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The Intraspine® in the Treatment of L5-S1 Degenerative Disc Disease. Preliminary Report

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Abstract

The L5-S1 spine segment is a common source of low back pain and sciatica . Because of the forces acting on this segment, as well as the range of motion it provides, it is susceptible to injury or degeneration. The use of the IntraSPINE® in the treatment of degenerative disease of the lumbar spine has already been evaluated and discussed in publications and scientific presentations. The specific aim of this study is to assess the clinical efficacy of the interlaminar device IntraSPINE®, used alone or in combination with other surgical procedure, for the treatment of degenerative disc disease in L5-S1 segment.

Material and methods: Between June 2011 and April 2015, an European prospective multi centric study was carried out on 48 patients (25 males and 23 females of average age 44.2) with back or back and leg pain, suffering from a pathologyonly at L5-S1 (39 cases) or with the involvement of the adjacent L4-L5 (9 cases). Patients with a congenital malformation of the lumbosacral segment were ruled out. All patients, except one who was treated as an emergency for acute cauda equina syndrome, were firstly submitted to conservative therapy for a mean of 14.5 months (2-22 months). Outcome measures (Visual Analogue Scale-back and leg pain-and Oswestry Disability Score Index) were measured preoperatively and at follow-up. The indication for surgery was massive herniated disc in 45%, facet arthropathy in 41%, stenosis in 12%, and 1 case showed a "black disk". In 94% of cases surgery was performed at a single level. The average operative time was 41 minutes and the mean length of hospitalisation was 2.5 days. There were no reported acute surgical complications. The minimum follow-up required by protocol was 3 months.

Results: All patients were followed-up with range from 3 to 48 months. VAS averages decreased from 7 to 2.5 (back) and 6.5 to 1.2 (leg) postoperatively. ODI fell from 54 to 16 (38 percent improvement).Two complications were observed: one recurrent disc herniation requiring re-operation and one pseudo-meningocele that required surgical dural repair.

Conclusions: The lumbosacral junction is a particularly complex area, where we can observe an high rate of acquired or congenital malformations of various types. The use of the interlaminar device must be preceded by an adequate assessment of the individual case in order to avoid making unnecessary or harmful surgery.In our experience, necessarily limited by the careful selection of cases, the results are encouraging but we need a larger case series to draw definite conclusion. Adding the measurement of the interspinous space represents a further improvement in the future Study development.

Keywords: *Interlaminar device; Lumbar Spine; Lumbosacral joint; Degenerative Disc Disease; Interspinous space; Biomechanics of Spine; Motion preservation*

Abbreviations: VAS: Visual Analogue Scale; ODI: Oswestry Disability Score Index; PET: pure polyethylene terephthalate; MRI: Magnetic Resonance Imaging; Ctscan: Computerised Tomography; MISS: minimally invasive spine surgery techniques; LSTV: Lumbosacral transitional vertebra; LRS: Lumbar rotoscoliosis ; SBO: Spina Bifida Occulta

Introduction

Back pain is one of the most common presenting complaints to Emergency Departments all over the world; 60-90% of the population will experience back pain in their lifetime. Back pain is second only to upper respiratory tract infection as a cause for lost work time. Over 5 million people are disabled with low back pain, which makes it the number one disability for workers less than 45 years old. [1-4]. The L5-S1 spine segment is a very common source of low back pain and sciatica . Because of the forces acting on this segment, as well as the range of motion it provides, it is susceptible to injury or degeneration.

Common causes of pain include disc herniation, disc degeneration, facet joint arthritis, spondylolisthesis, spondylosis, spondylolysis and spinal stenosis. Surgery is considered when conservative treatment has failed. Because of the functional and socioeconomic consequences of chronic low back pain, numerous surgical treatments to improve this condition have been attempted by spinal surgeons through the years [4].

A variety of "minimally invasive" procedures have been introduced including the positioning of the IntraSPINE®. This is a devicewith a unique interlaminar location, closer to the normal center of rotation, that may have mechanical advantages over traditional more posteriorly placed interspinous implants by allowing more physiological movement without blocking extension [5,6].

