

Biomechanical and clinical study of single posterior oblique cage POLIF in the treatment of degenerative diseases of the lumbar spine

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Abstract

Introduction Aim of the study was to evaluate the biomechanical stability and the clinical efficacy of a lumbar interbody fusion obtained by single oblique cage implanted by a posterior approach.

Method Through the realization of three finite element models (FEMs), the biomechanics of POLIF was compared to PLIF and TLIF. Ninety-four patients underwent interbody fusion by POLIF with instrumented posterolateral fusion. Clinical and radiographic outcomes were evaluated at regular intervals for at least 6 months.

Results The FEMs showed no statistically significant differences in stability in compression and flexion–extension. Mean preoperative VAS score was 7.1, decreased to 2.1 at follow-up. Mean preoperative SF-12 value was 34.5 %, increased to 75.4 % at follow-up. All patients showed a good fusion rate and no hardware failure.

Discussion POLIF associated to instrumented posterolateral fusion is a viable and safe surgical technique, which ensures a biomechanical stability similar to other surgical techniques.

Keywords Lumbar spine · Interbody fusion · Biomechanics · Cage · Degenerative diseases

Introduction

One of the most important goals for spinal surgery is the restoration of spinal stability through the achievement of a successful fusion. In the last years, various methods have been used to obtain lumbar fusion, from the traditional posterolateral fusion to the most recent interbody fusion techniques. Interbody fusion allows obtaining a biomechanically stronger construct, provides a better axial support with less graft subsidence and produces a better biologic fusion in lordotic alignment [1]. A successful interbody fusion could be obtained with several techniques: autologous bone graft, allograft bone, tricortical graft or bone chips. The introduction of threaded cage gives the possibility of minimizing complications of graft resorption and disc space collapse becoming the gold standard for interbody fusion [2]. The use of traditional posterior lumbar interbody fusion (PLIF) has been widely reported in the last years [3, 4]; nevertheless, this technique is characterized by a moderate rate of complications as double risk of neurological damage, increased blood loss, need of extensive bilateral laminectomy and facetectomy to obtain a correct insertion of both cages [5]. Some conditions as nerve root anomalies or epidural scarring may force to the insertion of a single cage to avoid complications. From a mechanical point of view, the consequent posterior element deficiency adversely affects the stiffness and resistance to flexion and torsion forces [6].

Despite these negative aspects, biomechanical and clinical results reported in medical literature for PLIF are very satisfactory [7], even when a single cage was implanted. In vitro biomechanical data and finite elements analysis widely demonstrated adequate stability for a single cage combined with posterior fixation in the lumbar spine [8, 9]. These data raise the question of whether a

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single oblique cage posteriorly inserted could provide biomechanical stability, clinical outcome and fusion comparable to traditional two cages PLIF or transforaminal lumbar interbody fusion TLIF. Despite a large number of studies about these topics, only few are prospective clinical studies; most are in vitro or biomechanical studies with no clinical application [10, 11]. The purpose of the present study was to evaluate the biomechanical stability and the clinical efficacy of a lumbar interbody fusion obtained by single oblique cage implanted by a posterior approach, named by the authors POLIF, associated to posterior instrumented fusion. Authors' hypothesis was that a single oblique cage provides a fusion and clinical results comparable to traditional techniques with a lower complications risk. To elucidate the biomechanics of the one oblique cage in lumbar instrumented PLIF, three finite element mathematic models (FEM) were realized and the POLIF was compared to the two most common lumbar interbody fusion techniques by a posterior approach, PLIF and TLIF. A clinical prospective study was also conducted on a continuous patient's series to validate its clinical efficacy.

