

# **Statement of Purpose**

Reported outcomes for refractory plantar fasciosis have focused on quantifying residual pain, and disability to determine recovery (Resolution). However, no prior investigation has evaluated whether other forms of recovery including behavioral adaptations (Readjustment), or cognitive coping (Redefinition) are possible. The purpose of this retrospective case series was to identify alternate forms of recovery following bipolar radiofrequency coblation with platelet rich plasma injection for refractory plantar fasciosis. Patient reported outcome measures were compared between patients who perceived themselves as recovered without/with residual deficits (Recovered-Resolved, Recovered-Not Resolved), vs. those not recovered. Holistic/procedure specific satisfaction, complications, and the re-operation/failure rate were recorded.

### Introduction

Plantar fasciitis (PF) is the most common cause of plantar heel pain, with approximately 2 million people seeking treatment in the United States each year (1-4). Conservative treatment is initially recommended, and 90% of patient's experience symptom resolution (5-6). The remaining 10% develop refractory PF, characterized by microscopic tears of the aponeurosis in the absence of inflammation (7-11). While operative interventions addressing the mechanical perturbation(s) have been popularized (gastrocnemius recession, plantar fascial release, heel spur exostectomy), none directly address the altered hemodynamic state, and prolonged convalescence periods/complications persist. A percutaneous treatment capable of directly addressing the altered hemodynamic state by focal angiogenic stimulation to the degenerated, dysvascular aponeurosis may establish a biologic healing response, reducing the convalescence period/complication rate.

Bipolar radiofrequency coblation (BRC) was first introduced in the field of cardiology (12). The minimally invasive, non-heat driven process (40-70 degrees Celsius) stimulates electrolytes in a saline solution; creating a plasma gas capable of breaking down molecular bonds in damaged tissue (13). The resultant inflammatory response also stimulates an influx of healing proteins, and growth factors which initiate, and promote biologic healing. Small case series on BRC in refractory PF have demonstrated significant: pain relief, functional improvement, satisfaction, and reduced complications (11, 14-18). However, these studies account for only 146 patients with short-term follow up ( $\leq$ 1 year). While BRC was initially met with great enthusiasm, and promising results for Achilles Tendonosis; varying results over longer follow-ups has since obviated any consensus regarding the procedures utility.

Platelet rich plasma (PRP) is a plasma concentrate of blood obtained from isolating, and concentrating platelets from an autogenous peripheral sample by differential centrifugation (19-21). The resulting plasma fraction contains platelets in supraphysiologic concentrations, two to ten times greater than baseline (21-22). More than 30 bioactive proteins are contained within platelets, many of which are essential for tissue healing and hemostasis (19). The alpha granules specifically contain cytokines, healing proteins, and growth factors in biologically determined ratios including: platelet derived growth factor (PDGF), vascular endothelial growth factor (VEGF), transforming growth factor beta (TGF-B), and insulin like growth factor (IGF). These factors initiate, and promote biologic healing through: angiogenesis, cell migration, cell proliferation, and matrix synthesis (20-28).

Within the medical community, investigations recently have focused on patient reported outcome measures (PROM's) for identifying post-operative recovery, operative success (29-36). However, investigations have demonstrated that recovery in some chronic foot and ankle conditions is not predicated on the complete resolution of all symptomatology (37-38). Patients capable of coping with any ongoing deficit(s) can still achieve recovery, despite persistent pain and disability. Pinsker et al. (37) first introduced Beaton's alternate recovery model (39) which consists of: Resolution, Readjustment, and Redefinition to the lower extremity. However, because PROMs rely on quantifying residual pain, and disability, they fail to assess the ability of patients to cope with any ongoing deficit(s); preventing them from capturing other forms of recovery.

The purpose of this retrospective case series was to compare the PROMS of patients who perceived themselves as recovered without/with residual deficits (without deficits, Recovered-Resolved)(with deficits, Recovered-Not Resolved) vs. those not recovered following BRC with PRP injection. Secondary objectives included an assessment of outcome based on holistic/procedure specific satisfaction, complications, and re-operation/failure rate. A priori hypotheses was that Recovered-Resolved (RR) and Recovered-Not Resolved (RNR) patients would report better PROM scores compared to Not Recovered patients (NR); with >75% being very satisfied/satisfied (scoring 1-2), and willing to recommend/re-undergo the procedure again. Conversely, Not-Recovered (NR) patients would report lower PROM scores; with >75% not satisfied (scoring 0), and unwilling to recommend/re-undergo the procedure again. To the best of our knowledge, this study is the first to assess the outcomes of BRC with PRP injection for refractory PF, and the first to attempt to broaden our definition of "recovery" in these refractory cases by applying the "Resolution, Readjustment, Redefinition" concept of recovery.

