

#### **EUROPEAN OZONE CONGRESS**

March 24-26 2017 Charité Berlin, Germany

# Scientific evidence about Ozone Therapy in Pain Medicine

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## What is ozone therapy?

The therapeutic use of medical ozone gas.
 Medical Ozone: ozone generated from medical oxygen at concentrations between 1 and 80 mcgr/mL.

Where to buy:



**Ozone Generator** 

Medical Device II-b type

## Ozone therapy regulation?

European directive 93/42 CEE:
 For medical devices
 Each country in EU develops its own law:
 RD 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios (BOE 6/11/2009)



**Ozone Generator** 

Medical Device II-b type

## Ozone therapy regulation?

+ Medical devices classification: Type I (bandage): Not invasive – selfevaluation Type IIa (scalpel, ultrasound device): + Short time invasive without permanent effect on the body or fluids – External design evaluation Type IIb (artificial implant, ozone generator) + Long time invasive and permanent effect on the luids - External design evaluation and Clinical Trials Type III (surgical absorbable suture):  $\Rightarrow$  Life risky or includes drugs – Previous design aproval, external evaluation and clinical trials

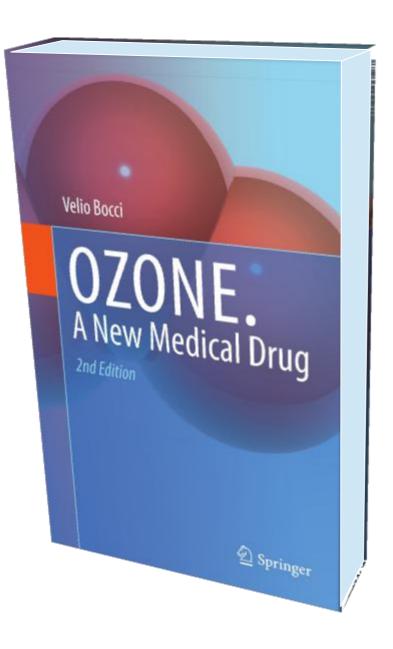
#### Decrease tissue inflammation:

- PLA2 and COX2 inhibition
- Modulation of pro-inflammatory cytokines (IL-1β, PgE2, TNFα, NO<sup>-</sup>)

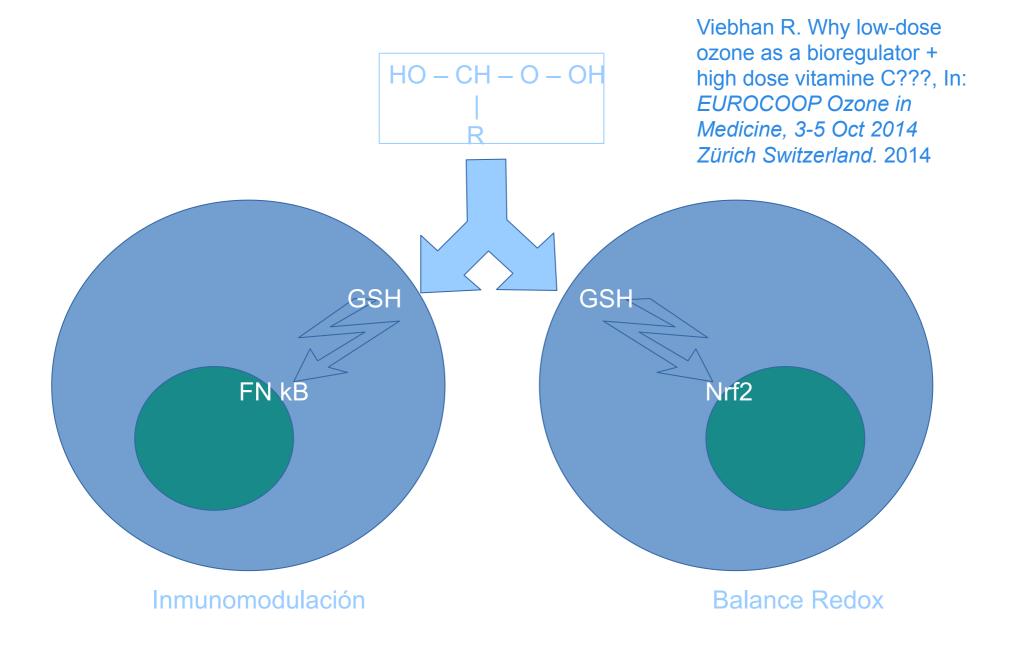
#### Reduce oxidative stress:

