Artículos Originales

IntraSPINE, an interlaminar, not interspinous, posterior motion preservation device in Lumbar DDD: indications and clinical results (over 2 year follow-up)

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ABSTRACT

All interspinous systems presently available significantly reduce, albeit in different degrees, flexion-extension and, in minor measures, bending and axial rotation. Thus we examine the efficacy of an inter*laminar* (IntraSPINE®) device in motion preservation in the treatment of lumbar DDD. 6 Italian centres enrolled a total of 120 consenting candidates over a period of 4 months. Patients were considered eligible for surgery based on the presence of ***degenerated disc*** with facet syndrome (group A), large extruded disc herniations (group B) or ***stenosis due to soft tissue*** "soft stenosis" (Group C); all pathologies were confirmed by radiographic analysis, and affected 1 or maximum 2 levels. All patients underwent 6 months conservative treatment prior to surgery. ***Only patients that had completed 2 year follow-up are included in these results. At present 84 patients have completed a 2 year follow-up.*** Group A: 31 patients. The mean VAS score improved from 8,1 to 1,3*, and the ODI from 33,8 to 12,8*. 2 patients required second surgery at 6 and 10 months; 1 patient with poor results refused further surgical treatment. Group B: 38 patients. The mean VAS score improved from 8,4 to 0,5*, and the ODI improved from 40,1 to 11,6*. No patient required further surgical treatment. No recurrences appeared. Group C: 15 patients. The mean VAS score improved from 8,0 to 1,1*, and the ODI improved from 36,5 to 11,5*. 1 patient required second surgery at 9 months for decompression. All poor results from each group are included in their respective score evaluation. The strict observation of the right indications is recommended to obtain good results. At present no device failures and/or anterior migrations have been reported. However, use of the device is recommended after failure of conservative treatment and as a first choice over more invasive surgical procedures.

* final scores

Key Words: Interlaminar, Implant, IntraSPINE® Lumbar Spine, Motion Preservation

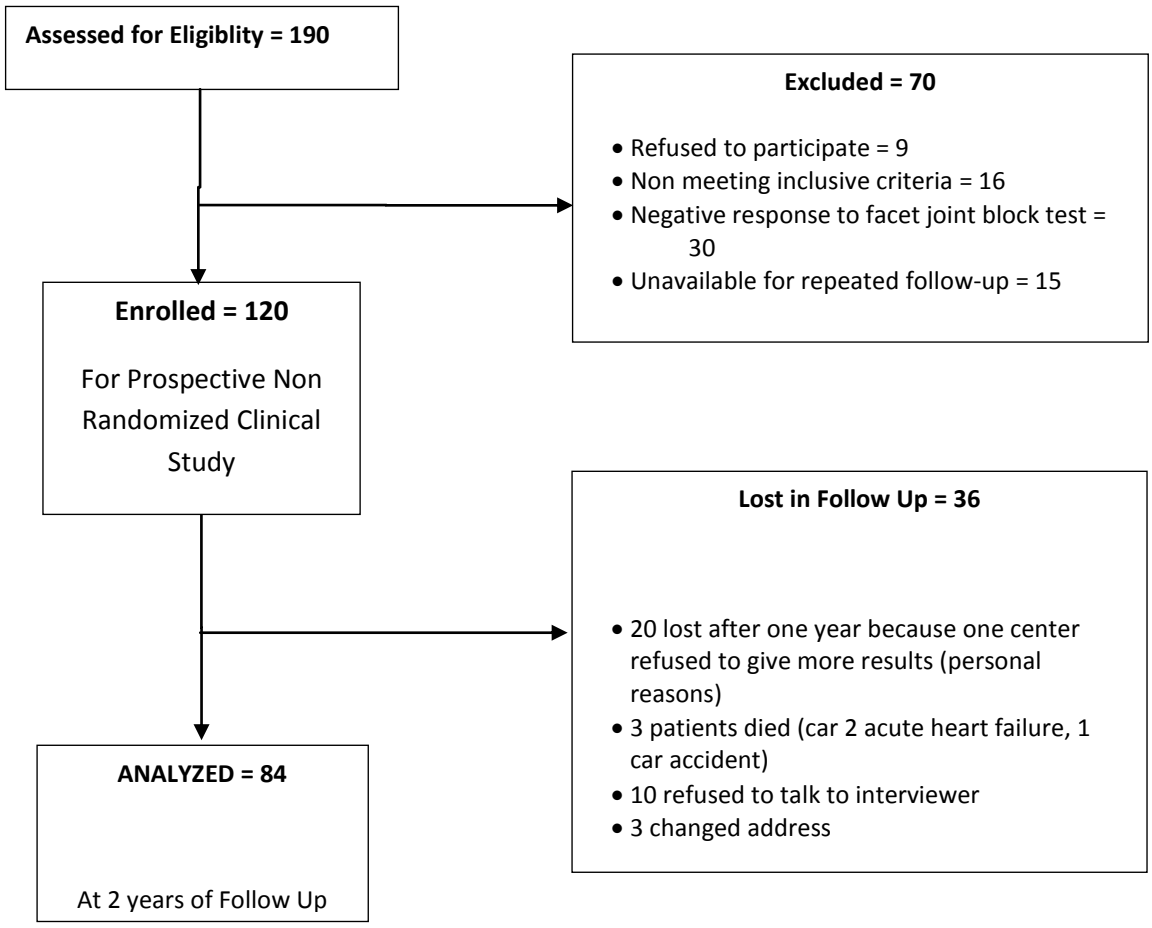
Abbreviations: ROM: Range of Motion, ASD: Adjacent Segment Disease, PMP: Posterior Motion Preservation, VAS: Visual Analogue Scale, ODI: Oswestry Disability Index,DDD: Degenerative Disc Disease, *AIR : Axis of Instantaneous Rotation*