Materials and methods

Study protocol

From October 2013 to October 2014, 94 patients (41 male–53 female) affected by lumbar degenerative diseases underwent interbody fusion by POLIF with posterolateral fusion and pedicle screw fixation. Inclusion criteria were lumbar degenerative spondylolisthesis, recurrent disc herniation with instability, discopathy, back and/or radicular pain from at least 3 months resistant to conservative treatment with severely restricted functional ability. Exclusion criteria were bilateral isthmic spondylolisthesis, spondylolisthesis greater than grade 2, active infection, symptomatic vascular disease. For every patient preoperative diagnosis, intra-operative data (operative time, blood loss), length of hospital stay and complications were recorded. Clinical outcome was evaluated at regular intervals by Visual Analog Scale (VAS) and SF-12. Radiographic evaluation included preoperative posteroanterior, lateral standard and dynamic X-ray, preoperative MRI, and X-rays at regular intervals (immediate postoperative, at 4, 6 months and every year). Cage positioning was evaluated by postoperative targeted CT scan. At 12 months follow-up, the presence of cage subsidence was evaluated according to Schiffmann criteria [12]. At 12 months follow-up also fusion rate was evaluated according to Lenke criteria [13].

Surgical technique

All patients were placed in a prone position on a carbon fiber operating table. A longitudinal incision was made and a bilaterally subperiosteal dissection of the paravertebral muscles was performed, to expose the affected level. For all patients, laminectomy and superior facetectomy of the symptomatic side were performed to obtain an adequate decompression of the neurological elements. Under fluoroscopic guidance, pedicle screws were inserted to stabilize the affected level. Then, a sequential distraction until the achievement of the desired anular tensions and disc opening discectomy was performed. Endplates of the vertebral body were prepared leaving intact the anulus. A graft obtained from the laminectomy was packed into a peek cage, which was inserted into the disc space under fluoroscopic control with an oblique inclination of 30°. The synthesis was completed with two prebent rods fixed to the screws and in compression. A posterolateral fusion with autologous bone graft was also performed in all patients.

Statistical analysis

Descriptive statistics were calculated. The results obtained were analyzed using the parametric Student *t* test and the Chi-square test for a non-parametric evaluation. Significance was accepted at $p < 0.05$. Tests were carried out with SPSS software (SPSS Inc, Chicago, IL, USA).

Finite element modeling

A finite element model of the L4–L5 spinal segment previously developed for the investigation of intervertebral disc degeneration has been employed [14]. The model featured a highly regular mesh including only quadratic hexahedral elements. Ligaments and annular fibers were represented as nonlinear fiber-reinforced membrane elements, the properties of which were calculated based on published in vitro studies [15]. The mechanical properties of the other structures (cortical and trabecular bone, bony endplate, ground matrix of the annulus fibrosus) were also adopted from the same studies (Table 1). The model was adapted to a lordosis angle of 5 degrees and to an intervertebral disc height in the center of the endplates of 9 mm, to best fit the three considered cages. The three models of cage considered (POLIF, PLIF, TLIF) were then incorporated, thus leading to the generation of three distinct models, Fig. 1. In all cases, the nucleus pulposus was completely removed. The annulus fibrosus was partially excised, in agreement with the specific surgical technique for each cage. Furthermore, the cartilage layer on the endplates was removed in the area in contact with the three

Table 1 Material properties employed in the finite element models

Material	Elastic modulus (MPa)
Cortical bone	12,000
Trabecular bone	200
Annulus ground matrix	1
Annulus fibers	Nonlinear (calibration)
Vertebral endplate	10,000
Posterior elements	3500
PEEK	4000
Titanium	110,000

cages. The bony structure has also been partially excised to provide the correct access pathway for posterior and transforaminal intervertebral cages, coherently with the relevant surgical technique.

For each of the three models, simulations have been run applying pure moments of 7.5 Nm in the three anatomical planes [16] in combination with a compressive preload of 500 N. Simulations both with and without posterior fixation have been run. In the relevant configurations, fixation rods have been included by means of beam elements having material properties and cross-section representing standard titanium rods for spinal fixation. The rods have been fixed to the pedicles and vertebral bodies using stiff beam elements representing the pedicle screws. Bonded contact has been simulated between the cages and the adjacent structures. For each configuration and loading condition, the stiffnesses of the three configurations have been evaluated.