 Increase in antioxidants enzymes (Catalase, Glutation-peroxidase, SOD)
 Degradation of MPS in disc herniation:
 Breakage of -SH=SH- (Fenton's reaction)
 Accelerates tissue healing:

- Inhibits tissue degradation: MMPs
- Stimulates tissue healing: PDGF, FGF



2011



WFOT's review on evidence based ozone therapy   WFOT - Mozilla Firefox     WFOT's review on evid ×		
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	<ul> <li>WFOT'S REVIEW ON EVIDENCE BASED OZO</li> <li>Download English version</li> <li>Download Spanish version</li> <li>Download Italian version</li> <li>Coming soon! Portuguese version</li> <li>Coming soon! Japanese version</li> </ul>	ONE THERAPY (1ST ED)



WFOT's Review on Evidence Based Ozone Therapy

WFOT Scientific Advisory Committee 2015

C World Federation of Ozone Therapy - WFOT, 2015

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#### + LEVELS OF EVIDENCE

- + 1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
- + 1+ Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
- + 1 Meta-analyses, systematic reviews, or RCTs with a high risk of bias
- + 2++
  - High quality systematic reviews of case control or cohort studies
  - High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that therelationship is causal
- + 2+ Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- + 2 Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- + 3 Non-analytic studies, eg case reports, case series
- + 4 Expert opinion

#### GRADES OF RECOMMENDATION

#### + A

- At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population;
- or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
- + B
  - A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results;
  - for Extrapolated evidence from studies rated as 1++ or 1+
- + C
- A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results;
- + or Extrapolated evidence from studies rated as 2++
- + D
  - Evidence level 3 or 4;
  - + or Extrapolated evidence from studies rated as 2+

#### PHARMACOLOGICAL MANAGEMENT

- + B
- Strong opioids should be considered as an option for pain relief for patients with chronic low back pain or osteoarthritis, and only continued if there is ongoing pain relief. Regular review is required.
- D
- Specialist referral or advice should be considered if there are concerns about rapid-dose escalation with continued unacceptable pain relief, or if >180 mg/day morphine equivalent dose is required.

#### **PSYCHOLOGICALLY BASED INTERVENTIONS**

- + C
- Referral to a pain management programme should be considered for patients with chronic pain.

#### PHYSICAL THERAPIES

+ B

- Exercise and exercise therapies, regardless of their form, are recommended in the management of patients with chronic pain.
- + A
- Advice to stay active should be given in addition to exercise therapy for patients with chronic low back pain to improve disability in the long term. Advice alone is insufficient.

#### PHARMACOLOGICAL MANAGEMENT

Non-opioid analgesics (simple and topical)

+	NSAID	В
+	Paracetamol	С
+	Topical NSAID	A
+	Topical Capsaicin	A
+	Topical Lidocaine	В
+	Opioids	B
Anti-	epilepsy drugs	
+	Gapentine	A
+	Pregabaline	A
+	Carbamazepine	В
Antic	lepressive	
+	Tricycle	A
+	Duloxetine	A
+	Fluoxetine	В
Com	bination therapy	A (neuropathic pain)

Others

Botulin toxin

not for pain

#### PSYCHOLOGICALLY BASED INTERVENTIONS

C

- + Pain management programs B
- + Education
- + Behavioural therapies C
- + Cognitive therapies C

#### PHYSICAL THERAPIES

+ Manual therapy	B (spine)
+ Exercise	В
+ Activity and excercise	A (lumbar)
+ TENS	B (spine)
+ Acupuncture	В

## **IASP 2009 recommendation**

Steoids/anesthetic injections C (transforaminal) or null

Termal Radiofrequency (RF)

#### **Spanish Foundation on Rheumatology**

B

C

Medel Rebollo, J et al. Técnicas mínimamente invasivas en el tratamiento del dolor crónico. Fund Esp Reum. 2013; 14 (4)

D (nerve) or null (myofascial syndrome)

#### Steroids/anesthetic injections:

- + Transforaminal
- + Facet

**Pulsed RF** 

- + Peripheral
- Termal RF
- Pulsed RF
- Neurostimulation D
- Pump/infussor
  A (short term)
  B (long term)

