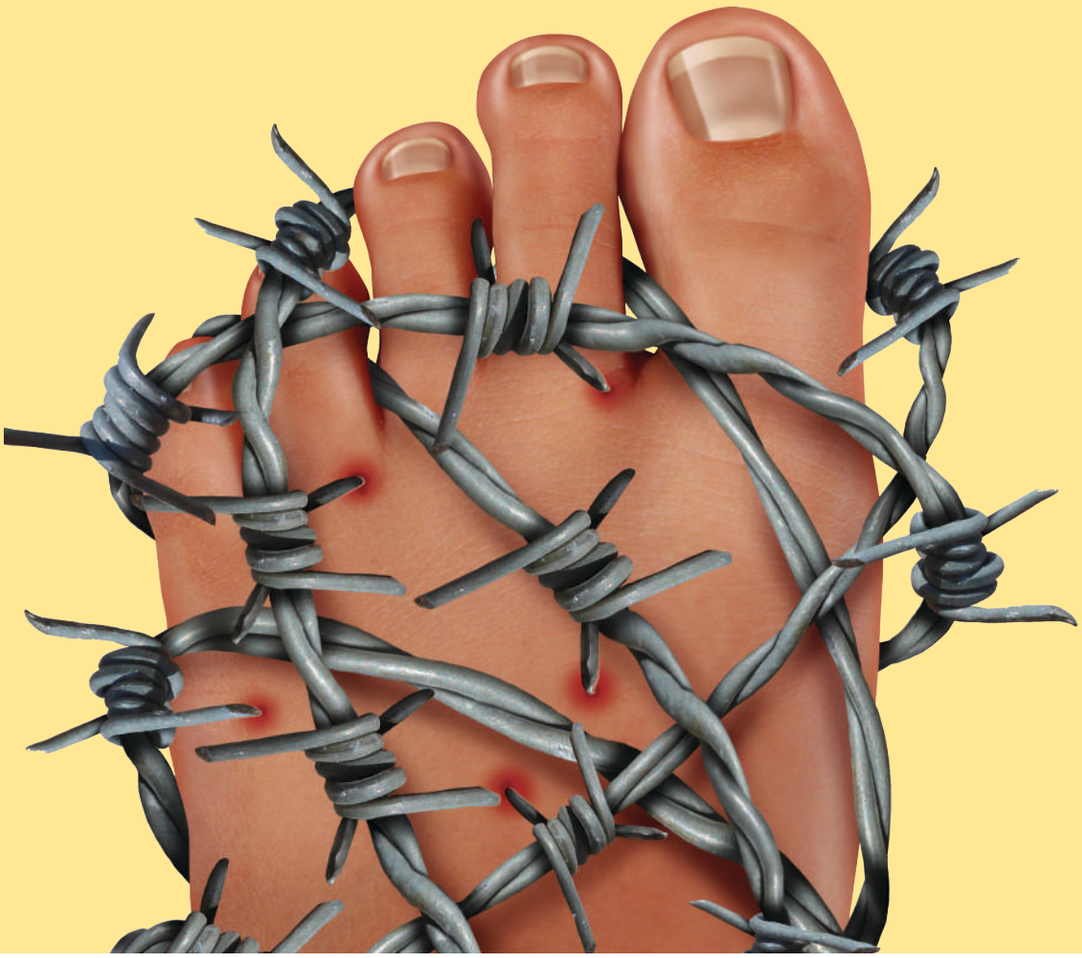
Acellerate GF™

Successful in Treating Diabetes-Related Peripheral Neuropathy



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Distal Symmetrical peripheral neuropathy (DSPN) is a common neurological complication associated with Diabetes. Because there are limited effective treatments, which tend to be directed more towards alleviation of pain and other symptoms, the need arose to find a treatment that would not only lower pain, but also heal nerve tissue. SPM has found that Acellerate GF™ has been very effective in both reduction of pain and the healing of damaged musculoskeletal and nerve tissue. First generation product, Plasmaneu*, was proven to be effective in treating neuropathy in HIV related DPSN. Acellerate GF, which has been enhanced with a higher concentration of platelets and growth factors, has provided outstanding results when used to treat patients suffering from Diabetes related peripheral neuropathy. The purpose of this report is to evaluate the efficacy of AcellerateGF in relieving or eliminating the symptoms of DSPN.

*Hays, Simmonds, Jordan, Lucas, Journal of Therapy and Management of HIV Infection, 2013,1,40-44: "Novel Approach to HIV Associated Neuropathy: Platelet Rich Plasma Successful in treating HIV-Associated Peripheral Neuropathy".