INTRODUCTION

Current surgical management of lumbar DDD (Degenerative Disc Disease) is not standardized. Similarly, the currently known sources of pain are multiple and their origin is not always easy to determine. Improvements are necessary in the clinical success rates of pain reduction, morbidity and function.

In low-back pain disorders, a literature analysis of lumbar fusion with different techniques reveals a trend that pedicle screw fixation enhances the fusion rate but not the clinical outcome (1). Fusion suggests to us that a damaged or partially immobilized interspace puts additional strain on the space above or below it, resulting in an Adjacent Segment Disease (ASD) (2). The percentage of ASD ranges from 5 to 18% in various published papers in the last year (3,4).

To prevent this problem, over the past two decades a new philosophy based on "Posterior Motion Preservation" (PMP) (5,6,7) has developed. Moreover, in recent years, many dynamic interspinous devices for PMP in the treatment of a lumbar spine degenerative diseases (8,9,10,11,12) have been introduced on the market. At the same time many papers have been published on the biomechanical effect (13, 14), results (15, 16) and complications (17, 18) of these devices.



The aim of this study is to evaluate the efficacy of a new device not for interspinous, but for *interlaminar assistance* (IntraSPINE®) in the lumbar DDD.

METHODS

After obtaining consensus and approval on the protocol from all the surgeons participating to the trial, the eligible subjects were decided. The multicenter prospective trial was conducted in 6 Italian centres and a total of *120 patients were enrolled in a period of 4 months. Patients were divided into 3 groups according to pathology prior to study initiation*; *Group A patients (total 43) all presented with degenerated spinal disc with facet syndrome; Group B patients (total 56) all presented with large extruded disc herniations; Group C patients (total 21) all presented with soft stenosis. Follow up with medical examination was carried out at 3 months, 6 months, 1 year and 2 years post-op.*

The Device

The IntraSPINE® device (Cousin Biotech, France) is a dynamic stabilization system manufactured in medical silicon 65 shore coated by *an adherent* pure polyester terephthalate sleeve *which accelerates formation of fibroblastic tissue around the device; after three weeks post-op, the device is completely surrounded by strong tissue thus will prevent any displacement. Contrarily, the anterior part, which must be placed between the laminae, has a frontal extremity covered by a silicone film that prevents adhesion to the neural structures in cases where the yellow ligament needs to be removed (Fig. 1).*

Figure 1: *The rigid anterior part, "the nose", duplicates the borders of the adjacent laminae it_distract. The soft "tunnelized" posterior does not limit movement of the implanted segment*.

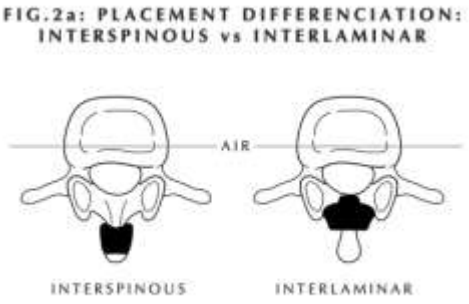


Figure 2a: *As shown in this figure, and intelaminar device can be placed much closer to the AIR than an interspinous device.*

the fundamental features of IntraSPINE® is the difference in compression ratio between the anterior and posterior parts of the device:

The function of the anterior part, "the nose", which is rigid and designed exactly to reproduce the inferior border of the superior laminae and the superior border of the inferior laminae, is able to distract and to re-open the neuroforamen, which in turn re-lifts and re-aligns the facet joints, as well as re-strain the thickened yellow ligament due to the reduction of the disc height. The posterior part which is completely tunnelized and thus compressible, does note refrain the spinous process movement and therefore does not reduce the ROM (Range of Motion).