Results

Patient's mean age was 50 years (24–77). The fused levels were L3–L4 ($n = 12$), L4–L5 ($n = 45$), L5–S1 ($n = 37$). Considering the etiopathology, 44 were discopathies, 35 degenerative spondylolisthesis grade I and II according to Meyerding, 15 recurrent disc herniations. Mean follow-up

was 8 months. Intra-operative blood loss was 200 ml (range 150–350 ml); no blood transfusion was required in any case. Mean operative time was 87' (range 78'–130'); mean length of stay was 5.7 days (range 5–7 days). Considering clinical outcome at 12 months minimum follow-up, all patients had achieved a satisfactory outcome with a complete return to every-day life. Mean preoperative VAS score was 7.1 (5.9–8.3), decreased to 1.5 (1–3) at 12 months minimum follow-up ($p = 0.004$). There was an improvement both in mental and physical component considering the SF-12 results at 12 months minimum follow-up: from 34.5 % (25.7–50.4 %) to 75.4 % (68.2–99.4 %) for physical components and from 38.8 % (23.4–41.8 %) to 72.3 % (65.5–76.3 %) for mental components ($p = 0.003$). At immediate postoperative CT scans control, there was an optimal cage positioning in 88 % of cases and a satisfactory one in 12 %, example in Fig. 2. At 12 months minimum follow-up, 47 % ($n = 44$) of the patients showed a good fusion rate; 35 % ($n = 33$) a satisfactory one; 18 % ($n = 17$) an unassessable one Fig. 3a–c. Neither cage migration nor hardware failure was observed at last radiographic control. No cage subsidence was observed at 12 months follow-up ($p = 0.08$) (Table 2). No major complications were observed. Two minor complications were observed in 2 patients: one had an immediate temporary transient neurologic deficit of the adjacent nerve root, the other a dural tear with no neurological sequelae.

Finite element modeling showed comparable results for the three configurations (PLIF, POLIF, TLIF) Fig. 4, with a tendency towards a higher stiffness for the PLIF which is presumably due to the higher contact area of the two cages. If posterior fixation was not simulated, a significantly lower stiffness was found for both POLIF and TLIF with respect to PLIF, except for flexion and extension moments with the POLIF construct. In this case, the longer aspect of the cage in the anteroposterior direction could partially compensate for the lower contact area if compared with the two cages. Nevertheless, stiffness differences are much less pronounced if posterior fixation is modeled. In this case,

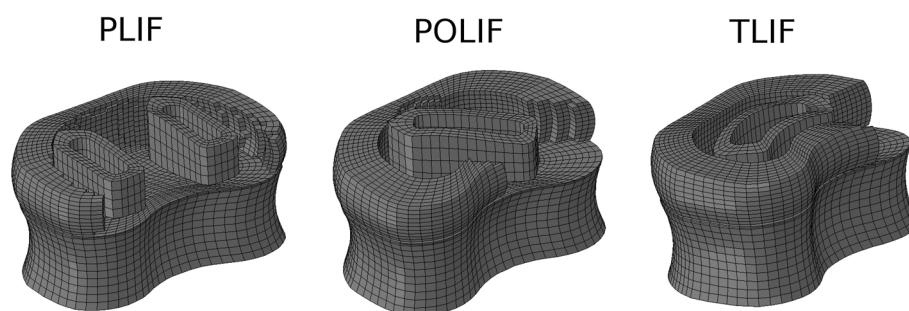


Fig. 1 Section views of the finite element models representing the three configurations investigated showing the positioning of the cages (PLIF, POLIF, TLIF), in which the portion of annular tissue removed

during the surgical procedure can be identified. For the sake of clarity, the L4 vertebra as well as the posterior elements are not shown