В

С

B

С

### Pain unit

#### "Standards and recommendations for quality and safety" Spanish Ministry of Health (2011)

Chronic pain; most frequent causes		
	Articular pain (arthritis)	
Museuleskolotal pain	Spine pain	
Musculoskeletal pain	Myofascial syndrome	
	Oncologic musculoskeletal injuries	
	Herpes zoster and post-herpetic neuralgia	
	Peripheral neuralgia	
Neuropatic pain	Diabetic neuropathy	
Neuropatic pain	Complex regional pain	
	Nerve injury	
	Post-amputation pain	
Mixed pain	Radicular pain due to spine diseases	
Visceral pain		
Vascular pain		
Central pain	Fibromyalgia	

### Pain unit

#### "Standards and recommendations for quality and safety" Spanish Ministry of Health (2011)

Chronic pain; most frequent causes		
	Articular pain (arthritis) B	
Musculoskeletal pain	Spine pain D	
	Myofascial syndrome	
	Oncologic musculoskeletal injuries	
	Herpes zoster and post-herpetic neuralgia D	
	Peripheral neuralgia D	
Nouropatia pain	Diabetic neuropathy D	
Neuropatic pain	Complex regional pain	
	Nerve injury	
	Post-amputation pain	
Mixed pain	Radicular pain due to spine diseases B	
Visceral pain		
Vascular pain		
Central pain	Fibromyalgia D	

### Ozone therapy and pain

Pribluda S. Tratamiento de la lumbociática y otros síndromes similares con ozono subcutáneo. Sem. Med. 1963; 123, 1026–1028.

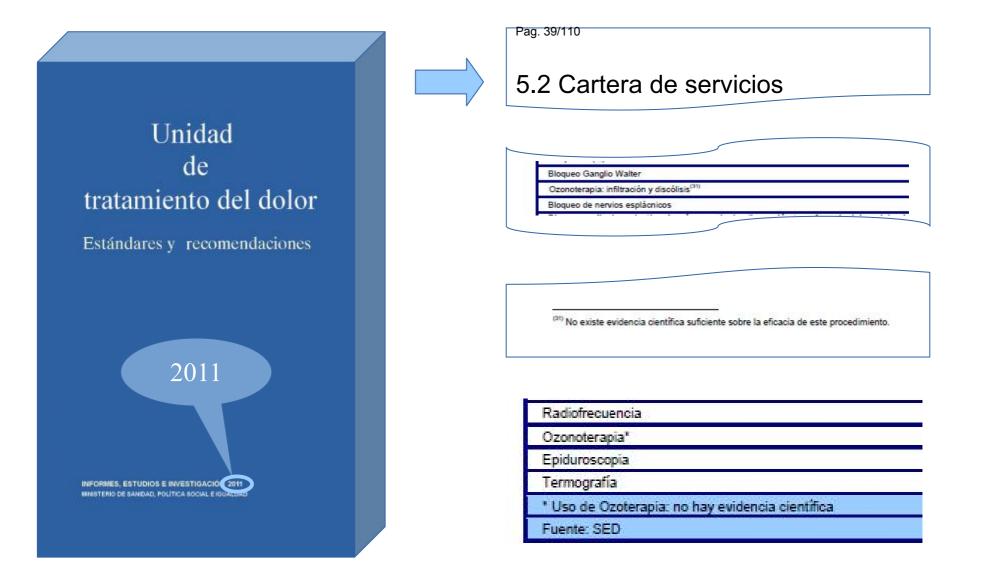
Verga C. Nuovo approccio terapeutico alle ernie e protusioni discali lombari. Rivista Di Neuroradiologia. 1989;(2):148.