James Hays is Founder of Plasma Solutions, LLC and developer of Acellerate GF™. Acellerate GF (AGF) is a combination growth factor and native, stem-cell activator treatment. AGF contains a proprietary solution of naturally occurring minerals in the bloodstream that causes (i) both platelet activation and aggregation in a plasma concentrate derived from a patient's own blood prior to injection into the patient, plus (ii) the release of a high concentration of growth factors. The high dose of growth factors in AGF accelerate the healing process by actively recruiting adult stem cells in high concentration that are native in the area of injury. These adult stem cells have the ability to create new cells at any age, including healing cartilage, tendons, muscle and nerve tissues. Acellerate GF starts the healing process with the patient's own stem cells.

Plasma Solutions, LLC is a Biologics company that develops, manufactures, and markets regenerative medicine products for the repair, restoration and revitalization of damaged and diseased cellular tissue for (i) musculoskeletal injuries and conditions, (ii) neuropathy, and (iii) chronic non-healing wounds.

Methods

During the period of September 2016 to August 2017, SPM has treated over 100 patients suffering from diabetes related peripheral neuropathy with Acellerate GF. While the following information is anecdotal, if may be helpful to those using Acellerate GF to treat neuropathy.

From our patient pool, we selected two patients to treat and track their progress.

Patient 1
63 y male
Diabetic
Neuropathy symptoms for 5 years
Severe pain level 10
Retired
Medication: Lyrica

Patient 2
55y female
Diabetic
Neuropathy symptoms for 1 year
Moderate pain level 5-6
Teacher
Medication: Lyrica , Gabapentin

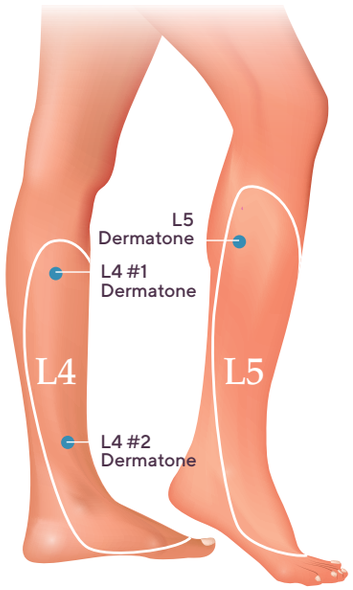
Results

All patients had completed history and physical exams. In addition to standard questionnaire for patients, all were asked to provide information on diet, exercise and lifestyle. As diabetes is impacted significantly by diet, it is very important that patients be compliant as it relates to food and beverage intake. We require that all of pour patients embark on a measurable exercise program if they are not already doing so. Another important fact is sleep/rest. Neuropathy tends to interfere with normal sleep patterns. We want to keep track of when our treatment starts to impact sleep patterns. Increased sleep indicates a reduction or elimination of night time pain and discomfort. Plasma Solutions provides a helpful guide to assist practitioners in this regard.

Both patients were treated utilizing the standard protocol for neuropathy. The results follow.

Treatment 1

Each patient injected bilaterally according to protocol. See diagram for injection locations. Approx. 1.5 cc per injection site. Each extremity was lightly massaged after injection.



24-hour follow-up call. Both patients were called on the following morning to assess their condition. During this call we want to see some amount of improvement overnight. Even slight relief of symptoms is considered success. An important question is related to quality of sleep during the preceding night. Generally, patients have difficulty sleeping because of cramping, numbness and tingling in the legs and feet. Many will report on intake that they have great difficulty achieving restful sleep. It should be noted that in many cases patients may report no significant change in symptoms during the first 24 hours. However, those same patients may report improved quality of sleep. This is an indicator of reduction of symptoms. This may be the first indicator.

24 hour follow-up questions:

1. After leaving the clinic did you experience any reduction in symptoms?
2. Did you do any exercise? (Note: we encourage light exercise like walking.)
3. How did you sleep last night?
4. When getting out of bed did you experience numbness or tingling in your feet?
5. What is your current pain level?
6. What did you eat for dinner last evening and breakfast today? (Emphasize healthy diet.)

Patient Report (After Treatment 1)

Both patients experience mild relief of symptoms.

Patient 1

Reported noticeable mild relief after treatment. He felt that "something was working" in his legs. He also reported feeling "more energy" overall during the evening hours.

He reported that his overnight sleep was more restful: and, some numbness in both feet when getting out of bed. However, he noted that it "may be" less than usual.

