

Spinal Ozone Therapy in Lumbar Spinal Stenosis

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SUMMARY - Lumbar spinal stenosis (LSS) is the first indication of lumbar surgery in the population over 65 years in the USA, according to the North American Spine Society. Degenerative aetiology is the most common, and as the elderly population grows, this pathology will increase in prevalence. The natural history of LSS shows that there is no need for surgery unless symptoms clearly progress or the clinical situation is unbearable. A high rate of complications with traditional surgery has encouraged the development of minimal invasive surgery and percutaneous techniques like ozone-therapy, for improving quality of life in these patients. *In vitro* studies have demonstrated the phospholipase A2 blocking action of ozone, which is the same enzyme steroids block to produce their antiinflammatory effect. The success of epidural and intraforaminal steroids injections in decreasing surgery rates and the published reports comparing these techniques versus ozone injections encouraged me to use perforaminal ozone injections to treat these patients. Based on the SICOT 953902 protocol widely used in Italy to treat lumbar spondylosis and the works on steroids injections in LSS, an experimental protocol was devised and used in a previous study to determine the indications and the optimal number of sessions in a group of 20 patients. Seventy-two patients have completed the protocol since September 2002 with no drop outs; 59 patients have a one year follow-up. One patient died five months after ending the protocol. No mayor side effects were observed; four patients returned to their baseline during the first year of follow-up. Evaluation was done using the Zurich Claudication Questionnaire (ZCQ) and Visual Analogue Scale (VAS) for low back pain and leg pain. These scales were fulfilled by the patients before the treatment and in the follow-up controls at one, three, six and 12 months. Forty-three patients were considered excellent and good results, reaching a ZCQ improvement over 60% or 40%. This is a 74% success rate out in the 58 patients evaluated at one year. Natural history positive evolution rate of LSS has been settled at around 15%, so the protocol seems to be useful for treating LSS patients. A randomized controlled study directly comparing treated and non-treated patients would be necessary to confirm these results.

Introduction

Lumbar spinal stenosis (LSS) refers to the narrowing of the neural canal containing the lumbar roots intradurally (central canal) and extradurally (lateral canal) (figures 1-2).

Although there have been references to this pathology since 1803¹, the modern concept was settled by Henk Verbiest in 1949².

Epidemiology

According to the North American Spinal Society (NASS)³, around 20% of the adult population suffers from this pathology (5% central stenosis and 15% lateral stenosis). In patients over 60 years old, it is well tolerated, being asymptomatic in more than 20% of patients with radiological LSS. On the other hand, 98% of patients under 60 years are

symptomatic. Nowadays, LSS has become the first indication for lumbar surgery in patients over 65 years in the USA.

Anatomy

The central canal has a variable anterior-posterior diameter⁴ that ranges from 15 mm in L1-2 to 12 mm in L5-S1. This gives us an area ranging from 85 to 100 mm². The lateral canal is present "as it is"⁵ in 72% of the L3-4 level and in 100% of L4-5 and L5-S1 levels⁶. Its dimensions range from 50 to 150 mm² and depend on the lumbar flexion to extension position.

Classification

According to the items affected, lumbar stenosis can be classified as⁷:

1) Central:

