COUSIN SURGERY

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INTRASPINE®

Direct Link

SURGICAL OUTCOMES OF PATIENTS WITH DEGENERATIVE LUMBAR DISC DISEASE POST-INTRASPINE® DEVICE FIXATION: THREE-YEAR PROSPECTIVE STUDY

D. Co-Minh, C. Vajeu, L. Montron, C. E. W. Aylott, R. Boulkedid, H. Ralaihova, N. Wiel, F. Hénin, O. Zourabichvili, M. Lopes

International Journal of Clinical Case Reports and Reviews - 2021
DOI:10.31579/2690-4861/130

Background: Lumbar degenerative disc disease is one of the most common conditions associated with chronic low back pain. IntraSPINE® is a novel inter-laminar device that allows more physiological rocking-type movements in flexion and extension.

Aim: To evaluate the results of patients with symptomatic Lumbar degenerative disc disease treated with an IntraSPINE® device and followed up over a 3-year period.

Materials and Methods: A Prospective longitudinal research study involving patients with imaging-confirmed Lumbar degenerative disc disease in whom conservative treatment was unsuccessful. Outcome measures were changes over baseline score on the Oswestry Disability Index (ODI), and low back and radicular pain assessed at 6, 12, 24 and 36 months postoperatively. Overall success, a composite outcome that included key safety and clinical considerations, was assessed. Secondary outcomes included satisfaction with symptoms, employment status and post-surgery medical interventions. To compare differences in longitudinal clinical score patterns over 36 months, a mixed-effect model ANCOVA with repeated measurements was performed, with adjustment for low back and radicular pain score and ODI score at baseline.

Results: 231 patients were recruited and 180 completed the study. A significant improvement in ODI score ($p=0.0597$), as well as in VAS (Visual Analogue Scale) scores for back ($p= 0.0228$) and leg pain ($p<0.0001$) was observed during the follow-up. For ODI score, the mean percentage decrease from inclusion to month 36 was 64.5%. These scores were respectively 66.2% for radicular pain and 46.4% for low back pain. In 73% of cases, surgery was considered successful. 89% of working patients returned to work and 68% of patients were very satisfied at month 12. Only four patients presented intraoperative complications.

Conclusion: Patients treated with IntraSPINE® showed significant and clinically meaningful improvements in disability and pain for up to 36 months. The results of this study also demonstrated very satisfactory safety data.

Key points:

- **IntraSPINE® reduces postoperative leg and back pain**
- **IntraSPINE® allows improvement in disability**
- **IntraSPINE® induces very satisfactory safety data**

Direct Link

LUMBAR MICRODISCECTOMY WITH INTRASPINE® – A CASE SERIES

CL. Gelder, M. Drozda, G. Spink

Columna - 2020
DOI: 10.1590/S1808-185120201903207243

Objective: To assess postoperative outcomes following lumbar microdiscectomy (LMD) with and without the use of a dynamic intralaminar device IntraSPINE®.

Methods: A non-randomized single-surgeon retrospective analysis. Consecutive elective surgery was performed on patients with lumbar disc disease over a 16-month period. The study group was determined by electronic theatre database. Ninety-two (62 LMD and 30 ILD) of the 95 eligible patients were included in the study, with three being excluded due to incomplete data sets. The pain scores were assessed pre- and postoperatively using a 4-point scale (0 – pain free; 1 – mild; 2- moderate; 3 – severe).

Results: The reduction in postoperative leg pain was similar (LMD 1.9 vs. IntraSPINE® 1.8) but the reduction in postoperative back pain was greater in the IntraSPINE® group (LMD 0.5 vs. IntraSPINE® 1.0; p = 0.17). Early recurrence of disc herniation (< 8 months) was lower in the IntraSPINE® group (6.7% vs. 19.4%; p = 0.097). The need for revision surgery was significantly lower in the IntraSPINE® group (p = 0.015). None of the IntraSPINE® recurrences required revision surgery, compared to 97% of the recurrences in the LMD group.

Conclusion: This case series raises the possibility that in selected patients, the use of the IntraSPINE® may improve back pain and reduce recurrent disc herniation/ revision surgery rates in lumbar microdiscectomy. A prospective randomized trial on the use of the IntraSPINE® should be considered, given the clinical and cost implications of revision surgery.

Key points:

- **IntraSPINE® reduces postoperative leg and back pain**
- **IntraSPINE® reduces recurrent disc herniation rate**
- **IntraSPINE® reduces revision surgery rate**

Direct Link

THE LIKELIHOOD OF REACHING SUBSTANTIAL CLINICAL BENEFIT AFTER AN INTERLAMINAR DYNAMIC SPACER FOR CHRONIC LOW BACK PAIN: A CLINICAL AND RADIOLOGIC ANALYSIS OF A PROSPECTIVE COHORT

J. Bae, SM. Lee, SH. Lee, SH. Shin, HJ. Kim, K. Hwan Kim

WORLD NEUROSURGERY - 2017
http://dx.doi.org/10.1016/j.wneu.2017.02.083

Introduction: Chronic low back pain (CLBP) often causes disabling pain that impairs a patient's quality of life. Surgical treatment is recommended for patients who do not respond to conservative treatments lasting more than 6 months. The purpose of this study is to present results after the use of an interlaminar dynamic spacer for CLBP.

Material and methods: We enrolled consecutive patients with CLBP irresponsive to more than 6 months of conservative treatment into the present study. Included patients underwent an interlaminar dynamic spacer insertion without direct decompression. We assessed radiographic parameters and health-related quality of life (HRQoL) data included visual analog scale back/leg pain and Oswestry Disability Index scores. Substantial clinical benefit achievement was assessed.

Results: Thirty-five patients (average age, 47.8 years; 21 female) were included. The mean preoperative symptom duration was 29.6 months. Surgeries involved 1-level (n =18) and 2-levels (n = 17) procedures. Operative levels included L4-5 (n = 8), L5-S1 (n = 10), L3-4-5 (n-2), and L4-5-S1 (n =15). The average follow-up period was 16.6 months. After the procedure, all radiographic parameters (including disc height, segmental extension angle, and foraminal area) improved significantly. All preoperative HRQoL parameters improved significantly at the final follow-up. Substantial clinical benefit achievement was observed in 75.8% of the cases on the Oswestry Disability Index, and in 72.7% and 84.8% of the cases on the visual analog scale back and leg pain, respectively.