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 fibre has been proposed as synthetic intervertebral disc prosthesis. The combination of these materials represents a composite which mimics the architecture of the intervertebral disc and resembles its viscoelastic properties [5,7] and makes the device able of support/replace the function of the disc itself. The implant comes in variable height with an artificial ligament allowing the stabilization of the instrumented level. The use of the IntraSPINE® in the treatment of degenerative disease of the lumbar spine has already been evaluated and discussed in published papers [6, 8,9,10, 11].

The specific aim of this study is to assess the clinical efficacy of the IntraSPINE®, used alone or in combination with other surgical procedure, for the treatment of degenerative disc disease in L5-S1 segment.

Material and Methods

Between June 2011 and April 2015, an European prospective multi centric study was carried out on patients with symptomatic L5-S1 degenerative pathology undergoing typical surgical procedures s such as discectomy, decompression, foraminotomy in combination with the use of an IntraSPINE®.

Patients with a congenital malformation of the lumbosacral junction were excluded. Further exclusion criteria were: age under 18 years , pregnancy , infectious diseases current or recent (last 30 days). Furthermore patients were submitted to surgery only after a period of at least 2 months of conservative treatment.

Pre-operative evaluation included patient history, neurological examination specific to back/leg pain, imaging (X rays, MRI, CT scans) and instability. Surgical data such as type and duration of surgery or size of the implanted device and operative and postoperative complications were evaluated . Pre and postoperative outcome measures were recorded and included VAS (back pain and leg pain) and ODI. The minimum follow-up required by protocol was 3 months after discharge with maximum of 4 years post-operatively.

During the Study period 48 patients were included, 25 males and 23 females, average age 44.2 (range 20-69 years) with back or back and leg pain. The demographic data of the patient group are reported in Table 1.

TOTAL	SEX	AGE yrs	WEIGHT Kg	Conservative * Treatment months	Instability
48	25 M/23 F	Mean 44.2 (Range 20-69)	Mean 79.055 (Range 124-54)	Mean 14.5 (Range 2-22)	6 L5-S1 4 L4-L5 2

Table 1: *General Data in 48 patients.*

** Conservative treatment in 47 patients; 1 patients with cauda equina syndrome was treated as an emergency.*

With regard to the imaging 43 patients were submitted to Magnetic Resonance (MRI) alone and/or Computerised Tomography (CT scan) in 13 patients and static/dynamic X-rays in 23 patients. Four patients were investigated by means of dynamic X-rays. In 1 patient CT scan was the only one imaging technique used. The affected level was exclusively L5-S1 in 39 patients while in 9 cases there was involvement of the adjacent L4-L5 level.

With the exception of one patient with acute cauda equine syndrome who was treated as an emergency, all others (47/48 patients) underwent a period of conservative therapy for a mean of 14.5 months (range 2-22 months)before being submitted to surgery.

All patients were monitored with follow-up ranging from 3 to 48 months (mean follow-up 11 months). Researchers entered patient information and outcomes into a secure purpose designed online web-based database. The complete clinical data are showed in Table 2.

SYMPTOMS	DURATION OF SYMPTOMS	LEVEL	PREOPERATIVE VAS Average	PREOPERATIVE ODI Average
BACK & LEG 42 * BACK 5 OTHER 1 * *	Mean 23 months (range 1-96)	L5-S1 39 L5-S1 + L4-L5 9	Back 7 (range 10-2) Leg 6.5 (range 0-10)	54 (range 92-16)

Table 2: *Clinical Data in 48 patients.*

**In 3 cases associated with neurogenic claudicatio*

** 1 patient showed cauda equina syndrome*

Results and Discussion

Most patients complained of both back and leg pain (42/48 cases). Three patients had neurogenic claudication, 5 had back pain in isolation and one presented with acute cauda equina syndrome. Preoperative symptoms had a mean duration of 23 months (range 1-96 months). The indication for surgery was a large herniated disk in 22 patients (46%), facet arthropathy in 19 (39%), spinal stenosis in 6 (13%), and 1 case (2%) showed a "black disk". Six patients had radiological evidence of instability, 4 at the L5-S1 and 2 at L4-L5. The L5 spinous process was measured in 26 cases showing an average length of 19 mm, range 12-27 mm. With regard to the type of surgery all patients received the IntraSPINE®: 16 patients were subjected to simple application of the device while in the remaining cases it was also preceded to microdiscectomy (26), "recalibrage" (4) or foraminotomy (2).

