

## Clinical Results with IntraSPINE®

Giancarlo Guizzardi<sup>1\*</sup>, Riccardo Morichi<sup>1</sup>

Department of Neurosurgery, University and City Hospital Careggi, Florence, Italy

\*Corresponding Author: Guizzardi Giancarlo, Department of Neurosurgery, University and City Hospital Careggi, Florence, Italy.

Received: September 19, 2015; Published: October 03, 2015

### Abstract

**Background:** The traditional therapeutical approach to chronic lumbar pain secondary to degenerative disc disease and osteoarthritis starts with local anesthetic and steroid injection. Spinal fusion represents the second step of the treatment. The main problem with fusion is the disruption of the biomechanics in the rest of the spine, leading to worsening of the adjacent segment disease. The motion preservation is the answer to the necessity to avoid the adjacent segment disease.

**Objective:** In this paper we analyze the effect of the Intraspine, one among the available motion-preserving devices, in order to verify its efficacy in stopping or reversing the progressive cascade associated with disc degeneration.

**Material and Methods:** This is a retrospective study that collects 281 patients with a minimum follow-up of 52 months, in whom one or more IntraSPINE® devices were implanted. Visual Analogue Scale and Oswestry low back pain disability questionnaire were used. Between 12 and 18 months after surgery, all patients were checked using a Magnetic Resonance Imaging.

**Results:** Clinical results were Excellent/Good in 256 patients (91.10%). The Magnetic Resonance Imaging, obtained in 210 patients, highlighted a moderate progression of the cascade in 20%, no changes in 50% and improvement in 30%. The results of the present series show a certain efficacy in reducing/ stopping the degenerative cascade, in particular when the device is implanted in the initial stages of the disease.

**Conclusion:** A larger experience is required however, at present, the absence of major complications, the minimally invasive surgical procedure and the good clinical results allow us to say that with this device, with a correct patient selection, we can have a “new arrow in our bow” for the treatment of the lumbar DDD.

**Keywords:** Interlaminar Device; Motion Preservation; Low Back Pain; Degenerative Disc Disease; Disc Rehydration

**Abbreviations:** ASD: Adjacent Segment Disease/Adjacent Segment Degeneration;; CT scan: computerized Tomography;; DDD: Degenerative Disc Disease;; LBP: Low Back Pain;; MRI: Magnetic Resonance Imaging;; ODI: Oswestry Disability Index;; PET: Polyethylene Terephthalate;; VAS: Visual Analogue Scale

### Introduction

Low back pain (LBP) has become one of the most serious public health problems, with a lifetime prevalence as high as 84% [1]. The total cost associated with LBP in the United States is estimated to exceed 100 billion dollars per year [2]. Common causes of lumbar back pain include disc herniation, disc degeneration, facet joint arthritis, spondylolysthesis, spondylosis, spondylolysis and spinal stenosis. Since in 1970's Kirkaldy-Willis first described the “Degenerative Cascade” of DDD [3-5] many efforts have been made to identify the best treatment able to stop or reverse the evolution of this process. Our understanding of spinal degeneration has advanced as we have appreciated that the degenerative cascade involves interplay of both biologic and biomechanical factors [6,7,8,10,11]. Biochemical events are important in the pathogenesis of the degenerative process as well as in the pain-signaling pathways responsible for the clinical features of the condition. As we better appreciate the biologic aspects of spinal degeneration, less-invasive, non-ablative treatments designed

**Citation:** Guizzardi Giancarlo and Riccardo Morichi. “Clinical Results with IntraSPINE®”. *EC Orthopaedics* 2.3 (2015): 101-106.

to reverse these biologic processes and restore the disc and facet functioning may become a reality. The traditional therapeutical approach to chronic lumbar pain secondary to degenerative disc disease (DDD) and osteoarthritis starts with local anesthetic and steroid injection. Spinal fusion represents the second step of the treatment [12]. Fusion aims to alleviate pain by preventing movement between affected spinal segments. The use of pedicle screw fixation enhances the fusion rate but is not necessarily associated with improved clinical outcome [13]. The main problem with fusion is the disruption of the biomechanics in the rest of the spine, leading to worsening of the adjacent level disease that, theoretically, can be prevented by performing motion-preserving surgeries. To overcome this problem, a wide range of non-fusion techniques has been proposed in the last decade [14]. In particular, interspinous devices are frequently used in the case of mild canal or foramina stenosis, with or without decompression, in order to provide spinal stabilization while still allowing motion at the instrumented level [15,16]. In this paper we analyze the effect of one out of the motion preserving developed device, the IntraSPINE®, in order to verify its efficacy in stopping or reversing the progressive cascade associated with DDD.