Conclusion: An interlaminar dynamic spacer significantly improves HRQoL scores in patients with CLBP who do not respond to conservative treatment. Although encouraging, these results should be confirmed with studies assessing a larger cohort and a longer follow-up.

Key points:

- **IntraSPINE® improves the quality of life**
- **IntraSPINE® decreases back pain (VAS reduction) and improves mobility (ODI reduction)**
- **IntraSPINE® restores disc height and limits excessive extension (restabilizes)**
- **IntraSPINE® reduces loads on the facets joint, reduces intervertebral pressure (disc) and open the foramen (by distracting the spinous processes) which indirectly decompresses nerve tissue**

Direct Link

LOOKING AT THE FUTURE OF MOTION PRESERVATION SURGERY IN THE LUMBAR SPINE WITH THE EXPERIENCE OF THE PAST

G. Guizzardi

Global Spine Journal - 2016
DOI: 10.1055/s-0036-1582979

Introduction: In the 1970's, Kirkaldy-Willis first described the "Degenerative Cascade" of DDD. Observation of demographic studies shows more back pain in younger adults (30 to 50 years) than in elderly adults (over 60 years) in which osteoarthritis problems are prevalent to disc problems. The aim of this study is to demonstrate if and when an interlaminar elastic motion preservation device for disc assistance can stop or reverse the degenerative cascade of the lumbar spine in younger adults. We used in this study a new motion preservation device not interspinous but interlaminar. The IntraSpine® device (Cousin Biotech, France), is manufactured in medical silicon 65 shore coated by an adherent pure polyester terephtalate sleeve and the frontal extremity is further covered by a silicone film that prevents adhesion to the neural structures in cases of surgical bone or soft tissue removal.

Material and Methods: Group 1: 60 patients (mean age 34.5 years, 38 female an 22 male) affected from back pain from a minimum time of two years and after the failure of conservative treatment for at least 6 months, received a minimally invasive surgical procedure implanting this IntraSPINE® device at one or two levels. Group 2: 54 patients (mean age 32,6 years, 24 male and 16 female) affected from big extruded disc hernia received the some implant after the removal of the hernia in the some surgical procedure at one level, to prevent the subsequent chronic LBP due to a rapid collapse of the disc height. From the literature we know that in this young group of patients the percentage of the chronic LBP in the late follow up (5 years) it's ~70%. The results with a minimum follow-up of 4 years were evaluated from the clinical point of view regarding the LBP with VAS and ODI tests. All patients were also subjected to an MRI control. The surgical procedure was performed by monolateral approach and in many cases in local anesthesia in group 1 and in general anesthesia and equally by monolateral approach in group 2. The source of the pain in this group of patients (facet joint pain) was demonstrated by a positive response to the facet joint block test (The response was considered positive for a transient reduction of pain at least of 70%). Prior to surgical procedure, all patients underwent an MRI, a CT Scan and a dynamic X-ray of the lumbar spine. The stage of the degenerative cascade was between grade III and IV according to Pfirrmann.

Direct Link

LOOKING AT THE FUTURE OF MOTION PRESERVATION SURGERY IN THE LUMBAR SPINE WITH THE EXPERIENCE OF THE PAST

G. Guizzardi

Global Spine Journal - 2016
DOI: 10.1055/s-0036-1582979

Results: Group 1: In ~20% also in presence of good clinical results we highlighted a moderate progression of the cascade, in about the 50% the Pfirrmann grade was unchanged, but in ~30% we highlighted a partial rehydration of the disc which means a initial reversion of the degenerative cascade (patients with the lower grades of degeneration). Group 2: the percentage of a very uncomfortable LBP in this group was 24%, and the number of the recurrences was 2 (5%) and in only 1 case we performed a new surgical procedure. The maximum amount of blood lost in both group was 80 cc and the mean time of the surgical procedure was 28 minutes (from 18 to 37) in the group 1 and 41 minutes (from 34 to 46) in the group 2.

Conclusion: The close observation of the right indications and the proper selection of patients is strictly recommended. The mininvasive and relatively easy surgical procedure do not induce the surgeons of an indiscriminate use of this device. The wrong level implant is the mast frequent mistake. From the observation of these very important points we believe that are obtained this very good results even should be necessary a big number of case study, a longer follow up and a randomized multicenter study. 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 prevent that this disease from acute becomes chronic, and thus its natural progression. Last but not least if we performed this surgical procedure in the earliest stages of the degenerative cascade, we can reverse its trend.

Key points:

- **IntraSPINE® leads to a partial rehydration of the disc**
- **IntraSPINE® reduces/stops the degenerative cascade, in particular when the device is implanted in the initial stages of the disease**

Direct Link

CLINICAL RESULTS WITH INTRASPINE®

G. Guizzardi, R. Morichi

EC Orthopaedics - 2015

Introduction: 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.

Key points:

- **IntraSPINE® allows improvement in disability (improvement of 74% of ODI score)**
- **IntraSPINE® reduces the pain (reduction of 71% and 87% for back and leg pain respectively)**
- **IntraSPINE® reduces/stops the degenerative cascade, in particular when the device is implanted in the initial stages of the disease**

Direct Link

THE INTRASPINE® IN THE TREATMENT OF L5-S1 DEGENERATIVE DISC DISEASE - PRELIMINARY REPORT

C. Aylott, JM. Cabezudo, G. Guizzardi, R. Morichi, M. Lopes

Orthopaedics - 2015

Introduction: 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 pathology only 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.

Direct Link

THE INTRASPINE® IN THE TREATMENT OF L5-S1 DEGENERATIVE DISC DISEASE.PRELIMINARY REPORT

C. Aylott, JM. Cabezudo, G. Guizzardi, R. Morichi, M. Lopes

Orthopaedics - 2015

Conclusion: 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.