The positioning of the interlaminar device, performed alone or at the same time of another procedure (microdiscectomy, "recalibrage" or foraminotomy) , was accomplished according to Guizzardi., *et al*. [10].

In 88% of cases (42 patients) the device was placed at a single level (L5-S1). In the remaining 6 patients the IntraSPINE® was implanted at a double level (L5-S1 and L4-L5), in two cases at the same time of a "recalibrage" and in 4 cases as the unique procedure . The average operative time was 40 minutes (range 25 -75 minutes) and the mean length of hospitalization was 2.5 days (range 2-4 days). No immediate surgical complication was observed. Surgical data are summarized in Table 3.

Type of SURGERY	Duration of SURGERY	Complication	Length of Hospitalization
Microdiscectomy + Device 26 Stand alone Device 16 Recalibrage + Device 4 Foraminotomy +Device 2	Mean 40 minutes (range 25-75)	None	Mean 2.5 days (range 2-4 days)

Table 3: *Surgical Data in 48 patients.*

VAS averages decreased from 7 to 2.5 (back) and 6.5 to 1.2 (leg) postoperatively. ODI fell from 54 to 16 (38 percent improvement). The type of surgery did not appear to affect the outcome. Clinical improvement was confirmed in all cases by a clinical evaluation including physical and neurological examination specific to back/leg pain. Two delayed complications were observed: one recurrent disc herniation requiring revision microdiscectomy and repositioning of the device; 1 pseudo-meningocele that required surgery for dural repair. No device-related complication was observed with particular reference to breakage , migration or infection. The results are reported in Table 4.

Length of Follow-up	VAS/ODI Average	Control Imaging	Delayed Complications	Device Related Complications
11.23 months (range 3-48 months)	VAS Back 2.5 VAS Leg 1.2 ODI 16	34 patients (12 MRI-11 CTscan and 11 Static/Dynamic X-rays)	2 *	None

Table 4: *Results.*
** 1 herniated disc recurrence; 1 delayed pseudomeningocele requiring dural repair.*

Discussion

Traditionally, the stepwise approach to spinal surgery for chronic lumbar back painsecondary to degenerative disc disease and osteoarthritis starts with local anaesthetic and steroid injection followed by spinal fusion. Fusion aims to alleviate pain by preventing movement between affected spinal segments; this commonly involves open surgery, which requires large soft tissue dissection with significant risk, morbidity and prolonged recovery time. Minimally invasive spine surgery techniques (MISS) such as laparoscopic anterior lumbar interbody fusion and MISS posterior instrumentation with pedicle screws and rods aim to reduce all these problems. Another consequence of spinal fusion is the disruption of the biomechanics of the rest of the spine which can lead to accelerated adjacent level disease [12]. Theoretically, this can be prevented by performing motion-preserving surgeries [4-11].

When contemplating surgery at the lumbosacral junction (L5-S1), two fundamental aspects should be considered :

A. The lumbosacral junction is a particularly complex area, where we can observe a high rate of acquired or congenital malformations of various types.
B. The forces acting on this segment, as well as the range of motion it provides, make it susceptible to injury or degeneration.

In 2002 Kamanli and Genc [13] reported a study population consisting of 503 healthy young male candidates for sports training. Lumbosacral transitional vertebral (LSTV) abnormalities were found in 37 (7%) of subjects and were unilateral in 14 (3%) subjects (lumbarisation/sacralisation). Lumbar rotoscoliosis (LRS) was present in 14 (3%) subjects and facet asymmetry in one subject. LSTV and LRS together were present in 3 subjects. Spina Bifida Occulta (SBO) was present in 107 of 503 candidates (21%). The distribution of SBO throughout vertebra levels was as follows: 86 only in S1, 11 in S1 + S2, 9 in L5, 1 in L5 + S1. SBO and LSTV were present together in 8 subjects. SBO and LRS were present together in three subjects. In 70% of cases, 356 subjects,imaging showeda normal lumbosacral junction.