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# Patient Perceived Recovery and Outcomes after Bipolar Radiofrequency Coblation with Platelet Rich Plasma Injection for Refractory Plantar Fasciosis Calvin J. Rushing DPM, Viraj R. Rathnayake DPM, Adam J. Oxios DPM, Gabriel P. Galan DPM, Derek P. Roland DPM, Joshua E. Epstein DPM, Gerald Merritt DPM, Steven M. Spinner, DPM Westside Regional Medical Center PMSR-RRA

# Patients/Materials & Methods

Results

Under Institutional Review Board (IRB) approval, a retrospective case series was conducted on all patients with refractory PF who underwent BRC with PRP injection by a single senior surgeon (S.M.S.) at our institution from July 2006 to July 2016. Patients were identified initially by the Current Procedural Terminology Code (28008), which was then cross-referenced with the International Classification Of Diseases, Ninth Revision, Diagnosis Code (728.71), and record to ensure accuracy. Patients with incomplete medical records, concomitant interventions, or less than one year follow up were excluded from the final analysis. The retrospective review, prospective data collection, and analysis was performed by resident FAS of varying post-graduate years.

From July 1, 2006 to July 1, 2016, 113 BRC and PRP injections (97 patients) were performed. Of the 97 patients identified, 12 were excluded for incomplete records, concomitant interventions, or follow up less than 1 year. Of the remaining 85 patients meeting the inclusion criteria, 42 (42/85, 49.4%) were lost to follow up (37/85, 43.5%) or refused to participate (5/85, 5.9%), leaving 43 of 85 eligible patients; representing a 50.6% response rate. These 43 patients underwent 52 procedures, with 9 patients (3 male, 6 female) undergoing BRC with PRP injection bilaterally; either as an index procedure (1 male, 3 female), or within 150 days of the contralateral extremity (2 male, 3 female). Thirty-three patients were female (33/43, 76.7%) and 10 patients were male (10/43, 23.3%) with a mean age of 59.4 years (range, 31 to 79 years), and mean follow up duration of 57.1 months (range, 12.1 to 118 months).

Following the retrospective review, prospective follow up was conducted via a telephone survey to obtain: PPR, PROM's, "holistic"/"procedure specific" satisfaction, complications, and the reoperation/failure rate. PPR was first assessed by asking the patient to choose the statement that best described their current state of recovery, as described prior (37-38). Patients who selected the statement "I am better with no residual symptoms" were classified as Recovered-Resolved (RR), "I am better with some residual symptoms or limitations that I can cope with" were classified as Recovered-Not Resolved (RNR), and "I am not better" were classified as Not Recovered (NR). PROM's were then assessed utilizing a modified FFI, and VAS for pain. "Holistic" satisfaction was accessed utilizing a semi-quantitative scale (2-very satisfied, 1 satisified, 0 not satisfied), followed by "procedure specific" satisfaction based on the willingness to recommend the procedure. A priori hypotheses was that RR and RNR patients would report better PROM scores compared to NR; with >75% reporting holistic/procedure specific satisfaction. Conversely, NR patients would report lower PROM scores; with >75% reporting no holistic/procedure specific satisfaction. Complications, and re-operation's were recorded, and the failure rate determined. Univariate descriptive statistics for demographic variables were generated for the entire sample, and then stratified by recovery group. Values are expressed as counts (percentage), and means (standard deviation) as appropriate. Fisher exact tests and Kruskal Wallis tests were used to compare categorical, and continuous variables respectively. Spearman correlation was used to assess relationships between holistic/procedure specific satisfaction, and the PROMS (FFI, VAS). Two sided p-values of <0.05 were considered statistically significant.

