

# Oxygen-Ozone Therapy for Degenerative Spine Disease in the Elderly

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**SUMMARY** - We describe our experience of oxygen-ozone therapy to treat degenerative spine disease in the elderly. From April 2002 to January 2005 we selected 129 patients with CT and/or MR evidence of spondyloarthrosis and disc degeneration of the lumbar spine. All patients enrolled in the study had contraindications to the administration of commonly used analgaesic and anti-inflammatory drugs. Oxygen-ozone therapy was given by CT-guided intraforaminal injection as the first treatment followed by four weekly paralumbar infiltrations on an outpatient basis. The full treatment lasted a month. Clinical outcome was assessed three months and one year after treatment. The good results obtained indicate that oxygen-ozone therapy is an ideal treatment with no side-effects in elderly patients with degenerative spine disease.

## Introduction

Gains in the average life span have been flanked by an exponential increase in degenerative spine disease in the elderly. In particular, spine disease other than disc degeneration (osteophytosis, pseudo-spondylolisthesis, canal stenosis, facet joint syndrome) is increasingly responsible for disability in people who already have other age-related conditions (e.g. endarteritis obliterans of the lower limbs, diabetes, cerebrovascular failure, etc.)<sup>1,2</sup>.

Concomitant disease is often a factor limiting the administration of analgaesic and anti-inflammatory drugs to relieve the pain caused by degenerative spine disease and hence improve patients' quality of life.

We studied 129 patients aged between 65 and 92 years to assess the therapeutic efficacy of intraforaminal infiltration of an oxygen-ozone gas mixture ( $O_2-O_3$ ) completed by outpatient paravertebral infiltrations in patients with contraindications to commonly used analgaesic and anti-inflammatory drugs. Clinical outcome was evaluated three months and one year after the end of treatment.

## Materials and Methods

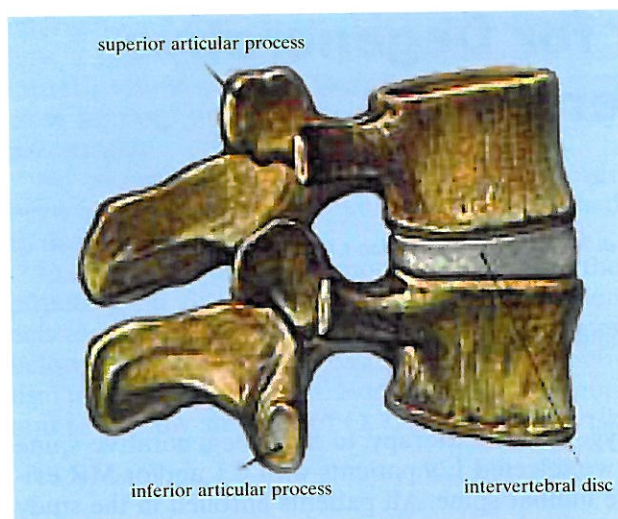
After reading and signing an informed consent form, 129 patients (57 men and 72 women aged between 65 and 93 years, average age 76 years) with chronic low back pain underwent CT-guided

infiltration of an  $O_2-O_3$  gas mixture. Patients were treated between April 2002 and January 2005.

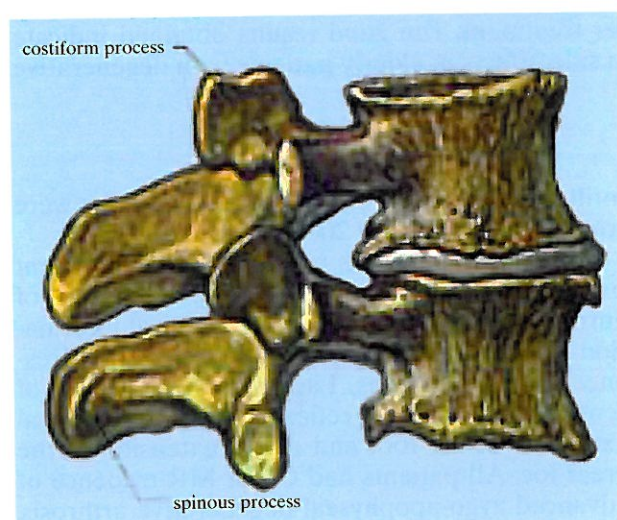
A clinical record was prepared for each patient on enrolment noting age, date of birth, date of enrolment, date of treatment and clinical information on the type of pain, pain irradiation, presence of paraesthesias, Lasègue's sign, degree of sensitivity, lower limb reflexes, plantar and dorsal extension of the foot and dorsal extension of the great toe. All patients had CT or MR evidence of advanced zygo-apophyseal degenerative arthrosis, multiple levels of lumbar disc disease, segmental canal stenosis, pseudo-spondylolisthesis and severe scoliosis. The patients enrolled in the study had chronic unilateral or bilateral low back pain irradiating along the regions innervating the lumbosacral plexus.

