

# Current Status of Interspinous Posterior Devices in USA and Italy: Finally the Pandora's Vase has been Uncovered

Alessandro Landi\*, Fabrizio Gregori, Biagia la Pira, Angela Ambrosone and Roberto Delfini

Department of Neurology and Psychiatry, division of Neurosurgery, "Sapienza" University of Rome, Italy

**Keywords:** IPD, Guidelines; Lumbar spine; Degenerative spine; Stenosis; Low back pain

## Introduction

Interspinous Posterior Devices (IPDs) are spinal implantable devices used to treat lumbar degenerative diseases, with lumbar stenosis as the main indication. They are defined as devices for dynamic stabilization, because their aim is to perform a decompression of the spinal canal in case of stenosis, while preserving biomechanical properties of the spinal metamere [1-7]. Lumbar stenosis is considered as the last phase of the degenerative cascade, the process of degeneration of spinal motor unit described by Kirkaldy-Willis, which identified as primary cause the hypermobility of the vertebrae [8,9]. Depending on the range of hypermobility, the degree of instability varies, going from a first phase (in which the damage-articular disk is moderate) defined as "micro-instability", to a second phase of overt instability, up to a third step of "steno-instability" [10-12]. It's important to underline how these three stages proceed in a progressive way, in relation to the progressive increase of the instability and the consequent development of the hypertrophic reaction of both ligaments and bone component [13-19]. Therefore, stenosis occurs in the third stage of the degenerative cascade, as the anatomic-pathological reaction to a metameric instability. And it is precisely on the concept of instability, which is at the base of the degenerative process, that evidences of the IPDs are based. As the conceptual evolution in surgery of dynamic stabilization (or "motion preservation surgery" and "neutralization dynamic instability") spread out, a dynamic device should not give additional movement to the vertebral segment, but rather neutralize those excessive degrees of motility that are responsible for the degenerative disease [10,18,19]. Indeed IPDs have been designed and developed as devices for dynamic stabilization and preservation of the movement, in order to maintain the motility of the vertebral body. Thus the treatment of the stenosis, either hard stenosis or soft, must be closely related to the concept of instability as underlying condition [10,12,17,18].

## Classification of IPD

Several studies in the literature tried to describe the interspinous devices, generating considerable confusion on their classification. Erroneously, they have been classified into statics and dynamics, but a clarification about their classification is needed. According to the biomechanical principles for which they work, IPDs can be classified into restricted, non restricted and fusion devices. The restricted IPDs are anchored to the spinous processes above and below, in order to control and neutralize hyperflexion and hyperextension movements. Non restricted IPDs are not anchored to the spinous processes, thus only movement of hyperextension can be neutralized. Instead, the fusion devices IFDs (Interspinous Fusion Devices) work completely different, because their target is the fusion of the spinal motor unit and not its dynamism. As a result of the aforesaid, it is appropriate to distinguish between IPDs (constrained and unconstrained) and interspinous fusion devices IFDs as two categories completely different on the basis of the therapeutic target [10,11,16-19].

## Mechanism of Action and Related Complications

IPDs are systems based on spinal distraction, in order to distract

posteriorly the metamere, reducing stenosis by the re-tensioning of the yellow ligament, and increasing the diameter of the vertebral foramen [7-9]. On the basis of the mechanism of action, we can make some considerations:

The IPDs, as described by many authors, have stenosis as primary surgical indication, with moderate intermittent claudication and/or signs of radiculopathy which were resolved with the forward flexion of the trunk. These authors emphasize also the re-tensioning of the yellow ligament, which, due to the disc collapse, folds on itself occupying more space in the spinal canal. This is only partial true. Indeed, it has been described in the literature that the yellow ligament, in case of stenosis, has also an important hypertrophic component. This hypertrophy occurs in the phase of instability for the simultaneous occurrence of three biochemical and structural modifications: over-expression of collagen type I mRNA, increased expression of matrix metalloproteinases, over-expression of Fractalkine. Therefore, it's obvious that a IPD cannot act on the central stenosis with soft component because there's no action on ligament hypertrophy and, as a consequence, it has a poor result on intermittent claudication [20,21].

The lumbar stenosis, on which are intended to act the IPDs, is caused not only by the hypertrophy of yellow ligament, but also and above all, by the hypertrophy of the facet joints and bone structures, setting up a framework of hard/soft stenosis. In this context, the major component of algo-dysfunctional symptoms is given by stenosis of the lateral recesses supported by the joint-hypertrophy. This stenosis can occupy more than 80% of the spinal canal and is responsible for both claudication and radiculopathy. In such cases, radiculopathy not derived by a compression of the emerging root, but rather by the level-passing root; in fact if we have a L4-L5 foraminal stenosis, it may involve the L4 emerging root, while if we have a central stenosis or a stenosis of the recesses, it involves the L5 passing-root. It's deductive that an IPD placed in L4-L5 can act only on the stenosis of the foramen, and on the L4 root, but not on the stenosis of the recesses, neither on the L5 root. Such stenosis must inevitably be surgically treated with decompression.