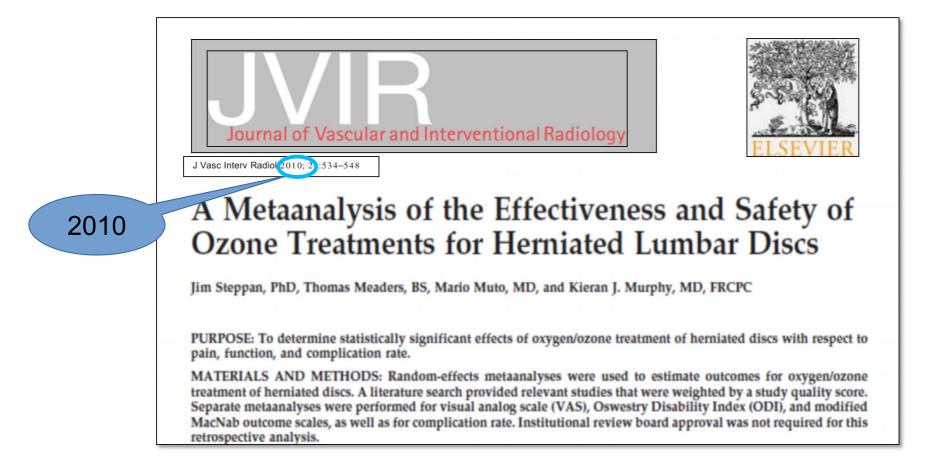
#### > 270 papers

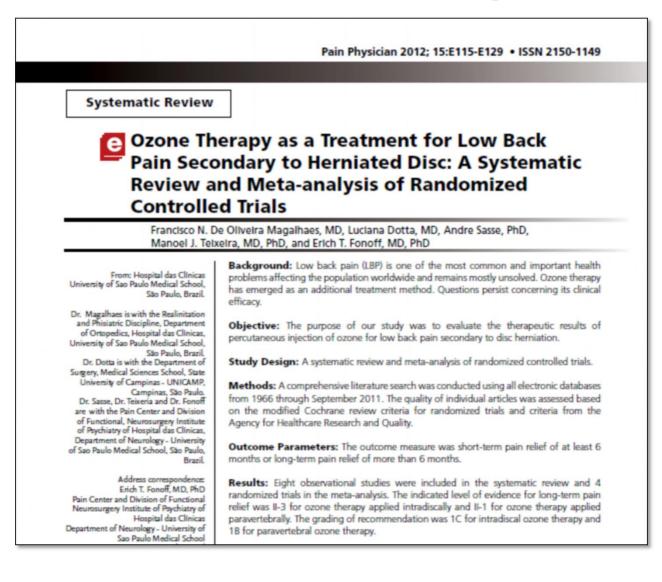
177 hernia discal lumbar38 hernia discal cervical37 gonartrosis18 otras causas

Perri M, Grattacaso G, di Tunno V, Marsecano C, Gennarelli A, Michelini G, et al. T2 shinethrough phenomena in diffusion-weighted MR imaging of lumbar discs after oxygen-ozone discolysis: a randomized, double-blind trial with steroid and O2-O 3 discolysis versus steroid only. Radiol Med. 2015 Mar 6; doi:10.1007/s11547-015-0519-z

### Ozone therapy and pain







#### OZONE THERAPY IN LOW BACK PAIN TREATMENT SYSTEMATIC LITERATURE REVIEW

2013



CENTRO COCHRANE DO BRABIL Rua Borges Lagoa, 564 Conj. 63 Vila Clementino - Bšo Paulo - BP CEP (ZIP Code): 04038-000 Phone/Fax: +55 11 5575-2970 Email: cochrane.dmed@epm.br Home Page: www.centrocochranedobrasil.org Ozone therapy in low back pain treatment: Systematic Literature Review

#### ABSTRACT

Context: Low back pain is one of the most frequent and important problems affecting the world population, and its treatment is still controversial. Ozone therapy has emerged as a treatment method, but there are still doubts regarding its effectiveness and safety.

Objectives: To determine the effectiveness and safety of ozone therapy in non-specific low back pain and lumbosciatalgia treatment.

Methods: Systematic review, according to the Cochrane Collaboration methodology. We included only randomized clinical trials that tested the isolated or associated ozone therapy compared to placebo or other active treatments.

Conclusions: There is evidence of long-term superiority of ozone therapy for the treatment of chronic lumbosciatalgia when compared to steroid injection, radiofrequency and open surgery. Further studies are required with appropriate methodology and comparison of ozone therapy with placebo procedures, as well as studies comparing different ozone doses and application methods.

Centro Coohrane do Brasil - www.centrocoohranedobrasil.org.br



No indication: Extra-articular + Oncologic + Refered + Nonspecific low back pain: + "There is no such a thing named nonspecific low back pain, but nonspecific doctors" William Kirkadly Willis MD.OS + Waiting for a clinical trial !!!