Patients with electromyographic evidence of neurogenic injury (diabetic neuropathy) and those with concomitant endarteritis obliterans of the lower limbs with grade II and IV intermittent claudication were excluded from the study.

Before treatment the skin area was disinfected and local anaesthesia administered by ethyl chloride spray in all patients. Infiltrations were performed by specialist neuroradiologists at the Neuroradiology Service at Istituto Clinico Città di Brescia. A CT scan was done to identify the point of infiltration and marked on the skin then the distance from this point to the spinal root canal was measured. A 22 G Terumo needle was positioned 2-3 mm from the foraminal region close to



A



B

Figure 1 Schematic drawing of degenerative disc disease. A) Normal. B) Degenerative arthrosis. In lumbar degenerative arthrosis the vertebrae are deformed: the intervertebral discs are flattened and jut out from the bone surface leading to inflammation which triggers marginal bony proliferation resulting in the patient's pain.

the ganglion of the nerve root to be treated. We usually used a 9 cm needle but a longer needle was used in some cases depending on the patient's size. Another CT scan was then performed to check accurate needle placement.

The  $O_2-O_3$  mixture was injected into the joints in patients with facet joint syndrome or immediately around the joint capsule when it was not possible to reach the intervertebral space (osteophytosis, asymmetric facet joints and particular shape of the joint aperture). Up to three periganglionic infiltra-

tions were made in patients with multiple levels of disease. Infiltration involved injection of 3 cc of the  $O_2-O_3$  gas mixture at 25  $\mu\text{g}/\text{ml}$  then the needle was retracted a few millimetres injecting another 5 cc of the mixture to involve the region surrounding the facet joint.

CT scans were done in all patients to check the correct distribution of the gas mixture in the root canal and facet joint. All treatments were performed using equipment fitted with a photometric detector monitoring the concentration of ozone in the gas mixture.

The treatment cycle was completed with four paravertebral infiltrations given weekly on an out-patient basis.

These infiltrations were done by injecting 10 cc of the  $O_2-O_3$  gas mixture at 25  $\mu\text{g}/\text{ml}$  into each infiltration point using 23 G Terumo needles and a medical ozone device (Alnitac Futura 2) fitted with a photometric detector monitoring the concentration of ozone in the gas mixture. The infiltration point was kept constant at 2 cm from the spinous apophysis of the diseased space. Multiple level treatments were usually performed.

All patients had follow-up checks at three months and one year after treatment. We used a modified version of McNab's method to define clinical outcome as follows:

- a. excellent: resolution of pain and a return to normal daily activities performed before the onset of pain.
- b. good or satisfactory: more than 50% reduction of pain.
- c. mediocre or poor: partial reduction of pain less than 70%.

## Results

At three months follow-up 74 (57.3%) patients referred a marked improvement in clinical symptoms with almost complete disappearance of low back pain, whereas 32 (24.8%) were satisfied with the treatment but had only a partial reduction of pain. The treatment produced little or no benefit in 23 (17.9%) of patients.

One year follow-up was done in 127 patients as two had died from natural causes in the meantime. Of these, 43 (33.9%) had maintained an excellent quality of life with an almost complete disappearance of low back pain.

The number of patients with good or satisfactory benefit after treatment had increased to 34 (26.7%): pain had returned but was decidedly less severe than before treatment.

Treatment was deemed mediocre or poor in 50 (39.4%) patients.