### Material and Methods

Authors retrospectively reviewed the clinical and surgical records of all patients, suffering from low back pain caused by different diseases, admitted to the Neurosurgical Department of Careggi University and City Hospital of Florence (Italy) and submitted to spinal surgery for implanting an IntraSPINE® from April 2007 and April 2011, representing the first four years of experience in the use of the device itself. All these patients have to date a minimum follow-up of 52 months. The length of follow-up was considered adequate to verify not only the immediate results but also their long-term stability.

As usual all patients were clinically controlled every six months. Low back pain was evaluated using the Visual Analogue Scale (VAS) [17] and the effect of back pain on the daily quality of life was assessed using Oswestry Disability Index (ODI) [18].

As regards the instrumental controls, all patients were subjected to static X-rays control as soon after surgery before discharge and a Static and Dynamic X-rays check after 6 months. The current protocol in our Department included an instrumental control by MRI between 12 and 18 months and a subsequent control between 36 and 48 months. Patients sometimes preferred to perform an initial check by CT-scan and postpone the MRI because slightly claustrophobic.

Among patients receiving postoperative MRI evaluation, the progression of the degenerative cascade was evaluated by using the Pfirrmann grading system [19]. Disc degeneration can be graded on MRI T2 spin-echo weighted images using a grading system proposed by Pfirrmann. This classification, not used on routine spine reports, is useful in discriminating severity of disc degeneration. Furthermore the ability of the prosthesis to prevent the space disc collapse when implanted in addition to a standard microdiscectomy was evaluated.

All patients who exhibit clinical disorders were clinically and instrumentally evaluated regardless the scheduled plan.

### Results and Discussion

Since the first IntraSPINE® implanted in April 2007, at the end of April 2011 a total of 380 devices have been implanted in 281 patients with the following indications: 96 Chronic low back pain in black disc with facet-syndrome ; 74 Soft and/or dynamic and foraminal stenosis; 61 Young patients submitted to microdiscectomy of a huge herniated disc, to prevent the collapse of the disc and the subsequent CLBP; to prevent ASD in 12 patients submitted to elastic stabilization ("topping off"), 38 Miscellanea ( Insufficiency of the supra- spinal fibrous complex ; previous surgery for synovial cyst removal, and so on). The most frequent surgical complication was a fluid collection at the surgical site, observed in 33 patients (11.74%) and not requiring surgical treatment.

Only one patient (0.355%) developed an infectious complication that required surgical treatment and removal of the device; this was a risky patient with old age and severe malnourishment.

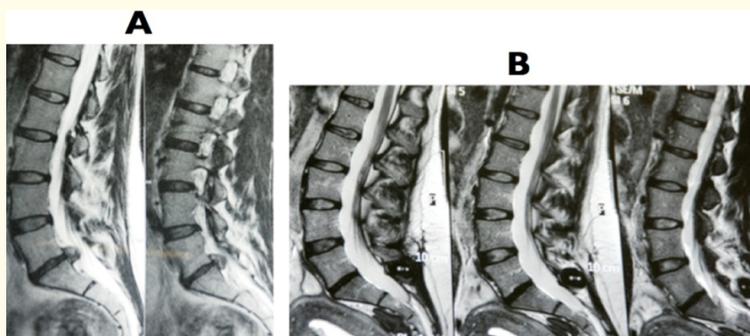
Another patient (0.355%) developed a delayed deep fluid collection, non-infectious, due to a local reaction determined by the continuous stimulus from the "bobbing" IntraSPINE. No breakage of the device was observed.

All patients were followed between 52 and 100 months (mean 68 months) . Control was performed both clinically and by means of instrumental investigations in all cases.

