

# artículo original

# BRIO3 Bioregulatory infiltration therapy with ozone for musculoskeletal pain management, the experience with 229 cases

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#### Keywords

ozone

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#### **Abstract**

Last decade was named the decade of the articulation and bone (1) according to a study by WHO musculo skeletal injuries are the most frequent cause of chronic pain and disability worldwide.(2) Thus the importance of obtaining the most comprehensive treatment that will resolve the pain and restore the functional level to the patient. The mainstream treatment with the available resources of NSAIDs, muscle relaxants, or corticosteroids are effective in the management of the acute pain, but do not offer advantages in the regeneration of the damaged tissue, and can have side effects and risks in the areas of coagulation, gastric lesions of nephrotoxicity well documented. The use of nontraditional therapies such as the injection of medical ozone widens our medical arsenal and allows us to combine different alternative therapies to resolve the osteo articular pathology. The innovative technique of Prolozone, designed by Dr. Shallenberger, makes use a combination of agents(local anesthetic procaine, mixture or vitamins, dextrose, and very low dosage of corticosteroids) with medical grade ozone to apply subcutaneously, intramuscularly or perilesionally depending on the case; positive results are reported(3).

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#### INTRODUCTION

Last decade was named the decade of the articulation and bone (1) according to a study by WHO musculo skeletal injuries are the most frequent cause of chronic pain and disability worldwide.(2) Thus the importance of obtaining the most comprehensive treatment that will resolve the pain and restore the functional level to the patient. The mainstream treatment with the available resources of NSAIDs, muscle relaxants, or corticosteroids are effective in the management of the acute pain, but do not offer advantages in the regeneration of the damaged tissue, and can have side effects and risks in the areas of coagulation, gastric lesions of nephrotoxicity well documented. The use of nontraditional therapies such as the injection of medical ozone widens our medical arsenal and allows us to combine different alternative therapies to resolve the osteo articular pathology. The innovative technique of Prolozone, designed by Dr. Shallenberger, makes use a combination of agents(local anesthetic procaine, mixture or vitamins, dextrose, and very low dosage of corticosteroids) with medical grade ozone to apply subcutaneously, intramuscularly or perilesionally depending on the case; positive results are reported(3).

This communication shows the personal experience of a physiatrist-specialized in bio regulatory medicine, ozone therapy and neural therapy-who applies the combination of these three modalities: Bio regulatory infiltration therapy and ozone (BRIO3) for the treatment of pain of musculo skeletal cause. The choice of the specific bio regulatory Medication to be used was defined through an individual approach in accordance with the anatomical area to be treated: it describes the cases, evolution of the pain, and return to work and daily activities by the patients.

#### **METHODS**

For the inclusion of the patients in this study they have been classified by the anatomical region of the pain and the combination of the homeopathic medication to be used for the injection therapy see (illustration 1)

A mixture of 2 or 3 ampules of the homeopathic preparations is combined with 2% procaine in equal volumes to maintain a procaine dilution at 1%. At each infiltration point an approximate of 0.5 to 1.5 cc is applied via subcutaneously, or perilesionally or intraarticularly depending on the anatomical region to be treated. Then the medical grade ozone is injected in the same area. Ozone is produced by an ozone generator EXT 120 Longevity at 18.8 ug/ml and the amount of ozone injected varied according to the area to be treated, in general from 6 to 12 cc at each injection point subcutaneously, and 15 to 20 cc intraarticularly.

□ Lumbosacral area	<ul> <li>traumeel</li> <li>colocynthis</li> <li>homaccord</li> <li>discus</li> <li>compositum</li> <li>spasscupreel</li> <li>coenzyme</li> <li>compositum,</li> <li>zeel.</li> </ul>
☐ Cervical region:	<ul><li>gelsemium</li><li>homaccord</li><li>spasscupreel</li><li>coenzyme</li><li>compositum</li></ul>
☐ Shoulder tendinitis	<ul> <li>ferrum</li> <li>homaccord</li> <li>neuralgo rheum</li> <li>injeel</li> <li>traumeel</li> <li>coenzyme</li> <li>compositum</li> </ul>
☐ Knee osteoarthritis ☐ Ankle osteoarthritis	<ul> <li>neuralgo rheum</li> <li>injeel</li> <li>Zeel</li> <li>Coenzyme</li> <li>compositum</li> </ul>
☐ Ankle sprain	<ul><li>traumeel</li><li>coenzyme</li><li>compositum</li></ul>
☐ fibromyalgia	<ul> <li>traumeel</li> <li>colocynthis</li> <li>homaccord</li> <li>coenzyme</li> <li>compositum</li> </ul>

• Heel homeopathic Medication available in El Salvador as ampoules for parenteral application (i.v, i.m, s.c)

The frequency of applications of BRIO3 was once a week and the pain perception of each patient was evaluated with the visual analog scale, VAN after each session, which allowed us to compare with the initial VAN scale; those cases which received more than one session of treatment had their ratio of improvement calculated by the percentage of improvement divided by the number of sessions.