Fig. 2 Postoperative CT scan showing cage positioning

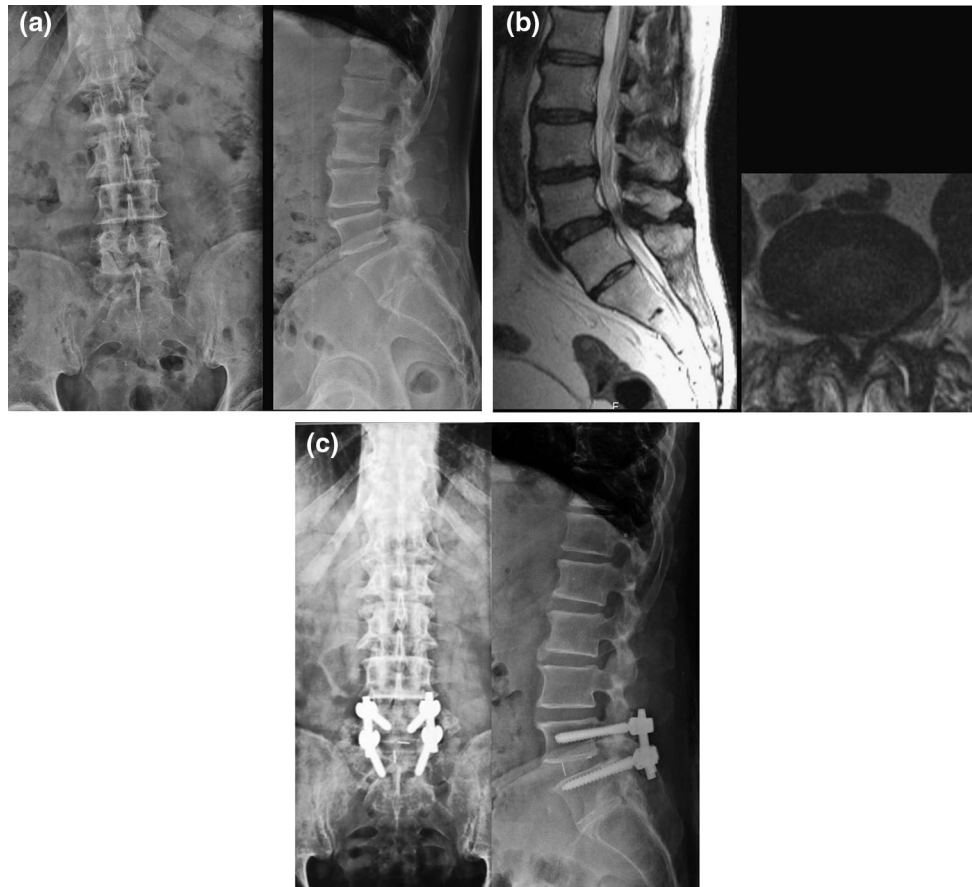
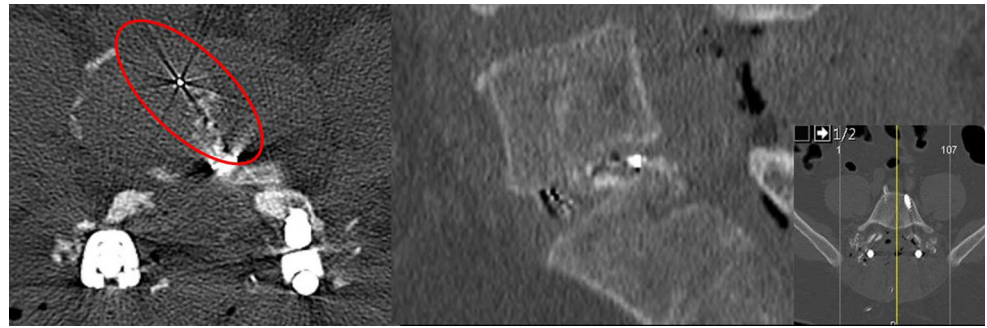


Fig. 3 **a** Preoperative X-ray of a 67-year-old man with symptomatic central stenosis and discopathy. **b** Sagittal and axial MRI. **c** The results at 12 months follow-up showing a good fusion rate

POLIF and TLIF provided a stability similar to that of PLIF, except for the pure compression load and, to a lesser extent, flexion. However, stiffnesses predicted for POLIF and TLIF were in all cases very similar.