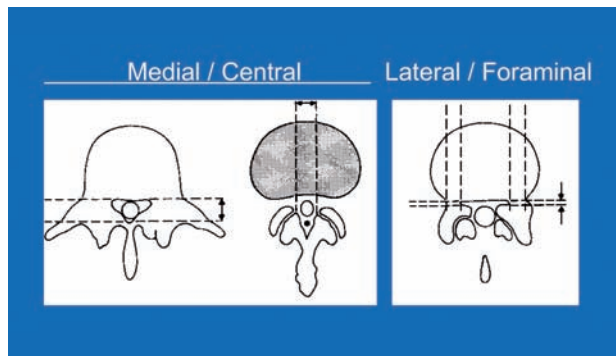


Figure 1

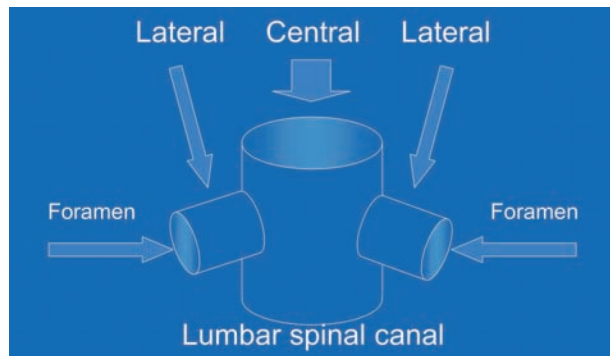


Figure 2

- a) Absolute: when the central canal diameter is below 10 mm or the area is below 65 mm².
 b) Relative: when the central canal AP diameter is between 10 and 12 mm (area between 65 to 85 mm²) and one of the following factors is present:
- Disc protrusion.
 - Body posterior osteophytes.
 - Flavum ligament hypertrophy.
- c) Combined: relative stenosis with the presence of more than one concomitant factor.
- 2) Lateral: narrowing greater than 50% of the area.
 3) Mixed: central + lateral.

Depending on the aetiology, LSS can be classified as 8:

- 1) Primary:
 a) Idiopathic: short pedicles, spondylolysis with spondylolysis.
 b) Achondroplasy.
 2) Secondary:
 a) Degenerative.
 b) Iatrogenic: post-surgery.
 c) Post-traumatic: body fracture, pedicle/isthmus fracture.
 d) Others: Paget disease, skeletal fluorosis, etc.

Clinical symptoms

- LSS give rise to three main symptoms:
- Neurological intermittent claudication.
 - Radicular pain and/or discomfort.
 - Low back pain.

The three symptoms are related to the patient's position. Seated position and slight lumbar flexion produces relief of pain due to an enlargement of the size of both canals. On the other hand, the upright position and lumbar extension reduce the size of the canals, worsening the symptoms. The lumbar pain is related to the anatomical damage of what Kirkaldy-Willis named the "three joint complex"⁹.

Two different factors have been proposed to explain the neurological alterations^{10,11}: a mechanical factor and a vascular factor. The mechanical factor is obviously deduced from the observation of the symptoms that clearly change in relation to the patient's position. The chronic compression of root and ganglion produces oedema and fibrosis in these structures, with hyperexcitability and ectopic firing. The anatomopathological findings also show vascular stasis and hypoxic changes, related indirectly to the mechanical factors, increasing the malfunctioning of the neural structures.

Diagnosis

Medical history and physical examination disclose the three typical symptoms, which are not present in all cases. We confirm the diagnosis with imaging (X-ray, CT, MRI) and neurophysiologic assessment.

Natural history

Before treatment, we must know the natural evolution of LSS to properly decide the best management for our patients. I emphasize two papers: the first one by Johnson¹² who followed 32 patients with LSS during 49 months; 70% remained without clinical changes, 15% worsened needing surgery and 15% improved the baseline; the second paper by Atlas et Al¹³, known as the Maine Lumbar Spine Study, followed 42 patients with conservative treatment for ten years; 36% of patients needed surgery, 40% of them being satisfied after the surgery; the remaining patients (64%) did not need surgery and 54% of them were satisfied.

Treatment

From these papers and other similar reports, there is strong evidence that treatment should be conservative unless there is severe pain, an unbear-

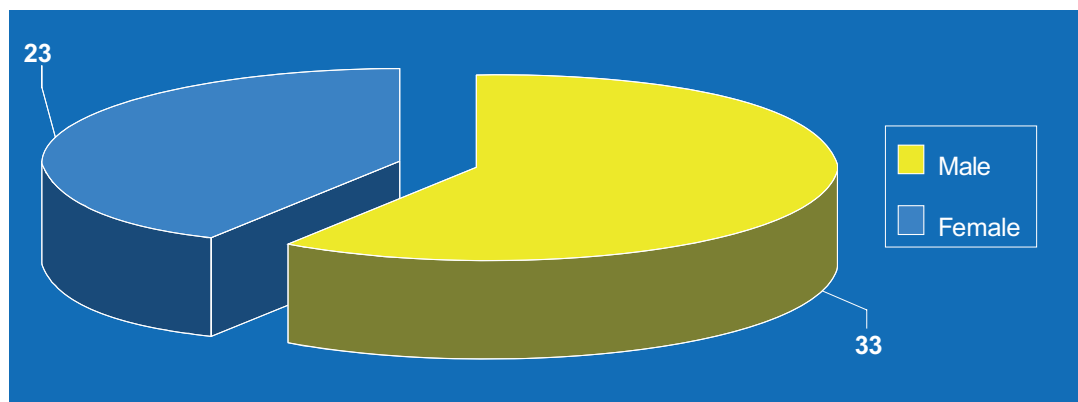


Figure 3

able clinical situation or progression of the neurological deficit.