Recovered-Not Resolved Not Recovered Total Sample P-value (n = 29) (n = 10)(n = 43) Patient Demographics Male, n(%) 8 (27.6) 10(23)Female, n(%) 9 (90) 3 (75) 33 (77) 0.53 21 (72.4) 54 (31 - 66) 59.4 (31-79) 0.56 Age (y), mean(range) 60.6 (39 - 76) 58.1 (50 - 66) 0.12 54.7 (12.1 - 118) 69.6 (33 - 107 42.8 (25 - 65) 57.05 (12.1 - 118) Follow-up (m), mean(range Total procedures, n (%) 6 (60) 0(0) 19 (44) 13 (45) Righ 3 (30) 15 (35) Left 12 (41) 0 (0) 1(10)4 (100) 9 (21) 0.009\* Bilateral 4(14)Patient Reported Outcome Measures Modified FFI score, mean(SD) 2.77 ± 4.56 <0.00\* 19.29 ± 0.7 56.91 ± 15.32 11.65 ± 18.03 <0.00\* 0.3 ± 0.72 3.1 ± 1.66 6.0 ± 2.94 1.51 ± 2.24 VAS score, mean(SD) Holistic Satisfaction <0.00\* Very Satisfied, n (%) 24 (82.7) 3 (30) 0(0) 27 (62.8) 12 (27.9) <0.00\* Satisfied, n (%) 5 (17.3) 7 (70) 0(0) <0.00\* 4 (9.3) No Satisfaction, n (%) 0 (0) 0(0) 4 (100) Procedure Specific Satisfaction Recommend/Re-undergo, n (%) 29 (100) 38 (88) <0.00\* 9 (90) 0 (0) Complications 9 (21) 0 (0) Residual pain, n (%) 5 (50) 4 (100) 1 (2.3) 1 (10) 0 (0) Plantar fibroma, n (%) 0 (0) <0.00\* 4 (9.3) Re-operation, n (%) 0 (0) 0(0) 4 (100) \*p-value < 0.05

#### **Recovery Group Identification and Trends:**

Overall, 67.4% (29/43) of patients perceived themselves as Recovered-Resolved (RR), 23.3% (10/43) as Recovered-Not Resolved (RNR), and 9.3% (4/43) as Not Recovered (NR). Between groups, no significant differences were identified with respect to: gender, age, or follow up duration. A trend toward identification with the RR group was observed for males (8/10, 80%), but the sample size precluded testing for statistical differences between sexes. Four of the 5 patients (4/5, 80%) who underwent staged BRC with PRP injection identified as RR (4/29, 13.8%); while the remaining patient identified as NR (1/4, 25%). In contrast, 3 of the 4 patients (3/4, 75%) who underwent bilateral BRC with PRP injection as an index procedure identified as NR (3/4, 75%), while the remaining patient identified as RNR (1/10, 10%). These findings demonstrate a trend for identification with NR group for patients who underwent bilateral interventions as an index procedure (3/4, 75%) vs. staged intervention (1/5, 20%). While these findings may be interrupted to suggest worse outcomes when management is not staged, the sample sizes were to small to determine statistical differences between these subgroups (Table 1).

#### Holistic And Procedure Specific Satisfaction:

In the RR group, all were very satisfied (24/29, 82.3%) or satisfied (5/29, 17.2%), and all (29/29, 100%) would recommend/re-undergo the procedure again. Similarly in RNR group, patients were either very satisfied (3/10, 30%) or satisfied (7/10, 70%), and all but 1 patient (9/10, 90%) would recommend/re-undergo the procedure again. The NR group (4/4, 100%) reported both holistic, and procedure specific dissatisfaction (Table). The priori hypothesis for recovery groups was met.

A logical gradient was identified with RR patients reporting the lowest residual pain scores (VAS 0.3, SD 0.72), and less functional limitation (FFI 2.77, SD 4.56). RNR patients reported significantly higher residual pain (VAS 3.1, SD 1.66), and functional limitation (FFI 19.29, SD 0.72). Despite this, RNR patients still identified themselves as "recovered"; suggesting there is a residual deficit level with which patients can cope. The NR group reported the highest residual pain scores (VAS 6, SD 2.94), and most functional limitation (FFI 56.91, SD 15.32). Between recovery groups, the PROM's were statistically significant; providing credibility to the proposed recovery theory for refractory PF (Table). A strong correlation between PROMS (FFI, VAS) and "holistic" patient satisfaction (r=0.63, p<0.00/ r=0.7, p<0.00) was identified; and a moderate correlation between the PROMS and "procedure specific" satisfaction (r=0.56, p<0.00/ r=0.51, p<0.00).