Discussion

Achievement of a solid fusion has become the gold standard in the treatment of degenerative spine diseases. The use of posterior and posterolateral fusion, consequently, has

become the predominant surgical modality in the treatment of degenerative conditions. In the last years, several studies showed that interbody fusion provides several advantages compared to other fusion techniques [17]. It immobilizes the degenerated spinal unit, gives a direct and indirect decompression on nerve roots and restores the load bearing ability of the anterior column. Therefore, PLIF involving bilateral cages with pedicle screws has been recommended for routine use [18]. Despite the satisfactory clinical and biomechanical results, bilateral cage PLIF is burdened by several complications. Complications as graft collapse, slippage,

Table 2 Summary of preoperative and postoperative data of disc height to evaluate subsidence incidence

	Difference between anterior disc height (mm)	Difference between posterior disc height (mm)
L3–L4		
Mean	1.97	0.956
DS	2.56	1.78
L4–L5		
Mean	1.95	0.867
DS	2.50	1.70
L5–S1		
Mean	1.77	0.68
DS	2.54	1.93

cage migration, dura and nerve root lesions have been estimated up to 4–10 % of cases treated with bilateral PLIF [18]. The rate of complications seems to decrease with the introduction of a unilateral cage interbody fusion as, for example, the standardized TLIF technique [18]. Both bilateral PLIF and TLIF, however, need great disc exposure to obtain an adequate cage positioning, thus making difficult to preserve facet joints during cage insertion and greatly reducing posterior tension bend stiffness [8]. In the traditional TLIF insertion, a total facetectomy is sometimes required to obtain a complete cage rotation. This particular kind of approach, leaving the facets on one side spared, prejudices the rotational stability more than with two cage PLIF, in which the facetectomy is bilateral but partial [19]. Rotational stability could be better preserved, using TLIF technique, when the foramen is approached from the external side.

POLIF technique allows the introduction of a unilateral oblique cage reducing the width of posterior exposure compared with bilateral PLIF. Moreover, cage insertion requires only a unilateral partial facetectomy, which preserves the posterior element stiffness better than TLIF. Several studies showed as the biomechanical differences in stability provided by the number of cage inserted or by their orientation were lowered when interbody fusion is associated to posterior pedicle screw fixation [5, 8, 19, 20]. Harris in a human cadaver study demonstrated also that, when associated to posterior pedicle screws fixation, the stability of a single oblique cage matches that of an intact motion segment [21]. Coherently, FEMs presented in this study showed that the stability is quite similar in the three analyzed techniques when they are associated to posterior fixation and fusion (Fig. 4).

In general, the clinical and radiographic outcome of the patients series described in this study was very good. The fusion rate reached in the present patients series at 12 months follow-up is 82 %. This percentage is comparable to that reported in medical literature for traditional PLIF and TLIF [3, 5, 22]. Nevertheless, the choice of using traditional radiographs to assess fusion instead of more accurate CT scans prevented a precise evaluation in the remaining 18 % of patients. At 18 months last follow-up neither hardware failure, nor screw or cage loosening, nor nonunion are visible. Encouraging results were registered also for the clinical scores. VAS and SF-12 data showed a great functional recovery and a complete regression of back and radicular pain at medium follow-up for 92 % ($n = 6$) of patients, fast complete regression for 6 % of patients ($n = 6$), unsatisfactory clinical results despite a good biomechanical outcome in 2 % ($n = 2$) of patients. A

