MINI-INVASIVE APPROACH TO DEGENERATIVE LUMBAR DISC DISEASE:

TRANSFORAMINAL MONOLATERAL INTERBODY FUSION AND INTERSPINAL FIXATION. CASE-CONTROL STUDY

APPROCCIO MININVASIVO ALLA PATOLOGIA DEGENERATIVA DISCALE LOMBARE MEDIANTE ARTRODESI INTERSOMATICA TRANSFORAMINALE MONOLATERALE E FISSAZIONE INTERSPINOSA ASSOCIATA.

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Degenerative lumbar disc disease

Definition and Epidemiology

Approximately 70-85% of all people experience back pain at some time in life, and patients with pain duration more than 3 months have slow and uncertain spontaneous recovery. The return-to-work rate of patients who don't recover after 2 years of absence from work has been shown to be close to zero.

Many can be ethiologies of law back pain: degenerative disk disease, internal disk disruption, lumbar disk herniation, facet joint arthritis, as causes aging-related. But also intra-abdominal pathologies, muscular stiffness, gynecological problems are all potential causes of low back pain.

Non-specific lower back pain caused by degenerative lumbar disease significantly impairs quality of life of patients, and is associated with higher pain scores and reduced function.

Low back pain secondary to degenerative disc disease is a condition that affects young to middle-aged persons with peak incidence at approximately 40 years. The prevalence of disc degeneration increases with age, but degenerated discs are not necessarily painful. Low back pain secondary to degenerative disc disease affects men more than women. Risk factors associated with the lumbar disc degenerative disease are advancing age, smoking, obesity, trauma, heavy weight lifting, height, genetic factors and hereditary factors.

Clinical aspects

Patients with Degenerative Disc Disease (DDD) or discogenic back pain can present with a constellation of symptoms that range from benign law back pain to excruciating back pain with lower extremity symptoms. The main symptom associated to low back pain is mono or bilateral sciatica that may radiate to the foot. It is a sharp shooting type of pain. Mild tingling sensation, dull ache, or burning sensation can occur, with a wide spectrum of sensory disturbances in legs. Sciatic pain may aggravate on standing, walking, bending, straining and coughing. In severe case a limitation of deambulation can occur.

The physical examination of a patient with primarily discogenic law back pain is often unremarkable. Back pain may be reproduced on palpation of the lumbar or lumbosacral spine. The range of motion of the lumbar spine may be limited. Pain usually is worsened with flexion and lessened with extension. Pain with extension of the back may herald facet joint disease. The gait may be antalgic, and transitions from one position to the next may be guarded. Straight leg raise and other tests for radicular signs are rarely positive.

Imaging studies

Upright plain radiographs are the initial study of choice. Lateral views may be helpful in the diagnosis, including flexion-extension imaging to determine the presence of instability (that represents for example a contraindication in case of stabilization with intraspinal device). Antero-posterior image assesses an eventual scoliosis. Other aspects that radiographs show are signs of osteophytes, foraminal narrowing, end-plate sclerosis, disk space narrowing, vacuum phenomenon within the disk and abnormalities that may indicate fracture, metastasis and intra-abdominal pathologies.

CT scan is more precise to describe bone anatomy and may be useful to add detailed informations about foramina, osteophytosis, level of arthrosis.

MRI is the imaging study of choice for DDD because it offers specific details of the status of the disk (fig. 1). A disk that appears normal on MRI is unlikely to be a pain generator and should prompt a search for another cause of back pain. Characteristics that should be examined on MRI are signs of degeneration (eg disk height, decreased signal on T2- weighted images), the presence of annular tears and disc bulging or erniation, and endplate changes [Braithwaite I, White J, Saifuddin A, Renton P, Taylor BA: Vertebral end-plate (Modic) changes on lumbar spine MRI: Correlation with pain reproduction at lumbar discography. *Eur Spine J* 1998;7: 363-368].

Endplate changes that are associated with DDD have been well characterized by Modic et al [Modic MT, Masaryk TJ, Ross JS, Carter JR: Imaging of degenerative disk disease. *Radiology* 1988;168:177-186]. The authors correlated changes seen on different MRI sequences and with histopathologic findings. Type I changes are decreased signal intensity on T1- weighted images, with increased signal intensity on T2-weighted images. This corresponded in the study to areas of degeneration, increased reactive woven bone, and vascularized granulation tissue. Type II changes demonstrate increased signal intensity on T1-weighted images and isointense or slightly increased signal on T2-weighted images. The histologic specimens showed replacement of hematopoietic elements with fat and evidence of chronic repetitive trauma. Type III changes are manifested by decreased signal intensity on both T1- and T2-weighted imaging and correspond to advanced degeneration with replacement of the fat with sclerotic bone.

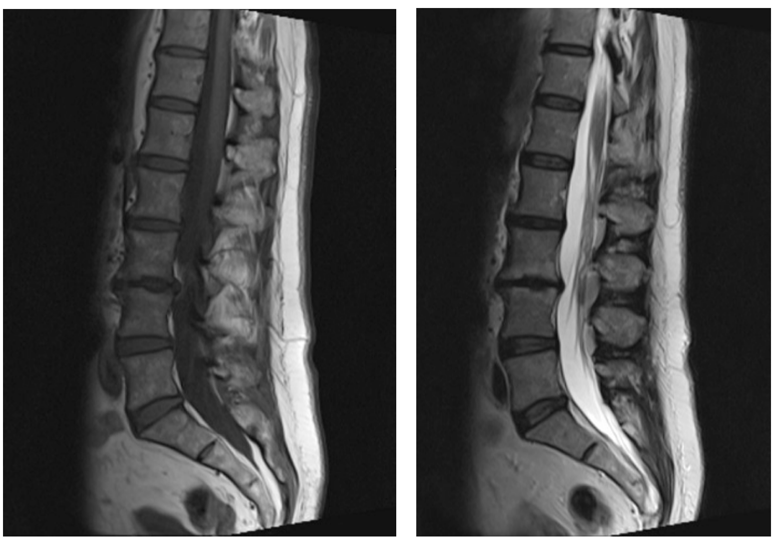


Fig. 1: MRI study of L3-L4 disc degeneration. a) T1 weighted seq; b) T2 weighted seq., Modic 2 on bodies' edges and height reduction of disc

Options of treatment for DDD

Surgical treatment for lumbar degenerative disc disease remains controversial. The mainstay of treatment for lumbar DDD are conservative treatments such as activity modification, medications, and physical therapy and some studies have identified negative outcomes after surgical treatment.

Conservative treatment

Approximately 90% of individuals with LBP will have resolution of their symptoms within 3 months, with or without treatment; most will have cessation of discomfort within 6 weeks [Andersson GB: Epidemiological features of chronic low back pain. Lancet 1999; 354:581-585]. With this type of natural history, the initial treatment of all patients with LBP without a neurologic emergency (eg. acute radicolar deficit) should be nonsurgical.

Physical therapy, with strengthening of core muscle groups (both abdominal wall and lumbar musculature), has demonstrated positive effects in patients with discogenic pain [Dickerman RD, Zigler JE: Disocgenic back pain, in Spivak JM, Connolly PJ (eds): *Orthopaedic Knowledge Update: Spine,* ed 3. Rosemont, IL: American Academy of Orthopaedic Surgeons, 2006, pp 319-330]. A more recent literature review suggest better results with mobilization in the treatment of low back pain as opposed to bed rest. Exercise has been shown to improve function and decrease pain in adult patients with chronic low back pain [Hagen KB, Jamtvedt G, Hilde G, Winnem MF: The updated cochrane review of bed rest for low back pain and sciatica. *Spine* 2005;30:542-546. Hayden JA, van Tulder MW, Malmivaara A, Koes BW: Exercise therapy for the treatment of non-specific low back pain. *Cochrane Database Syst Rev* 2005;(3):CD000335].

Chiropractic manipulation and physical therapy has been shown to be beneficial for the treatment of acute low back pain [Cherkin DC, Deyo RA, Battié M, Street J, Barlow W: A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. *N Engl J Med* 1998;339:1021- 1029. Assendelft WJ, Morton SC, Yu EI, Suttorp MJ, Shekelle PG: Spinal manipulative therapy for low back pain. *Cochrane Database Syst Rev* 2004;(1): CD000447]. Cochrane literature reviews have found that back schools (interventions that comprise exercise and education components) demonstrate effectiveness in short- and intermediate-term settings in relation to LBP and return-to-work status in comparison with spinal manipulation, exercises, advice, and placebo [Heymans MW, van Tulder MW, Esmail R, Bombardier C, Koes BW: Back schools for nonspecific low back pain: A systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 2005;30:2153- 2163. Heymans MW, de Vet HC, Bongers PM, Knol DL, Koes BW, van Mechelen W: The effectiveness of high-intensity versus low-intensity back schools in an occupational setting: A pragmatic randomized controlled trial. *Spine* 2006; 31:1075-1082]. A more recent review [Straube S et al: Back schools for the treatment of chronic low back pain: possibility of benefit but no convincing evidence after 47 years of research—systematic review and meta-analysis. Pain 2016 Oct; 157(10):2160-2172] showed as the evidence base for the use of back schools to treat chronic low back pain is weak; in nearly a half-century since back schools were first trialled, no unequivocal evidence of benefit has emerged.

Recent trends in the treatment of low back pain have centered on a multidisciplinary approach. The disciplines usually include a physical dimension and a combination of one or more of the following: social, occupational, and psychological [Guzmán J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C: Multidisciplinary rehabilitation for chronic low back pain: Systematic review. *BMJ* 2001;322:1511-1516. 36. Brox JI, Sørensen R, Friis A, et al: Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. *Spine* 2003;28:1913-1921].

There is a long history of treating low back pain with medication. The use of narcotics over the long term should be avoided because of concerns about addiction, altered cognition in older patients, and interaction with other medications. Nonsteroidal anti-inflammatory drugs (NSAIDs) are effective for short-term symptomatic relief in patients with acute back pain. The use of muscle relaxants are effective but must be used with caution because of their possible side-effect [van Tulder MW, Touray T, Furlan AD, Solway S, Bouter LM, Cochrane Back Review Group: Muscle relaxants for nonspecific low back pain: A systematic review within the framework of the cochrane collaboration. *Spine* 2003;28: 1978-1992]. Tricyclic and tetracyclic antidepressants in one study produced symptom reduction in this patient population, whereas selective serotonin reuptake inhibitors did not [Staiger TO, Gaster B, Sullivan MD, Deyo RA: Systematic review of antidepressants in the treatment of chronic low back pain. *Spine* 2003;28: 2540-2545].

Surgical Options

Patients that fail to respond to conservative treatment may require surgical intervention, such as lumbar interbody fusion (LIF), as R.B. Cloward said in 1954 "The treatment of ruptured intervertebral discs by vertebral body fusion" (from Annals of Surgery).

Fig. 2 R.B. Cloward

Arthrodesis of a painful lumbar motion segment remains a controversial form of treatment of symptomatic disk disease in selected patients. Fusions have been criticized for providing inconsistent results until more recent years, when a diffuse consensus has benn reached in the necessity of obtaining fusion to treat symptoms of low back pain. Interbody fusion may be done from either a posterior or an anterior approach, or both combined for a circumferential fusion.

The recent improvements in fusion rate, however, not always relate with patient outcomes, and usually are accompained with increased complication rates, and also increased blood loss, and dilated surgical time.

The large discrepancy in patient outcomes reported in the literature is probably related to uncorrect indications and tratification of patients. Also a partial understanding of mechanism of lumbar back pain may account for some of this discrepancy.