Although it is the first option for the majority of patients, conservative treatment has not been standardized^{14,15}. It is based on:

- Analgesic drugs.
- NSAID.
- Gabapentin and pregabalin (under testing).
- Steroids: oral, epidural, intraforaminal.
- Physical therapy.
- Lumbar support.

Surgical treatment comprises two groups of techniques:

- Neural decompression:
 - Bone removal:
 - Laminectomy (total, partial).
 - Facetectomy.
 - Recalibrating.
 - Spur removal.
 - Interspinous devices.
- Spine fixation:
 - Non-instrumented.
 - Instrumented:
 - Posterior.
 - Anterior: PLIF, TLIF, ALIF.

The first group of techniques is devoted to improving the neurological symptoms. The second group is for low back pain and instability if present. Surgical treatment is not standardized either¹⁶ and has to be indicated individually¹⁷ as each case is different. On the other hand, patients are usually elderly, with concomitant pathology, high surgical risk and multilevel disease. Moreover, there is a high rate of iatrogenics^{18,19} (instability, fibrosis, dural tears, root damage, fusion failure, implant malposition, infection, ...) and NASS²⁰ refers up to 23% of re-operations during the first year.

Rational use of ozone therapy

There are several reasons to justify the use of ozone in LSS:

- According the natural history of LSS, the majority of patients do not substantially worsen over time, so surgical treatment can wait in most cases.
- Epidural steroid injections reduce pain and surgical rates in LSS^{21,22,23,24,25,26,27,28}; as ozone blocks phospholipase A2 like steroids do²⁹, it makes sense to substitute steroid with a much safer drug with the same mechanism of action.
 - Ozone also improves the microcirculation³⁰ which is a factor of neurological pain in LSS.
- Intraarticular ozone injections ameliorate pain and inflammation in knee osteoarthritis^{31,32,33}, so it should also work in facet joint osteoarthritis.
- Intraforaminal ozone injections ameliorate radicular pain in lumbar disc herniation better than steroids (and the effect is long-lasting!)³⁴.

Patients

From this empirical approach, in September 2002 we started to treat patients with mild and moderate LSS, first to establish the optimal dosage, and then to settle the clinical outcomes in an open prospective non-controlled study.

Clinical criteria

Inclusion criteria in our series have always been:

- Age > 50 years.
 - Neurological intermittent claudication +/- low back pain.
 - Conservative treatment for > 3 months.
- Exclusion criteria are:
- Previous surgery.
 - Vascular claudication.
 - Peripheral neuropathy (diabetes, f.i.).
 - Urgent surgical indications:
 - Fixed/progressive motor deficit.
 - Cauda equina syndrome.
 - Ozone-therapy contraindication.

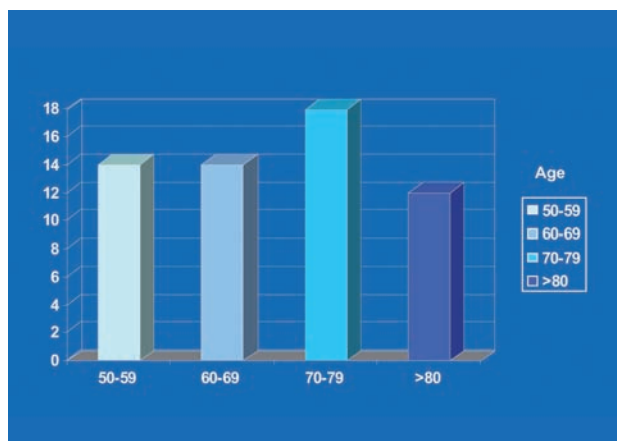


Figure 4

Levels	Patients
L4-L5	4
L3-L5	10
L4-S1	14
L3-S1	26
L2-S1	4

Figure 5

Imaging criteria

Indications are:

- Relative central stenosis (no pedicle shortening):
 - Degenerative disc protrusion/spondylosis.
 - Flavum ligament hypertrophy.
 - Small osteophytes.
 - Lateral stenosis:
 - Any aetiology but synovial cyst.
 - Mixed stenosis (central+lateral):
 - "Three joint" degeneration.
- Contraindications are:
- Absolute central stenosis.
 - No recent fracture related to stenosis.
 - No spondylolisthesis greater than grade I.
 - No scoliosis greater than 15°.

Basic statistics

From September 2002 to June 2006 I have treated 72 patients with mild and moderate LSS according to the Zurich Claudication Questionnaire. From them all, one died of natural causes five months after ending the treatment; 13 have a follow-up of less than one year. I have included in this paper the remainder of the group (58 patients).

Gender, age and level distribution are shown in figures 3, 4 and 5.

Method

Ozone treatment

I used the SIOOT (Italian Society of Oxygen-Ozone Therapy) protocol 953902 with small modifications; this protocol is widely used in Italy and

Spain to treat low back pain and mild lumbar disc herniation:

- ten twice weekly sessions + five weekly sessions.
- two perforaminal injections (right and left) per level.
- 2 cc from spinous process – No fluoroscopy.
- Local anesthesia.
- 10 cc-20 microgr/ml each injection.

In a preliminary study³⁵ we tested the best dosage between ten and 20 sessions, finding 15 to be the most successful in a homogeneous group of LSS patients.

Only ten patients had 12 sessions because of an asymptomatic clinical situation. I decided not to exclude them from the study, but to see if this group had a different outcome, which it did not.

The original protocol uses intramuscular injections with a 40 mm length needle. I use a spinal 85 mm long needle to reach the foramen by putting the tip of the needle on the most lateral side of the vertebral lamina. You should be careful in this manoeuvre, because you can touch the root with the tip of the needle if you go too laterally; although there is no risk in this, your patient will feel an electric shock.

Figures 6 and 7 show the different distribution of gas depending on the position of the needle.

The ozone generators used were Multiossigen 99 IR and Iral with CE compliance number. All the disposable material was ozone resistant. The syringes used were BD 60 cc and the needles were Spinocan 25G×3½”.

Follow-up controls

Patients were followed after the treatment for one, three and six months; then one year (58

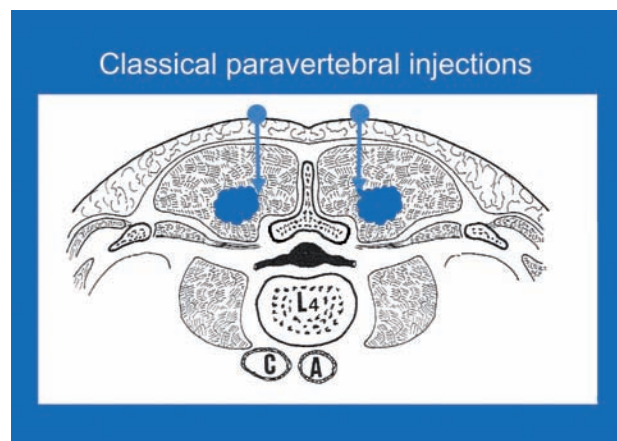


Figure 6

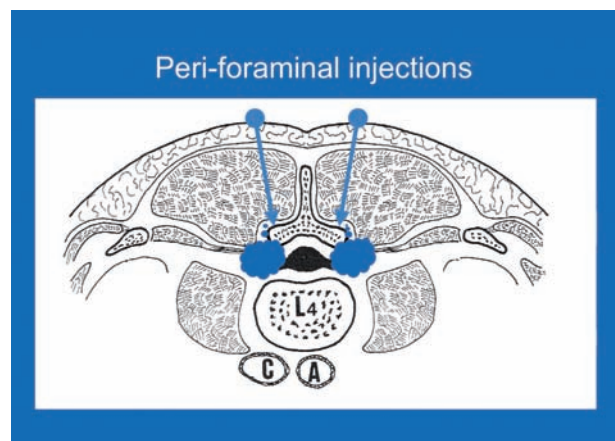


Figure 7

patients), two years (28 patients) and three years (6 patients). This paper makes a short reference to the two-year group, without statistical significance, and no reference to the three-year group.