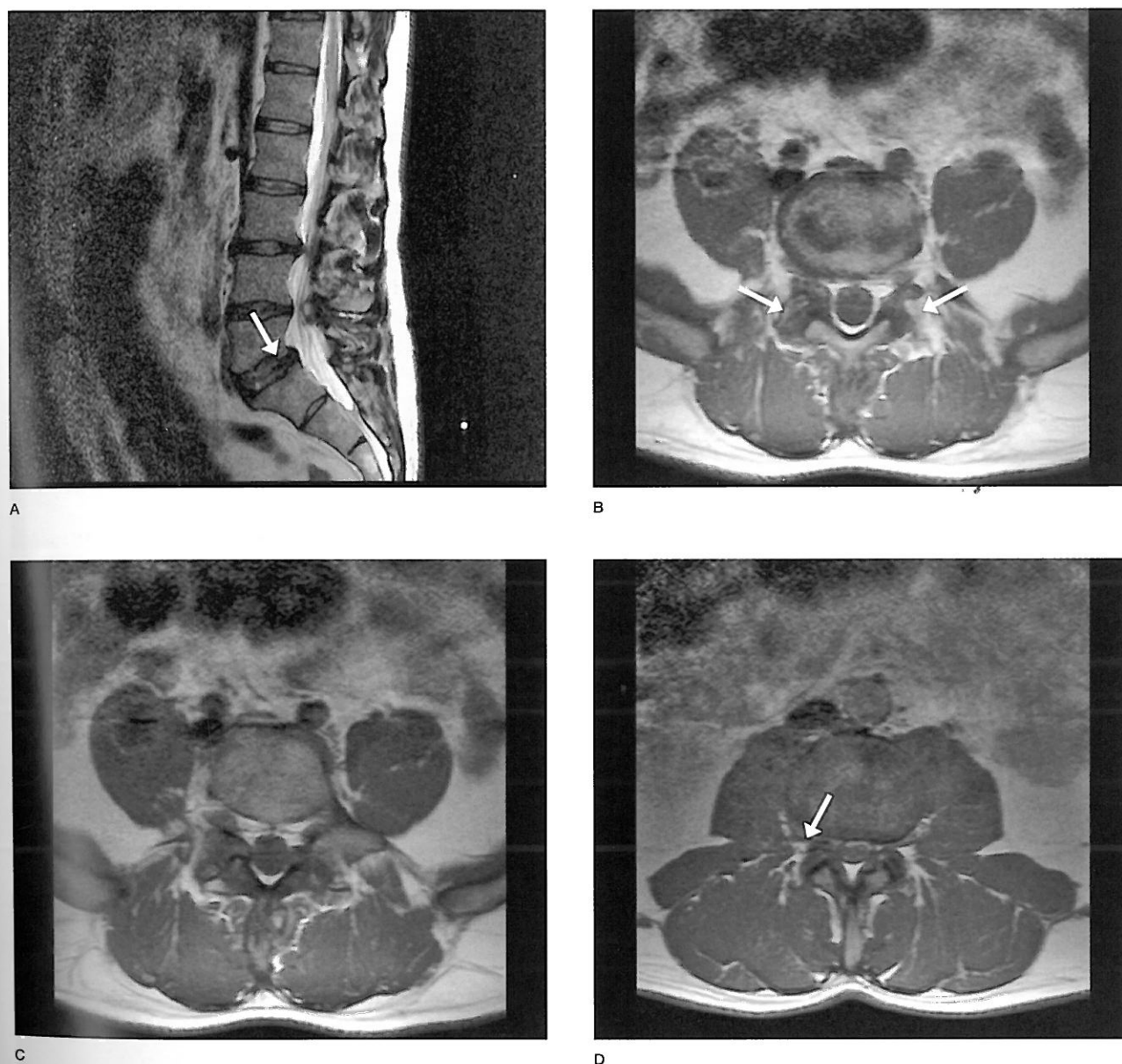


Figure 2 A 66-year-old man with chronic low back pain complicated by right sciatic nerve pain. MR scan (A-C) depicts spondylolisthesis of L5 over S1 (arrows) associated with degenerative arthrosis of the facet joints. Circumferential protrusion of the L3-L4 disc is also present mainly in the right intra-extraforaminal region (arrow) (D). The patient underwent  $O_2-O_3$  treatment with CT-guided intraforaminal infiltration into both L3-L4 (right monolateral) and L5-S1 (bilateral) followed by 4 outpatient treatments with paravertebral intramuscular injections into the two levels. At 1 year follow-up the patient referred an excellent resolution of clinical symptoms (assessed by our modified McNab method).

