# INTRADISCAL OZONE TREATMENT OF NON-CONTAINED DISC HERNIATIONS: 18 MONTHS FOLLOW-UP

**SUMMARY**

Study Design In the past 10 years, intradiscal ozone treatment has proved to be an effective modality in treating patients affected by degenerative disc disease (DDD). Few Authors pubblished that ozone is highly effective in various states of degeneration of the intervertebral disc.

Objective The intent of the Author was to observe clinical and morphologycal results of the intradiscal ozone treatment in patients affecetd by non-contained disc herniations on a 18 months clinical follow-up.

Methods 104 patients were included in the study on the base of precise inclusion and exclusion criteria. The patients were followed on 18 months period by Visual Analogic Scale (VAS), Japanese Orthopedic Association Scale (JOA) and Overall Patient Rating Scale (OPRS). Disc herniation morphology was evaluated after 5 months with an adeguate MRI or CT scaning.

Results There was a 3.77 points of gain on the VAS scale and a 54.7% of improvement on the JOA scale. The mean beneffit of 71.55% and a median of 80% was found on the OPRS. On 5 months follow-up 22% of patients had an immodified herniation volume, 41% had a reduction in the volume while 37% had a complete disapearance of disc herniation.

Conclusions The intradiscal ozone treatment demonstrated to be an effective modality of treating patients that have overpassed conservative measures and have not yet fullfilled the indications for surgical treatment.

**SOMMARIO**

Negli ultimi 10 anni la discolisi con ozono ha dimostrato di essere un metodo efficace nel trattamento di problemi degenerativi del disco intervertebrale. Numerosi Autori hanno messo in evidenza effetti positivi nelle più svariate patologie discali.

L'obiettivo dell'Autore era la valutazione clinica e morfologica della discolisi con ozono nei pazienti affetti da ernie discali non contenute sulla base di un folow-up di 18 mesi.

104 pazienti sono stati inclusi nello studio sulla base di specifici criteri di inclusione ed esclusione. I pazienti sono stati seguiti clinicamente mediante le scale di valutazione per il dolore e funzionalità: Visual Analogic Scale (VAS), Japanese Orthopedic Association (JOA) scale e la Overall Patient Rating Scale (OPRS). Dopo 5 mesi è stata eseguita la valutazione morfologica del volume erniario con le immagini RMN o TC.

I risultati ottenuti sono alquanto incoraggianti con un guadagno di 3.77 punti sulla scala VAS e un miglioramento del 54.7% sulla scala JOA. Miglioramento medio di 71.77% e mediano di 80% sulla OPRS. Le immagini radiologiche hanno messo in evidenza una scomparsa completa dell'ernia in 37% dei pazienti, una riduzione volumetrica in 41% mentre in 22% il volume erniario è rimasto invariato.

I risultati indicano che la discolisi con ozono è effettivamente una valida alternativa nei pazienti che hanno oltrepassato le possibilità di trattamento conservativo ma non hanno ancora raggiunto le indicazioni all'intervento chirurgico.

**INTRODUCTION**

Lumbar disc herniation is a pathologic condition most commonly responsible for lumboradicular pain, and the condition for which lumbar surgery is carried out most frequently. It is well known that the majoriy of patients suffering lumboradicular symptoms from a disc herniation will get better spontaneously and that the herniation will, eventually, disapear in a few months without any treatment. For more than 50 years, standard and, afterwards, microdiscectomy have been used to manage lumbar disc herniation.

In a number of reports on the long-term outcome of lumbar discectomy for lumbar disc herniation, the success rates were fairly consistent (between 76% and 93%), although evaluation methods varied, and approximately 10% of the patients underwent revisions. The latest study on this problem reported an average recovery rate exceeding 70%, with the rate of recurrence of 12.5%, results comparable with the respective rates in other studies. Yorimitsu et al., found residual LBP in 74.6% of patients in their group of whom 12.7% had severe symptoms (JOA score,1 point). Moreover, in a substantial proportion of patients with gradually increasing symptoms after primary successful surgical treatment, many authors seem to agree that peridural scar formation with tension on neural tissue plays an important role. Patients with extensive peridural scars are 3.2 times more likely to experience recurrent radicular pain than those with less extensive peridural scarring.

For 50 years too, surgeons have been searching for a method which will allow to reduce or eliminate the herniated disc material without the need for performing an open surgery. So, a number of mini-invasive percutaneous techniques were developed. The common principle of these techniques was that of acting directly on the disc content without accessing the spinal channel. Two main types of percutaneous treatments were concieved: a mechanical removal (endoscopic discectomy, automatized discectomy, laser discectomy) and a chemical disruption of the nucleus polposus (chimopapain, collagen, hydrocortisone, aprotin).