Evaluation scales

The evaluation of the patients was done previously and in each follow-up control, with three scales:

- Zurich Claudication Questionaire.
- Leg pain VAS.
- Low back pain VAS.

These scales were used since in the time I started the study, the USA FDA department advised them for medical surgical devices in LSS patients as it was the only validated method^{36,37}. Thus, I should be able to compare clinical outcomes with other papers.

Zurich Claudication Questionaire (ZCQ) is a scale divided into four domains:

- Symptom severity:
 - seven questions (1 to 5 points).
- Physical function:
 - five questions (1 to 4 points).
- Satisfaction:
 - six questions (1 to 4 points).

A score of one point means the situation is Excellent (18 points) and four to five points means Very Poor (79 points).

Data between domains should not be added. To show data properly, the punctuation in each domain was divided between the number of questions to be able to compare between them and test the correlation. Due to the fact that the "Symptom severity" domain ranges up to five points, and the other domains range up to four points, the first

original data were corrected to a four point scale, only for graphic representation. VAS ranges from 0 (no pain) to 10 (most un-bearable pain). All data were collected on a form with the patient's ID, date of control and control number. The score was written down by the patient in the waiting room just before the control. Afterwards these data were inserted into a Microsoft Excel-2003 sheet for simple calculations. Statistical analysis was performed over the data with Statgraphics Plus Version 4 standard edition. All software runs on a laptop with Microsoft Windows XP professional SP2.

Results

According to ZCQ, 43 patients were considered excellent and good results, reaching a ZCQ improvement over 60% or 40% respectively. This rate is 74% of success out of the 58 patients evaluated at one year. Baseline ZCQ was 8.78 out of 13, with "Symptoms severity" score of 3.38 (corrected to 2.71 in graphics), "Physical function" score of 2.82 and "Satisfaction" score of 2.58. One month after treatment, the improvement was around 33%. Three months later, the improvement was around 56%, reaching up to 60% at one year follow-up control (figures 8 and 9). If we see the ZCQ results at one year, 34 patients (59%) improved over the baseline more than 60%; nine patients (15%) improved between 40% and 60%; three (5%) improved between 21% and 40% and 12 (21%) improved 20% or less. We considered recurrence those patients (46) with improvement over 20% who worsened significantly and permanently during the follow-up. Four patients (8.7%) fulfilled