Many authors reported that the use of IPDs has become an acceptable alternative even in cases of lumbar instability. In the light of the biomechanical explanation of the pathologic substrate responsible for the degenerative disease, given by Kirkaldy-Willis, it is quite clear that IPDs cannot help in this event, but even accelerate the degenerative cascade if implanted in an unstable patient. Indeed, the biomechanical alteration that acts on the metamere, due to the IPDs, poses the spinal

\*Corresponding author: Alessandro Landi, Department of Neurology and Psychiatry, division of Neurosurgery, "Sapienza" University of Rome, Italy, Tel: 39 0649979105; E-mail: [dott.alessandro.land@gmail.com](mailto:dott.alessandro.land@gmail.com)

Received December 18, 2015; Accepted December 28, 2015; Published December 31, 2015

**Citation:** Landi A, Gregori F, la Pira B, Ambrosone A, Delfini R (2015) Current Status of Interspinous Posterior Devices in USA and Italy: Finally the Pandora's Vase has been Uncovered. J Spine 4: 274. doi:10.4172/2165-7939.1000274

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motor unit in a dynamic overload and thus of progression of the instability [22-26].

The IPDs works by a posterior distraction of the spinous processes, but does not act symmetrically to the endplates and, therefore, cannot homogeneously reduce the intradiscal pressure, because the posterior disc discharge even increases the load on the anterior disc itself, causing forced displacement of the nucleus pulposus within the posterior disc (as normally occurs in the movements of flexion of the trunk) increasing the risk of disc herniation. Rohlmann et al, analyzing the various rigid and dynamic stabilization systems, stressed that the only system capable of significantly reduce the intradiscal pressure is the rigid stabilization with screws and rods placed in distraction; the authors also underline that the distraction with dynamic IPDs, reduces the bulging disc in extension but increases in flexion, so the risk of a herniation of the nucleus pulposus is higher [27]. In the light of this actually IPDs have an increased risk of causing a progression of disc degeneration [28,29]. Moreover the implant of IPDs, whether restricted or non-restricted, causes an overload on an already damaged disk and, as a consequence, accelerates the degenerative process, leading to a progression of the instability.

The implant of IPDs also causes consequences on the entire column; in particular their implanting in distraction reduces the degree of lordosis, causing abnormal sagittal balance and spino-pelvic alignment.

## Indications

The indications for the use of the IPD have been provided by the manufacturers and over time have spread out, improving the use for the most degenerative lumbar spinal diseases, ranging from disc herniation to spinal instability. Actually, the indications for use of IPDs are shrinking. In particular, on the basis of biomechanical features, literature data and our clinical experience, we can affirm that:

There's no indication for foraminal stenosis, because, in the medium-long term, the only action of IPDs is to accelerate the segmental degenerative process; There's no indication for central stenosis, Their action does not solve the claudication, and the gold standard treatment remains central decompression with laminectomy; There's no indication for spondylolisthesis: the shear stress acting on the disc is high and the slippage cannot be augmented. There's no indication in low back pain due to micro-instability, black disc and recurrent disc herniation: they do not reduce micro-instability but increase it, overloading the disc, promoting the degeneration, worsening the instability and low back pain. In conclusion, our experience and literature data revealed that there are no indications at this time in implanting IPDs in degenerative lumbar spine.

According to our assumption, in the last 24 months there have been some important developments in scientific and forensic way, both in Italy and in the United States, to regulate the disproportionate use of such devices.

## Updates

In the light of debatable results reported by the scientific community about the effectiveness of the IPDs, and the high rate of complications and re-operation showed, the North American Spine Society NASS performs and publishes in 2013 a revision of "evidence based clinical guideline for the diagnosis and treatment of degenerative lumbar spinal stenosis" that were previously drawn up from the NASS in 2006 . This revision provides a clinical analysis and an extensive literature review about the different treatments available for lumbar stenosis, giving each a degree of recommendation from A to I: A is the degree of absolute

recommendation, the gold standard, while I means the total lack of recommendation. The IPDs are currently classified I, because "there is insufficient evidence at this time to make a recommendation for the placement of an interspinous process device spacing in patient with lumbar spinal stenosis" [30]. In Italy, in 2013, at the same time with the review of the NASS, it has been identified a committee, composed by two neurosurgeons and two orthopedics, in order to analyze the clinical indications of interspinous devices and to provide a critical analysis of the evidence in the literature, trying to define the possible guidelines. Based on this study, on January 23rd, 2015, an ordinance from the Ministry of Health, signed by the major scientific societies including the Italian SINCH (Italian Society of Neurosurgery) and SIOT (Italian Society of Orthopedics) was published, which finally clarify the indications of these devices in our country. This document shows that absolute contraindications to the implantation of IPDs are: "instability, herniated discs, herniated discs recurrence, synovial cysts, hard stenosis, osteoporosis, limiting the potential use for soft stenosis in patients with high ASA score". Moreover, this document imposes that "the implantation of IPD should only occur in the context of controlled clinical trials after obtaining the approval of the ethics committees and notified to the Directorate General of Medical Devices". With this document The Italian Health Ministry confirms the international guidelines set by NASS, aligning to the worldwide trend of drastic reduction of the IPDs implant.

## Conclusions

The preservation of the physiological characteristics of the spine, which is the goal of motion preservation surgery, should particularly be aimed towards the whole motor unit intended to be responsible for the segmental movement. In the light of this, IPDs do not seem to respect the biomechanical characteristics of the motor unit, accelerating the degenerative process and worsening the clinical symptoms of patients. So this kind of device does not seem to have a definite and correct clinical indication at the moment. Despite this, IPDs with their main aim as the treatment of instability, have a restricted range of clinical indications and their use can definitely be a source both for the patient and the surgeon. In conclusion these implants must not become a trend but only a weapon in the surgeon's hands and, as with every weapon, is extremely dangerous in wrong hands. So the spinal surgeon is the only one who can decide when to use it and must know in detail the effects of this weapon to use it correctly with no damage for the patient.

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