Knox and Chapman [Knox BD, Chapman TM. Anterior lumbar interbody fusion for discogram concordant pain. J Spinal Disord 1993;6:242–4] founded poor results in two-level fusions and in almost half (47%) of single-level fusions for lumbar degenerative disc disease. Carragee et al. (2006) also reported that only 43% of patients undergoing spinal fusion for lumbar degenerative disc disease met the criteria for minimum acceptable outcome.

In contrast, Fritzell [Fritzell P: Fusion as treatment for chronic low back pain: Existing evidence, the scientific frontier and research strategies. Eur Spine J 2005;14: 519-520] showed that there is evidence in the literature that fusion is more efficacious than nonsurgical treatment in the setting of chronic lumbar back pain. After that, also the studies of the Swedish Lumbar Spine Study Group found that fusion for lumbar degenerative disc disease results in superior outcomes relative to standard nonsurgical care [Fritzell P, Hägg O, Wessberg P, Nordwall A, Swedish Lumbar Spine Study Group: 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain. A multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine* 2001; 26:2521-2532]. The group showed in addition that lumbar fusion, although initially more expensive, may in the long run be a cheaper form of treatment than non surgical care. All of the treatment effects in that study were found to be in favor of surgery [Fritzell P, Hägg O, Jonsson D, Nordwall A, Swedish Lumbar Spine Study Group: Cost-effectiveness of lumbar fusion and nonsurgical treatment for chronic low back pain in the Swedish Lumbar Spine Study: A multicenter, randomized, controlled trial from the Swedish Lumbar Spine Study Group. *Spine* 2004; 29:421-434]. Finally, the group compared three types of fusion in the lumbar spine: posterolateral, posterolateral with instrumentation, and circumferential. The investigators found that the highest fusion rate was garnered by the circumferential group (91%), followed by the posterior instrumented (87%) and the noninstrumented (72%) groups. However, the higher fusion rates came with higher rates of complications [Fritzell P, Hägg O, Wessberg P, Nordwall A, Swedish Lumbar Spine Study Group: Chronic low back pain and fusion: A comparison of three surgical techniques. A prospective randomized study from the Swedish lumbar spine study group *Spine* 2002;27: 1131-1141].

Surgical options for lumbar degenerative disc disease include anterior lumbar interbody fusion (ALIF), posterior approach fusion procedures such as posterior lumbar interbody fusion (PLIF) and posterolateral lumbar fusion (PLF), anterior and posterior lumbar fusion (APLF), and total disc replacement (TDR). Posterior lumbar interbody fusion and PLF are popular procedures for spinal surgeons performing lumbar surgery. These procedures involve a bone graft between the vertebrae to unite the bones of opposing vertebral endplates adjacent to the degenerative disc, and may also include other instrumentation. These procedures often required long time operative procedures, blood loss, long post-operative time for recovery and many days of hospitalization.

Anterior lumbar interbody fusion with posterior percutaneous pedicle screw fixation has also gained popularity during the last decade. In the middle of last decade, lumbar TDR was approved in the United States, which may have changed the trend in surgical management of lumbar degenerative disc disease.

In the last ten years alternative and minimally invasive techniques have been explored to reduce morbidity of these procedures and to improve the feedback of patients. The principle tenets of minimally invasive spine surgery are to reduce approach-related morbidity without sacrificing a thorough and effective treatment of the patient’s pathology.

1. Interbody fusion

Classical Interbody Fusion and a variety of surgical techniques and innovative procedures introduced during the last decade pursue the aim of achieving fusion, according to the idea that fusion in mandatory to treat degenerative lumbar disc disease.

Lumbar interbody fusion involves placement of an implant (cage, spacer or structural graft) within the intervertebral space after discectomy and endplate preparation. Lumbar interbody fusion (LIF) is performed using five main approaches; posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), anterior lumbar interbody fusion (ALIF), oblique lumbar interbody fusion (OLIF) and extreme lateral interbody fusion (XLIF, Fig. 3). There is no clear definitive evidence for one approach being superior to another in terms of fusion or clinical outcomes.

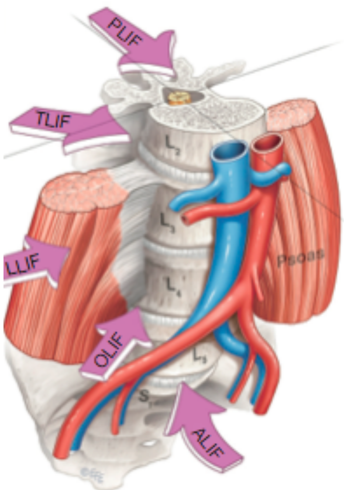


Fig. 3: Possible approaches to lumbar disc

The growth of new techniques attempts to shorten operative times and achieve faster recovery with reduced operative complications. Initial descriptions of ALIF and PLIF have been challenged by the evolving alternate approaches, such as the transforaminal, lateral and more recently oblique techniques.

PLIF: In the PLIF (Posterior Lumbar Interbody Fusion, Fig. 4) technique, surgical access to the intervertebral disc is gained from a posterior direction. An open midline approach with bilateral muscle strip dissection is used to access the posterior column of the vertebral body. Once the spinous process and laminae at the appropriate levels are identified, a laminotomy may be performed medial to the facet and the dura retracted to exposure a corridor to the disc space. The endplates and disc space can then be prepared to allow implant/spacer insertion.

Fig. 4: cage insertion by PLIF technique

TLIF (Transforaminal Lumbar Interbody Fusion, Fig. 5): direct, unilateral access to the intervertebral foraminal space whilst reducing direct dissection and surgical trauma to spinal muscles and structural integrity. By opening the neural foramen on one side only, damage to important anatomical structures such as nerve roots, dura and ligamentum flavum may be reduced. A midline or bilateral paramedian mini-open incision is used, allowing access to the disc space. The spinal canal is entered via a unilateral laminectomy and inferior facetectomy, which facilitates bone graft placement.

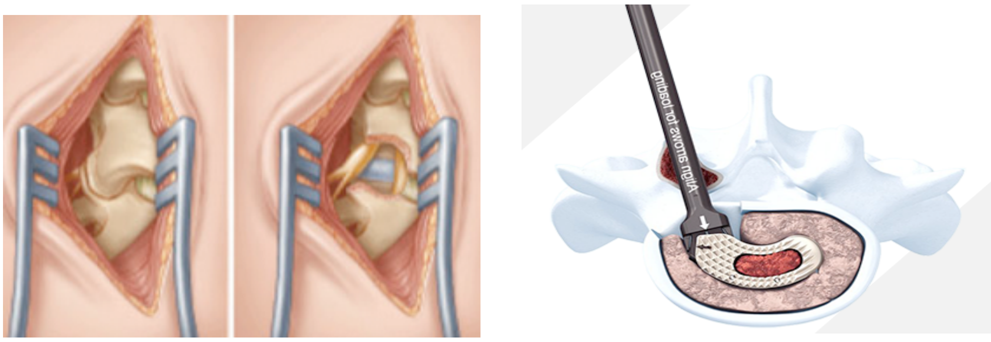


Fig. 5: cage insertion by TLIF technique

ALIF (Anterior Lumbar Interbody Fusion, Fig. 6): The anterior retroperitoneal approach facilitates adequate access to the entire ventral surface of the exposed disc, allowing comprehensive discectomy and direct implant insertion. For this technique, the patient is prepared and positioned supine. Incision and approach include midline, paramedian (all levels) or Mini-Pfannenstiel (L5/S1) incision with a retroperitoneal corridor and vascular mobilization and dissection. The ALIF approach is suitable for levels L4/L5 and L5/S1, primarily the latter due to vascular anatomy. ALIF approach is limited for L2/3 and L3/4 secondary to extensive peritoneal and kidney (L2/3) retraction and the risk of superior mesenteric artery thrombosis, although rare.

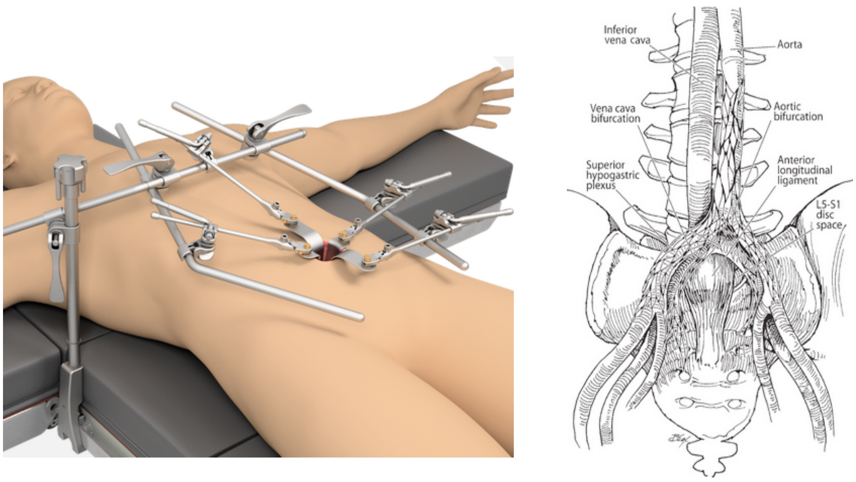


Fig. 6: cage insertion by ALIF technique

OLIF (Oblique Lateral Interbody Fusion, Fig. 7): involves an access to the disc space via a corridor between the peritoneum and psoas muscle. Does not require posterior surgery, laminectomy, facetectomy or stripping of spinal or paraspinal musculature. Does not dissect or traverse the psoas muscle. For this technique, the patient is positioned laterally. A lateral and paramedian incision is performed based on position and angulation of the disc on image intensification when the patient is positioned. Neuromonitoring is not necessary.

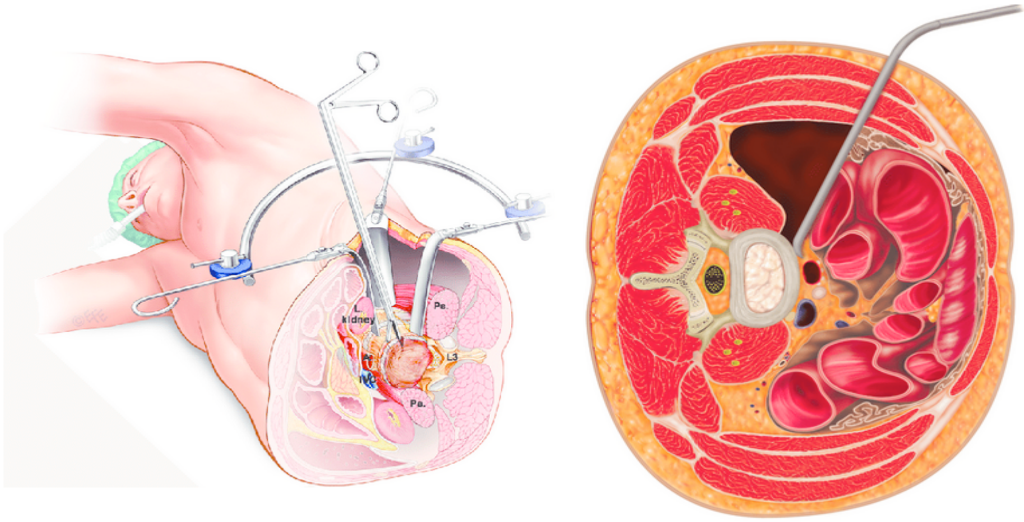
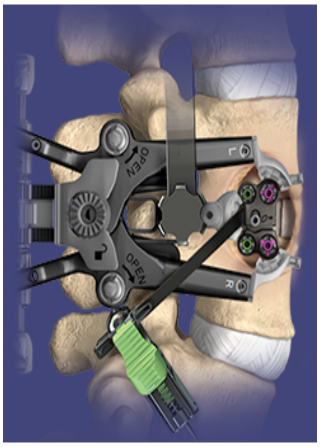


Fig. 7: cage insertion by OLIF technique

XLIF (Extreme Lateral Interbody Fusion, Fig. 8): involves accessing the disc space via a lateral retroperitoneal, transpsoas corridor. Is suitable for conditions that require access to the interbody disc space from T12/L1 to L4/5. This technique is not suitable for the L5/S1 level, due to the location of the iliac crest that obstructs lateral access. Furthermore, at more caudal levels of the lumbar spine, the lumbar plexus courses more anteriorly and the iliac vessels course more laterally, which increases risk of injury via a lateral approach. The patient is positioned laterally, either left or right side up depending on surgeon's preference and ease of access. A small lateral incision is performed based on position and angulation of the disc on image intensification when the patient is positioned. Neuromonitoring is essential for the transpsoas access to the disc space.