Key points:

- **IntraSPINE® reduces back and leg pain (VAS reduction)**
- **IntraSPINE® improves mobility (ODI reduction**
- **IntraSPINE® is a safe treatment**
- **IntraSPINE® is an efficient treatment for DDD in L5-S1 segment**

Direct Link

COMBINATION OF INTRASPINE INTERLAMINAR DEVICE WITH LUMBAR DISCECTOMY IN PATIENTS WITH L5/S1 DISC HERNIATION

S. Feng, Z. Fan, X. Li, J. Lin, Y. Yang, Q. Fei

Research Square - 2020
DOI: 10.21203/rs.3.rs-64740/v1

Background: It is commonly recognized that interspinous spacers were not generally suitable for the application in L5-S1 level due to the short S1 spinous process. In this retrospective study, the feasibility and validity of the IntraSpine® interlaminar device in the treatment of lumbar disc herniation on the L5/S1 level were evaluated.

Methods: During the January 2018 and December 2018, a total of 30 patients, who were hospitalized in our hospital due to lumbar disc herniation (LDH) on the L5/S1 level, were included in the current study. The clinical symptoms before surgery, post-operation (3 days after surgery), 6 months after surgery, 12 months after surgery, and final follow-up were assessed using the back and leg visual analog scale (VAS), Oswestry disability index (ODI). Sagittal diameter of the lumbar spinal canal (SD), posterior disc height (PDH), left and right foramina height (LFH and RFH), left and right foramina width (LFW and RFW) were measured by sagittal reconstructions of CT scans. The range of motion (ROM) of L5-S1 level was estimated by lumbar dynamic X-ray images.

Results: The back VAS, leg VAS, ODI, were significantly improved after surgery ($P<0.05$). The SD, PHD, LFH, RFH, LFW, and RFW after the operation and in the follow-up period were statistically different from those before surgery ($P<0.05$). The ROM of L5/S1 level at final follow-up was not statistically different from that before surgery ($P = 0.299$). 93.3% of patients demonstrated successful outcomes.

Conclusion: The combination of IntraSpine® interlaminar device with lumbar discectomy is an effective minimally invasive procedure for the treatment of L5/S1 disc herniation, which can delay and prevent the reduction of the disc height after discectomy in L5/S1 segment.

Key points:

- **IntraSPINE® is an effective minimally invasive procedure for the treatement of L5-S1 disc herniation**
- **IntraSPINE® prevents the reduction of disc height after discectomy**

Direct Link

CLINICAL RESULTS WITH INTRASPINE®

G. Guizzardi, R. Morichi

EC Orthopaedics - 2015

Introduction: 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.

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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.

Key points:

- **IntraSPINE® allows improvement in disability (improvement of 74% of ODI score)**
- **IntraSPINE® reduces the pain (reduction of 71% and 87% for back and leg pain respectively)**
- **IntraSPINE® reduces/stops the degenerative cascade, in particular when the device is implanted in the initial stages of the disease**

Direct Link

LUMBAR HERNIATED DISC TREATED BY MICRODISCECTOMY ALONE OR MICRODISCECTOMY PLUS AN INTERLAMINAR SHOCK ABSORBING DEVICE: RETROSPECTIVE STUDY WITH MINIMUM 3-YEARS FOLLOW-UP

OV. Corriero, R. Morichi, A. Vagaggini, L. Paoli, G. Guizzardi

Journal of Spine - 2014
DOI:10.4172/2165-7939.1000159

Introduction: The long-term results after surgery for symptomatic lumbar herniated disc have been found to have a low success rate in about one third of patients (30% to 40% according to different Authors) who report low back pain rather uncomfortable and restrictive. Nevertheless the long-term results have been scarcely investigated. The aim of this paper is to investigate the long-term results after surgery for lumbar herniated disc in two groups of patients receiving different surgical treatments.

Material and methods: A retrospective study has been performed, on a series of 89 consecutive patients, affected by lumbar herniated disc, receiving different surgical treatments: a simple microdiscectomy (Group A: 45 cases) or a microdiscectomy associated with the implantation of an interlaminar prosthesis (Group B:44 cases). General and clinical data resulted homogeneously distributed in both Study Groups.

Results: The follow-up ranged from 3 to 5 years. An independent observer was able to evaluate all patients but one, out of the Group B, who resulted lost to follow-up. Two recurrences resulted in Group A (4,4%) and 1 in Group B (2,2%). The comparison between the 2 Study Groups showed the absence of low back pain during the follow-up period in 74% of patients who received the implant while patients treated by means of simple standard microdiscectomy remained pain free only in 41%. Furthermore uncomfortable low back pain was registered in 21% of patients of Group B against 51% out of Group A. As regards to Macnab Criteria evaluation, that expresses the Quality of Life, 71% of patients resulted Excellent and 22% Good in the Group B, while in the Group A 40% were Excellent and 20% Good. In both groups no poor results were observed.

Conclusion: The number of patients included in this experience is limited and there is a need for a larger series to confirm observations and results, nevertheless we can affirm the goodness of the path undertaken.

Key points compared to microdiscectomy alone::

- **IntraSPINE® is a more efficient treatment than simple microdiscectomy in patients affected by lumbar hernatied disc:**
- **IntraSPINE® reduces low back pain (in 74% of patients) more effectively than simple microdiscectomy (pain free in only 41% of patients)**
- **IntraSPINE® improves quality of life more than simple microdiscectomy**

Direct Link

MICRODISCECTOMY WITH AND WITHOUT INSERTION OF INTERSPINOUS DEVICE FOR HERNIATED DISC AT THE L5-S1 LEVEL

M. Galarza, R. Gazzeri, P. De la Rosa, JF. Martínez-Lage

Journal of Clinical Neuroscience - 2014
DOI: 10.1016/j.jocn.2014.02.029
Level of evidence: Grade B

Introduction: The role of interspinous devices (ISD) after lumbar herniated disc surgery for the prevention of postoperative back pain is controversial. The aim of this comparative prospective study was to determine outcomes in a selective cohort with L5-S1 disc herniation and degenerative disc changes after microdiscectomy with or without insertion of an ISD.

Material and methods: One hundred and two consecutive patients underwent an L5-S1 microdiscectomy with or without implantation of an ISD. Group 1 consisted of 47 patients, with mild (n = 22), moderate (n = 14) or severe (n = 11) degenerative disc changes who had microdiscectomy alone. Group 2 comprised 45 patients with similar types of disc changes who underwent microdiscectomy with an ISD implant. The Visual Analogue Scale (VAS) was used to grade low-back pain and postoperative clinical status was rated according to the modified MacNab criteria.