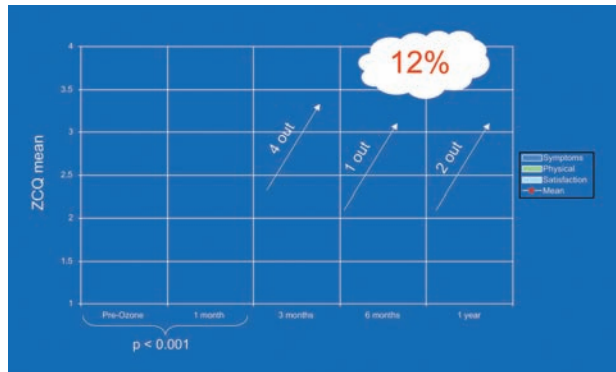


Figure 8

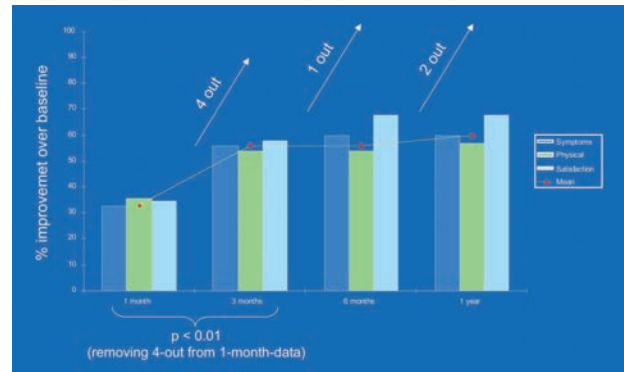


Figure 9

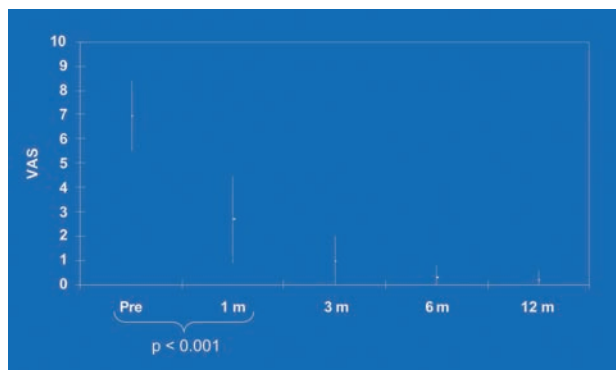


Figure 10

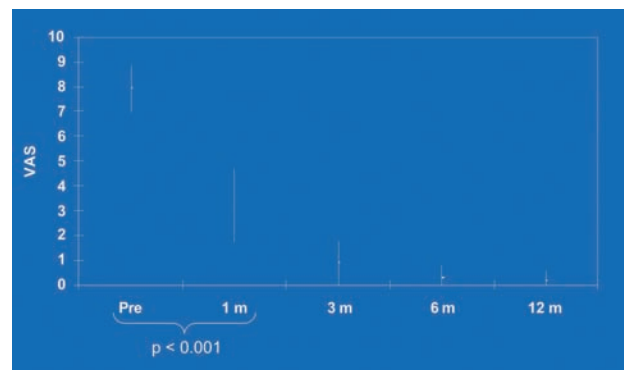


Figure 11

these criteria. One went for surgery; three repeated the treatment. These three patients were not re-included in this study. We considered failure the fair and poor results, with improvement equal to or less than 40%. Twelve patients fulfilled these criteria; three (25%) returned to the baseline situation and went for surgery. VAS improvement reflects the results shown in ZCQ graphics. Low back pain dropped from 6.93 to 0.18 and leg pain from 7.97 to 0.17 (figures 10 and 11). No major complications were observed. No patient abandoned the treatment. There is only one missing case due to death for natural reasons. The 12-session patients group (10 patients) showed no statistically significant difference from the 15-session group (48 patients) regarding ZCQ or VAS results.

Discussion

It is very difficult to compare this cohort with other published series. Most of the surgical papers are retrospective and heterogeneous in techniques

and the good results range from 45% to 86%³⁸. The scales used also differ so direct matching is not possible^{39,40}. Katz et Al^{41,42,43} refer to clinical outcome of hemilaminectomy in LSS using ZCQ and VAS as evaluation scales. Zucherman et Al⁴⁴ compared X-Stop interspinous device vs epidural blocks in a group of 200 patients randomized between the two techniques. Seventy-three per cent had significant improvement at six months; results tended to worsen over time⁴⁵, and two-year follow-up showed 63% of significant improvement. Evaluation scales were ZCQ and VAS. Inclusion and exclusion criteria are nearly the same as those in this study, so the results can be compared. The complications rate is the most important goal of ozone therapy compared with any paper on non-conservative treatment. Surgical reoperations range from 10-23%. The length of the treatment is around two months. No patient abandoned the treatment in our series, but it would be useful to shorten the treatment without worsening the results. A higher ozone concentration may help, but the higher the ozone concentration used,

the greater the pain during the injection. A recent paper by Bonetti et Al⁴⁶ showed an improvement in LSS with intraforaminal injection. Direct comparison between these two techniques may help to establish an optimal treatment.

Conclusion

Seventy-four per cent of patients improved significantly (excellent and good results) from the baseline after one year. Peak improvement was achieved in the first six months after treat-

ment. The rate of recurrence was 8.7 at one year, over 79% of patients with excellent, good and fair results. My major concern is long-term recurrence to be able to establish a long-term prognosis in case of initial success. We know from the literature that there is a positive evolution of LSS in around 15% of patients, so this technique may be useful for treating patients with mild and moderate LSS according to ZCQ. A randomized controlled study directly comparing treated and non-treated patients, or ozone therapy versus other strong validated treatments, would be necessary to confirm these results.

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