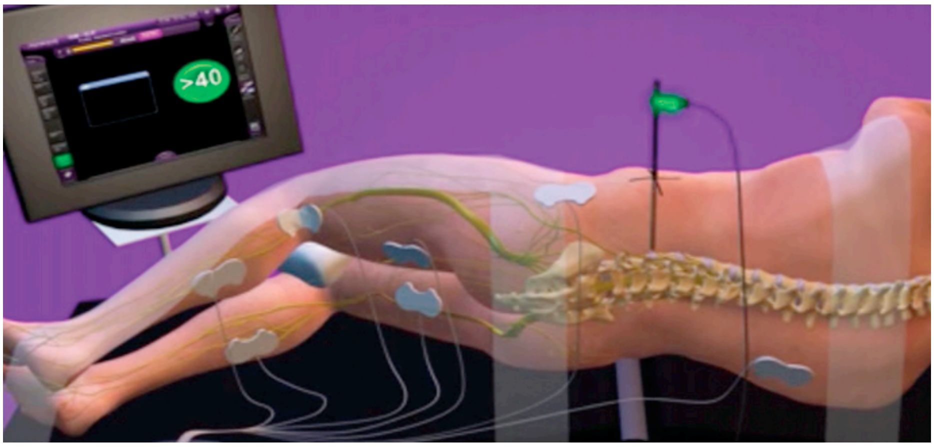


Fig. 8: cage insertion by OLIF technique

2. *Posterior Fixation by Interspinous device*

Spinous process fixation is advertised as a minimally invasive spine surgery technique that stabilizes the lumbar spine with less dissection and trauma to the vertebra than the current gold standard, pedicle screw fixation. Interspinous fixation devices (IFD) aim to provide rigidity comparable with pedical screw fixation by bilaterally securing plates to the lateral aspects of 2 adjacent spinous processes, effectively clamping the motion segment together. IFD implantation has been applied to posterolateral and interbody fusion procedures. Certain IFD products are designed to achieve additional stability through interspinous bony fusion. Proponents have noted that IFD placement is a more expedient procedure that requires a single, less obtrusive midline incision. The primary evidence for IFDs rests with ex vivo biomechanical studies, which have demonstrated that stand-alone IFDs provide rigidity that is comparable with pedical screws in flexion-extension but not in axial rotation or lateral bending. Moreover, these studies only evaluated the devices in a short-term setting and do not account for long-term in vivo stresses.

IFDs also reduce disk load and preserve adjacent facet joint anatomy, potentially reducing the risk of developing adjacent segment disease. Multiple IFDs have been designed and are indexed in the literature using various terminology, including spinous process clamps, plates, and anchors. The theoretical but limited biomechanical benefits of IFDs over pedical screw seem promising.

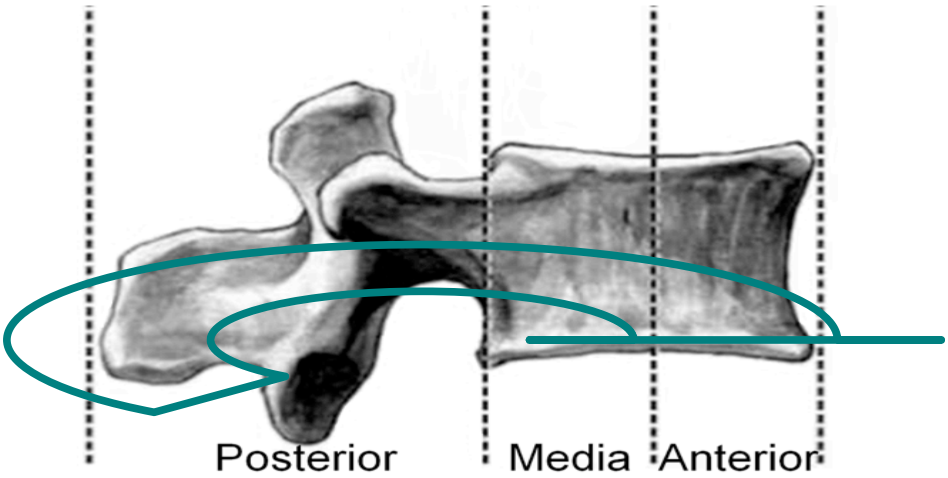
This technique offers several advantages. First, the risk of screws malpositioning is eliminated. Second, it is less invasive on muscular tissue if compared to bilateral screw placement. Then it requires shortly operative times, as it will be shown by our experience.

However, there is sparse literature confirming that these benefits have translated into sound clinical outcomes. Other novel surgical technologies, such as interspinous spacers, previously have been applied clinically before sufficient evidentiary support existed regarding the device's efficacy and complications.

Interspinous devices, used to obtain fusion, ranges from paired plates with teeth to U-shaped devices with wings that are attached to the spinous process. They are positioned removing interspinous ligament and, after radiological control of position and dimension, fixed by the proper clamping system.

3. Our proposal for a circonferential stabilization

Nowadays one of the best surgical technique to approach lumbar disc degeneration is considered circonferential fixation. With this approach either anterior column and posterior column are fixed.



Anterior/posterior or 360° fusion surgery has been shown to have a high arthrodesis rate [Thalgott JS, Chin AK, Ameriks JA, Jordan FT, Giuffre JM, Fritts K, Timlin M (2000) Minimally invasive 360 degrees instru- mented lumbar fusion. Eur Spine J 9(Suppl 1):S51–S56]. However, this type of combined procedure has been reported to have significant complication rates [Oskouian RJ Jr, Johnson JP (2002) Vascular complications in anterior thoracolumbar spinal reconstruction. J Neurosurg 96(Suppl 1):1–5. Garg J, Woo K, Hirsch J, Bruffey JD, Dilley RB (2010) Vascular complications of exposure for anterior lumbar interbody fusion. J Vasc Surg 51(4):946–950. Scaduto AA, Gamradt SC, Yu WD, Huang J, Delamarter RB, Wang JC (2003) Perioperative complications of threaded cylin- drical lumbar interbody fusion devices: anterior versus posterior approach. J Spinal Disord Tech 16(6):502–507. Brau SA (2002) Mini-open approach to the spine for anterior lumbar interbody fusion: description of the procedure, results and complications. Spine J 2(3):216–223] and cost [Alt V, Chhabra A, Franke J, Cuche M, Schnettler R, Le Huec JC (2009) An economic analysis of using rhBMP-2 for lumbar fusion in Germany, France and UK from a societal perspective. Eur Spine J 18(6):800–806. Guyer RD, Tromanhauser SG, Regan JJ (2007) An economic model of one-level lumbar arthroplasty versus fusion. Spine J 7(5):558–562].

Anterior fixation is achived with substitution of intervertebral disc with a cage (peek, titanium), in order to induce fusion between the two vertebral bodies. Posterior fixation is achived often with peduncular screwing (monolateral or bilateral).

Our study propose to compare classic peduncular screws fixation versus interspinous fixation, a less invasive technique for posterior fixation, in two groups of patient. The aim is to reach sagittal stability while largely preserving the paraspinal muscles, avoiding the posterior neural elements, and conserving the facets on one side, reducing risks of posterior screwing.

DESIGN OF THE STUDY

STUDY'S PURPOSE

Posterior lumbar interbody fusion (PLIF) is an effective surgical procedure for lumbar degenerative disease. Augmented by pedicle screws, this fusion procedure can achieve immediate stabilization and a higher fusion rate. However, complications associated with the implantation of the pedicle screws, including nerve root injury, screw misplacement, screw loosening, and implant breakage, have also been increasingly reported.

Some interspinous fusion stabilizations have been designed for fusion procedures. These interspinous fusion stabilizations are designed to reduce the disadvantage of pedicle screw placement. They are characterized by lower blood loss, shorter operative time, and less invasiveness [Fidler MW. Spinal fusion: a combined anterior and supplementary interspinous technique. Eur Spine J, 1997, 6: 214–218. Tomii M, Itoh Y, Numazawa S, Watanabe K, Nakagawa H. Spinous process plate (S-plate) fixation after posterior interbody fusion for lumbar canal stenosis due to spondylolisthesis. Neurosurg Rev, 2013, 36: 139–143 discussion 143]. Biomechanical tests have demonstrated that these interspinous fusion stabilizations could provide similar stability to pedicle screws [Kettler A, Drumm J, Heuer F, et al. Can a modified interspinous spacer prevent instability in axial rotation and lateral bending? A biomechanical in vitro study resulting in a new idea. Clin Biomech (Bristol, Avon), 2008, 23: 242–247. Doulgeris JJ, Aghayev K, Gonzalez-Blohm SA, Lee WE 3rd, Vrionis FD. Biomechanical comparison of an interspinous fusion device and bilateral pedicle screw system as additional fixation for lateral lumbar interbody fusion. Clin Biomech (Bristol, Avon), 2015, 30: 205–210. Gonzalez-Blohm SA, Doulgeris JJ, Aghayev K, Lee WE 3rd, Volkov A, Vrionis FD. Biomechanical analysis of an interspinous fusion device as a stand- alone and as supplemental fixation to posterior expandable interbody cages in the lumbar spine. J Neurosurg

Spine, 2014, 20: 209–219. Karahalios DG, Kaibara T, Porter RW, et al. Biomechanics of a lumbar interspinous anchor with anterior lumbar interbody fusion. J Neurosurg Spine, 2010, 12: 372–380].

We associated posterior fusion, by implantation of interspinous fusion device, and anterior fusion, with intersomatic cage positioned by transforaminal monolateral approach, in order to achieve 360° stabilization with less complication, shorter surgery time and hospitalization, and less blood loss.

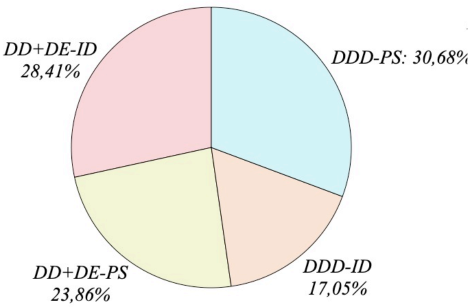
MATERIALS

Our cohort is represented by 102 patients operated on for degenerative lumbar disc disease over a period of 5 years, from the 1th of January 2014 to 31th December 2018. Patients have been followed for a minimum period of 12 months.

The cohort has been divided in 2 subgroups of patients by diagnosis. One group (DDD, 50 pts) is formed by patients with pure degenerative lumbar disc disease, and the other by patients with degenerative lumbar disc disease and discal erniation (DD+DE, 52 pts). 14 patients have been excluded from the study because intraoperatively no intersomatic cages have been placed for technical reasons, 8 in the first group and 6 in the second one.

Each group has then been divided in 2 subgroups according to the surgical treatment: intersomatic fusion (with cage) and posterior fusion with bilateral pedical screws (PS) or interspinous device (IS, fig. 9).