The 1999 Cochrane study group found the following for different surgical treatment modalities in lumbar disc herniation:

1. There is strong evidence (Strength A) that chemonucleolysis with chymopapain produces better clinical outcomes than placebo.
2. There is considerable evidence (Strength A) of the clinical effectiveness of discectomy for carefully selected patients with sciatica caused by lumbar disc prolapse. Discectomy provides faster relief from the acute attack (Strength A), although any positive or negative effects on the lifetime natural history of disc problems are unclear (Strength C).
3. There is strong evidence (Strength A) that surgical discectomy produces better clinical outcomes than chemonucleolysis.
4. There is moderate evidence (Strength B) that clinical outcomes of microdiscectomy are comparable with those of standard discectomy.
5. There is moderate evidence (Strength B) that automated percutaneous discectomy produces poorer clinical results than standard discectomy or chemonucleolysis.
6. There is no acceptable evidence (Strength D) of laser discectomy.
7. There is limited and inconclusive evidence (Strength C) of the relative efficacy of different doses of chymopapain, chymopapain compared with collagenase, and collagenase compared with placebo.

In the 90's a new mental trend regarding disc herniation problem started to rise in the minds of spine physicians: pure mechanical compression on nerve root is not sufficient for to cause the clinical symptoms of pain. This attitude emerged from the recent findings that indicated that there is a great amount of biochemical (inflammatory and autoimmune) reactions involved in producing and sustaining the pain and dysfunction indicating indirectly the way of treatment development in which the sole mecanical removal of the disc is probably not the solution of the problem. There must be a concomitant chemical treatment of the biochemical processes that are probably at the base of the pain and dysfunction arousal.

It was demonstrated in the lab that epidural application of nucleus pulposus can induce pronounced morphological and functional changes in the nerve roots and pain-related behavior and that the application of autologous nucleus pulposus to nerve root increases endoneurial fluid pressure and decreases blood flow in the dorsal root ganglia with concomitant increase in its excitability and mechanical hypersensitivity.

From all the substances that are produced by degenerated disc, phospholipase A2 was found in great quantities. This substance can cause nerve root injury by partial demyelination that increases nerve root mechano-sensitivity making the nerve root more susceptible to mechanical pressure. The mechanical factor may then trigger hyperexcitability and the ectopic nerve impulses in primary afferent axons that cause neuropathic paresthesia and pain.

Another substance found at the site of disc disease in great amount is tumor necrosis factor a, a cytokine, that was demonstrated to induce nerve injury as well as to poteniate the production and action of Inteleukin 1, Interferon, Nitric oxide ecc. all of whom are known to have neurotoxic effects.

Other inflamatory and neurotoxic products were found too, at the site of disc degeneration, all of which probably, have some influence in the pathological process that conducts to the clinical signs and symptoms of disc herniation.

Results from various studies have shown that medical ozone is a very potent oxidant and as such it may have effect on the inflammatory as well as autoimmune processes. The experimental studies performed until today seem to indicate that the ozone, at appropritae doses, induces the development of excessive amounts of reactive oxidative substances (ROS). These, by inducing excessive production of antioxidant enzimes, have a modulating effect on production of pro-inflammatory cytokines as well as on inhibition of synthesis of prostaglandines, bradikinines and other algogenic composits.

Ozone has a dose-related biological action. At high concentrations (30-70 mg/ml 02), it may cause alterations of tissue structure; at medium

concentrations (20-30 mg/ml 02) it seems to affect the regulation of the immune system and at low concentrations (< 20 mg/ml 02) it improves the microcirculation.
Reffering to the histological work of Iliakis et al, the intradiscal application of ozone-oxygen mixture at high concentrations initialy gives rise to formation of an interstitial oedema together with eosinophilic degeneration of cytosol and nucelus pulposus cell shrinkage. On the first day the alterations are mild and became more pronounced at the end of the first week with cellular degeneration. In the second week the oedema decreases and there is disc volume decrease due to cellular degeneration. At the end of the fifth week there is a complete degeneration of the nucleus with loss of cells and replacement of the matrix by fibrous connective tissue. Similar results were reported also by Jucopilla et al in their experimental work on pigs.
The primary effects of ozone inside the intervertebral disc are supposed to be the next: reduction of the inflamation due to oxygenation of the algogenic pro-inflamatoy mediators; direct interaction of the oxygen-ozone mixture with the mucopolisaharids of the nucleus polposus with conseguent reduction in water content and disc volume; improvement of the local microcirculation with reduction of the venous stasis and better arterial blood supply with consecutive diminuition of the ischemic changes at the nerve root level.
Ozone, both in vitro and in vivo, if applied in adeguate concentrations, has no toxic effects. The primary conndition is the dose range as the ozone quantity must not exceed the enzimatic antioxidant (superoxid dismutasis and catalasis and glutatione) capacity of the organizm. These enzimes impedes the accumulation of superoxid anion and hydrogen peroxide (H2O2). There is not to be afraid of free radical formation as these form at a pH of m 8 while at a [ 7.5 the predominant mecchanism is the ozonolisis that principaly determines the production of peroxids and not of free radicals. Also, experimental tests in animals and human did show essentially lack of negative effects. Experimental studies too, indicates that the ozone application to the human body, if in adeguate doses and concentrations, have no mutagenic properties.