IntraSPINE®, with respect to other posterior devices the advantage that it may be implanted more anteriorly (interlaminar) and thus placed even closer to the center of instantaneous rotation of the segment, which in turn allows for better decompression and correction of the physiological lordosis ***(Fig. 2).***

Figure 2 b: The 3D CT Scan reconstruction shows the exact positioning of the device with respect to the laminae.

A semirigid ligament can be used in cases of insufficiency of the supraspinous ligament ***so to*** *as so perform a sort of ligamentoplasty.* The biomechanical tests that confirm this aspect were performed in the institution ENSAM (École Nationale Supérieure d'Arts et Métiers) in Paris and the results will be argument of a different paper that we are preparing with the engineers of the same institution.

Patient Selection and Pathologies

The inclusion criteria comprised patients:

1. of both sexes, with chronic low back pain thought to be secondary to degenerative disease, aged between 18 and 70 years (inclusive) who had all already undergone conservative treatment for at least 6 months.
2. who were eligible for surgical procedure for
   a. Degenerated disc with facet syndrome
   b. Large extruded disc hernias
   c. Stenosis due to soft tissue "soft stenosis"
   d. The pathology must involve 1 or maximum 2 levels*, from L3 to S1*

The candidates were evaluated prior to surgery through radiographic analysis with MRI, CT Scan with sagittal, coronal and 3D reconstructions, as well as dynamic lumbar X-rays, so as to correctly determine the trial pathologies.

Key Exclusion Criteria

Despite the simple device and its relatively easy surgical technique, which is discussed further on in this paper, it is of utmost importance to keep in mind that the right indication is always the key point to obtaining good results. For this reason, patients with pathologies such as osteoporosis, spine bone tumours, allergies to one or several components, infections, previous surgery of the lumbar spine, and instability, were excluded from the trial. Other contraindications included discogenic pain, spondylolisthesis due to isthmic lysis, spondylolisthesis due to instability and lamina or spinous process congenital malformation. Moreover, the late stages of the degenerative disc pathologies like a disc height less than 7mm (measured in the central part of the intervertebral space, with the use of the 2D CT scan "bone windows" sagittal reconstruction), were also considered exclusion criteria. Finally pregnancy, growth period in children, previous lumbar surgery and compensation problems.

Patient Groups

The measurement scales used to evaluate the *low back pain and function scores in the patients were VAS (0-10) and ODI (0-50) respectively.*

Group A (patients affected by degenerated disc with facet syndrome)

The Facet Joint Block Test was performed on all the patients of this group so as to correctly diagnose facet syndrome. The test was carried out by administering 2 separate injections under fluoroscopy (19,20) of maximum 1cc per facet (left /right) of the painful segment, of anaesthetics and corticosteroids. *Results were considered positive where at least 70% of pain reduction was achieved.*

Group A was made up of 31 patients (16 females and 15 males) between the ages of 30 to 70 years (inclusive) and with a mean age of 42 years. Out of the 31 total, 27 patients underwent single level placement, and 4 double.

Group B (patients with large extruded disc hernias)

This group was comprised of patients with large extruded disc hernias. Hernias were considered to be "large" in those cases where the extruded fragment occupied 1 to 2 thirds of the canal area.

Use of the device in these patients was chosen after the removal of the extruded fragment, and without performing discectomy, so as to prevent the rapid collapse of the disc height and the consequent discomforting chronic low back pain (21), due to facet joint syndrome.

Group B was made up of 38 patients (17 females and 21 males) between the ages of 24 to 65 years (inclusive) and with a mean age of 39 years. All patients from Group B underwent single level surgical procedure.

Group C (patients affected by "soft stenosis" without decompression)

According to the literature (22), soft stenosis is a reduction of the canal area caused **by** thickening of the yellow ligament with/without discal bulging, with consequent protrusion of these 2 soft structures into the canal. In all of the patients of this group, the prevalent symptomatology was low back pain and not leg pain.

Thanks to the function of the anterior part of the device, IntraSPINE® was used so as to re-strain the thickened yellow ligament, thus reducing its width, which in turn increased the area of the canal. For this reason, no decompression was carried out on these patients.