Age of the patients (Fig. 10) ranges between 34 and 78 yy, with a median age of 50,1 years in the group of patients treated with intersomatic fusion and Pedical Screws placement (PS), and of 52,1 years in the group of patients treated with intersomatic fusion and Interspinous Device placement (ID). According to diagnosis the distribution by age is showed in fig 10 : the mean age in the subgroup with disc degeneration and disc herniation was 50,2 years, and in the subgroup with pure disc degeneration 51,9 years.



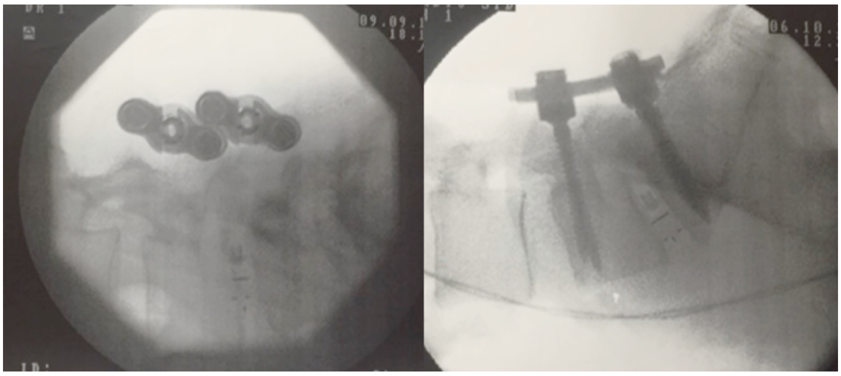
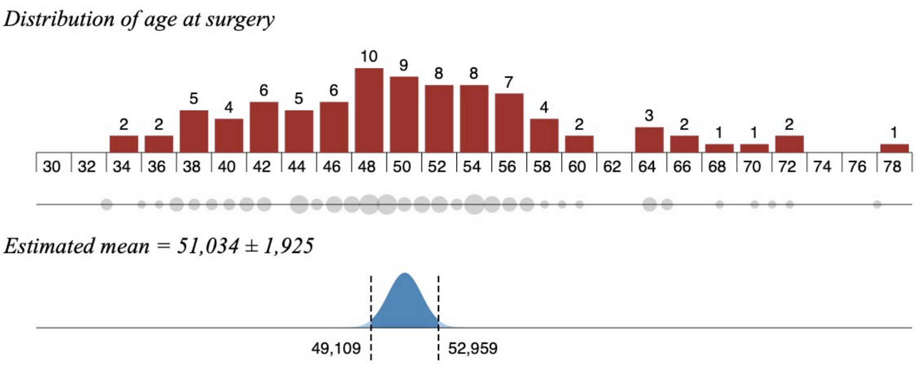
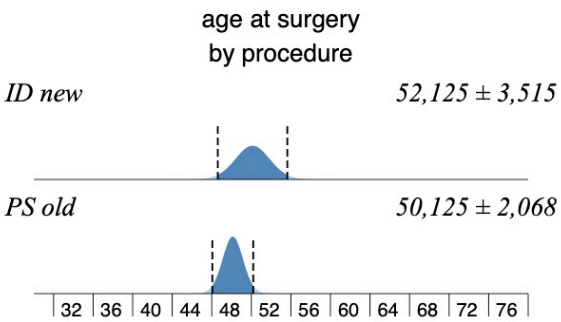


Fig. 9a: Distribution of four groups. 9b: control of a patient of ID group; 9c: control of a patient of PS group





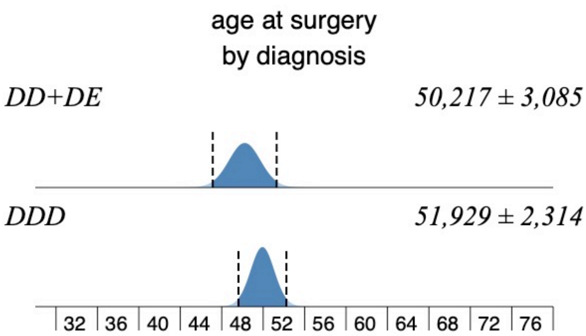


Fig. 10: Distribution of ages

Sex distribution is overall of 33 Males (37,5%) and 55 Females (62,5%) (Fig.). In the DDD group distribution is 15 males to 27 females. In the DD+DE there are 18 males and 28 females, distributed as shown in Fig. 11.

Most involved anatomical levels have been L4-L5 (40/88 pts) and L5-S1 (42/88 pts), with a prevalence for L5-S1 (37/48 pts) in the groups treated with pedical screw placement, and for L4-L5 (32/40 pts) in the groups treated with interspinous device placement (Fig. 12, 13).

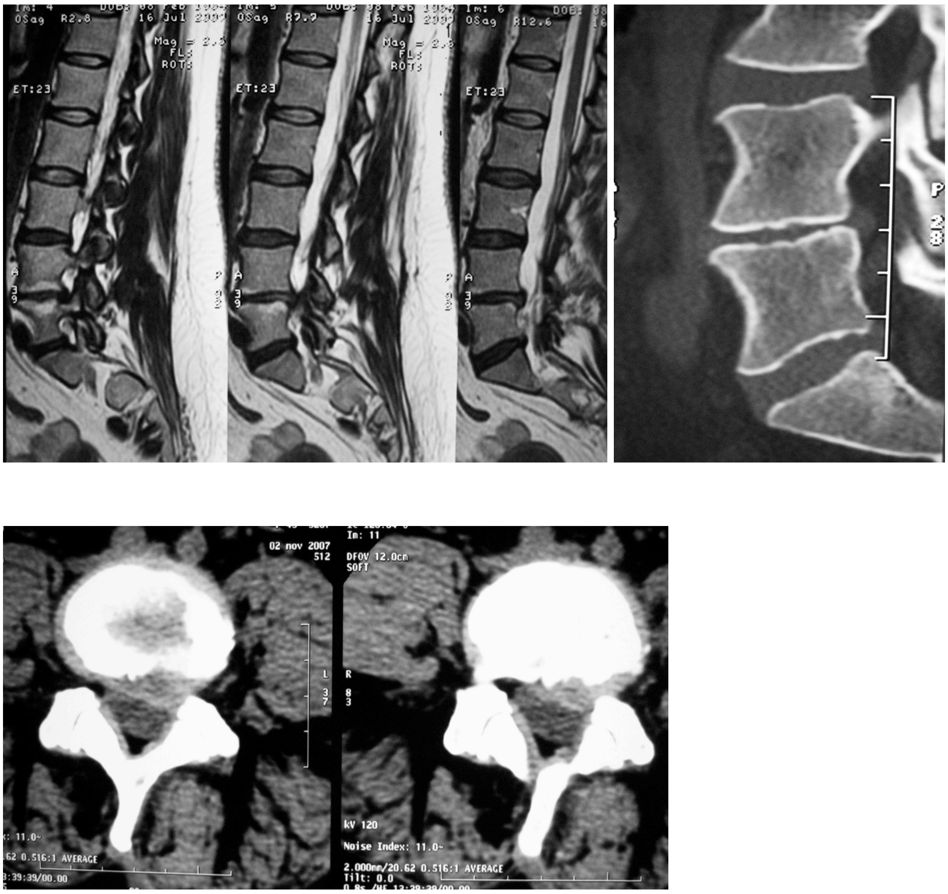
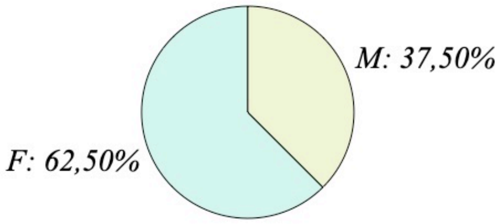


Fig. DDD associated with left intraforaminal disc erniation

Distribution of sex.