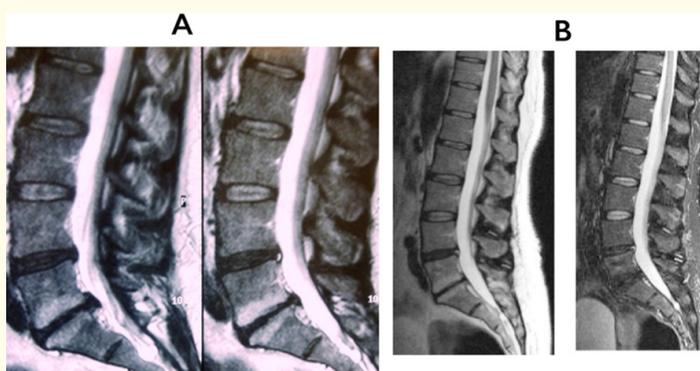
Clinical results were Excellent / Good in 256 patients (91.10% ) with a reduction of the VAS and the ODI: the average VAS passed from 7 to 2 ( back) and from 7.5 to 1.0 (leg); the average ODI decreased from 54 to 14.

With respect to the instrumental results all patients were submitted to Static and/or Dynamic X-rays at the first check; 210 patients ( 74.73%) was checked by means of an MRI during follow -up period and 168 ( 59.78%) received both MRI and CT scan during the fol-

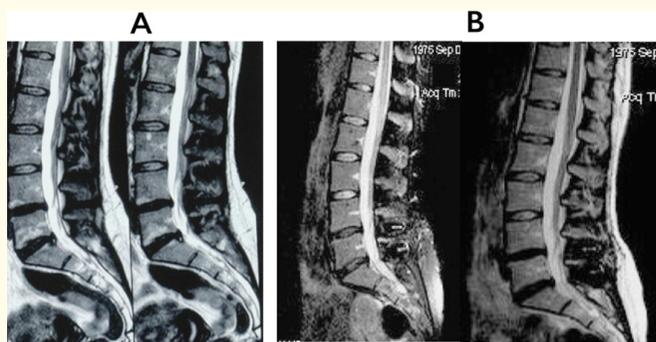
Among the 210 patients submitted to MRI, 42 cases (20% ) showed a moderate progression of the degenerative cascade, also in presence of good clinical results. In 105 patients (50%) the Pfirrmann grade resulted unchanged. But in 63 patients (30%) the MRI highlighted a partial rehydration of the disc which probably means an initial reversion of the degenerative cascade. In these cases the clinical status resulted dramatically improved. Furthermore in 51 patients submitted to microdiscectomy of a huge herniated disc who already received the MRI control, the IntraSPINE® showed the ability to prevent the space disc collapse.



**Figure 1A-1B:** T2 weighted Magnetic Resonance Images preoperative (A) showing L5-S1 huge disc herniation and postoperative (B) showing a light rehydration of the disc with a Modic signal slightly attenuated(2013).



**Figure 2A-2B:** T2 weighted Magnetic Resonance Images preoperative (A) in a patient submitted to elastic stabilization at L5-S1 and "topping off" at L4-L5 and L3-L4 (2009) and postoperative (B) showing a light rehydration of the disc with a Modic signal slightly attenuated(2013).



**Figure 3A-3B:** T2 weighted Magnetic Resonance Images preoperative (A) in a patient with CLBP (2008) and postoperative (B) showing a radiological improvement with Modic signal about disappeared and rehydrated discs (2012)

## Discussion

The posterior fusion by means of transpedicular screws is not free from complications and have flourished in recent years studies on the biomechanics that would help to clarify the etiology of the adjacent segment disease observed in patients submitted to this kind of surgical treatment. A wide range of non-fusion techniques has been proposed in the last decade. In particular, interspinous devices are frequently used in the case of mild canal or foramina stenosis, with or without decompression, in order to provide spinal stabilization while still allowing motion at the instrumented level. Several studies reported the biomechanical behavior of such implants through in vitro flexibility tests. Despite their different designs, they show similar stabilizing effect and pressure reduction in extension, leaving flexion, lateral bending and torsion amplitudes almost unaffected. Usually implanted through a minimally invasive approach, they include various materials and designs. The aim of interspinous spacers is to preserve motion while unloading the facet joints, and increase central canal and neuroforaminal dimensions either by flexing the spinal segment or blocking extension. Interspinous implants can provide good clinical outcomes but are more reliable when combined with a direct decompression [20]. Failures can occur due to local bone resorption [21] leading to loss of constraint or spinous process fracture [22,23] over distraction may lead to segmental kyphosis [24-26] with a negative impact on sagittal balance and the physiological axes of rotation. The IntraSPINE® with its unique interlaminar location, closer to the normal center of rotation showed in the Laboratory tests mechanical advantages over a traditional more posteriorly placed interspinous implant by allowing more physiological movement without blocking extension. Furthermore this new device with a core in medical silicone and an outer shell in pure polyethylene terephthalate (PET) shows material properties very suitable for spinal applications. The use of a gel like core and an outer shell reinforced by continuous wounded PET fiber has been proposed as a synthetic intervertebral disc prosthesis. The combination of these materials represents a composite which mimics the architecture of the intervertebral disc and resembles its visco-elastic properties [27] and makes the device able of support/replace the function of the disc itself. The fundamental feature of the IntraSPINE® is the difference in compression ratio between the anterior and posterior part of the device: the anterior part is rigid, designed exactly to reproduce the inferior border of the superior laminae and the superior border of the inferior laminae, is able to distract and reopen the neuroforamen; the posterior part is compressible and does not refrain the spinous process movement. The major advantage of the device is the possibility of being implanted more anteriorly, in the "interlaminar" space, thus allows better decompression and correction of physiological lordosis.