Results and conclusions: Mean VAS score for low-back pain improved significantly at 1 year follow-up from 7.3 at baseline to 2.75 ($p < 0.001$) in Group 1 and from 6.7 to 1.5 ($p = 0.001$) in Group 2. VAS score at 1 year showed significant improvements in 21 Group 1 patients versus 30 Group 2 patients ($p = 0.001$). Forty four percent of Group 1 patients and 80% of Group 2 patients showed improvement using the modified MacNab criteria. Patients in both groups reported significant improvement in sciatic pain and disability after microdiscectomy with or without an ISD implant. Patients with mild degenerative disc changes were more likely to achieve improvement of their low-back pain when treated with both microdiscectomy and ISD insertion.

Key points compared to microdiscectomy alone::

- **IntraSPINE® is a more efficient treatment than simple microdiscectomy in patients affected by lumbar hernatied disc:**
- **IntraSPINE® reduces low back pain (in 30 patients) more effectively than simple microdiscectomy (in 21 patients)**
- **IntraSPINE® improves quality of life more than simple microdiscectomy**
- **IntraSPINE® reduces sciatic pain**
- **IntraSPINE® improves mobility**
- **Patients with mild degenerative disc changes were more likely to achieve improvement of their low-back pain when treated with both microdiscectomy and IntraSPINE® insertion**

Direct Link

INTRASPINE®, AN INTERLAMINAR, NOT INTERSPINOUS, POSTERIOR MOTION PRESERVATION DEVICE IN LUMBAR DDD: INDICATIONS AND CLINICAL RESULTS (OVER 2 YEAR FOLLOW-UP)

Drs. G. Guizzardi, R. Morichi, S. Pradella, B. Piccardi, E. Amoruso, M. Ceccarelli, C.M. Mattioli, M. Spezia, and P. Petrini

Neurocirugía-Neurocirurgia - 2011

Background & Aim: 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 interlaminar (IntraSPINE®) device in motion preservation in the treatment of lumbar DDD.

Material and methods: 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.

Results & Conclusion: 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 points:

- **IntraSPINE® reduces chronic low back pain (VAS reduction)**
- **IntraSPINE® improves mobility (ODI reduction)**
- **IntraSPINE® is an efficient treatment for facet joint syndrome, extruded disc herniation and soft stenosis**
- **IntraSPINE® surgical technic is simple and has a low learning curve**
- **IntraSPINE® MIS technic using monoliteral approach is safe with bleeding reduction**
- **IntraSPINE® is a cost-effective alternative treatment (Reduction of hospital stay and costs)**

Direct Link

APPLICATION OF THE INTRASPINE® INTERLAMINAR DEVICE IN PATIENTS WITH OSTEOPOROSIS AND SPINAL STENOSIS: TWO CASE REPORTS

KL.Yeh, SH. Wu and SS. Wu

Journal of International Medical Research - 2021
DOI: 10.1177/03000605211049961

Introduction: Osteoporosis is a rising concern in the aging population and should be considered before performing spinal surgery for older patients. Nonfusion surgery using interlaminar or interspinous devices is gradually gaining acceptance because adjacent segment disease seldom occurs postoperatively; however, other complications may occur.

Material and methods: This report discusses the surgical outcomes of two women with osteoporosis treated by laminectomy and interlaminar device (IntraSPINE®) placement.

Results: Both patients had experienced low back pain for several years and had developed vertebral compression fractures. Several conservative treatments, including rehabilitation and local injections, were ineffective. Their bone mineral density levels were -3.0 and -2.8, indicating severe osteoporosis according to the definition established by the World Health Organization. They chose to undergo nonfusion surgery with IntraSPINE® interlaminar device placement. Their pain significantly decreased postoperatively, and their visual analog scale scores decreased from 8 to 2 and 3. Their extremity numbness and back pain resolved within 3 months. Both patients were satisfied with the surgical outcomes. No complications had occurred by 1 year postoperatively.

Conclusion: These cases indicate that osteoporosis may not be an absolute contraindication for nonfusion spinal surgery. This report suggests a possible alternative surgical treatment for patients with osteoporosis that is refractory to conservative treatments.

Key points:

- **IntraSPINE® reduces back and thigh pain (VAS reduction)**
- **IntraSPINE® improves mobility and enables the patient to resume her usual activities**
- **IntraSPINE® is suitable for elderly patients with severe osteoporosis**

Direct Link

CLINICAL RESULTS WITH INTRASPINE®

G. Guizzardi, R. Morichi

EC Orthopaedics - 2015

Introduction: 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.

Key points:

- **IntraSPINE® allows improvement in disability (improvement of 74% of ODI score)**
- **IntraSPINE® reduces the pain (reduction of 71% and 87% for back and leg pain respectively)**
- **IntraSPINE® reduces/stops the degenerative cascade, in particular when the device is implanted in the initial stages of the disease**

Direct Link

INTRASPINE®, AN INTERLAMINAR, NOT INTERSPINOUS, POSTERIOR MOTION PRESERVATION DEVICE IN LUMBAR DDD: INDICATIONS AND CLINICAL RESULTS (OVER 2 YEAR FOLLOW-UP)

Drs. G. Guizzardi, R. Morichi, S. Pradella, B. Piccardi, E. Amoruso, M. Ceccarelli, C.M. Mattioli, M. Spezia, and P. Petrini

Neurocirugía-Neurocirurgia - 2011

Background & Aim: 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 interlaminar (IntraSPINE®) device in motion preservation in the treatment of lumbar DDD.

Material and methods: 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.

Results & Conclusion: 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.

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- **IntraSPINE® is a cost-effective alternative treatment (Reduction of hospital stay and cost)**

Direct Link

SURGICAL OUTCOMES OF PATIENTS WITH DEGENERATIVE LUMBAR DISC DISEASE POST-INTRASPINE® DEVICE FIXATION: THREE-YEAR PROSPECTIVE STUDY

D. Co-Minh, C. Vajeu, L. Montron, C. E. W. Aylott, R. Boulkedid, H. Ralaihova, N. Wiel, F. Hénin, O. Zourabichvili, M. Lopes

International Journal of Clinical Case Reports and Reviews - 2021
DOI:10.31579/2690-4861/130

Background: Lumbar degenerative disc disease is one of the most common conditions associated with chronic low back pain. IntraSPINE® is a novel inter-laminar device that allows more physiological rocking-type movements in flexion and extension.