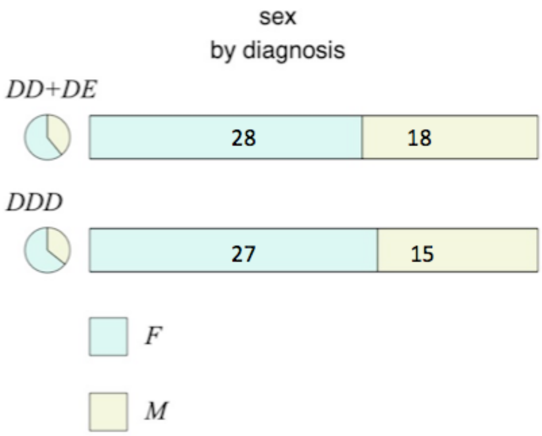


Fig. 11: Distribution of sex between groups

Distribution of spine level

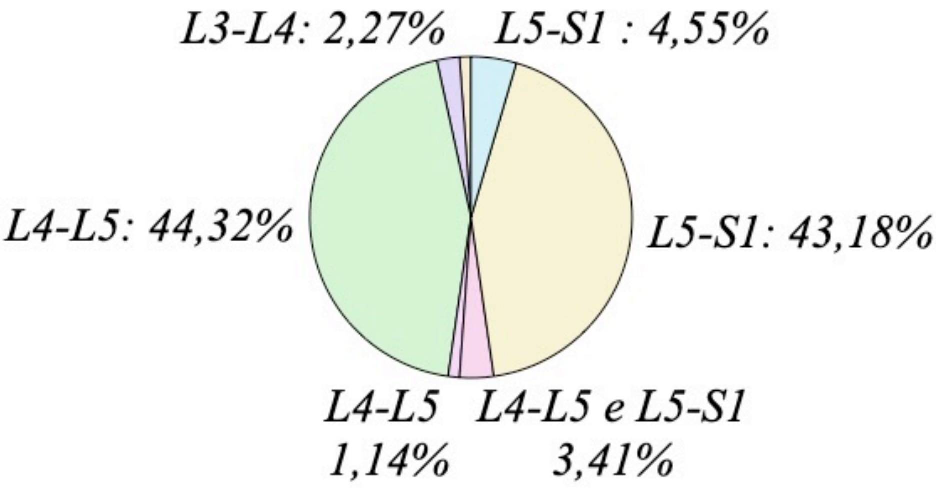


Fig. 12

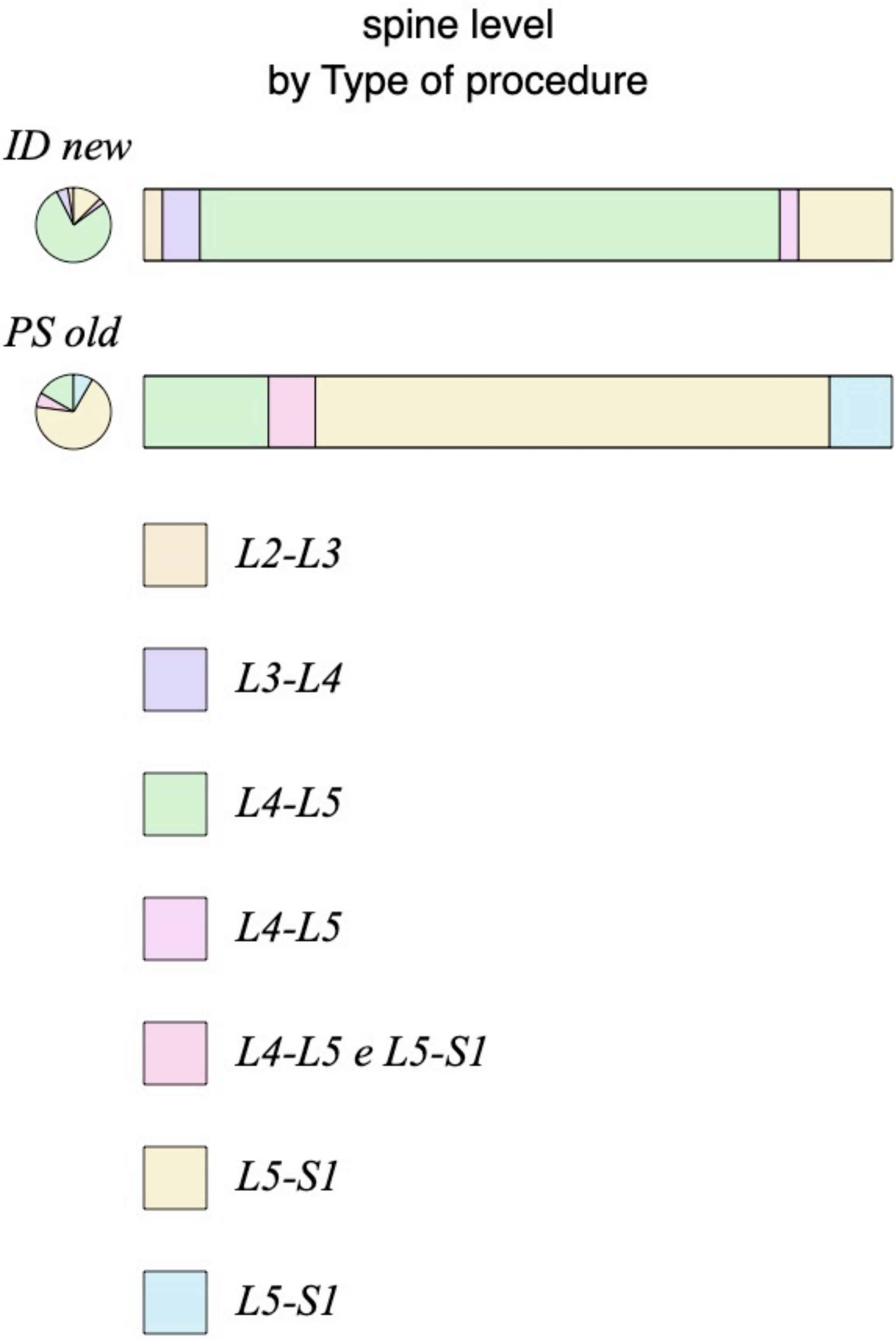


Fig. 13 Spine level involved analized by type of procedure. With the new technique (Interspinous Device) the majority of patients have L4-L5 involved; patients treated with Pedical Screwing were mostly L5-S1

About clinical presentation (Fig. 14), patients referred lombalgia (75%, 66 pts) with (30%, 26 pts) or without (45%, 40 pts) radicular irradiation. Sixteen patients presenting with radicular irradiation without lombalgia (18%); 6 patients presented with caludicatio neurogena. A percentage of 32 of patients with radiculopaty at time of presentation harboured also a decreasing in strenght (28 pts).

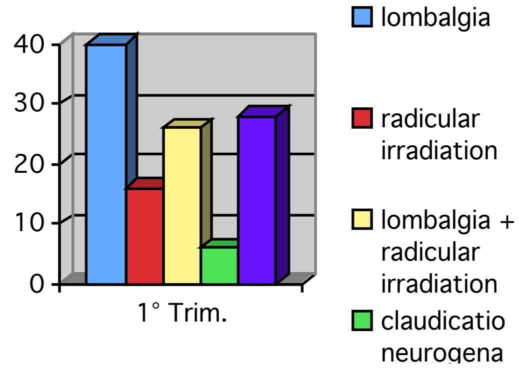


Fig. 14: Clinical presentation

Patients have been followed for a minimum of 12 months (344 days, fig. 15).

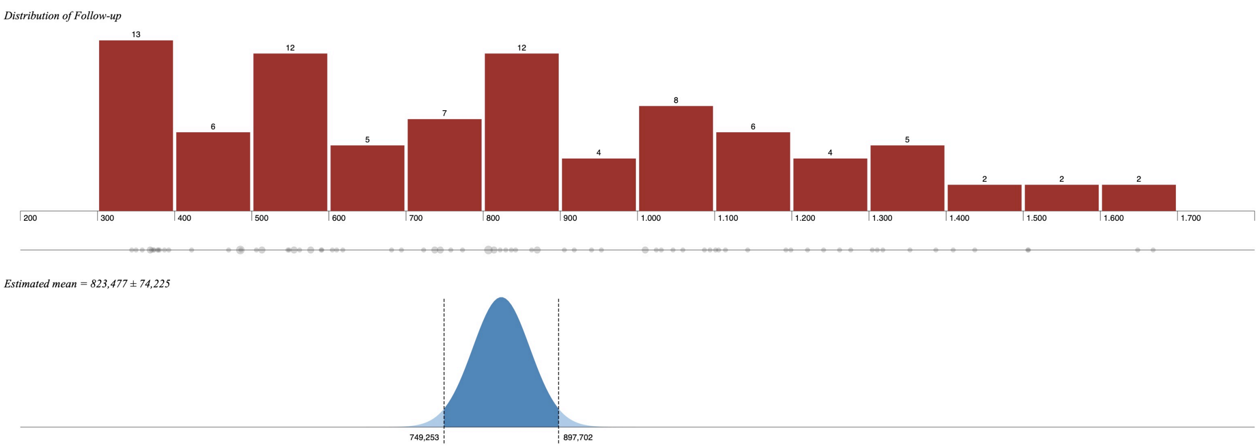


Fig 15: distribution of follow up

SURGICAL TECHNIQUE

All patients underwent surgery with general anesthesia and complete neuromuscular blockade. Patients were positioned prone (Fig.16) on a spinal table to optimize lumbar lordosis and minimize venous bleeding from increased abdominal pressure. The entire procedure was performed through a single posterior midline incision.

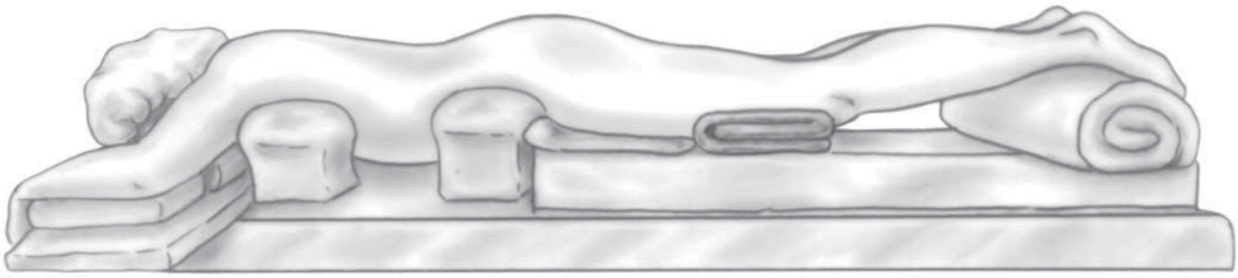


Fig. 16: prone position

1. Transforaminal cage placement

With subperiosteal muscle dissection using a monopolar a wide exposure to the lateral aspect of the facet joints was obtained (Fig. 17).

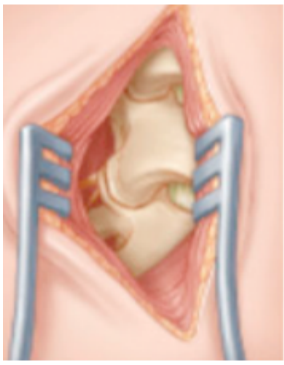


Fig. 16: lateral aspect of facet joint exposure

Partial monolateral laminectomy with removal of superior facet joint was performed in order to expose the access to the intersomatic space (Fig. 17).

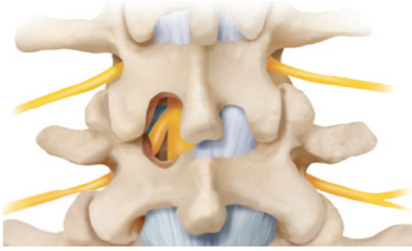


Fig. 17: prone position

Through this unilateral transforaminal approach the degenerated disc was removed. After having exposed the vertebral body end plates with a rasp, a PEEK cage filled with autologous bone was implanted into the interbody space to replace degenerated disc (Fig. 18).

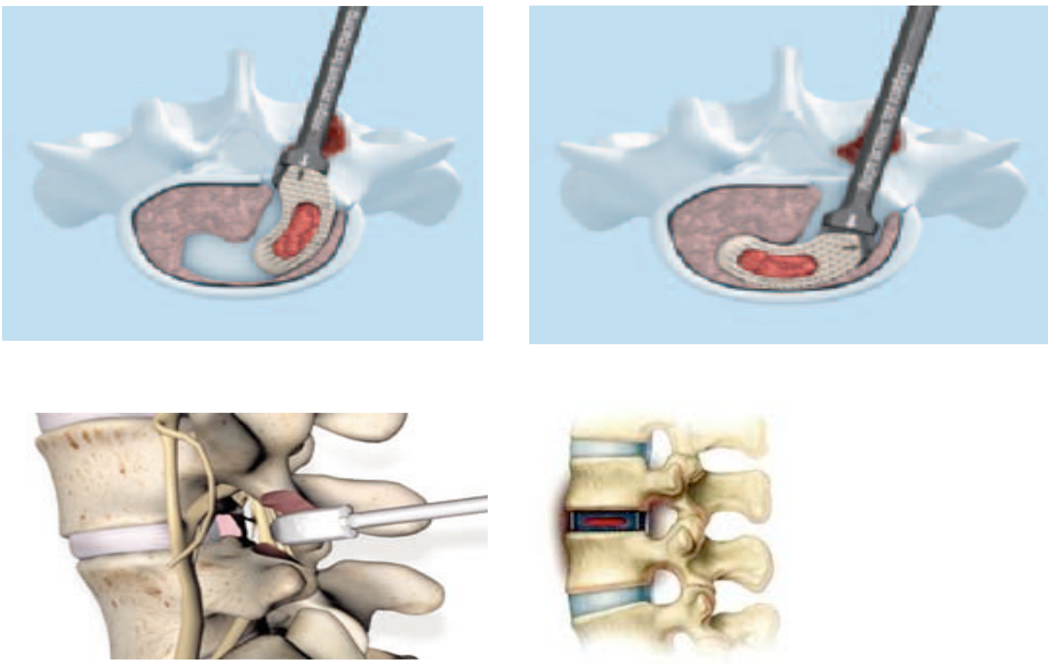


Fig. 18: discectomy and cage positioning

2. IFD (Interspinous Fixation Device) Implantation

A posterior fixation device intended to provide stabilization of segments of lumbo-sacral spine. In our series we used it to support fusion and not as a stand-alone device.

The device we used contains two titanium alloy plates and is assembled by sliding the lock plate (Fig. 19), which possesses a torque-controlled set screw, over the post plate until contact is made with the spinous processes. Once in contact, the device plates are compressed such that the plate fixation spikes become seated within the bones of the respective spinous processes. The set-screw mechanism is then engaged to lock the device in place. Additionally, the device possesses an open bone graft enclosure to support placement of bone graft material within the interspinous space, and is available in multiple device footprints to adapt to specific levels and anatomy.

