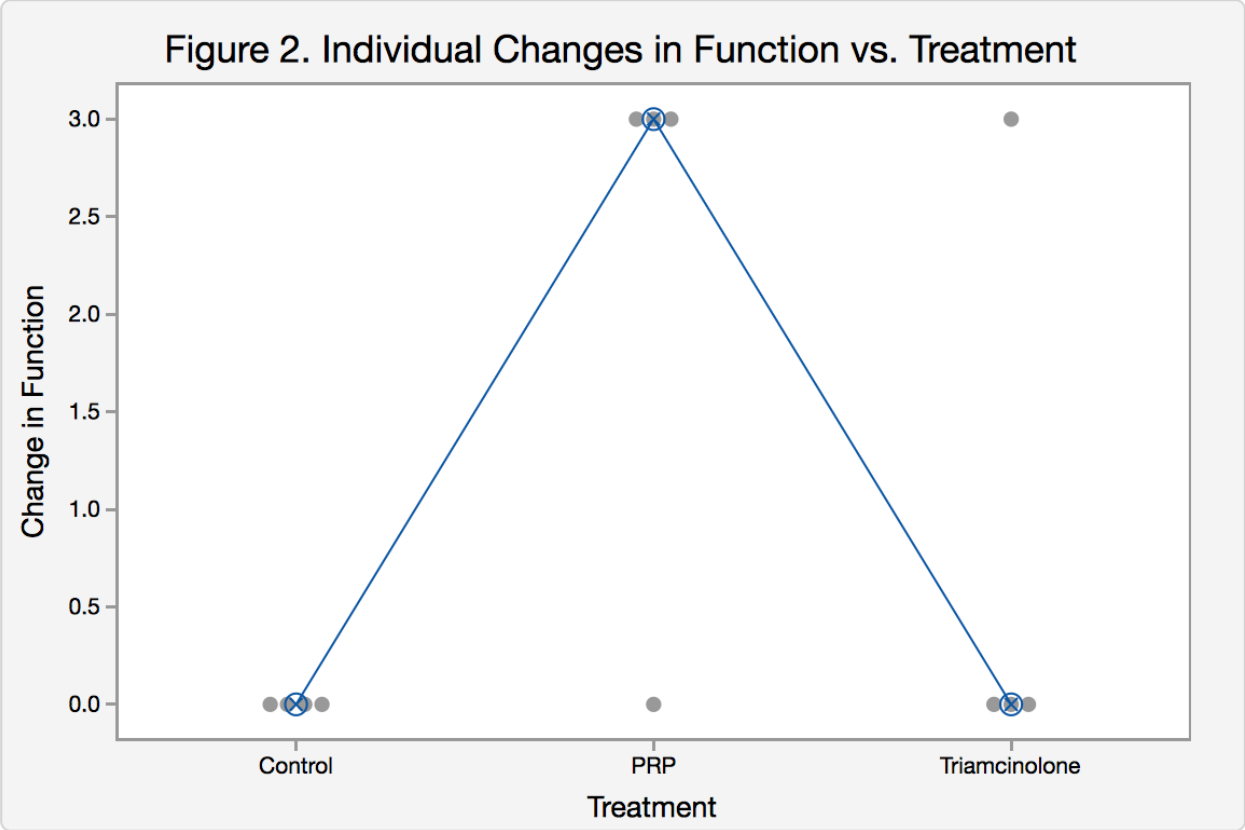
Variable	Δ Pain	Δ Function
BMI*	-0.53 (P = .08)	-.20 (P = .52)
Age*	.00 (P = .99)	-.28 (P = .37)
Gender*	-.27 (P = .39)	-.12 (P = .71)
Pre-procedure pain*	.50 (P = .10)	.36 (P = .25)
Pre-procedure function*	.08 (P = .80)	-.48 (P = .11)

**Spearman correlation coefficients. No significant correlations between covariates and outcome variables.*

FIGURES



PRP, platelet-rich plasma. Individual changes in pain after 12 weeks plotted for each treatment. Adjusted median for each group connected by blue line. There was no significant difference in medians as determined by Kruskal-Wallis testing (P = .31).



PRP, platelet-rich plasma. Individual changes in function after 12 weeks plotted for each treatment group. Adjusted median for each group connected by blue line. There was no significant difference in medians as determined by Kruskal-Wallis testing (P = .09).