Aim: To evaluate the results of patients with symptomatic Lumbar degenerative disc disease treated with an IntraSPINE® device and followed up over a 3-year period.

Materials and Methods: A Prospective longitudinal research study involving patients with imaging-confirmed Lumbar degenerative disc disease in whom conservative treatment was unsuccessful. Outcome measures were changes over baseline score on the Oswestry Disability Index (ODI), and low back and radicular pain assessed at 6, 12, 24 and 36 months postoperatively. Overall success, a composite outcome that included key safety and clinical considerations, was assessed. Secondary outcomes included satisfaction with symptoms, employment status and post-surgery medical interventions. To compare differences in longitudinal clinical score patterns over 36 months, a mixed-effect model ANCOVA with repeated measurements was performed, with adjustment for low back and radicular pain score and ODI score at baseline.

Results: 231 patients were recruited and 180 completed the study. A significant improvement in ODI score ($p=0.0597$), as well as in VAS (Visual Analogue Scale) scores for back ($p= 0.0228$) and leg pain ($p<0.0001$) was observed during the follow-up. For ODI score, the mean percentage decrease from inclusion to month 36 was 64.5%. These scores were respectively 66.2% for radicular pain and 46.4% for low back pain. In 73% of cases, surgery was considered successful. 89% of working patients returned to work and 68% of patients were very satisfied at month 12. Only four patients presented intraoperative complications.

Conclusion: Patients treated with IntraSPINE® showed significant and clinically meaningful improvements in disability and pain for up to 36 months. The results of this study also demonstrated very satisfactory safety data.

Key points:

- **IntraSPINE® reduces postoperative leg and back pain**
- **IntraSPINE® allows improvement in disability**
- **IntraSPINE® induces very satisfactory safety data**

Direct Link

CLINICAL RESULTS WITH INTRASPINE®

G. Guizzardi, R. Morichi

EC Orthopaedics - 2015

Introduction: 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.

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Direct Link

INTRASPINE®, AN INTERLAMINAR, NOT INTERSPINOUS, POSTERIOR MOTION PRESERVATION DEVICE IN LUMBAR DDD: INDICATIONS AND CLINICAL RESULTS (OVER 2 YEAR FOLLOW-UP)

Drs. G. Guizzardi, R. Morichi, S. Pradella, B. Piccardi, E. Amoruso, M. Ceccarelli, C.M. Mattioli, M. Spezia, and P. Petrini

Neurocirugía-Neurocirurgia - 2011

Background & Aim: 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 interlaminar (IntraSPINE®) device in motion preservation in the treatment of lumbar DDD.

Material and methods: 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.

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** final scores*

Key points:

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- **IntraSPINE® is a cost-effective alternative treatment (Reduction of hospital stay and costs)**

Direct Link

NEW COMBINATION OF INTRASPINE DEVICE AND POSTERIOR LUMBAR INTERBODY FUSION FOR RARE SKIPPED-LEVEL LUMBAR DISC HERNIATION: A CASE REPORT AND LITERATURE REVIEW

S. Feng, Z. Fan, J. Ni, Y. Yang and Q. Fei

Journal of International Medical Research - 2020
DOI: 10.1177/0300060520949764

Background: Posterior lumbar interbody fusion is an open surgical technique that has been widely used for the treatment of degenerative lumbar disease. However, traditional lumbar spinal fusion, especially long-segment fusion surgery, is associated with several complications.

Methods: The IntraSPINE® (Cousin Biotech, Wervicq-Sud, France) is a new device for non-fusion lumbar spine surgery that is used as an alternative for the treatment of degenerative lumbar disease.

Results: Although the designer of the IntraSPINE® proposed indications for its use, including combination of the device with lumbar spinal fusion for the treatment of degenerative lumbar disease, use of the IntraSPINE has not been reported in the clinical literature.

Conclusion: In the present case, we boldly combined the IntraSPINE® device and posterior lumbar interbody fusion for the treatment of skipped-level lumbar disc herniation to explore the indications of the IntraSPINE® and report its clinical outcomes.

Key points:

- **IntraSPINE® is an efficient option for the topping off technique to a PLIF**
- **IntraSPINE® maintains the stability of the lumbar spine**
- **IntraSPINE® preserves the motion of the spine to prevent the occurrence of ASD with minimal trauma and bleeding**

Direct Link

INTERLAMINAR LUMBAR DEVICE IMPLANTATION IN TREATMENT OF BAASTRUP DISEASE (KISSING SPINE)

K. Mostofi, B. Gharaei Moghadam, M. Peyravi

Journal of Craniovertebral Junction and Spine - 2018
DOI: 10.4103/jcvjs.JCVJS_139_17

Introduction: Baastrup disease (BD) is characterized by the degenerative changes of spinous processes and interspinous soft tissues. It is more common among aged persons. This disorder is a relatively common cause of low back pain. Its incidence is underestimated. A few studies have investigated BD epidemiology and proposed treatment efficacy. The aim of this paper is to establish impact and outcome evaluations of managing the patients with Baastrup disease who have been treated by implementing of floating interlaminar device (FID).

Material and method: Between January 2015 and September 2017, 47 patients have been operated by implementing of FID for BD in our Department of Neurosurgery.

Results: Of the 47 patients, 20 were female and 27 were male with an average age of 51.78. On average, we followed the cases up to 11 months. The most frequent level of disorder was L4-L5 followed by L3-L4 level. The condition of 45 patients improved after surgery according to Oswestry low back pain score and 39 patients could return to their work.

Conclusion: The results from our study corroborate that implementing of FID is a good alternative treatment for patient chronic low back pain due to BD This technique contributes to improving a better living situation for the patients given the correct indications.