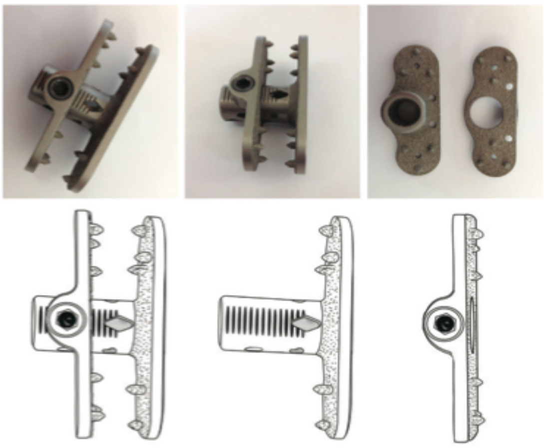


Fig. 19: Interspinous Fixation Device used in the study

SPF approach and instrumentation were performed according to the device's surgical technique guide. A small midline incision was first made over the index spinous processes. Musculature of the contralateral side to the access for cage implantation was then incised via a standard midline approach. The supraspinous ligament was preserved. The interspinous ligament was pierced as far anteriorly as possible using a dilator. Using a spreader placed within the interspinous space, the appropriate size of the implant was then determined. The spinous processes were then decorticated, using a rasp, in order to facilitate fusion. The two component of the device were positioned at the two side of the interspinous space. The device was placed as anteriorly as possible in order to grip the thicker bone mass at the laminar junction (Fig. 20).

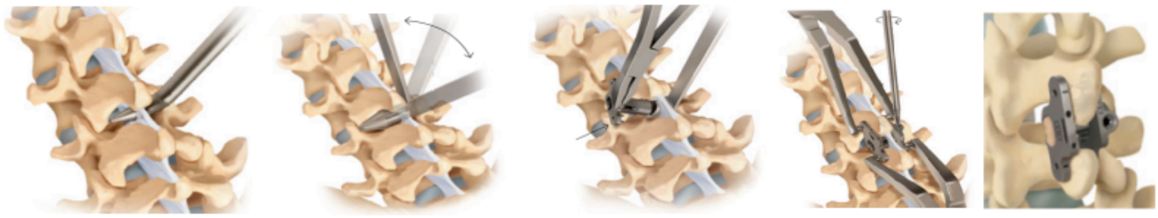


Fig. 20: steps of Interspinous Device placement

The position was controlled, checking the device did not protrude above the lumbodorsal fascia and that the fixation spikes effectively engaged the spinous processes prior to final compression. Bone substitute was then properly located, Additional angulation of the plates was performed if necessary. Final plate compression and set-screw tightening were then performed. Final device placement was confirmed via lateral fluoroscopic imaging (Fig. 21).

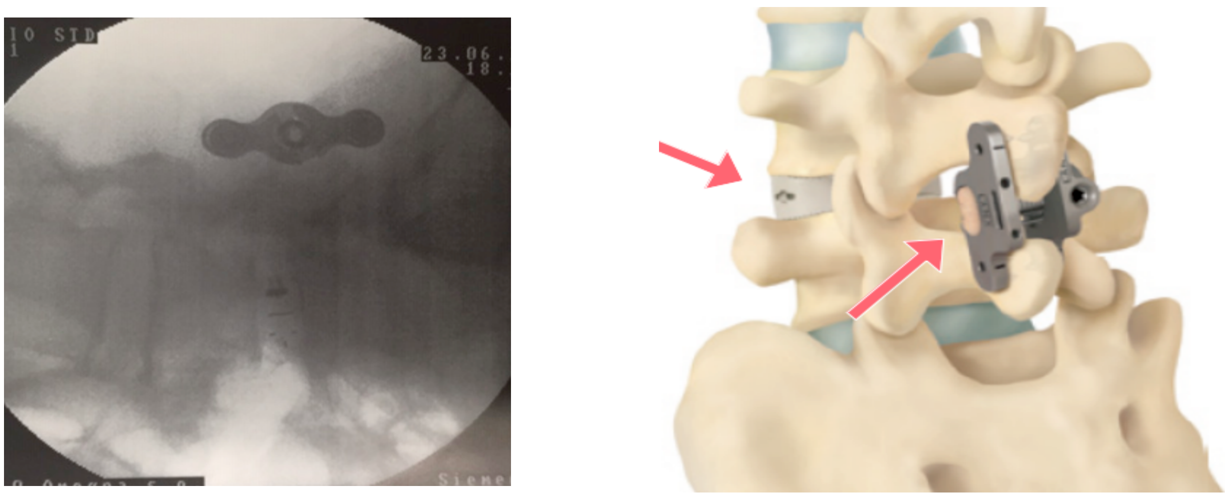


Fig. 21: fluoroscopy control

3. Pedical screwing

With a similar midline incision used for intersomatic cage placement, prolonged a few centimeters in cranio-caudal direction (Fig. 21a), a wide exposure of the lateral aspects of the facet joints was obtained bilaterally (Fig. 21b) through a careful subperiosteal dissection.

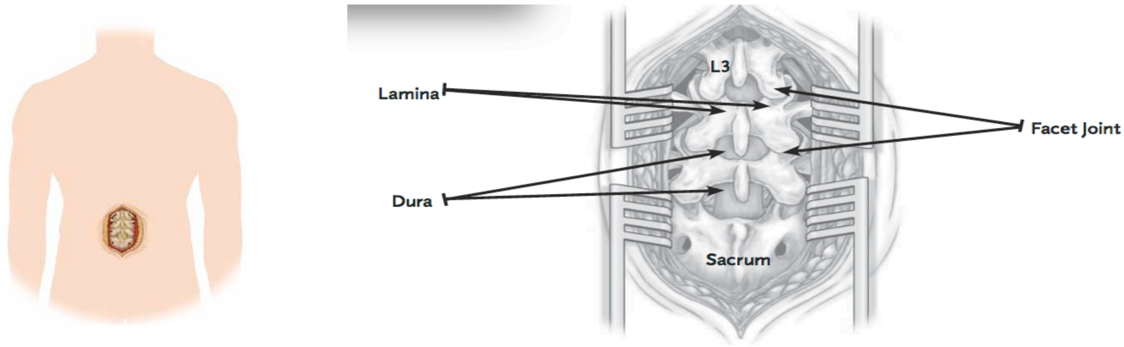


Fig. 21a: prolonged midline incision; 21b: bilateral exposure

Segmental, bilateral polyaxial titanium pedicle screw have been placed at all levels treated using lateral fluoroscopic guidance.

The entry point of the pedicle screw is at the junction of the superior facet process, transverse process and the pars interarticularis (Fig. 22a). A marker is normally placed and an Antero-Posterior (AP) fluoroscopy is made to check the location of the pedicle. The cortical bone overlying entry point is removed to expose cancellous bone then pedicle is probed with dedicated instrument. The trajectory is directed from lateral to medial - tipically 15 degree in lumbar spine - to follow the angulation of the pedicle (Fig. 22b). Another fluoroscopy control can be made to check cranio-caudal direction of the screw to be in the vertebra’s body (Fig. 22c).

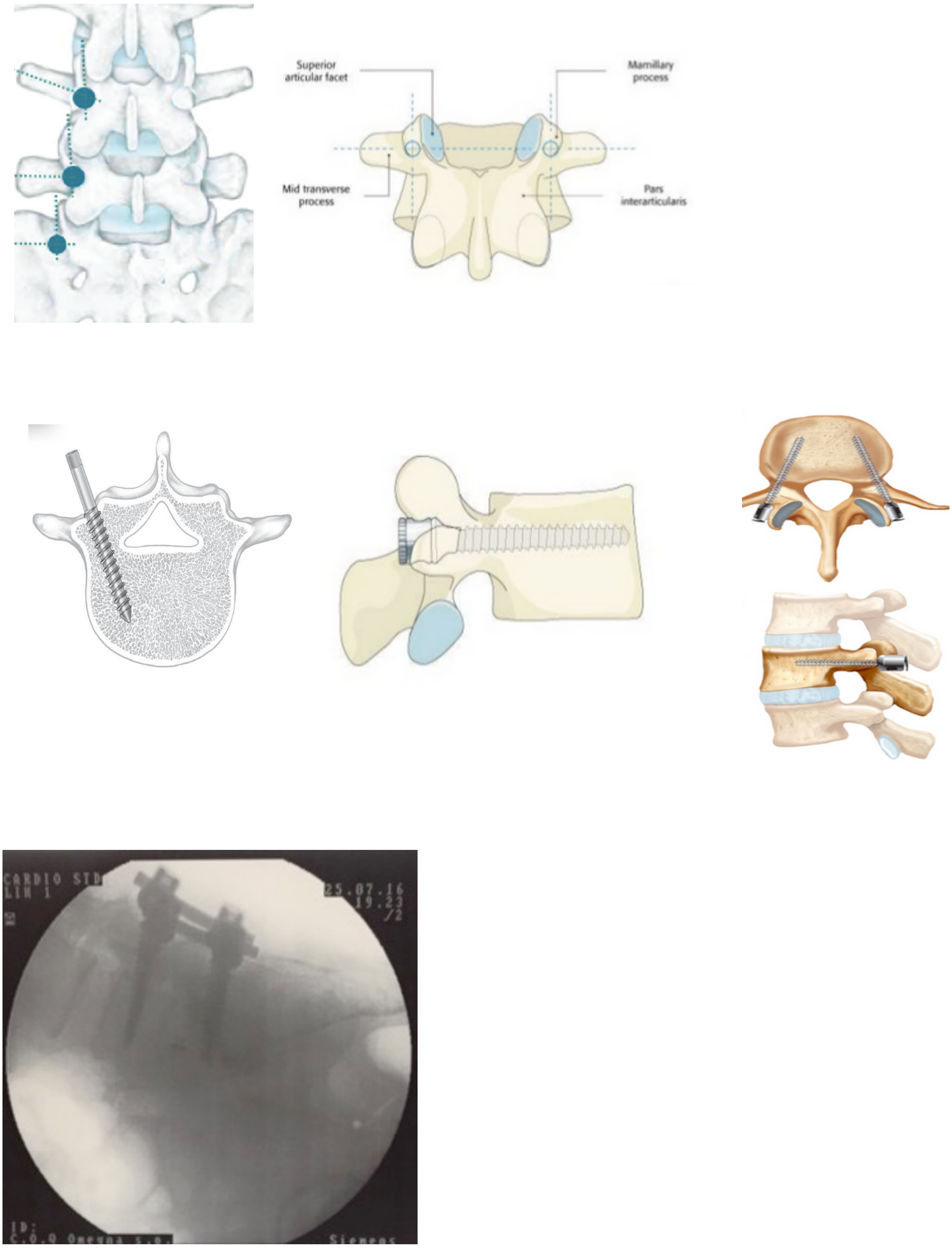


Fig. 22a: entry point; 22b: cranio-caudal and latero-medial direction of the screws ; 22c: final fluoroscopy control

Once all screws have been placed, conjunction rods are positioned between omolateral screw's heads (Fig. 23a) and posterolateral intertransverse fusion with local autograft and allograft (Fig. 23b) was performed.

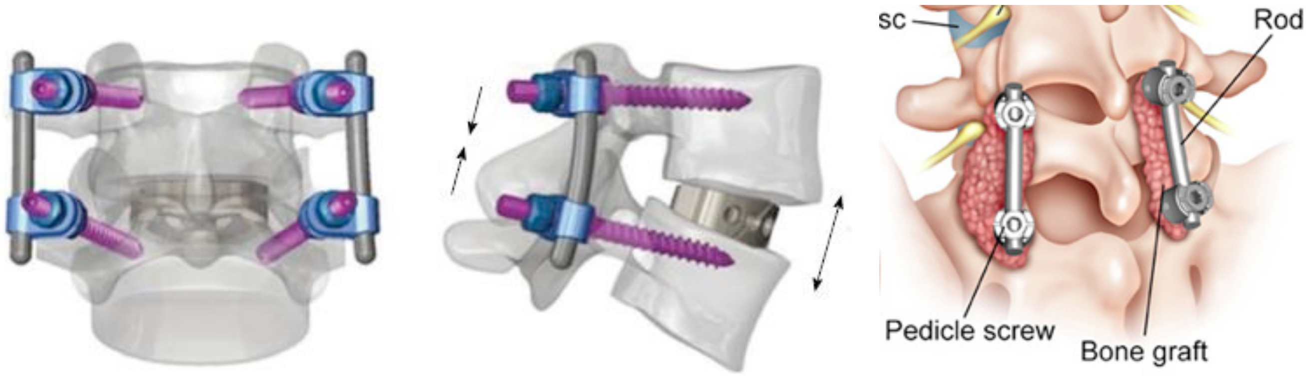


Fig. 23a: conjunction of the heads of the screws by rods; 23b: posterolateral fusion by bone autograft.