Patient indicated that both dinner on the previous evening and breakfast were consistent with the diet program provided by primary physician.

Patient 2

Noticed very slight changes in symptoms immediately following treatment. Patient walks one mile daily at a local track, and did so after treatment. During the evening hours, patient reports a reduction in symptoms. Patient reported having very restful sleep. This is significant because patient often has leg cramps a night. Patient does not suffer from numbness in feet.

This patient reports a healthy diet consisting of mainly fresh fruits and vegetables, poultry and fish.

Following Treatments

Treatment 2

One week after the first Acellerate GF treatment both patients returned to clinic for the second treatment.

Patient 1 Reported a slight improvement in overall condition. Symptoms of numbness, tingling and pain are still present, but he feels that he is getting better. He is attempting to get exercise, starting with short distance walking. His goal is to increase his walking to a mile or more daily. He is happy to be getting more sleep. He and his wife are very encouraged by his improvement to this point.

Patient 2 Reported no significant improvement other than less frequency of cramping at night. Her pain and tingling during daytime hours has not been impacted. Pain level is 6.

Both patients consented to further treatment and received Acellerate GF injections according to protocol.

Treatment 3

Two weeks after treatment 2, both patients returned to clinic for treatment 3.

Patient 1 Reported significant progress after the second Acellerate GF treatment. All symptoms have declined by 40-50%. He reports that he is able to go on daily walks in his neighborhood and is starting to do light chores at home. He reduced his medication for pain shortly after treatment 2 and now takes it sporadically. His goal is to discontinue medication. He puts great effort on dietary compliance. He rates his pain at level 5.

Patient 2 Reported significant progress after second Acellerate GF treatment. She indicates that after her second treatment her symptoms began to decline within a few hours of treatment. Her pain and discomfort had been reduced by 50% within 3 days of treatment. During the previous two weeks she has had periods of being symptom free. She describes her pain today as very tolerable and not interfering with her daily activity. She continues to take medications for pain and reports restful sleeping patterns. Pain level is 4-5.

Both patients consented to a third treatment with Acellerate GF, and were treated according to protocol.

Treatment 4

Two weeks after treatment 3, patients returned to clinic for treatment 4.

Patient 1 Has improved 50-60% since the start of treatment. While he still exhibits neuropathy symptoms, most notably tingling, his pain has decreased significantly (3 on scale), as well as numbness in his feet. He describes both as "tolerable". Because of this he is able to exercise daily, do gardening and other household chores. He reports feeling very little discomfort and a greatly improved quality of life.

Patient 2 Indicates that she encounters neuropathy symptoms "occasionally now" and believes she is still improving. On examination, she had no pain in her lower extremities. There was also no tingling sensation. She continues to walk daily and maintains a healthy diet. She has discontinued medication for pain and would only take it if pain returned at a high level.

Both patients felt that their treatments were successful.

Both patients consented to a fourth Acellerate treatment. They were treated according to protocol.

Patients were advised that we would do a follow-up appointment in one month. At that point, if they were still having symptoms, we could continue treatment with a series of three injections.

Conclusions

AcellerateGF was proven to be effective in reducing the effects of DPSN. Both patients experienced a decrease in pain and discomfort rapidly. Both patients experienced significantly better quality of sleep and more mobility. Overall, there was significant improvement in Quality of Life. When used according to protocol, AcellerateGF combined with patient compliance as it relates to proper diet and exercise is safe and effective.

TABLE 1: EFFICACY Measurement Scale Patient #1

PATIENT #1	Treatment #1	Treatment #2 week 2	Treatment #3 week 4	Treatment #4 week 6
Pain intensity	10	7-8	4-5	2-3
Sensory Perception	8-10	7-8	5	2
Quality of Life	3	5	7	9-10
Mood	5-6	6-7	8	10
Function	4-5	5	7-8	10

TABLE 2: EFFICACY Measurement Scale Patient #2

PATIENT #1	Treatment #1	Treatment #2 week 2	Treatment #3 week 4	Treatment #4 week 6
Pain intensity	6-7	6	4-5	1
Sensory Perception	5	5	4	2
Quality of Life	7	7-8	5-6	8
Mood	6-7	7	8	10
Function	8	8	8-9	10

1. Pain intensity: 1-10. 10 is worst.
2. Sensory perception: numbness 1-10. 10 is worst
3. Quality of Life: 100 being best possible for patient, relative to condition.
4. Mood: 1-10. 10 represents patient feeling in excellent mood
5. Function: 1-10. 10 represents fully functioning and independent.