**MATERIAL & METHODS**

PATIENT POPULATION
Patient population included 104 patients of both sex's treated for disc herniation between July 2000 and Jannuary 2002. Age ranged between 20 and 60 years. Each patient had gone a through clinical investigation done by the treating surgeon and by a physiotherapist. All of the patients had performed a neuroradiological investigation by MRI and/or CT scaning. All of the patients had faild to respond to conservative measures of pharmacological and/or physiotherapeuthic treatment instituted for at least 1 month. All of the patients treated were detaily explaind in what the treatment consisted, on the possibilities of success as well as on risk factors and all of the patients accepted the treatment by signing the informed consensus.
Elements for inclusion in the study:
- acute pain symptomatology lasting for at least 1 month not responsive on conservative treatment modalities
- non-contained disc herniation at one or more levels situated between L2 and S1
- level of disc herniation corresponding to the level of symptoms
- confirmation of patology by MRI / CT scanning

Elements of exclusion from the study:
- severe motor palsy (Fisher < 4)
- other spinal problems (tumors, lysis, fracture, deformity, stenosis, ecc)
- prevoius spinal surgery
- history of spinal trauma
- history of mental disease
- use of narcotics or therapy for mental illness
- emotional traumas in the last 36 months

**PERCUTANEOUS TECHINQUE**
The intradiscal application of ozone-oxygen mixture was performed in operating theatre under deep sedation. The patient was prepared by the anesthesiologist with pharmacological sedation (Atropin, Diazepam, Midazolam) half an hour before the procedure and then brought to the operating room and positioned in lateral decubitus living the affected side upwards with the legs folded. The operating table was folded as to assume an upwards convecs shape. This alowded the surgeon to have an easyer access to the lower discal space even in the patients with a high iliac crest or important spondiloarthrosic deformities. The injection needle for ozone-oxygen delivery was a 22 G Chiba type Beckton-Dikins (27 cm) needle that was introduced by standard postero-lateral, extra-articular percutaneous approach. All the procedure was done under continous fluoroscopic control. Ones in place, the position was confirmed by latero-lateral and antero-posterior imaging but without contrast medium as to avoid any interference of ozone with other chemycal substances. The ozone-oxygen mixture was produced in real-time by a medical ozone generator Ozonline E 80 (Medica srl) CE certified. The gas concentration range was i40 mg 03 / ml 02 in quantity between 15 - 40 ml for a single lumbar level. The syrinx used was a Terumo type - 50 ml. Between the syrinx and the needle a bacteriological milipore filter was positioned before infiltrating the gas mixture inside the disc space. The ozone-oxygen mixture was infiltrated inside the disc space at an aproximate velocity of 10 ml / min. The gas mixture inside the disc space appeared on the fluoroscopic imaging as a positive contrastografy. Some of the gas mixture escaped from the disc space and run into the epidural space both in cranial as well as in caudal direction. During the gas infiltration the patient was deeply sedated by Propofol. The patient was dismissed the next morning. For the first two days we reccomended not to assume the sitting position but walking was incouraged.

**PATIENT EVALUTATION METHODOLOGY**
The patient's pain, function and disability were evaluated by the Visual Analogic Scale (VAS), Japanese Orthopedic Association questionary (JOA) and Overall Patient Satisfaction Scalle (OPRS).
The evaluation was done before the procedure and on 2, 6, 12 and 18 months after the procedure.
Approximately 5 months after the procedure, 89 patients performed MRI/CT controll scaning. The tendency was to perform the same kind of imaging as was done previously to surgery. The evaluation of the controll scans was done by the neuroradiologist and the surgeon. The volume reduction of the herniation was evaluated in lateral and saggital planes. The timing of 5 months was prefered as on a longer period the disc herniation may disapear spontaneously.