Indication:

Lumboradicular pain by disc herniation:
 Not for calcified disc hernia
 Not for progressive neurological deficit
 Poorer results in foraminal herniation

**Recommendation level B** 

Low back pain by spondylolistesis grade I
 Faliure of conservative treatment
 Instead of steroids or RF
 (Bonetti M. 2003, 2005)
 Recommendation level D

#### Indication:

Low back pain by spondylosis:

 Poorer result in case of scoliosis or spine instability

 Low back pain by facet joint disease:

 Poorer result in case of scoliosis or spine instability

 Lumbar spinal stenosis:

 Poorer result in case of scoliosis or spine instability

(Alexandre A. 2012, Andreula C. 2004, Baeza J. 2006, Bonetti M. 2002, 2006, 2007, 2011)

**Recommendation level D** 

### Ozone therapy and knee osteoarthritis

Moretti B., Lanzisera R., Morese A. [O2-O3 vs chondroprotectors in the treatment of osteoarthritis of the knee] Riv. It. Ossigeno-Ozonot. 2004; 3: 65-72

Moretti, M. Effectiveness of Treatment with Oxygen-Ozone and Hyaluronic Acid in Osteoarthritis of the Knee. Int J Ozone Ther 2010; 9: 25–29

Jesus, C, Trevisani, V, Santos F. Comparison Between Intra Articular Ozone and Placebo in the Treatment of Knee Osteoarthritis: A Multicentric, Comparative, Randomized and Double-Blinded Clinical Trial. ACR/ARHP Annual Meeting 2015

**Recommendation level B** 

Injections: + Intradiscal (ID)<sup>1</sup> + Intraforaminal (IF)<sup>2</sup> + Facet joints (deep paravertebral) (DPV)<sup>3</sup> + Intramuscular (calssic paravertebral) (CPV)<sup>4</sup> + Intralessional – pars interarticularis<sup>5</sup> + Epidural: Interlaminar<sup>6</sup>

Hiatus sacral<sup>7</sup>

- Juncopilla N, Franzini M. The therapy involving the infiltration of oxygen-ozone intradisc and interfacet. 1er Congresso de la Sociedad Española de abordajes percutaneos vertebrales. Barcelona; 1995.
- Muto M, Andreula C, Leonardi M. Treatment of herniated lumbar disc by intradiscal and intraforaminal oxygen-ozone (O2-O3) injection. J Neuroradiol. June 2004;31(3):183–9
- Scuccimarra A. [The "Laminoforaminal Technique" in Oxygen-Ozone Therapy for Lumbar Disc Herniation]. Riv Ital Ossigeno-Ozonoterapia. 2003;2(2):193–6.
- Verga C. Nuovo approccio terapeutico alle ernie e protusioni discali lombari. Rivista Di Neuroradiologia. 1989;(2):148.
- Bonetti M. [CT-Guided Oxygen-Ozone Infiltration into Isthmic Lysis Points in the Management of 1st Degree Spondylolisthesis and Spondylolysis]. Riv Ital Ossigeno-Ozonoterapia. 2003;2(1):31–8.
- Borrelli E. Mechanism of action of oxygen ozone therapy in the treatment of disc herniation and low back pain. Acta Neurochir Suppl. 2011;108:123-5. doi: 10.1007/978-3-211-99370-5\_19.
- Mattozi I, Laurini G, Muzzi G, Franzini M, Bigiotti A. Intrasacral epidural injection with oxygenozone for the treatment of low back pain. Comparison and evaluation with other techniques and rehabilitation and return to work. European Journal of Clinical Investigation. 2003;(33 (suppl.
- 1)):45.

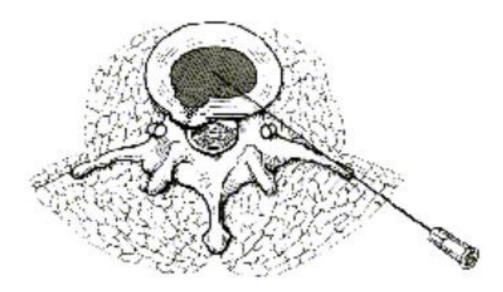
- Indirect Endovenous Ozone therapy\*:
  - + Systemic ozone application
  - Withdraw 100-150 cc of peripheral venous blood and mix it with the same volume of ozone at 20 to 60 mcgr/mL concentration for 10 seconds
  - + Remove the gas and infuse back the blood using a closed disposable system
  - + 3 papers1-3 advice its use for:
    - + Complementary treatment
    - + Failure of treatment with injections