Group C was made up of 15 patients (9 females and 6 males) between the ages of 35 to 64 years and with a mean age of 56 years. Of the total 15, 12 underwent single level placement, and 3 double.

Surgical Technique

The patient was placed on the operating table in prone-knee position or prone with lumbar spine in kyphosis. The segment to be treated was identified by fluoroscopy. After general or local anaesthesia a skin incision from 3,5 (single level) to 6 cm (two levels) was performed in line with the lateral border of the spinous processes. With monolateral approach this is carried down to the fascia. A lot of respect was given to keeping the supraspinous ligament intact. Removal of the interspinous ligament is performed. A special distractor is inserted into the middle of the interspinous space to enlarge the area and to restore the right tension of the supraspinous ligament (tension band function) (23). The correct implant size is indicated with the use of a sizing instrument (8, 10, 12, 14 mm) positioned in the interlaminar space close to the yellow ligament. After compression of the device with the appropriate holder forceps the IntraSPINE® is inserted with a clockwise movement. The distraction and compression instruments are removed with a circular anti-clockwise movement. The immediate stability of the device is controlled by forcefully pushing and pulling the same. The skin is closed in the usual fashion and any drain is utilized. The use of a postoperative brace is not necessary but the patient is invited to avoid flexion movement for 3 weeks.

The mean time of the surgical procedure is generally between 30 minutes and 1 hour and the patients can be discharged from the hospital within 24 hours.

STATISTICAL METHODS

The same statistical method was used for the three patient groups, and the collected data was analysed with an ANOVA (Analysis of Variants), *on the VAS and ODI scores*.

The descriptive statistics used were mean with standard deviation and median with maximum and minimum. The *t*-Test was carried out to compare the VAS and ODI results between pre-op *and final follow-up at 2 years*. Data was considered significant at $p < 0,05$.

RESULTS

The clinical results were conducted by collecting and evaluating the scores of the low back pain (VAS) and function (ODI) measurement scales. *Only the last collection* was carried out by telephone interview and overseen by two independent observers (S.P. and B.P.).

At present 84 patients were eligible for the follow up with an average time of 29 months (range 28 to 40). For all three groups, the VAS and ODI pair t-Tests at pre-operative and 2 years were less than 0,001.

Group A (patients **affected by** degenerated disc and facet syndrome)

In this group, 3 patients had poor results, 2 of which required a second surgery “fusion” after 6 and 10 months and the third refused to receive further surgical treatment. The three poorer results are included in the score evaluation (***Fig. 3 and Fig. 4)***.

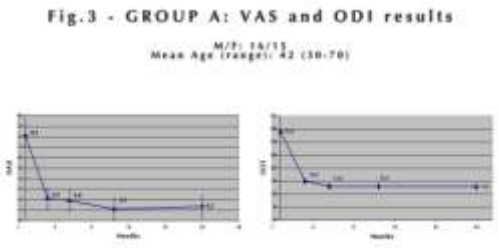


Figure 3 : *The mean percent change of the symptoms severity score collected at pre-op, 3 months, 6 months, 1 year and 2 years.*

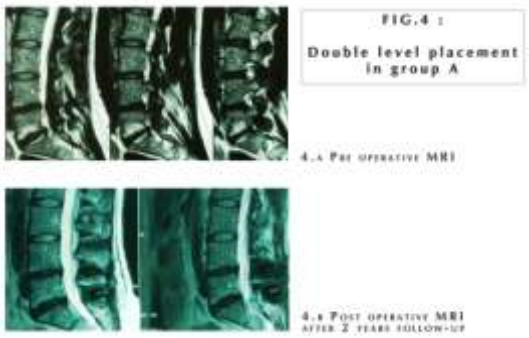


Figure 4 : *The result of double level placement.*

At present no further surgical procedures have been necessary in this group and especially no recurrences have appeared **(Fig. 5)**.