The efficacy of this interlaminar device, in addition to a standard microdiscectomy, in low back pain recurrence preventing has already be published [28]. The rationale for considering the positioning of an interlaminar device as a solution for avoiding the low back pain recurrence is the ability of the prosthesis to prevent the rapid disk space collapse after surgery by supporting the discal pump [29].

The results obtained in patients out of the present series submitted to MRI evaluated according to radiological criteria [19-31] with about 30% improved and 50% not deteriorated over time, attest the capacity on the IntraSPINE® to support the biomechanics of the

spine in an effective manner and to slow down or partially reverse (disc rehydration) the natural evolution of the degenerative cascade. In all these cases the imaging result was correspondent to the clinical status.

The absence of major complications is a further advantage in favor of the use of the device without forgetting that in the first instance is always mandatory an attempt with conservative therapy for at least two months.

Finally, but not in order of importance, the possibility of implanting this device (IntraSPINE®) in a fast and easy manner, without the necessity of a larger surgical incision or of a second operation, represents an adjunctive advantage for patients that merit to be stressed. In fact one of the major concerns dealing with fusion procedures are the length of the surgical incision joined to the extensive trauma of the surrounding tissues and the large amount of blood lost.

## Conclusion

There is a large broad spectrum of available treatment options including both conservative and surgical approaches. Novel strategies involving minimally invasive and motion sparing techniques have emerged within the last decade among which the IntraSPINE®. The laboratory tests showed that IntraSPINE® is able to reduce the intradiscal pressure in flexion and extension. Furthermore it preserve the ROM in flexion & extension

In clinical practice, the absence of major complications, the minimally invasive surgical procedure and the good clinical results allow us to say that with a correct patient selection, we can have a “new arrow in our bow” for the treatment of the lumbar DDD.

We are aware of being only the beginning of a journey that will route to get to define what is the best treatment strategy for the DDD. Nevertheless, to date, in the light of our results we feel we can recommend the use of the IntraSPINE® as first choice instead of more invasive surgeries and especially in the early stages of degenerative disease in order to slow its natural evolution, of course after failure of a mandatory attempt with conservative therapy.

## Acknowledgements

Authors wish to acknowledge the contribution of Lucia Benvenuti MD in the preparation of this manuscript.

## Conflict of Interest

Giancarlo Guizzardi is receiving grant as inventor of the device Intraspine. Riccardo Morichi doesn't have any financial interest in the materials presented/discusses in this paper.

## Bibliography

1. Balagué F, *et al.* “Non-specific low back pain”. *Lancet* 379.9814 (2012): 482–491.
2. Katz JN. “Lumbar disc disorders and low-back pain. socioeconomic factors and consequences”. *The Journal of Bone & Joint Surgery* 88 Suppl. 2 (2006): 21–24.
3. Kirkaldy Willis WH, *et al.* “Lumbar spinal stenosis”. *Clinical Orthopaedics and Related Research* 99 (1974): 30–50.
4. KirkaldyWillis WH. “The Pathology and Pathogenesis of Low Back Pain. In: Kirkaldy-Willis WH, editor. *Managing Low Back Pain*. Churchill Livingstone; (1983).
5. Kirkaldy-Willis WH, *et al.* “Pathology and pathogenesis of lumbar spondylosis and stenosis”. *Spine (Phila Pa 1976)* 3.4 (1978): 319-328.
6. Anandjiwala J, *et al.* “Adjacent segment degeneration after instrumented posterolateral lumbar fusion: a prospective cohort study with a minimum five-year follow-up”. *European Spine Journal* 20.11 (2011): 1951-1960.
7. Park P, *et al.* “Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature”. *Spine* 29.17 (2004): 1938-44.
8. Throckmorton TW, *et al.* “The impact of adjacent level disc degeneration on health status outcomes following lumbar fusion”. *Spine* 28.22 (2003): 2546-2550.