\* Bocci V. Ozone: A new medical drug [Internet]. Netherlands: Springer; 2005. 295 pp. Retrieved from: http://www.springer.com/biomed/book/978-1-4020-3139-7

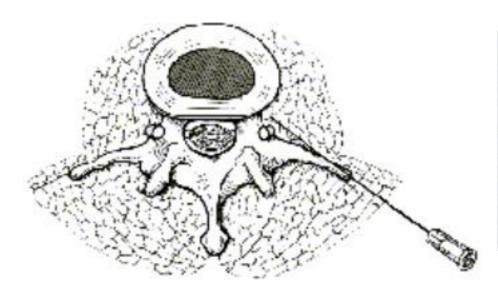
Alexandre A, Coró L, Paradiso R, Alexandre AM, Fraschini AL, Spaggiari PG. Treatment of symptomatic lumbar spinal degenerative pathologies by means of combined conservative biochemical treatments. Acta Neurochir 2011;108(Supl.):127-5.

Dall'aglio R, Gomez Moraleda M, Cardoso C, Alexandre A, Fraschini F. Biochemical and Pharmaceutical Aspects of Entrapment: the Possible Role of Free Radicals and Ozone in Nerve Root Compression. Riv Ital Ossigeno-Ozonoterapia. 2004;3(2):105–11.

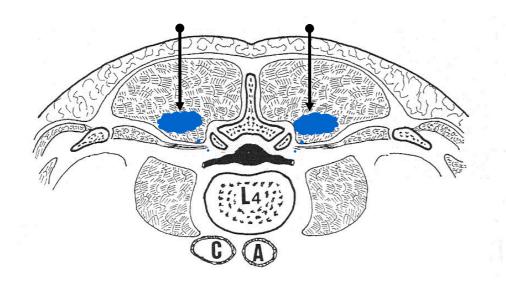
Calunga Fernández JL, Ramos Parra TL., Castillo P, Menéndez S, Carballo A, Céspedes J. Ozonoterapia combinada en el tratamiento del paciente portador de hernia discal lumbar: estudio preliminar. Rev Cubana Invest Bioméd [Internet].2007; 26(1). Available in: http://scielo.sld.cu/scielo.php?script=sci\_arttext&pid=S0864-03002007000100003&Ing=es.



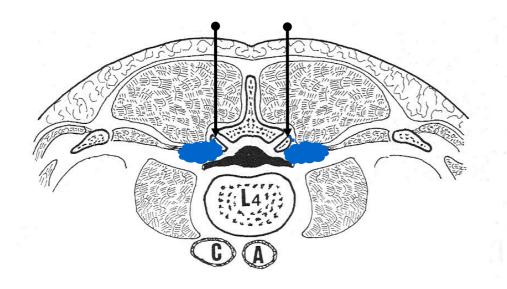
7-10 cm from spinous process
Chiba needle (22G x 11")
Oblique 45° from medial line (20° caudal in L5-S1)
5 ml @ 30γ - 40γ



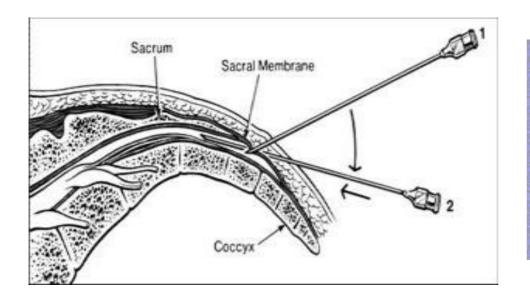
7-10 cm spinous process
Chiba needle (22G x 11")
Oblique 45° from medial line (20° caudal in L5-S1)
10 ml @ 25γ



3-4 cm from spinous process
2 inj. in the superior vertebrae and 2 inj in the inferior vertebrae
Intramuscular needle (18G x 40 mm)
Perpendicular
Intramuscular
5-10 ml @ 10-20 γ



2-3 cm spinous process
Spinal needle (25G x 90 mm)
Perpendicular
Perifacetary / periforaminal
10 ml @ 20 γ



Spinal needle (25G x 90 mm) + introductor
Hiatus sacral
Epidural
20 ml @ 20 γ

#### + Disc herniation\*:

CPV: IB evidence level: positive results 70%
 ID/IF: IC evidence level: positive results 80%

#### Indications\*\*:

- + Failure of conservative meassures for 2 months
- + Symptoms and imaging correlation (TAC/RM)
- + Neurophysiological assesment if needed

\* Magalhaes F., Dotta L., Sasse A., Teixera MJ., Fonoff ET. Ozone therapy as a treatment for low back pain secondary to herniated disc: a systematic review and meta-analysis of randomized controlled trials. Pain Physician. April 2012;15(2):E115–129.