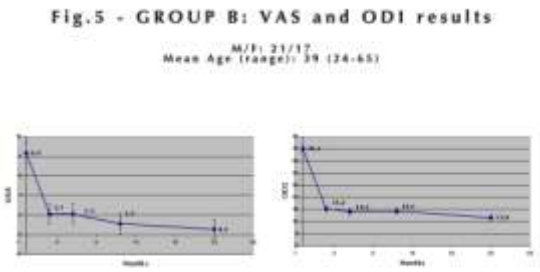


Figure 5 : *The mean percent change of the symptoms severity score collected at pre-op, 3 months, 6 months, 1 year and 2 years*

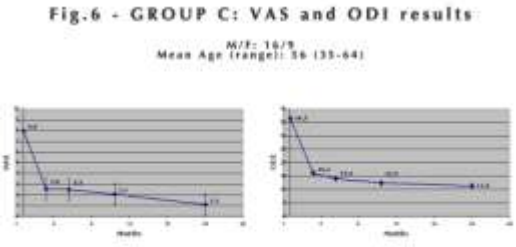


Figure 6: *The mean percent change of the symptoms severity score collected at pre-op, 3 months, 6 months, 1 year and 2 years*

Group C (patients affected by "soft stenosis" without decompression)

In this group, only 1 patient required a second surgery after 9 months (decompression) and this poor result is included in the score evaluation (Fig. 6).

Safety/Complications

No device-related intraoperative complication occurred and the surgeons were able to complete implantation of the IntraSPINE® in all patients. Minor complications like minor fluid collection with wound swelling were reported in 7 patients from all 3 groups (5,39%). No spinous process fracture and increased pain at implanted level was described by the surgeon in any patient. Moreover, no major complications like nerve root motor deficit, dural tear, or bleeding occurred in the perioperative period. However, posterior displacement or inaccurate positioning (2 to 4mm posterior to the laminae) was found in 7,1% of cases, but this positioning did not influence the outcome of results**.** Finally, at present no device failures and/or anterior migrations have been reported.

The overall re-operation rate was 3,5% (3/84).

DISCUSSION

The aim of our study was to evaluate the efficacy of the IntraSPINE® device on lumbar DDD in young and old patients. The notable results obtained at a 2 year follow-up demonstrate how an interlaminar device can alleviate the patient from chronic low back pain, and we believe that this is thanks to its placement closer to the AIR compared to other devices (interspinous). This allows us to better assist the posterior part of the disc and in turn reduce the load in this area and in the facet joints. The material used for this device is not as rigid or incompressible as the titanium/peek/carbon material generally used for interspinous devices and this prevents further unnecessary load or possible breakage of the spinous processes, as already mentioned in the safety/complication paragraph. It must be said that devices that are manufactured in rigid materials, may only be considered as "spacers", and "spacers" generally induce segmental kyphosis (13).

To prevent all these problems, we developed this interlaminar device (IntraSPINE®) that at present is used in Europe, central and southern America *and in some countries of Asia and the Middle East*.

With our results we clearly demonstrate that, even if the number of patients is low, with a mini-invasive surgical procedure, that can be performed via a mono-lateral approach and in local anesthesia, you can achieve good results relatively to the improvement of chronic low back pain: it is of utmost importance that the invasivity of this procedure, that is completely

reversible, cannot at all be compared to a transpedicular fixation and fusion arthrodesis, even if performed by percutaneous approach. The learning surgeon curve is very low and the patient hospital stay, blood loss and costs are significantly reduced.

To be noted that close observation of the right indications and an accurate selection of patients is strictly recommended, even if the minimally invasive and relatively easy surgical procedure encourages the surgeons to an incorrect use of the device, as this could lead to a vast amount of unsatisfactory results.

In observation of these important points, we believe we can obtain further commendable results even with a greater number of case studies, a longer follow-up, and/or a randomized multicentre study that we are scheduled to start in the next few months. In this future randomised international study we will compare the conservative treatment with the surgical insertion of IntraSPINE® for patients affected by chronic low back pain due to facet joint syndrome.

To be underlined are the important results obtained from use of the device in group C treated for "soft stenosis" without any type of decompression (for this reason we believe that these good results are thanks only to the device itself – by re-stretching and reducing the size of the yellow ligament we can reduce the compression of the dural sac).

To be emphasized is the fact that, at present, we have no recurrences in group B treated for large extruded disk hernias and low development of low back pain. It is well described in the late follow-up control, that this type of pathology creates, especially in young patients, very discomfortable low back pain (21). To be noted that in our study this result remained constant between the first post-operative control at 3 months and final control at 2 years.

However, in spite of the good results we have obtained, we should recommend the use of this device only after failure of conservative treatment, or as first choice over more invasive surgical procedures.

The only one tip that we would like to recommend from our experience, is that if the surgeon is not sure on the implant size after distraction, because one size is too small and that next size is too large, we prefer to use the larger. This preference is due to the rigid "nose" (anterior part) of the device that can be "captured" by the laminae to obtain the correct distraction, achieve immediate stability of the device and also to avoid any posterior displacement.

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