METHODS

We analyzed our cohorts of 88 patients that underwent surgery between the 1th of January 2014 and 31th December 2018.

Patients selected for the study have a diagnosis of Degenerative Disc Disease (DDD) alone (42 pts) or DDD and disc erniation (DD+DE, 46 pts). Surgical indication was given only by the senior surgeon. Between these two subgroups, patients were blindly selected for the surgical procedure, fixation with pedical screws (PS) or with interspinous device (ID).

Every surgical procedure has been conducted under general anesthesia according to the surgical technique described before, by a single senior surgeon, after collection of patient's consent.

In the group of patients with DDD alone, 27 patients have been treated with cage placement and screw fixation (DDD-PS) and 15 patients were treated with cage placement and fixation by interspinous device (DDD-ID). In the group of patients with DD and DE, 21 patients have been treated with cage placement and screw fixation (DD+DE-PS) and 25 patients were treated with cage placement and fixation by interspinous device (DD+DE-ID).

We collected data from surgical procedures about length of surgery, blood loss and intraoperative complications. Then during follow up we recorded VAS at 6 months as clinical outcome, fusion rate at 12 months as radiological outcome (evaluated by CT scan), and complications occurred in the 6 months after surgery. For statistical analysis intraoperative complications and complications occurred during follow up have been summed up together as rate of overall complications of the two surgical procedures.

Statistical Analysis

Data have analyzed with either Student's T-test, Mann-Whitney, Kruskal-Wallis, z-score or chi-square test according to characteristics of parameters.

RESULTS

Analysis inclusion criteria required patients to have undergone TLIF (Trans Foraminal Interbody Fusion) with Interspinous Posterior Fixation or Pedical Screwing at one (85 pts) or maximum two levels (3 pts), for degenerative changes in the lumbar spine. Primary diagnoses included degenerative disc disease (DDD) and Degenerative Disc Disease with Disc Herniation. Patients with prior fusion surgery, stenosis, spread osteophytes and scoliosis were excluded. All diagnoses were confirmed by plain anterioposterior and lateral and flexo-extension X-ray, computed tomography (CT) scans, and/or magnetic resonance imaging (MRI). Conservative treatment had been in all cases either non-responsive or insufficient.

Surgical procedure was blindly proposed to every patient, but both (Pedical Screw Fixation or Interspinous Device Fixation) were explicated. Then in every case surgical procedure has been selected according to patients' consent.

Length of surgery

Analyzing data recorded about length of surgeries, TLIF + implantation of interspinous device (ID *new*, for Intraspinous Device *new* technique) required mean operative times inferior to TLIF + pedical screwing (PS *old*, for Pedical Screwing *old* technique), 112,5 minutes vs 135 minutes. The difference in length of surgeries resulted to be statistically significant (Mann-Whitney, P<0,001, Fig. 24a).

Difference in duration of surgery analyzed by diagnosis (DDD vs DDD with Discal Erniation) on the other hand was not statistically significant (Mann-Whitney, P<0,618, Fig. 24b).

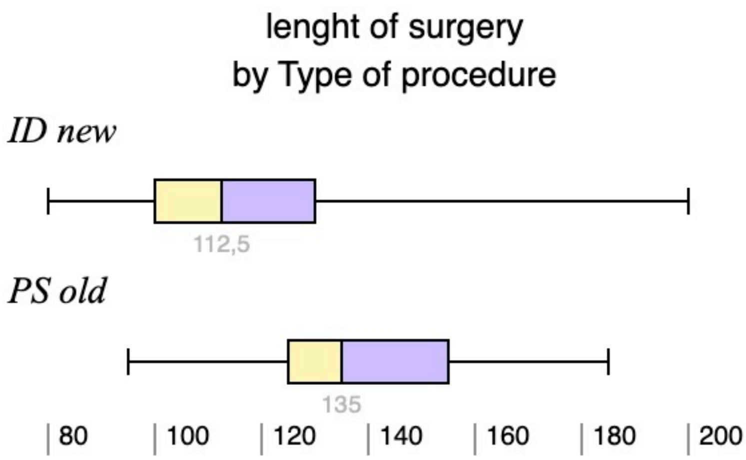


Fig. 24a Lenght of surgery analized by type of procedure: new technique has time of surgery significantly shorter

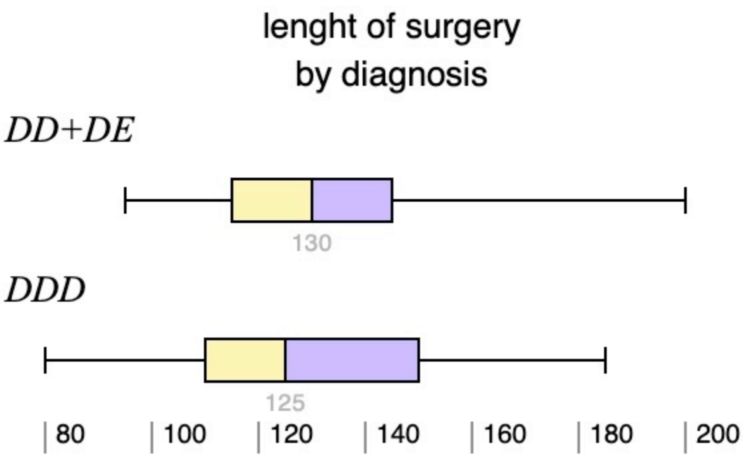


Fig. 24b Lenght of surgery analized by diagnosis: there is no statistically significant difference according to diagnosis (DDD associated or not associated to disc erniation)

Blood loss

Comparing blood loss between the two surgical procedure showed a statistically significant reduction in the group treated with Interspinous Device placement (called ID *new*) vs patients treated with Pedical Screwing (Mann-Whitney, P<0,001, Fig. 25), with a mean loss of 1,3 pt of hemoglobin in the first group and a mean loss of 2 pt of hemoglobin in the second group of patients.

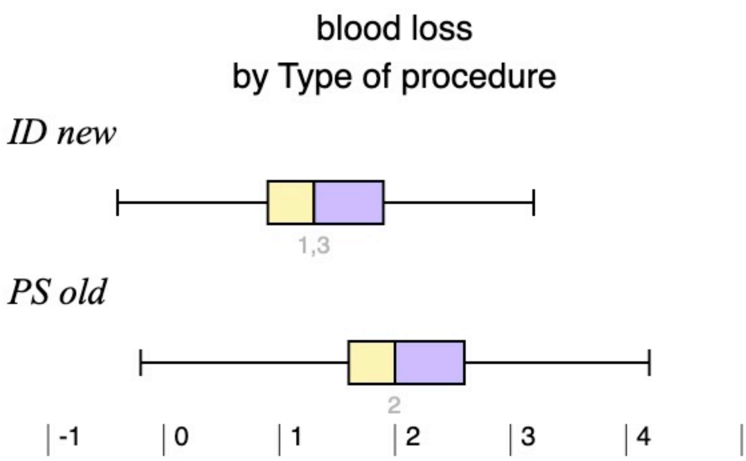


Fig. 25 Blood loss analized by type of procedure: patients treated with Interspinous Device fixation experienced blood loss significantly reduced then patients treated with pedical screwing

Follow up and Clinical Evaluation

Patients were followed as usual protocol of the senior surgeon:

- X-ray and clinical evaluation at 1 month and 6 months after surgery: data about pain were collected at 6 months using VAS scale and compared to values registered before surgery;
- CT scan and clinical evaluation at 12 months after surgery collecting data about success of fusion (Yes/No);
- Complication occurred during follow-up (CSF collection, mobilization of implanted devices, necessity of second surgery, recurrence of radicolopathy)

Clinical outcome

Clinical data before surgery have been recorded using VAS scale, used also for assessing clinical outcome at 6 months after surgery. No difference of VAS values has been detected analyzing patients by diagnosis: mean value of VAS was 7 either in the group of patients harbouring DDD alone or associated with disc herniation (Fig. 26a).

After sugery values of VAS decreased to 3 as mean value in every of the four group of patients divided by diagnosis and type of surgical procedure, but with any statistically significance ((Kruskal-Wallis, p = 0,958, Fig. 26b).

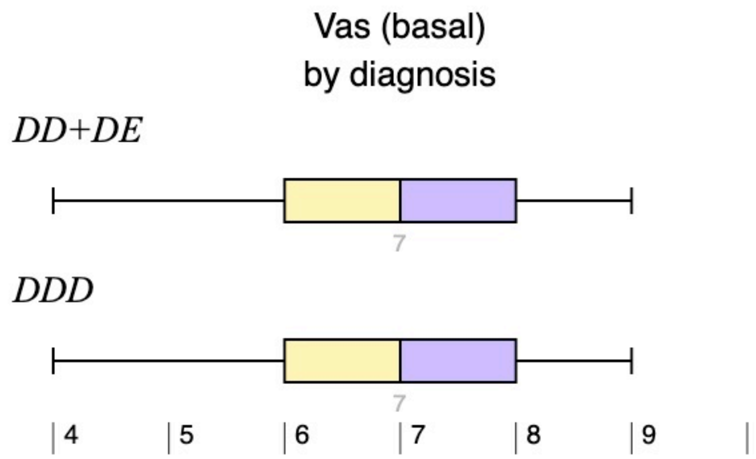


Fig. 26a Clinical valuation misured with VAS score according to diagnosis

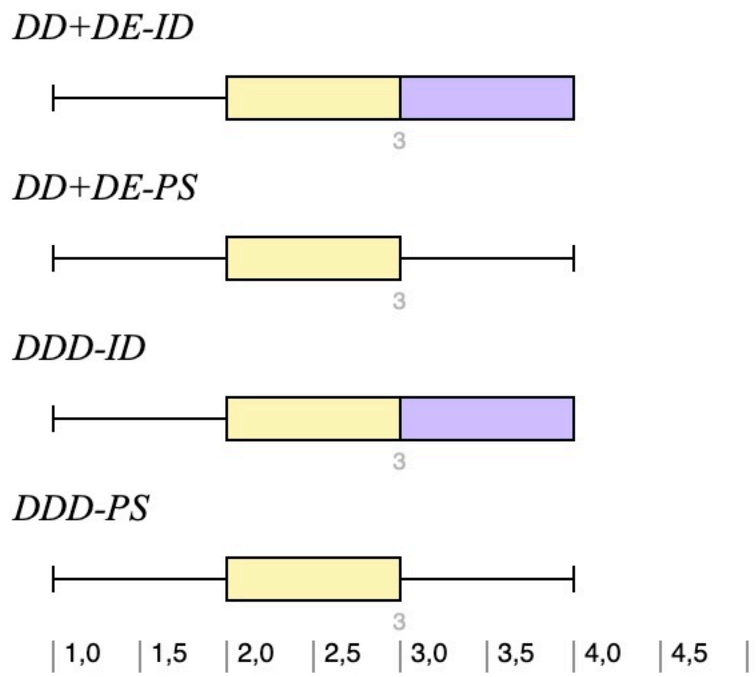


Fig. 26b Clinical outcome in the four groups of patients

Fusion rate

Patiens have been evaluated with X-ray early after surgery (1 and 6 months) to exclude complications as mobilization of implanted material. Then at 12 months after surgery were controlled with CT scan (Fig. 27) to assess fusion and exclude other complications as Adjacent Segment Disease (a condition that sometimes occurs after a spinal fusion surgery to join or "lock" two or more bones together, stopping the natural motion at that level).