\*\* Murga M. [Ozone spinal infiltration. Indications, techniques and clinical experience]. Rev Esp Soc Dolor. 2005;12(II):10–7.

## Disc herniation\*: Radicular pain:

- + Contained/protruded hernia:
  - + ID + IF in the same surgical act.
- + Extruded hernia:
  - + ID (15 ml)
  - + ID + IF in the same surgical act.
- + Emiigrated hernia:
  - + IF a 1-2 levels (according to the level of emigration)
- Low back pain (if present):
  - + Facet joint disorder:
    - + DPV
  - + Muscular pain
    - + CPV

Alexandre A., Bricolo A, Millesi H. Advanced Peripheral Nerve Surgery and Minimal Invasive Spinal \* Surgery. Acta Neurochir. 2005; Supl. 2. 156 pp.

Spondylotic low back pain<sup>1-4</sup>: Bilateral DPV injection at each level +/- imaging help  $\Rightarrow$ Facet joint low back pain<sup>4</sup>: DPV injection around the facets +/- imaging help  $\Rightarrow$ Lumbar spinal stenosis<sup>2-5</sup>: IF or Sacral epidural injections Add ID if there is a symptomatic LDH  $\Rightarrow$ DPV (bilateral) injection at each level for LBP

- Bonetti M, Cotticelli B, Richelmi P, Valdenassi L. [Rofecoxib and O2-O3 Therapy vs O2-O3 Therapy in the Management of Spondylarthrosis]. Riv Ital Ossigeno-Ozonoterapia. 2002;1(2):171–8.
- 2. Bonetti M, Fontana A, Mardighian D. Oxygen-ozone therapy for degenerative spine disease in the elderly. Riv Ital Ossigeno-Ozonoterapia. 2006;5(1):25–32.
- Bonetti M, Fontana A, Parodi F. Oxygen-Ozone Therapy Associated with Magnetic Bioresonance in Degenerative Arthrosis of the Spine: Preliminary Findings. Int J Ozone Ther. 2007;6(1):29–35.
- Bonetti M, Fontana A, Martinelli F, Andreula C. Oxygen-ozone therapy for degenerative spine disease in the elderly: a prospective study. Acta Neurochir Suppl. 2011;108:137–42.
- 5. Baeza-Noci J. Spinal Ozone Therapy in Lumbar Spinal Stenosis. Int J Ozone Ther. 2007;6(1):17–24.

#### Side effects

Marchetti O., La Monaca G. An unexpected death during oxygen-ozone therapy. Am. J. Forensic Med.
 Pathol. 2000. 21(2): 144-147

• Corea F., Amici, S., Murgia N. A case of vertebrobasilar stroke during oxygen-ozone therapy. J. Stroke Cerebrovasc. Dis. 2004, 13(6): 259-261

 Lo Giudice G., Valdi F., Gismondi M. Acute bilateral vitreo-retinal hemorrhages following oxygen-ozone therapy for lumbar disc herniation. Am. J. Ophtalmol. 2004, 138: 175-177

Zambello A., Bianchi M., Bruno F. Safety in ozone therapy. Riv. It. Ossigeno-Ozonot. 2004, 3: 25-35

• Scarchilli A., Malpieri R. Meningeal irritatation after paravertebral oxygen-ozone injections. A case report. Riv. It. Ossigeno-Ozonot. 2004, 3: 35-36

 Gianneschi F., Cervelli C., Milani P. Ventral an dorsal root injury after oxygen-ozone therapy for lumbar disc herniation. Surg. Neurol. 2006, 66: 619-621

• Pellicano G., Martinelli F., Tavanti V. The Italian Oxigen-Ozone Therapy Federation (FIO) study on Oxygen-Ozone Treatment of herniated disc. Int. J. Ozone Therapy, 2007, 6: 7-15

• Bo W, Longyi C, Jian T, Guangfu H, Hailong F, Weidong L, et al. A pyogenic discitis at c3-c4 with associated ventral epidural abscess involving c1-c4 after intradiscal oxygen-ozone chemonucleolysis: a case report. Spine. April 15, 2009;34(8):E298–304.