## Discussion

At one year follow-up after  $O_2-O_3$  treatment 33.9% (43/127) of our patients reported a clear-cut improvement in quality of life following a resolution of pain and a return to normal daily activities previously abandoned.

Ten patients no longer required walking aids (crutches and corsets). After a partial resolution

of pain, 34 out of the 127 patients treated (26.7%) experienced a recurrence of symptoms but pain was judged to be much milder than before  $O_2-O_3$  treatment and almost all patients requested another cycle of treatment. Of the 50 patients with a poor outcome at one year follow-up (39.4%) only one patient with multiple levels of segmental canal stenosis opted for surgical decompression.

The good treatment outcome obtained at three

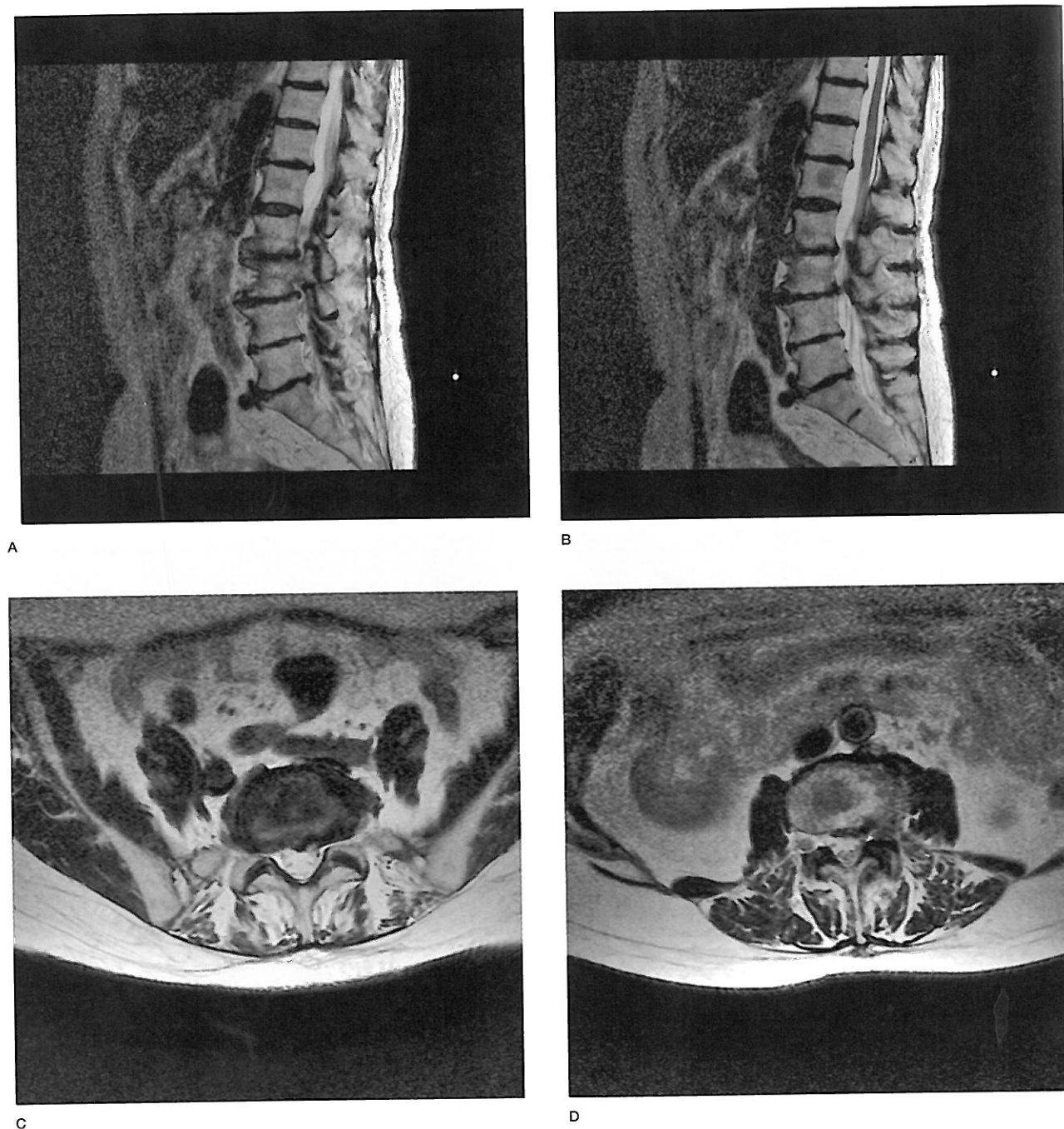


Figure 3 A-D A 74-year-old woman with chronic low back pain. MR scan (A-B) depicts advanced lumbar spondyloarthrosis with multiple levels of disc degeneration: the discs are thinned and present a hypointense signal in T2, mainly in L5-S1 (C) and L3-L4 with associated disc protrusion showing a left intraforaminal focus (D). She was treated by a three-level approach first with intraforaminal  $O_2-O_3$  infiltration (L2-L3, L3-L4 and L5-S1) followed by 4 paravertebral intramuscular injections. Clinical outcome was deemed excellent at 1 year follow-up.

Figure 4 A 74-year-old woman with low back pain complicated by a 1 month history of severe left sciatic nerve pain irradiating along the region innervating the left L4, treated with  $O_2-O_3$  administration with a poor clinical outcome. A-C) Sagittal MR scans show 1st degree listhesis of L4 over L5 according to Meyerding (arrows) and a large extruded L3-L4 disc (arrowheads). D) The L5-S1 disc also shows severe zygo-apophyseal degeneration (arrows). E) The axial scan at the L4-L5 passage documents the reduced canal diameter caused by the listhesis. F) Large extruded left L3-L4 herniation (arrow).