9. Hillibrand S and Robbins . "Adjacent segment degeneration and adjacent segment disease: the consequence of spinal fusion?" *The Spine Journal* 4.6 Suppl (2004): 190S-194S.
10. Yong-Soo Choi . "Pathophysiology of Degenerative Disc Disease". *Asian Spine Journal* 3.1 (2009): 39-44.
11. Farfan HF. "Mechanical Disorders of the Low Back". *British Journal of Surgery* 16.12 (1974): 988.
12. Baliga S., et al. "Low Back Pain: Current Surgical Approaches". *Asian Spine Journal* 9.4 (2015): 645-657.
13. Boos N and Webb JK. "Pedicule screw fixation in spinal disorders: a European view". *European Spine Journal* 6.1 (1997): 2-12.
14. Mayer HM and Korge A. "Non-fusion technology in degenerative lumbar spinal disorders: facts, questions, challenges". *European Spine Journal* 11. Suppl 2 (2002): S85-91.
15. Lindsey DP, et al. "The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine". *Spine* 28.19 (2003): 2192-2197.
16. Swanson KE., et al. "The effects of an interspinous implant on intervertebral disc pressures". *Spine* 28.1 (2003): 26-32.
17. Knop C., et al. "Development and validation of the Visual Analogue Scale (VAS) Spine Score". *Unfallchirurg* 104.6 (2001): 488-497.
18. Fairbank JC and Pynsent PB. "The Oswestry Disability Index. Spine (Phila Pa 1976)". *Spine* 15.25 (2000): 2940-2952;discussion 2952.
19. Pfirrmann CW, et al. "Magnetic resonance classification of lumbar intervertebral disc degeneration". *Spine* 1.26 (2001): 1873-1878.
20. Kabir SM., et al. "Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence". *Spine* 1.35 (2010): E1499-E1506.
21. Sobottke R., et al. "Clinical outcomes and quality of life 1 year after open microsurgical decompression or implantation of an intraspinal stand-alone spacer". *Minimal Invasive Neurosurgery* 53.4 (2010): 179-183.
22. Barbagallo GMV, et al. "Analysis of complications in patients treated with the Xstop Interspinous Process Decompression System: proposal for a novel anatomic scoring system for patients selection and review of literature". *Neurosurgery* 65.1 (2009): 111-120.
23. Kim DH., et al. "Occult spinous process fractures associated with interspinous process spacers". *Spine* 15.36(16) (2011): E1080-E1085.
24. Schulte LM., et al. "Change in sagittal balance with placement of an interspinous spacer". *Spine* 15.36(20)m (2011): E1302-E1305.
25. Anasetti F, et al. "Spine stability after implantation of an interspinous device: an in vitro and finite element biomechanical study". *Journal of Neurosurgery: Spine* 13.5 (2010): 568-575.
26. Crawford RJ., et al. "The effect of interspinous implant surgery on back surface shape and radiographic lumbar curvature". *Clinical Biomechanics* 24.6 (2009): 467-472.
27. Gloria A., et al. "A multi-component fiber- reinforced PHEMA-based hydrogel/HAPEXTM device for customized intervertebral disc prosthesis". *Journal of Biomaterials Applications* 25.8 (2011): 795-810.
28. Corriero OV, et al. "Lumbar Herniated Disc Treated by Microdiscectomy Alone or Microdiscectomy Plus an Interlaminar Shock Absorbing Device: Retrospective Study with Minimum 3-Years Follow-Up". *The Spine Journal* 3 (2014): 159.
29. Martin MD, et al. "Pathophysiology of lumbar disc degeneration: a review of the literature". *Neurosurgical Focus* 13.2 (2002): E1.
30. Modic MT, et al. "Imaging of degenerative disk disease". *Radiology* 168.1 (1988): 177.
31. Modic MT and Ross JS. "Lumbar degenerative disk disease". *Radiology* 245.1(2007): 43-61.

**Volume 2 Issue 3 October 2015**

**© All rights are reserved by Guizzardi Giancarlo and Riccardo Morichi.**