#### Conclusions

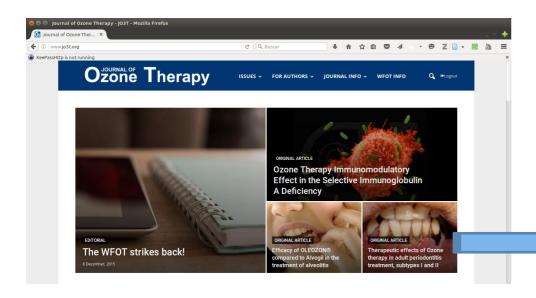
Ozone therapy is safe and effective to treat lumbosciatic pain due to lumbar disc herniation.

There are some evidence that it can be useful to treat other spines diseases

There is strong evidence that it can be safe and effective to treat knee osteoarthritis.

There are some evidence about its use in other painful situations (FM, TMJD, Neuralgias, ...)

## THANK YOU!





#### http://www.jo3t.org

#### ORIGINAL ARTICLE

#### JO<sub>3</sub>T

Therapeutic effects of Ozone therapy in adult periodontitis treatment, subtypes I and II.

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<sup>1</sup> Dra. In Stornatology. Second Degree Specialist in Periodontics. Master in Sciences in Attention of Dental Urgenoles. Master in Sciences in Community Buccal Health. Director of the Oareer in Stornatology. Auxiliary Professor. University of Medical Sciences of Matarzas, Oubs. <u>Imabreu.mts@informed.sid.cu</u>

<sup>2</sup>Odontologist. Pathfinder Institute. Santa Barbara, Oalifornia. USA

<sup>3</sup> Dr. in Ohemical Sciences. Full Researcher. Centro Nacional de Investigaciones Olentíficas (ONIO), Havana, Ouba

#### ABSTRAOT

Introduction: Conventional treatments of the periodontitis rely on surgery and antibioticotharapy. The properties of the ozone offer a more innocuous and more economic new alternative therepeutic. Objective: to evaluate the effectiveness of the ozone therapy in the treatment of periodontitis type I and II,

Objective: to evaluate the effectivaness of the ozone therapy in the treatment of periodomitis type I and II, and to identify the advarse events

Methods: It was carried out a clinical trial, phase III, randomized, controlled and to simple blind in patients that went to Odombogical Clinic 'III Congress of PCC' of Matanzas, January 2013 - January 2015. The sample belonged to 50 patients, divided in 5 groups of 10 patients each one: Group A - Treaties with eacons gat. Group B - OLEOCON®. Group C - oxonized water. Group D - treatment of oxose combined with the three modalities (gas, ozonized water and OLEOZON®. Group Z (control) - convuntional treatmant. The groups A, B, C and D were the experimental groups. Clinic and microbiolgical evaluation was measures. Effectivuness of he treatment, and adverse evaluated. The results showed up in graphics, the percentage and Square Chi ware used. The ethical principles ware completed. Results: Clinical evaluation west satisfactory to the month of the treatment in 84,6% of the studied places.

Results: Clinical evaluation went satisfactory to the month of the treatment in 84.6% of the studied places, with better results in the group D (96%), with significant differences between the experimental groups and the control. The microbiological evaluation was satisfactory and increased to 83.4% to the six months of the study. The experimental group D prevailed (96.6%). The effectiveness was good in 85.4% of the sample, prevailing in the experimental group D with 96.6%, followed by the group A. The percentage of adverse scents was low, 1.5%.

Conclusions: The clinical and microbiological evaluation showed satisfactory results, associated to a low percentage of adverse evants (with gas ozone only). The combined ozone therapy was the most effective treatment for this type of periodontitis.

Key words: ozone therapy, treatment, periodontitis

#### INTRODUCTION

Advances in medicine as a science, in the world, have incorporated knowledge and practices, whose results evidence to be of high value for development and progress of humanity<sup>1</sup>.

Among contemporary medicine trends stands out, with an increasing dynamism in recent years, incorporation of natural and traditional medicine to professional practice, not as an alternative method but as true discipline which is necessary to constantly study, improve and develop, due to its proven ethical and scientific advantages.

This medicine, internationally known as alternative, energetic, natural, complementary or holistic is a reality made present in the whole world and is part of each country's cultural heritage. It uses practices that have varied from country to country and generation after generation, for hundreds of years before development of current conventional medicine.