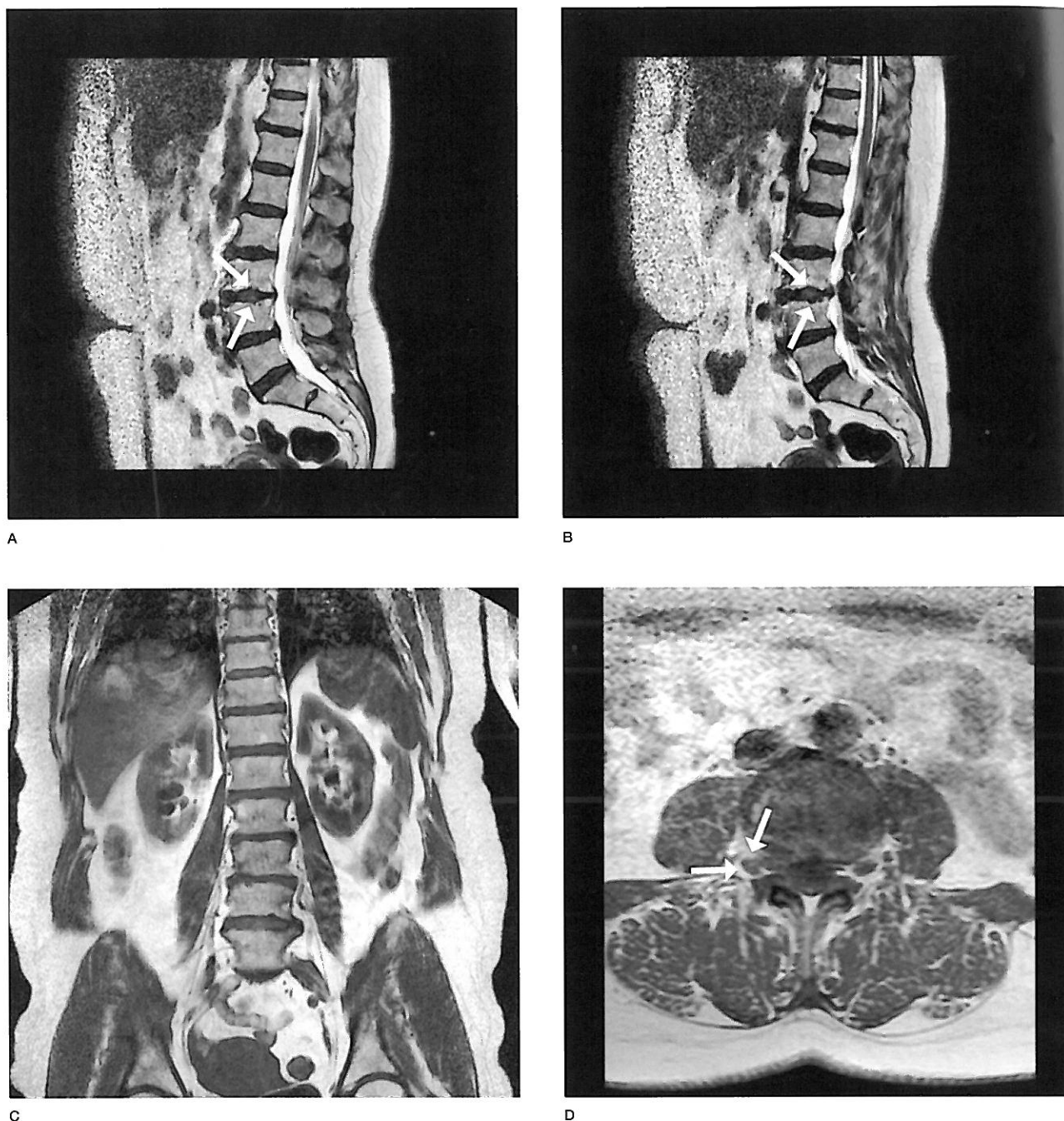


Figure 5 A 67-year-old man with low back pain lasting several months sometimes complicated by right sciatic nerve pain, treated by  $O_2-O_3$  administration with an excellent clinical outcome. A,B) Sagittal MR scan shows L3-L4 disc degeneration with associated osteochondrosis of the opposite end plates (arrows). C) Coronal MR scan shows an initial scoliosis secondary to the degenerative spondyloarthrosis. D) The L3-L4 disc protrusion is focused in the right preforaminal region (arrows).

months follow-up is due to the capacity of  $O_2-O_3$  injection into the ganglionic region to normalize the level of cytokines and prostaglandins, increase superoxide dismutase (SOD) and minimize reactive oxygen species (ROS) thereby

enhancing local periganglionic circulation with a eutrophic effect on the nerve root<sup>3,8</sup>. This effect, however, appears to subside in the long-term especially when the morphostructural changes to the spine result in continuous pain stimulation. The