Besides the application of the BRIO3 a rehabilitation program was indicated that consisted of physical therapy and stretching routines, and assisted exercises to improve range of motion or strengthening depending on each cases' individual needs.

The statistical analysis was obtained using GRAPH PAD PRISM 5.0 descriptive statistics and kruskal wallis.

#### **RESULTS**

Description of the clinical experience and improvement on pain on 229 patients with musculo skeletal painful syndromes treated at a private rehabilitation center with BRIO3 between the months of March 2015 to February 2016 with a weekly application and a duration of treatment from 1 to 6 sessions.

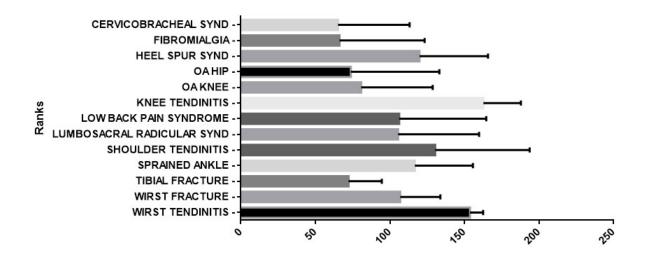
The total population of the study was grouped by anatomical pain syndromes, with the most amount of patients the following groups: low back pain syndrome, cervicobrachialis syndrome, Lumbosacral radicular syndrome, shoulder tendinitis, fibromyalgia and osteoarthrosis.

DIAGNOSIS	N	MEDIA OF SESSIONS	MEDIA INITIAL PAIN VAN	MEDIA PAIN AFTER TREATMENT VAN	AVERAGE OF IMPROVEME NT (IC)
LOW BACK PAIN SYNDROME	91	2.3	8.9	4.1	48%(44-51)
CERVICOBRACHIALIS SYNDROME	37	2.6	8.7	3.8	47%(40-55)
SHOULDER TENDINITIS	23	2.2	9	3	61%(54-69)
FIBROMYALGIA	18	3.6	9.3	4.4	49%(38-59)
KNEE OSTEOARTHRITIS	13	3	9	4.8	42%(34-50)
SPRAINED ANKLE	11	2	8.5	3.3	58%(45-70)
LUMBOSACRAL RADICULAR SYNDROME	8	2.2	9.1	4.2	53%(37-69)
HIP OSTEOARTHROSIS	5	4.2	9.2	3.4	58%(28-88)
HEEL SPUR SYNDROME	5	1.8	9	4	50%(13-66)
KNEE TENDINITIS	4	1.2	9	4	50%(27-62)
WRIST TENDINITIS	2	1.5	9	3.5	55%
WRIST FRACTURE	2	2	9	4	50%
TIBIAL FRACTURE	2	2.5	9.5	4	55%
PIRIFORM SYNDROME	1	3	9	9	NO IMPROVEME NT
PERONEAL TENDINITIS	1	1	9	3	60%
MUSCULAR TRAUMA OF THE THIGH	1	3	10	3	70%
LCA TENDON REPAIR	1	1	10	4	60%
FINGER FRACTURE	1	1	9	3	60%
CARPAL TUNNEL SYNDROME	1	2	9	2	70%
ANKLE OSTEOARTHRITIS	1	3	10	2	80%
METATARSAL FRACTURE	1	1	9	4	50%
AQUILES TENDON REPAIR	1	3	9	3	60%
ADDUCTOR TENDINITIS	1	1	9	5	40%

The percentage of global improvement was above 40% in the described cases, with the exception of 1 case of piriform syndrome. (table 1)

The relationship with the number of BRIO3 sessions and the perception of pain improvement with the visual analog scale with respect to the beginning of the treatment was different for each group p < 0.005, however the groups with pain caused by tendinitis showed a visibly different tendency being the most improved cases of the study (illustration 1)