Key points:

- **IntraSPINE® (Floating interlaminar device) is an effective surgical treatment for Baastrup disease**
- **IntraSPINE® reduces pain (VAS reduction) and improves mobility (ODI reduction) at 4 weeks and up to 11 months-follow up**

Direct Link

BIOMECHANICAL EFFECT OF AN INTERLAMINAR DEVICE ON RANGES OF MOTION, INTRADISCAL PRESSURE, AND CENTERS OF ROTATION

G. Guizzardi, S. Persohn, S. Campana, C. Aylott, P. Petrini, and W. Skalli

The Open Access Journal of Science and Technology 3 - 2015
DOI:10.11131/2015/101160

Introduction: The IntraSPINE® is a new interlaminar device that has been proposed with the aim to decompress the spinal canal without reducing the extension motion. The purpose of this study was therefore to evaluate the biomechanical behavior of L4-L5 spinal units implanted with this interlaminar device, in terms of ranges of motion, intradiscal pressure, and centers of rotation.

Material and Methods: Six human lumbar spines were harvested within 10 days after death. A specific spine testing device was used to apply moments up to 10 Nm in flexion-extension, lateral bending (left-right flexion) and left-right axial rotation (torsion), with measurement of vertebral 3D motion and of intervertebral disc pressure. Protocol was repeated for each specimen in 5 configurations: intact specimen; after L4-L5 bilateral medial hemifacetectomy and both yellow ligament resection; after implantation of the interlaminar device at the L4-L5 level; after removal of the L4-L5 supraspinous ligament, resection of the posterior third of the disc and addition of an artificial ligament; after device and artificial ligament removal.

Results: The implant reduced increases in segmental flexion seen following injury particularly when applied with the artificial ligament. Intradiscal pressure reduced following application of the implant without reducing extension range. A small posterior shift of the Mean Centers of Rotation (MCR) was noticed after instrumentation. Torsion and lateral bending range was unaffected by the interlaminar device.

Conclusion: This biomechanical study yields a better understanding of this interlaminar implant effect. A large clinical trial with follow-up would be required to evaluate and confirm in vivo the observed in vitro biomechanical behavior of the device.

Key points:

- **IntraSPINE® has a unique anterior location**
- **IntraSPINE® reduces intradiscale pressure (particularly when artificial ligament is applied)**
- **IntraSPINE® does not limit extension range**

Direct Link

BIOMECHANICAL CONSIDERATION ON POSTERIOR MOTION PRESERVATION SYSTEMS

G. Guizzardi, P. Petrini

Columna - 2011

Introduction: In the last few years the market has been literally invaded by interspinous/interlaminar systems for motion preservation. The type of material, the surgical technique and moreover the placement of these devices (interspinous or interlaminar) substantially influence the ROM, but in different ways. The authors, that have been using these devices for about 10 years, analyse both the segmental mobility and the sagittal balance after these devices have been implanted.

Material and Methods: We resent a new device (IntraSPINE®) for the treatment of the degenerative pathology of the lumbar spine. The device, in medical silicone 65 shore coated by a pure polyester therepthalate sleeve, has with respect to other posterior devices, the advantage that it may be implanted more anteriorly (interlaminar) and thus gets placed even closer to the centre of instantaneous rotation of the segment. The difference in compression ratio between the anterior and posterior parts of the device, do not limit the ROM.

Results: The results are undoubtedly in favour of interlaminar rather than interspinous systems and this seems obvious if we consider simply the different distances of the two types of implants from the axis of instantaneous rotation. The path we must take has yet to come to an end, but the consciousness and understanding of this data by all those who use these devices appears fundamental for their correct use, but most of all so that the correct system be used for the various situations.

Conclusion: We nevertheless feel we should recommend the use of this device after failure of conservative treatment, as a first choice over more invasive surgical operations and especially in the first phases of degenerative cascade in order to slow down its natural evolution.

Key points:

- **IntraSPINE® does not limit extension and controls flexion by moderately limiting it and consequently unloading the pressure on the disc**
- **IntraSPINE® reduces intradiscale pressure**

Direct Link

EVALUATION OF EFFECT OF POSTERIOR DYNAMIC STABILIZATION INTRASPINE® SYSTEM ON SAGITTAL SPINAL BALANCE USING EOS® X- RAY IMAGING SYSTEM

S. Bistazzoni, M. De Angelis, M. D'ercole, C. Chiaramonte, A. Carotenuto, G. Cardarelli, F. Ricciardi, G. Innocenzi and G. Guizzardi

J Neurol Neurophysiol - 2017
DOI:10.4172/2155-9562.1000439

Introduction: Aim of this prospective study is to assess the effect of posterior dynamic stabilization IntraSPINE system on sagittal spinal balance, using EOS® X-Ray imaging system.

Material and method: Between March and December 2015, 8 patients affected by lumbar soft stenosis underwent indirect decompression of the lumbar canal by positioning of IntraSPINE® device. Sagittal balance was evaluated considering following parameters: C7 Plum Line (C7PL), Thoracic Kyphosis (TK), Lumbar Lordosis (LL), Pelvic Tilt (PT), Pelvic Index (PI) and Sacral Slope (SS). The EOS® 2D/3D system and corresponding sterEOS 3D software for surface 3D reconstruction has been used to calculate the above mentioned parameters. All patients had neurogenic claudication and low back pain for more than 6 months and resistant to drug treatment. They underwent clinical examination before surgery and 1 month after surgery. Statistical analyses were performed using Stata software. All results were considered significant if $p<0.05$.

Results and conclusion: C7PL, TK, LL, PI and SS were not modified after surgery. PT increased after surgery. VAS, ODI and JOA significantly increased after surgery. The results show that the posterior dynamic stabilization offered by this device leads to a good symptoms control and does not seems to change the sagittal balance.

Key points:

- **IntraSPINE® reduces pain (VAS reduction) and improves mobility (ODI reduction)**
- **IntraSPINE® does not impact the sagittal balance**
- **IntraSPINE® controls symptoms after surgery**



BDYN

Direct Link

SURGICAL TIPS FOR THE IMPLANTATION OF BDYN DYNAMIC STABILIZATION SYSTEM: COMBINING SPINAL NAVIGATION WITH MOTION PRESERVATION FOR LOW-GRADE LUMBAR DEGENERATIVE SPONDYLOLISTHESIS

N. Serratrice, B. Tarabay, J. Faddoul, G. N. Abi Lahoud

Acta Neurochirurgica - 2023
DOI: 10.1007/s00701-023-05716-1

Background: As required in every dynamic stabilization system, the implantation of the BDyn device implies a perfect positioning of the screws and rods to benefit from its biomechanical properties. To achieve this goal, intra-operative imaging seems mandatory.