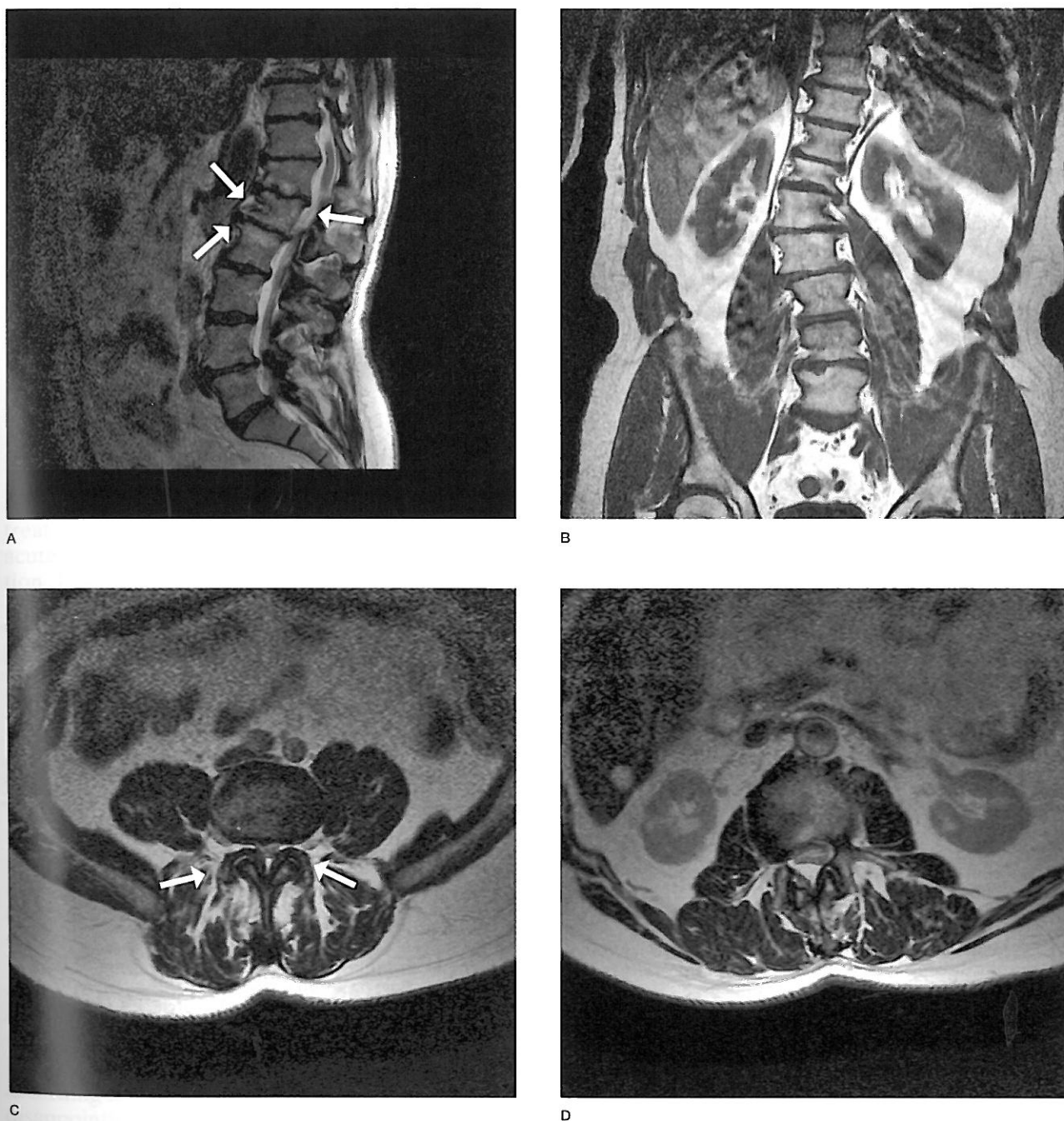


Figure 6 A 71-year-old man with chronic low back pain treated by  $O_2-O_3$  administration with a good clinical outcome. A) Sagittal MR scan shows severe degenerative arthrosis at the dorsolumbar and lumbosacral passage (arrows). B) Coronal MR scan shows dorso-lumbar scoliosis secondary to the degenerative spondyloarthrosis. C) The L4-L5 disc shows severe degeneration as do the facet joints (arrows). D) Scoliotic L1 vertebral body tending to rotate anti-clockwise.

patients most refractory to treatment proved to be those with canal stenosis resulting in mechanical nerve root compression by bony structures which prevented long-lasting pain relief due to the continuous recurrence of the nociceptive stimulus

caused by mechanical stress. Of the 34 patients with satisfactory outcome 29 requested a second cycle of treatment and of the 50 patients who failed to benefit from treatment 22 opted for a new cycle of  $O_2-O_3$  infiltrations.

O<sub>2</sub>-O<sub>3</sub> administration proved an effective treatment for root pain caused by spondylolysis thanks to its well-known pain relieving properties<sup>8,14</sup>.

The treatment is a valid alternative to many drugs like corticosteroids which have non negligible adverse effects (e.g. sensory impairment, bowel/bladder dysfunction) especially problematic in the elderly<sup>15,17</sup>.

By contrast, biochemical studies have demonstrated the lack of side-effects linked to short and long-term O<sub>2</sub>-O<sub>3</sub> administration.

## Conclusions

Conservative O<sub>2</sub>-O<sub>3</sub> treatment is effective in relieving chronic low back pain and can offer significantly long improvements in quality of life in patients like the elderly with contraindications to drug management or concomitant age-related diseases. The lack of side-effects means that O<sub>2</sub>-O<sub>3</sub> treatment can be repeated at six month to one year intervals to guarantee pain-free cover and avoid recourse to surgery.

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