#### NUMBER OF SESSIONS / PERCEPCTION OF IMPROVEMENT RATIO



#### DISCUSSION

The management of pain by the bio regulatory medicine approach is based upon the use of a mixture of homeopathic medications, which are produced from a variety of mother tinctures prepared from natural components, plants, minerals and animal products by a specific pharmacological process of dilution and dinamyzation (vigorous shaking) of the products. It also combines some concepts of classical homeopathy as described by its founder Samuel Hahnemann; concepts such as the law of similar "similia similibus curentur" where the substance capable of causing a symptom when administered in small minimal dosages, homeopathic dilutions is capable of resolving that same symptom. Besides the use of classical homeopathic remedies, the bio regulatory medicine makes use of micro dosages of vitamin combinations, minerals and phytoterapeutics that help regulate the function at the cellular level. Product of the investigation of the German Professor Dr. Harmut Heine was the published paper in 1998 about the mechanism of immunological assistance or Bystander reaction that explains how these homeopathic medications act. This Bystander reaction consists of the induction of cells by the administration of a relatively nontoxic antigen that posteriorly will have an effect on the modulation of inflammatory process that are already occurring somewhere else in the body. In order to activate this reaction, the use of homeopathic products at low dosages act as antigens that are taken up by the APC antigen presenting cells to the lymphocytes TH0. The antigen then processed is presented as a motive in the APC (antigen presenting cells) to then activate the lymphocytes TH3 that will induce a regulatory mechanism for inflammatory process or allergies according to where the balance between the equilibrium TH1 and TH2 lies(4).

Some of these homeopathic medications have scientific evidence because of its clear benefits in the osteo muscular pathology(5). (traumeel, zeel, discus compositum)

In the private practice of the rehabilitation field we mostly treat patients in the subacute and chronic phases; the majority of the patients have previously consulted a general practitioner or even a specialist such as an orthopedist or neurologist and have received treatment with conventional medication such as muscle relaxants, anti-inflammatory medication non steroid and also corticosteroid injections without success. The patients come to the center with high expectations to receive a treatment that will significantly improve their pain and return them to work and their daily activities. Traditionally the physical therapy programs tend to be lengthy and represent a significant amount of resources from the patient both in time and economical resources that they need to destine to the treatment (in average of 1 to 2 cycles of 10 to 15 sessions per patient).

It is precisely the difficulty to adhere to lengthy rehabilitation treatments that motivates the use of non-conventional therapies with the application of BRIO3 that subjectively, and in the perception of the rehabilitation center, succeeds in significantly improving the pain that the patients perceive and allowing them to do much fewer sessions of physical therapy and to return at a much faster rate to their daily activities, thus reducing work inhabilitation days than with physical therapy alone.

The statistical analysis of these case studies throws some interesting findings; the tendinitis diagnosis presents a much higher result of improvement in pain perception compared to the other groups p<0.05. these results are in accordance to the findings of Moretti (6) who compared the effectiveness of oxygen-ozone application in tendon pathologies with steroid injections obtaining good results without the know side effects of steroids. The mechanisms proposed to give an explanation to these findings are exposed by Dr. Shallenberger for the PROLOZONE Technique where the purpose of this treatment is to improve oxygenation of the tendon, improve circulation, control of production of free radicals and to improve tissue acidosis, to reduce inflammation and to enhance mitochondrial activity. We hope to be able to reproduce the same results with a combination of bio regulatory medication along with ozone therapy BRIO3.

The results observed in the clinical practice are quite favorable in the treatment of tendinitis, especially shoulder tendinitis which tend to evolve to a chronic stage of tendinosis and where the physical therapy alone is insufficient. The cases treated with BRIO3 for shoulder tendinitis have satisfactorily resolved the pain and have been able to return to work and daily activities completing their physical therapy program in less time and fewer sessions.

The application of ozone therapy to these 229 patients has resulted in an enriching experience finding it a highly effective treatment for pain management of musculo skeletal lesions. The results observed so far motivate us to further continue with clinical studies with analytical and prospective studies to be able to know and verify its advantages over other officially accepted treatments.

#### REFERENCES

- 1. Gordin K. Comprehensive scientific overview on the use of platelet rich plasma prolotherapy (PRPP). J Prolotherapy. 2011;3(4):813–25.
- 2. Lim SS, Vos T, Flaxman AD, Danaei G, Shibuya K, Adair-Rohani H, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. The lancet. 2013;380(9859):2224–60.
- 3. Shallenberger F, HMD A. Prolozone<sup>™</sup>–Regenerating Joints and Eliminating Pain. J Prolotherapy. 2011;3(2):630–8.
- 4. Heine H, Schmolz M. Induction of the immunological bystander reaction by plant extracts. Biomed Ther. 1998;16:224–6.
- Parsons CJ. THE USE OF HEEL REMEDIES IN MUSCULOSKELETAL DISORDERS. 2009 [cited 2016 Feb 15]; Available from: http://www.biopathica.co.uk/Articles/Arthritis%20Rheumatic%20Conditions%20Sporting%20Inj uries/69%20-%20Musculo.pdf
- 6. Moretti M. Can Oxygen–Ozone Injections in Sport Overuse Tendinopathies Be a Valid Alternative to Cortisone Therapy. Int J Ozone Ther. 2010;9(1):21–4.