**RESULTS**

The results were evaluated for the pain, sensory and motor dysfunction and for disc volume reduction.
· The pain was evaluated by Visual Analogic Scale. It evaluated the pain intensity before and after the treatment.
On 18 months follow-up, there was a median improvement on the VAS scale of 3.77 points with a maximum of 7.9 and a minimum of 0.5.
· The Japanese Orthopedic Association scalle evaluated the pain levell and the sensory, motor and sphincteric dysfunction. The overall improvement on a 18 months follow-up was 54.7%. There were no patients with sphincteric dysfunction before as well as after the procedure. The motor dysfunction improved earlier than the sensitive probably because the sensory disturbance arise before the motor one and is longer-lasting.
· The Overall Patient Rating Scale evaluated the patient satisfaction with the treatment on a scale from 0 to 10, zero beeing before the procedure. The evalutaion is not purely symptomatological as it may be falsed by impression of the patient on treating physican as well as by general impression on how the case was conducted. Nonetheless, it is a valuable rating on how the patient feels and his attitude towards the disease.
On 18 months follow-up, the mean improvement was in order of 71.77% and a median one of 80% confronted with the pre-procedure state of health.
· In 89 patients the control CT/MRI scaning was proformed. The scaning was done on a mean period of 5 months after the procedure. Attention was posed on performing the same kind of imaging as preoperatively. The evaluation showed that 37% of patients had a complete reduction of their herniation (superior to 80% of the preoperative volume). In 41% of patients the volume reduction was between 40 and 80% while in 22% of the selected patients there was no visible modification of disc herniation volume. A correlation between the clinicaly improved patients and disc volume reduction group of patients was not found.
Five patients had to be operated upon by microdiscectomy for a non-positive result with discolisis. The mean time passed between the discolisis and the surgery was 6 weeks as to evaluate if there was any kind of late improvement. Waiting more than this was not suitable as the patients could have

get better even spontaneously.
Four patients were submited to a repeated intradiscal procedure with ozone 3 months after the first procedure. All of these patients were of age undre 30 and had a partial improvement (not greater than 50%) after the first procedure.

There were no complications observed although there are theorethical possibilities for complications. Eventual risks and complications may be divided in two groups: one related to the procedure (nerve root damage, infection and epidural or paravertebral hemorrhage) and one related to the ozone (systemic hypotension, bradicardy, vagal shock, meningeal irritation).
Special attention should be payed on patients reffering hyperthiroidism, arterial hypertension, kahectic patients, patients that reffere states of general hypersensitivity as well as patients affected by phavysm.

**DISCUSSION**

It seems quite reasonable to suppose that clinical signs and symptoms of disc herniation are not caused primarly by the mechanical compression but that the biochemical factors play an important role in inflammatory sensitation and imune response in the peridural environment of the nerve root. For these reasons it is to presume that a mechanical removal of the herniated tissue by open or percutaneous surgical procedures may not be needed and that the biochemical treatment could be sufficient to treat these patients.
It has not to be forgoten that a disc herniation is neither a tumor nor a vascular lesion that, if not removed or occluded, may endanger the life of the patient. Studies have shown that there are no great differences, on a long-term follow-up (>5 years), between the patients treated surgicaly and those that had a conservative or no treatment.
The confirmation that the disc volume is not the most important but just one of the factors that infulence the arousal of symptoms comes from our observation of the results seen on control CT/MRI scans. Although only 37% of patients had a herniation volume reduction superior to 80% and 22% had their disc herniation immodified, the pain, motor and sensitive disturbances have improved in all of these patients in order of at least 60%.
The author is convinced that the disc herniation pathology has to be treated just in those patients that present with clinical signs and symptoms of the disease and that the treatment has to be proportionate to the severity of clinical signs and symptoms. In the patients in whom a disc herniation is found accidentaly and there are no signs or symptoms of nerve root damage, the treatment has to be that of a “wait and treat when and if the symptoms should arous”. It means that the disc disease is not a real pathological condition but primarly a degenerative and aging condition in which the absence of symptoms implicates a no-treatment attitude.
In this context, the intradiscal application of ozone-oxygen mixture has an important impact on the treatment of disc disease as it treats both the symptoms as well as the cause. It is a very simple and low-cost method both in terms of procedure costs as well as in terms of returning to working activities (5-7 days of home stay). It demonstrated to have a high improvement rate on clinical symptoms and an elevated impact on the cause of the problem. All of these in an almost total absence of risks and complications both on short and long-term follow-up
The intradiscal ozone treatment for disc herniation is not ment as a method that intends to eliminate any of to-date gold-standard treatments (pharmacological, physiatric and surgical treatments). As for the chemonucleolysis with chymopapain, evidence supports ozone methodics as a possible, minimally invasive, option to be planned as an intermediate stage of treatment situated in between conservative management on one side and the open surgical intervention on the other. That means it is applicable to the patients that have overpassed the conservative treatment modalities but have not yet indications for surgical treatment. This particularly as it has been shown that if the clinical indications are uncertain, postponing surgery for further assessment of clinical progress may delay recovery but will not produce long-term harm.
It is author’s oppinion that the intradiscal application of ozone should be included into the treatment modalities for disc herniation as an intermediate modality before passing to open surgery.

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