Rate of fusion of the whole population of the study has been of about 66% (58 pts), as reported in literature; for 11% (10) of patients we don't have imaging to confirm fusion; in 22,7% (20 pts) of patients CT scans showed absence of fusion. Through this 22,7%, 12 patients (13,6%) reported a clinical improvement without confirmed fusion at radiological studies.

Analyzing the sample by surgical procedure we observed that there are no significant differences between rate of fusion comparing Pedical Screwing (PS *old*) and Interspinous Device (ID *new*) placement (chi-square, p = 0,576, Fig. 28). Radiological outcome of the two subgroups, by surgical technique, can therefore be considered overlayable.

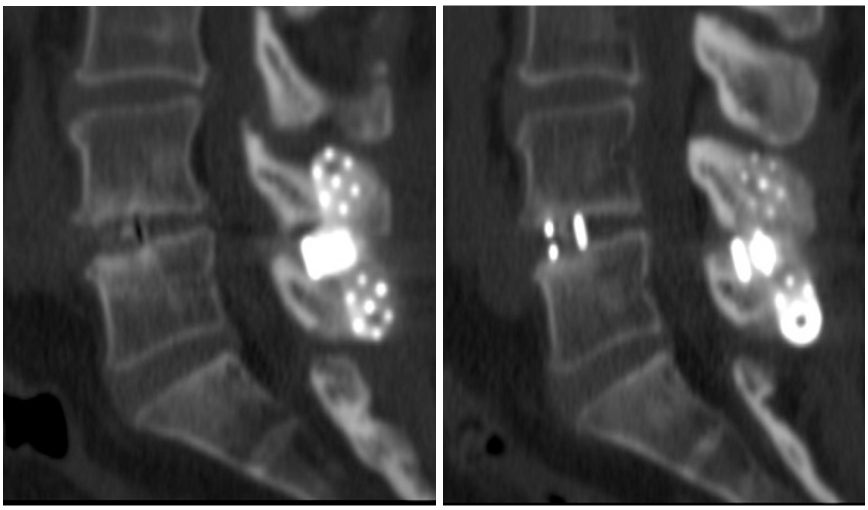


Fig. 27 example of CT scan control 12 months after surgery in which is confirmed anterior and posterior fusion

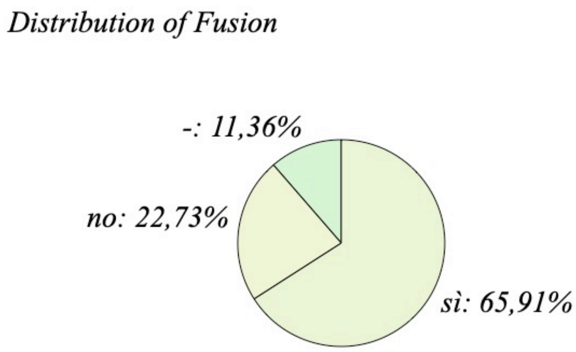


Fig. 28a: Overall rate of fusion

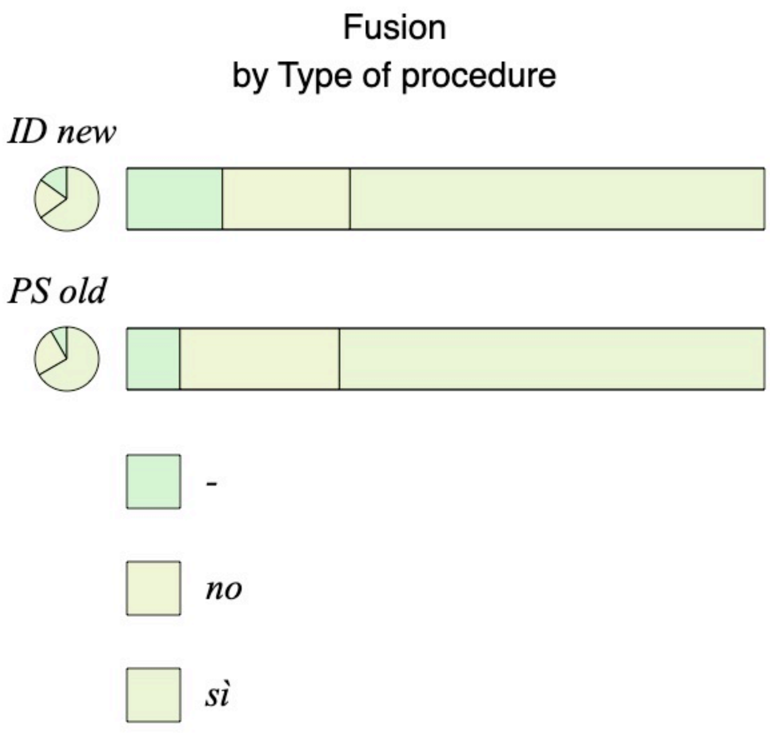


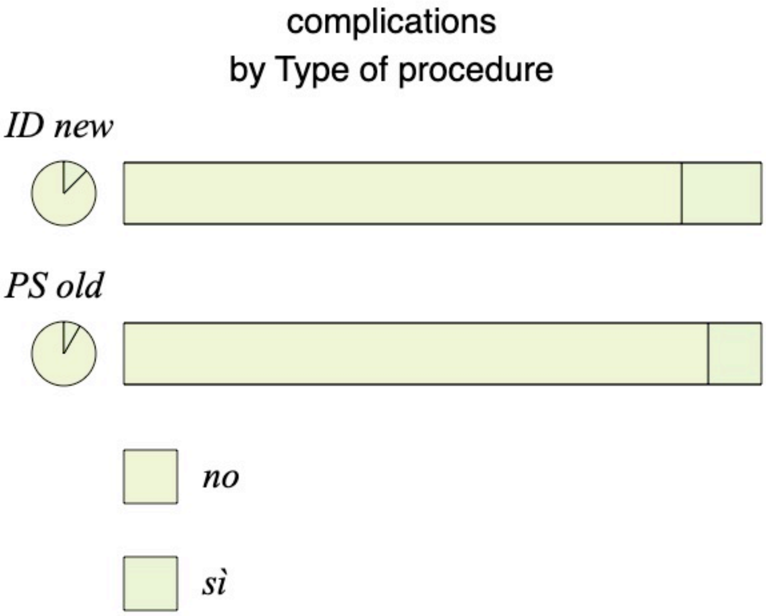
Fig. 28b: Fusion analized by type of surgical procedure

Complications

As complications we considered either adverse events that occurred during surgery (dural rupture, severe blood loss requiring transfusion) either late complications as dislocation of implant that required a reintervention.

The overall rate of complications has been of 11% (9 pts, two of which presented more than one complication). Among these 9 patients 5 complicated with intraoperative dural rupture, 2 patients treated with Pedical Screwing (*old* technique) and 3 patients treated with Interspinous Device placement (*new* technique). In 2 cases a displacement of intersomatic cage occurred and late reintervention has been required to replace the implant (both among patients treated with *new* technique). One patient treated with Pedical Screwing presented increase of White Blood Cellules without others signs of infection. One of the cases complicated with dural injury among patients teated with *new* technique presented fever in the 2th post-operative day; antibiotic therapy was introduced following antibiogram's results. Two patients required blood transfusion during surgery, one between patients treated with Pedical Screwing and one in the group treated with Interspinous Device (one of the patients who required a revision surgery for cage displacement).

From statistical point of view it is not possible to reach significative conclusions. We can however observe that analizing data sort by surgical technique either by diagnosis rate of complications is almost overlayable (Fig. 29).



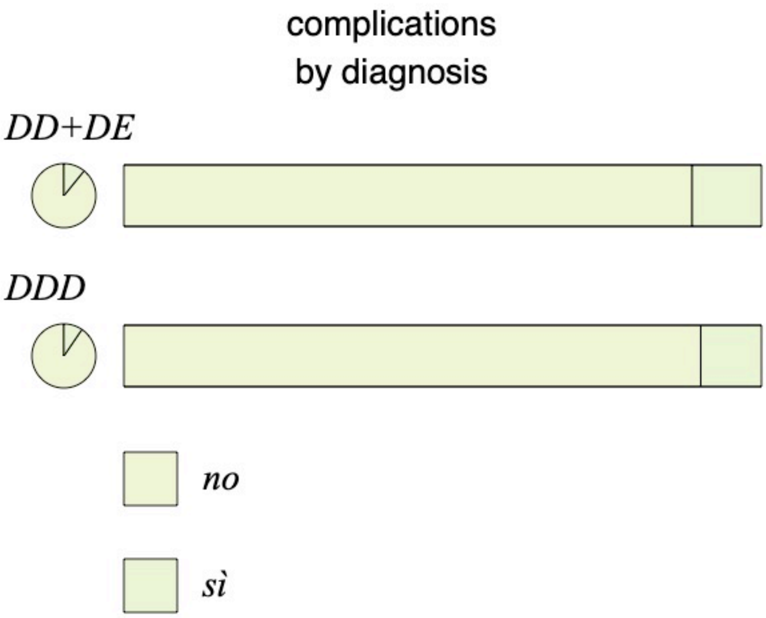


Fig. 29: comparing rates of complications there is no difference comparing the two techniques or the two different diagnosis

DISCUSSION

We presented a serie of 88 patients affected by simptomatic DDD alone or associated with disc erniation, treated with circumferential fixation. Mean age of patients was of 51 years, with a prevalence of female (62,5%). Mean VAS before surgery was of 7, in both group of patients with DDD alone or associated to DE. Referred symptoms have been lombalgia (66 patients) with or without (26 and 40 pts) radicular irradiation. Sixteen patients presenting with radicular irradiation without lombalgia and 6 patients referred a caludicatio neurogena. Twentyeight patients with radiculopaty at time of presentation harboured also a decreasing in strenght.

Circumferential fixation has been pursued by intersomatic cage placement and traditional Pedical Screwing (48 patients) or Interspinous Fixation (40 patients).

Rate of fusion, valuated by CT scan at 12 months after surgery, and clinical outcome, valuated with VAS values at 6 months, despite an absence of statistical significance, were founded to be overlapping in the two group (patients treated with *old* or *new* technique).

Otherwise statistical significant has been showed by reduction of surgical times and blood loss in cases treated with *new* technique (Mann-Whitney, P<0,001).

CONCLUSIONS

Degenerative disc disease, alone or associated with disc erniation or other degenerative pathologies of lumbar spine, is a diffuse condition that negatively affect quality of life of a large amount of middle-aged population. In the lase twenty years intense has been the debact between conservative or sjurgical treatment. Meanwhile new surgical strategies are explored to reduce complications, invasiveness and improving outcome of patients.

We compared two series of patients affected by DDD alone or in association with disc erniation treated with circumferential fusion. Both group of patients have been treated with intersomatic cage placement for intersomatic fusion, but to reach posterior arthrodhesis either classical Pedical Screwing versus Interspinous Fixation have benn used.

Analazing our data, for equal rates of fusion and of complications and overlaping of clinical outcome, cases treated with Interspinous Fixation showed a statistically significative decrease of surgical time and blood loss.

We can conclude for our series a superiority of the *new* technique for selected cases.

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