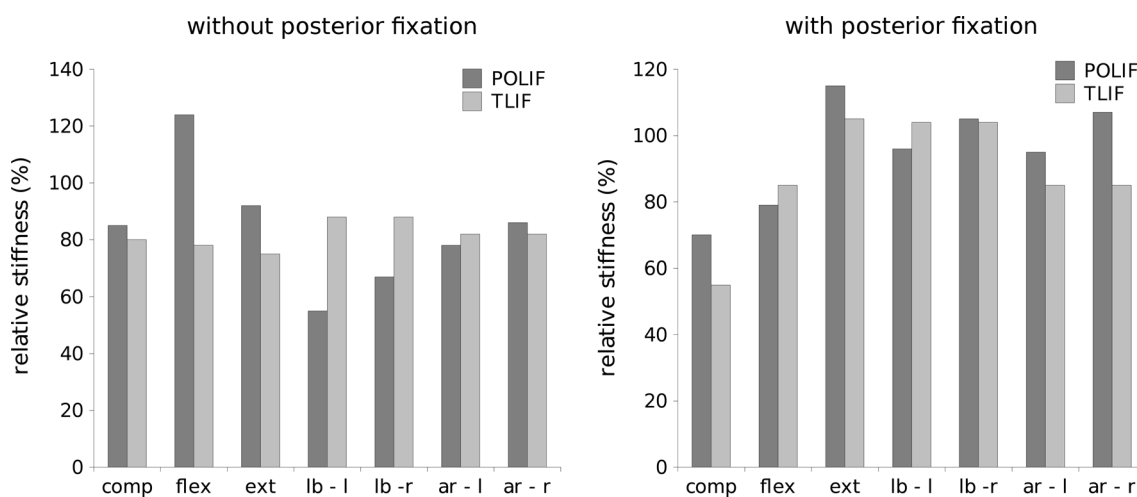


Fig. 4 Relative stiffness of the POLIF and TLIF configurations with respect to the PLIF, without (*left*) and with (*right*) posterior fixation, predicted for different loading conditions. *Comp* compression, *flex* flexion plus compressive preload, *ext* extension plus preload, *lb-l* left

lateral bending plus preload, *lb-r* right lateral bending plus preload, *ax-l* left axial rotation plus preload, *ax-r* right axial rotation plus preload

faster recovery and shorter hospital stay are registered for all patients if compared to these reported in medical literature for bilateral PLIF and TLIF [11, 18]. As postulated also by other authors, these improved immediate postoperative results could be attributed to reduced intra-operative blood loss, less invasive posterior element dissection, shorter operative time. An oblique unilateral insertion reduces exposure and enables precise and easier implantation if compared to bilateral PLIF and TLIF. POLIF advantages versus the two traditional techniques include also a not negligible lower risk of injury to neural structures related to excessive root retraction and for bilateral cage insertion of epidural fibrosis. In patients with unilateral symptomatology, POLIF gives the advantage to insert cage only from the symptomatic side so as to avoid retraction of the nerve root and dural sac of the asymptomatic side, giving so better clinical results at long-term follow-up. Moreover, the implantation of a single cage significantly diminishes the cost as widely illustrated by Molinary in his study [10].

Some limitations have to be acknowledged to this study, despite the advantages of the technique mentioned above. POLIF cannot be used in high-grade spondylolisthesis or bilateral isthmic spondylolysis or listhes, in which a bilateral approach is mandatory to obtain a good reduction and to restore a satisfactory mechanical stability. Regarding the FEMs, simplifications were made in the modeling of the contacts between cages and endplate, in which slippage was not allowed, and in neglecting a possible inelastic behavior of the vertebral bone under high loads. Although our clinical and radiological results are encouraging, which indicate that POLIF is an equivalent treatment if compared to bilateral PLIF and TLIF, broader patient series and long-term outcome studies are needed to completely validate this surgical technique.

Conclusion

The reported data allow concluding that POLIF associated to posterior fixation and fusion enables sufficient decompression to the neural structures, and achieves solid fusion maintaining minimal invasion to the posterior elements. It allows reduction of operative time, of rates of complications, of costs; it needs a short learning curve ensuring a biomechanical stability similar to that obtained with other traditional surgical techniques with comparable and faster return of patients to every-day life.

Compliance with ethical standards

Conflict of interest The author declares they have no competing interest.

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