

# Injections of Bone Marrow Aspirate Concentrate as Treatment for Discogenic Pain

Dr. Michael Wolff, Southwest Spine and Sports

JonMark Shillington, University of Arizona College of Medicine - Phoenix

## Abstract

Low back pain (LBP) affects up to 84% of the U.S. adult population with the highest rate of incidence between the ages of 45 and 64 years. While the causes are numerous and complex, one of the primary causes of LBP is discogenic, mechanical pain. This can be secondary to internal disc disruption (IDD) and/or degeneration of the intervertebral disc (IVD), also known as degenerative disc disease (DDD).

Physical and medical therapies are successful in relieving pain in approximately 90% of LBP cases. The remaining 10% generate a serious public health problem known as chronic low-back pain (CLBP).

Effective treatment for discogenic LBP – and therefore for CLBP – would provide physical and financial relief for a large population of individuals as well as for the health care system and employers affected by the patients' condition. One promising treatment option involves the use of Mesenchymal Stem Cells (MSC), which may allow for regeneration of the disc itself. Treatment with MSCs via injections derived from autologous Bone Marrow Aspirate Cells (BMACs) would capitalize on the regenerative potential of MSCs while reducing the risk of infection or rejection, both significant risks of treatment from a heterologous source.

## Introduction

Current treatment options for discogenic CLBP range from conservative therapies to invasive surgical procedures. While each treatment modality has shown varying degrees of success, none has demonstrated consistent high degrees of efficacy.

The most common surgeries involve destructive procedures such as insertion of metal prosthetics (artificial discs) or spinal fusions. The disturbance of natural motion and function can actually accelerate the degenerative cascade at the operative vertebral level and adjacent segments. There is a clear need for effective, early treatment for discogenic LBP that may prevent, slow, or reverse degeneration in the intervertebral disc.

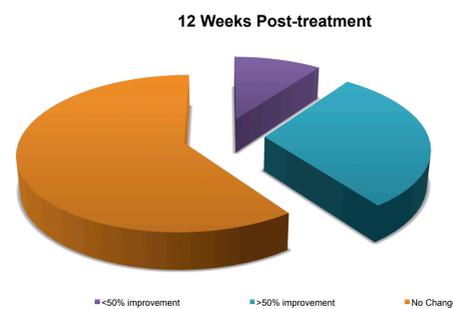


Figure 1: At 12 weeks post-treatment, 40% of patients reported noticeable treatment. Thirty percent said that they had experienced greater than 50% improvement over their original pain level.

Platelet Rich Plasma (PRP) and Mesenchymal Stem Cells (MSCs) possess a combination of growth factors and potential for differentiation which play crucial roles in the the healing and regeneration of injured tissue. Bone Marrow Aspirate Concentrate (BMAC) is rich in platelets and is also a source of MSCs. As an autologous source of platelet concentration and MSCs, BMAC has the potential to facilitate the regeneration of vertebral discs while lowering the risks of infection or rejection inherent in the use of MSCs from a heterologous source.

The purpose of this study is to retrospectively evaluate the clinical outcomes in a population of patients with discogenic CLBP, treated with intradiscal injection of autologous BMAC.. While the sample population will be small, the analysis could provide meaningful insight into the efficacy of the treatment overall and into the efficacy of the treatment based on different pre-treatment scenarios. These insights will contribute to the continued development of the treatment as an option for patients with CLBP and other types of degenerative joint pain.

	2 Week	6 Week	12 Week	6 Month	12 Month
Outcomes					
% Improvement Reported by Patient					
<50%	1 (3.0)	5 (16.1)	3 (9.4)	1 (3.5)	3 (13.0)
>50%	3 (9.1)	5 (16.1)	9 (28.1)	5 (17.2)	7 (30.4)
No Change	23 (69.7)	18 (58.1)	18 (56.2)	22 (75.9)	10 (43.5)
Worse <50%	6 (18.2)	2 (6.5)	1 (3.1)	1 (3.5)	2 (8.7)
Worse >50%	0 (0)	1 (3.2)	1 (3.1)	0 (0)	1 (4.5)

Table 1: Frequencies and proportions of percentage improvement/worsening as reported by patients.