More recently Apazidis., et al. [14] performed a Study on the prevalence of LSTV by reviewing 1100 abdominal films. Two hundred eleven subjects were identified as eligible for the study, and 75 (35.6%) were classified as positive for a transitional lumbosacral vertebra. The literature supports a 30% prevalence of some degree of segmentation anomaly at the lumbosacral junction. This anomaly may

contribute to incorrect identification of a vertebral segment, leading to wrong-level spine surgery and poor correlation with clinical symptoms [15].

Abnormal L5-S1 transitional anatomy has also been shown to be associated with altered L5-S1 articular morphology [16]

Spines with sacralized fifth lumbar vertebrae are quite commonly encountered. Sacralisation stiffens up the most caudal motion segment making the adjacent segment work harder increasing susceptibility to degenerative change resulting from the altered load-bearing patterns through this region [17].

In the US, the reported prevalence of a spondylolysis or pars fracture is 6% to 7%, with 11.3% of cases occurring at the L4-L5 level, and 82% occurring at the L5-S1 level [18]. It is therefore clear that the evaluation, management and role for surgical intervention inpatients with degenerative disease of the lumbosacral joint is controversial.

The two major concerns are the correct selection of the patients for surgery and the use of materials that have demonstrated a good mechanical behavior , in particular in terms of stress resistance and motion preservation.

In outlining the protocol of this study we have established very strict inclusion criteria according to which every major or minor malformation of the lumbosacral junction had to be excluded with absolute certainty. In doubtful cases fine cut CT imaging was used to define the bone anatomy.

The biomechanical characteristics of the IntraSPINE® have already been published. Specifically, the device resulted effective in reducing intradiscal pressure without limiting the extension motion [5].

About its clinical efficacy we must emphasize that in a retrospective study on patients with herniated disc operated on by microdiscectomy with or without the placement of the Intraspine® [8], Authors underlined the ability of the prosthesis to favorably influence the outcome as regard to the low back pain recurrence, and its capacity to prevent the rapid collapse of the disc space [11] also supporting the discal pump [19]. Other recent publications certify the good results of Intraspine® after failure of conservative therapy and as a first choice over more invasive surgical operations, especially in the first phases of degenerative cascade in order to slow down its natural evolution [9-11].

In particular, we must point out that in none of the cases of this series we have observed breakage or migration of the implant, thus it seems that the IntraSPINE® is adequate to support the mechanical stress imposed by this anatomical region.

For the sake of completeness we have to report a complication occurred outside of the Study time and therefore not included in this report. It was a patient in which about one year after surgery an ulcerated skin lesion appeared at the surgical site with an underlying non infected fluid collection, which required the device removal. Based on laboratory tests and histopathology we had to conclude that the collection was due to an inflammatory process due to local friction from an excessively mobile device, due to the inadequate size of the device itself.

This fact allows us to address one of the most important points of discussion: to prevent dislodgment of an interspinous spacer, the accurate depth and width of the interspinous space needs to be preoperatively established to facilitate the best intraoperative selection of correct spacer size both to prevent a change in lordosis and dislodgment of the spacer. This topic has recently been the subject of an interesting publication [20].

These preliminary results need to be verified and confirmed with further studies. A prospective study with a control group to evaluate the ability on the IntraSPINE to improve surgical outcomes in patients undergoing microdiscectomy, foraminotomy or “recalibrage” with or without the simultaneous implantation of the device itself should be taken into consideration .

Conclusion

The lumbosacral junction is a particularly complex area, where we can observe a high rate of both acquired or congenital malformations and pathologies The use of the interlaminar device must be preceded by an adequate assessment of the individual case in order to avoid making unnecessary or harmful surgery. In our experience, necessarily limited by the careful selection of cases, the results are encouraging but we need a larger case series ideally with a randomized control group to draw definite conclusions.

The second critical point is that, given the well-founded need to continue collecting data, it is necessary to insert a further parameter represented by the measure of the interspinous space. By adding this parameter, we will achieve a double objective: to carry out a selection of the size of the device on a rational and not empirical basis and to contribute to a statistical survey that will be useful later in the purchasing and production.

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Conflict of Interest

Giancarlo Guizzardi is receiving grant as inventor of the device Intraspine. The other Authors declare that they have no financial interest in the materials presented/discussesin this paper.

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