Complications, Reoperations, and Failure Rate: Nine patients (9/43, 20.9%) reported continued heel pain of varying severity, and 1 (1/43, 2.3%) developed an asymptomatic plantar fibroma at the operative site. Five (5/9, 55.6%) of the 9 patients who continue to experience heel pain, and the patient developing the fibroma identified in the RNR group. These patients did not feel the residual pain limited/restricted their daily lives to any significant extent, nor prevented their recovery. The remaining 4 (4/9, 44.4%) with persistent pain identified as NR, and felt the residual pain severely limited/restricted their activities of daily living. Thus, only 4 of the original 43 patients (4/43, 9.3%) in our cohort continue to have pain that prevents their recovery. The reoperation rate was 7% (3/43), and occurred in 3 of the 4 patients (3/4, 75%) who identified as NR (4/43, 9.3%); all of whom underwent bilateral BRC with PRP injection as an index procedure. The overall failure rate of combined BRC with PRP injection was 9.3% (4/43) at a mean of 57.1 months post-op.



### Functional Status And Pain:



To the best of our knowledge, this study is the first to assess the outcomes of BRC with PRP injection for refractory PF, and the first to broaden our traditional definition of "recovery" in this patient cohort. PPR was grouped into: Recovered-Resolved (67.4%), Recovered-Not Resolved (23.3%), and Not-Recovered (9.3%). Between recovery groups, the PROM's demonstrated statistical significance; providing credibility to the proposed recovery theory. As expected, RNR and NR patients reported poorer PROM scores, with lower "holistic" and "procedure specific" satisfaction compared to RR patients. However, within the RNR group patients still perceived themselves as recovered despite their residual deficit(s) at a mean of 69.6 months (range, 33 to 107 months). Saliently, both RR and RNR patients reported similarly high levels of holistic (90.7%; 39/43), and procedure specific satisfaction (88.4%; 38/43). Had these outcomes been accessed with traditional PROMs alone; alternate forms of recovery could not have been identified. Admittedly, recovery in chronic foot and ankle conditions has been under-investigated, and is likely a much more complex, multifactorial process not always predicated on the resolution of all symptomatology. Other factors in chronic musculoskeletal conditions such as anxiety, and depression are known to affect patient's perception of pain disability, satisfaction, and perhaps perceived recovery (40-41). Physician-patient communication has been identified as a strong predictor of post-operative patient satisfaction, and may influence PPR. For this reason we recommend FAS emphasize improvement, rather than resolution when setting patient expectations, and discussing the postoperative course for refractory PF patients undergoing BRC with PRP injection Alternate forms of recovery have been well described, and recently applied to the lower extremity for

chronic conditions where complete symptom resolution is not always possible (37-38). In these conditions, most patients perceive a satisfactory outcome if able to reach an improved residual deficit level with which they can cope (37). These alternative recovery theory(s) have been slow to migrate to orthopedic subspecialties, in part due to the pendulum shift from physician recorded clinical indicators (PRCI's) to PROM's (38). While PROM's provide direct, patient centric data regarding an intervention; too many measures evaluating similar conditions are currently in use, and compound the difficulty in comparing operative interventions (46). In our investigation we utilized the modified FFI to access patients residual deficit level, mainly for it's user friendliness, and ease of use with our protocol. Since its introduction, the FFI has become one of the widest utilized and studied, validated foot specific instruments for measuring pain, and disability (46). However, like other PROMS; the FFI relies primarily on measuring a patient's residual symptoms/limitations to determine whether resolution has occurred. Weather a patient is cable of coping with an improved residual deficit is not considered, preventing it from capturing other forms of recovery. In conclusion, BRC with PRP injection is a viable percutaneous procedure affording a reduced

convalescence period, and low complication rate. While our results should be interpreted as positive; additional research is warranted to delineate the optimum technique/protocol, as well as stratify perceived recovery/outcomes between specific subgroups. While the complete resolution of symptomatology may not occur in all refractory cases, the improvement post-operatively will allow the majority of patients to perceive themselves as recovered. FAS should be cognizant of the inherent limitations of traditional outcome measures, and our traditional definition of "recovery" should be broadened when interrupting outcomes in these refractory cases. Physician-patient communication has been identified as a strong predictor of patient satisfaction, and may influence PPR. Moving forward, it is prudent FAS emphasize improvement, rather than resolution when setting patient expectations, and discussing the postoperative course for patients with refractory PF undergoing BRC with PRP injection.





## Discussion

# References

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