## Methods

For this procedure, an autologous Bone Marrow Aspirate sample was drawn from each patient's hip. The BMA was then filtered and processed to produce BMAC. In a separate procedure the BMAC was injected into the affected lumbar disc under fluoroscopic guidance.

Follow-up with the patients occurred at 5 specified, post-procedure intervals through office visits, written questionnaires, and telephone communication. Patients were asked to report improvement or worsening of their pain in percentage form.

Patients were also asked to complete the following assessments:

- Oswestry LBP Disability Questionnaire
- Short Form (SF) 36 Health Survey
- Visual Analog Scale

The patients' responses to the assessments were scored according to appropriate guidelines and the gathered data was examined in light of the aforementioned areas of interest.

## Results

Of the 33 initial patients, 31, 32, 29 and 23 respectively provided follow-up information at 6 weeks, 12 weeks, 6 months, and 12 months after treatment. When asked whether they had experienced overall improvement in their CLBP, 29 of the 33 patients reported at least some improvement. Four patients reported no change or worsening pain. The patients were asked at each of the aforementioned follow-up intervals to assign a percentage by which their pain had improved or worsened. The responses to that question are in Table 1. Over 30% of patients responding at the 12 month interval reported at least a 50% improvement in their level of pain.

	Baseline	2 Week	6 Week	12 Week	6 Month	12 Month
Instrument	Mean Score					
VAS	5.3	5	3.8	3.1**	3.8**	3.8*
SF-36	53.5	49.5*	60.3	72.1*	72.1**	64.1
OSWESTRY	36.8	38.5	26.6	22.1**	20.7**	24*

\*\* Denotes P-Values < 0.05 using Wilcoxon Sign Rank after adjusting for multiple comparisons from baseline.

\* Denotes P-Values < 0.10 using Wilcoxon Sign Rank.

Table 2: Mean values of patients' responses to VAS, SF-36 and Oswestry.

Mean Responses

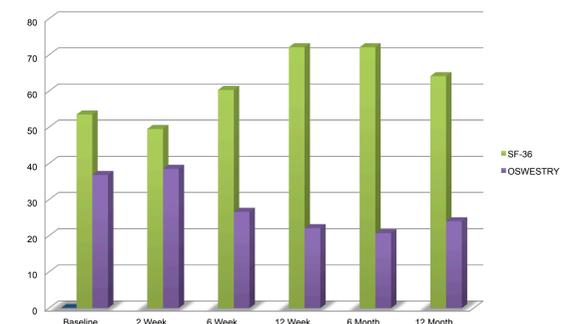


Figure 2: Mean values of patients' responses to SF-36 and Oswestry, demonstrating overall trend of improvement

The patients were also asked to complete three evaluative instruments: the Oswestry Low Back Pain Disability Questionnaire, the Short Form 36 Health Survey (SF-36), and a Visual Analog Scale (VAS). Table 2 shows the mean responses to the three questionnaires. Included in the table is a denotation of statistically significant values as determined using Wilcoxon Sign Rank. Responses to each of the three questionnaires demonstrated statistically significant improvement at the six month interval. Responses to the SF-36 showed an improvement of 34.7%, and responses to the Oswestry questionnaire showed an improvement of 43.8%

## Discussion and Conclusions

An effective, curative treatment CLBP would mark a major watershed in the provision of health care in the U.S. The expense incurred is shared between individual patients, the providers who care for them, the insurance companies that dictate care options, and the companies or employers affected by the patients' ability to perform their job responsibilities. While symptomatic management has continued to make minor strides in its effort to relieve patients' pain, physicians and other health care providers have remained unable to provide curative treatment to long-suffering patients. Therefore, the possibilities surrounding innovative, regenerative treatments demand investigation. The employment of Bone Marrow Aspirate Concentrate, with its inherent supply of platelets and Mesenchymal Stem Cells represents one such treatment.

## Acknowledgements

I wish to thank my mentor Dr. Michael Wolff and Amanda Busch from Southwest Spine and Sports. I would also like to thank the research faculty and staff at UACOM-Phx with special thanks to Dr. Matthew McEchron, and Paul Kang.