Method: Through a case report of a patient with symptomatic grade I lumbar degenerative spondylolisthesis, we present the surgical tips for the implantation of BDyn dynamic stabilization system under the assistance of spinal navigation Surgivisio® 2D/3D.

Conclusion: The pedicular screw convergence, their placement in the pedicles, and the proper alignment of the BDyn System placed in neutral position are important steps of the surgery. Intra-operative spinal navigation helps achieving precise and safe positioning of the dynamic stabilization BDyn device taking optimal advantages of its biomechanical characteristics.

Keypoints:

- **Pedicle screws must be implanted in a convergent direction and in the upper part of the pedicle of the superior vertebra and in the lower part of the pedicle of the inferior vertebra**
- **A minimal distance of 27 mm must exist between two adjacent screw heads to accommodate the cylinder of the BDYN™ rod**
- **Place the BDYN™ rods as possible in neutral cylinder position, while maintaining the patient's natural lumbar lordosis using a prone position during surgery.**
- **After the final tightening of the screws, the BDYN™ rods should be well aligned in order to obtain the best mechanical functioning of the system.**

Direct Link

RADIOLOGICAL FACTORS AFFECTING FUNCTIONAL OUTCOME AFTER THE IMPLANTATION OF BDYN DYNAMIC STABILIZATION SYSTEM FOR LOW-GRADE LUMBAR DEGENERATIVE SPONDYLOLISTHESIS

N. Serratrice, J. Faddoul, B. Tarabay, C. Attieh, S. Taifour, B. Benkessou, I. Obeid, G. N. Abi Lahoud

Neurochirurgie - 2023
DOI: 10.1016/j.neuchi.2023.101456

Background: The objectives of this study are to identify radiological factors associated with good functional outcomes after the implantation of BDyn dynamic stabilization system in the setting of painful low-grade degenerative lumbar spondylolisthesis (DLS).

Material and methods: In this monocentric, retrospective study, we followed 50 patients, a 5-yearsperiod, with chronic lower back pain, radiculopathy and/or neurogenic claudication evolving for at least one year that failed conservative treatment. All patients presented low-grade DLS and underwent lumbar dynamic stabilization. Radiological and clinical outcomes were assessed preoperatively and 24 months after surgery. Functional evaluation was based on the Oswestry Disability Index (ODI), the Numerical Rating Scale (NRS), and the Walking Distance (WD). Radiological analysis was based on lumbar X-rays and MRI parameters. Patients were divided into two groups according to the reduction in the postoperative ODI score (more or less than 15 points), and statistical analysis was performed between both groups to find predictive radiological factors for a satisfying functional outcome.

Results: Clinically, 80% (40 patients) had a satisfying functional result, and 20% (10 patients) were considered having a poor outcome according to the ODI score. Radiologically, the loss in segmental lordosis was statistically associated with bad functional outcomes (18° for ODI decrease > 15 versus 11° for ODI decrease < 15). There is also a tendency showing that a higher Pfirmann disc signal grade (grade IV) and a severe canal stenosis according to Schizas classification (grade C & D) are predictive of a poor clinical result, but that must be confirmed in future studies

Conclusion: BDyn appears safe and well-tolerated. This new device should be effective for the treatment of patients with low-grade DLS. It provides significant improvement in terms of daily life activity and pain. Moreover, we have been able to deduce that a kyphotic disc is associated with a bad functional outcome after BDyn device implantation. It may represent a contraindication for the implantation of such DS device. Moreover, it seems that it is better to implant BDyn in DLS with mild or moderate disc degeneration and canal stenosis.

Keypoints:

- **Controls and preserves mobility**
- **Alternative to fusion surgery for grade I DLS**
- **Does not impact adjacent levels and protects them**

Direct Link

DEGENERATIVE LUMBAR SPONDYLOLISTHESIS. COHORT OF 670 PATIENTS, AND PROPOSAL OF A NEW CLASSIFICATION

O. Gille, V. Challier, H. Parent, R. Cavagna, A. Poignard, A. Faline, S. Fuentes, O. Ricart, E. Ferrero, M. Ould Slimane, the French Society of Spine Surgery (SFCR)

Orthopaedics & Traumatology: Surgery & Research (OTSR) - 2014
http://dx.doi.org/10.1016/j.otsr.2014.07.006

Background: Degenerative spondylolisthesis is common in adults. No consensus is available about the analysis or surgical treatment of degenerative spondylolisthesis. In 2013, the French Society for Spine Surgery (Société Française de Chirurgie du Rachis) held a round table discussion to develop a classification system and assess the outcomes of the main surgical treatments.

Materials and Methods: A multicentre study was conducted in nine centres located throughout France and Luxembourg. We established a database on a prospective cohort of 260 patients included between July 2011 and July 2012 and a retrospective cohort of 410 patients included in personal databases between 2009 and 2013. For patients in the prospective cohort clinical assessments were performed before and after surgery using the self-administered functional impact questionnaire AQS, SF12, and Oswestry Disability Index (ODI). Type of treatment and complications were recorded. Antero-posterior and lateral full-length radiographs were used to measure lumbar lordosis (LL), segmental lordosis (SL), pelvic incidence (PI), pelvic tilt (PT), sagittal vertical axis (SVA), and percentage of vertebral slippage. Mean follow-up was 10 months. We started a randomised clinical trial comparing posterior fusion of degenerative spondylolisthesis with versus without an inter-body cage. 60 patients were included, 30 underwent 180° fusion and 30 underwent 360° fusion using an inter-body cage implanted via a transforaminal approach. We evaluated the quality of neural decompression achieved by minimally invasive fusion technique. In a subgroup of 24 patients computed tomography (CT) was performed before and after the procedure and then compared.

Results: Mean age was 67 years and 73% of degenerative spondylolisthesis were located at L4-L5 level. The many surgical procedures performed in the prospective cohort were posterior fusion (39%), posterior fusion combined with inter-body fusion (36%), dynamic stabilization (15%), anterior lumbar fusion (8%), and postero-lateral fusion without exogenous material (2%). Peri-operative complications of any severity occurred in 17% of patients. The AQS, ODI and SF12 scores were improved significantly at follow-up.

Direct Link

DEGENERATIVE LUMBAR SPONDYLOLISTHESIS. COHORT OF 670 PATIENTS, AND PROPOSAL OF A NEW CLASSIFICATION

O. Gille, V. Challier, H. Parent, R. Cavagna, A. Poignard, A. Faline, S. Fuentes, O. Ricart, E. Ferrero, M. Ould Slimane, the French Society of Spine Surgery (SFCR)

Orthopaedics & Traumatology: Surgery & Research (OTSR) - 2014
http://dx.doi.org/10.1016/j.otsr.2014.07.006

Conclusion: We found no differences in clinical improvements across surgical procedure types. Circumferential fusion (360°) was associated with greater relief of nerve root pain and better lordosis recovery after 1 year compared to postero-lateral fusion (180°). Post-operative CT images showed effective decompression of nervous structures after minimally invasive fusion. Longer follow-up of our patients is needed to assess the stability of the results of the various surgical procedures.

Key points :

- **Improvements statistically significant (P < 0.001) from pre-operatively to post-operatively: :**
  - o Quality of life and functional disorders
  - o Leg and back pain
  - o Disability
  - o Physical Component Summary SF12
  - o Mental component summary SF12

Direct Link

FINITE ELEMENT MODELLING OF HYBRID STABILIZATION SYSTEMS FOR THE HUMAN LUMBAR SPINE

E. Demir, P. Eltes, A. Castro, D. Lacroix and I. Toktas

Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine - 2020
DOI: 10.1177/0954411920946636

Background: Intersomatic fusion is a very popular treatment for spinal diseases associated with intervertebral disc degeneration. The effects of three different hybrid stabilization systems on both range of motion and intradiscal pressure were investigated, as there is no consensus in the literature about the efficiency of these systems.

Materiels and Methods: Finite element simulations were designed to predict the variations of range of motion and intradiscal pressure from intact to implanted situations.

Results: After hybrid stabilization system implantation, L4-L5 level did not lose its motion completely, while L5-S1 had no mobility as a consequence of disc removal and fusion process. BalanC hybrid stabilization system represented higher mobility at the index level, reduced intradiscal pressure of adjacent level, but caused to increment in range of motion by 20% under axial rotation. Higher tendency by 93% to the failure was also detected under axial rotation. Dynesys hybrid stabilization system represented more restricted motion than BalanC, and negligible effects to the adjacent level. BDyn hybrid stabilization system was the most rigid one among all three systems. It reduced intradiscal pressure and range of motion at the adjacent level except from motion under axial rotation being increased by 13%. Fracture risk of B-DYN and Dynesys Transition Optima components was low when compared with BalanC. Mobility of the adjacent level around axial direction should be taken into account in case of implantation with BalanC and BDyn systems, as well as on the development of new designs.

Conclusion: Having these findings in mind, it is clear that hybrid systems need to be further tested, both clinically and numerically, before being considered for common use.

Direct Link

IN VITRO OXIDATIVE DEGRADATION OF A SPINAL POSTERIOR DYNAMIC STABILIZATION DEVICE

B. Lawless, D. Espino, D. Shepherd

Journal of Biomedical Materials Research Part B: Applied Biomaterials - 2017
DOI: 10.1002/jbm.b.33913

Aim: This study quantified the changes of the frequency dependant viscoelastic properties of the BDyn (S14 Implants, Pessac, France) spinal posterior dynamic stabilization (PDS) device due to in vitro oxidation.

Materials and Methods: Six polycarbonate urethane (PCU) rings and six silicone cushions were degraded using a 20% hydrogen peroxide/0.1 M cobalt (II) chloride hexahydrate, at 378C, for 24 days. The viscoelastic properties of the individual components and the components assembled into the BDyn PDS device were determined using Dynamic Mechanical Analysis at frequencies from 0.01 to 30 Hz. Attenuated Total Reflectance Fourier Transform Infra-Red spectra demonstrated chemical structure changes, of the PCU, associated with oxidation while Scanning Electron Microscope images revealed surface pitting.

Results: No chemical structure or surface morphology changes were observed for the silicone cushion. The BDyn device storage and loss stiffness ranged between 84.46 N/mm to 99.36 N/mm and 8.13 N/mm to 21.99 N/mm, respectively. The storage and loss stiffness for the components and BDyn device increased logarithmically with respect to frequency.

Conclusion: Viscoelastic properties, between normal and degraded components, were significantly different for specific frequencies only. This study demonstrates the importance of analyzing changes of viscoelastic properties of degraded biomaterials and medical devices into which they are incorporated, using a frequency sweep.

Direct Link

VISCOELASTIC PROPERTIES OF A SPINAL POSTERIOR DYNAMIC STABILISATION DEVICE

B. Lawless, S. Barnes, D. Espino, D. Shepherd

Journal of the Mechanical Behavior of Biomedical Materials - 2016
https://doi.org/10.1016/j.jmbbm.2016.03.011

Aim: The purpose of this study was to quantify the frequency dependent viscoelastic properties of two types of spinal posterior dynamic stabilisation devices.

Materials and Methods: In air at 37 °C, the viscoelastic properties of six BDyn 1 level, six BDyn 2 level posterior dynamic stabilisation devices (S14 Implants, Pessac, France) and its elastomeric components (polycarbonate urethane and silicone) were measured using Dynamic Mechanical Analysis. The viscoelastic properties were measured over the frequency range 0.01–30 Hz. The BDyn devices and its components were viscoelastic throughout the frequency range tested. The mean storage stiffness and mean loss stiffness of the BDyn 1 level device, BDyn 2 level device, silicone component and polycarbonate urethane component all presented a logarithmic relationship with respect to frequency.

Results: The storage stiffness of the BDyn 1 level device ranged from 95.56 N/mm to 119.29 N/mm, while the BDyn 2 level storage stiffness ranged from 39.41 N/mm to 42.82 N/mm. BDyn 1 level device and BDyn 2 level device loss stiffness ranged from 10.72 N/mm to 23.42 N/mm and 4.26 N/mm to 9.57 N/mm, respectively. No resonant frequencies were recorded for the devices or its components.

Conclusion: The elastic property of BDyn 1 level device is influenced by the PCU and silicone components, in the physiological frequency range. The viscoelastic properties calculated in this study may be compared to spinal devices and spinal structures.

NOTES

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