Lumbar-sacral fusion by a combined approach using interbody PEEK cage and posterior pedicle-screw fixation: Clinical and radiological results from a prospective study

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KEYWORDS
Spinal fusion; Neurosurgical procedures; Orthopedic surgical procedure; Lordosis; Combined approach; Sagittal balance

Summary
Introduction: This prospective series evaluated the clinical and radiological results of a circumferential lumbar fusion achieved by a combined approach in one stage (anterior then posterior) using interbody PEEK cages and posterior pedicle-screw fixation. Hypothesis: The combined approach in one stage is a safe and efficient technique with few complications to achieve a fusion with a satisfying clinical and radiological outcome. Materials and methods: Thirty-nine consecutive patients were prospectively included, with a one-year clinical and radiological minimum follow-up, from December 2008 to July 2011. All patients suffering from degenerative disc disease or low-grade isthmic spondylolisthesis requiring LSS1, L4L5 or L4S1 spinal fusions were included. Clinical outcome was assessed using VAS, ODI and Rolland–Morris scores. Radiological outcome was assessed by analyzing PI, PT, lumbar lordosis, segmental lordosis, disc height, C7/CSFD ratio on full spine radiographies and the quality of bone fusion on a CT scan at 1-year follow-up. Blood loss, surgery time and adverse events were also recorded. Results: Twenty-nine patients (74%) were operated for a lumbar degenerative disc disease and 10 patients (26%) for an isthmic spondylolisthesis. Mean age was 46 (± 10.1) years old. Clinical
Outcome were satisfactory. VAS, ODI and Rolland–Morris scores substantially improved. Mean follow-up was 22.5 months (± 8.7). Mean surgery time was 227 min (± 41.4) for complete surgical procedure time. Mean blood loss was 308 mL (± 179.2) for total surgery. Fusion was assessed in all cases. Disc height and segmental lordosis significantly improved in postoperative. The segmental lordosis at operated level(s) increased by 8.5° (± 5) regardless of the level, and by 11.6° (± 6) for L5–S1.

Conclusion: The combined procedure meets the requested criteria for a lumbar fusion in terms of clinical and functional results, fusion rates, and restoration of segmental lordosis. It cumulates the advantages of the anterior and posterior approach performed alone and should be considered by surgeons before realizing a lumbar fusion.

Level of evidence: Level III prospective study.
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Introduction

One of the most common surgical procedures to treat degenerative disc disease in the lumbar spine is represented by spinal fusion, defined as the bone fusion of the vertebrae achieved after surgery [1]. Different surgical approaches, methods of fusion, types of instrumentation, and bone grafts have been developed in the past 20 years to improve the bone fusion success and clinical outcome [2–5]. Interbody fusion techniques have been developed to provide solid fixation of spinal segments while restoring a proper disc height and sagittal balance [6]. Although there is still controversy regarding the best technique, there seems to be a trend toward the use of the interbody technique, reported to achieve up to 95% to 100% of fusion. The interbody lumbar fusions may be achieved by: anterior lumbar interbody fusion (ALIF); transfemoral lumbar interbody fusion (TLIF); posterior lumbar interbody fusion (PLIF), or a combined approach (anterior + posterior). The purpose of this study was to prospectively evaluate a cohort of patients following a one-step ALIF with PEEK cage combined with posterior pedicle-screw fixation. Our hypothesis was that combined lumbo-sacral fusion is a safe and efficient surgical technique, with less dural tears and limited blood loss to obtain fusion, restore a proper disc height and segmental lordosis with a good functional outcome.

Material and methods

All patients ≥ 18-year-old with a degenerative disc disease or low-grade spondylolisthesis by isthmic lysis requiring a L5S1, L4L5 or L4S1 spinal fusion who underwent spinal fusion by a combined approach at our institution from December 2008 to July 2011 were included in the study. A minimum 1 year clinical and radiographic follow-up was obtained for all the subjects.

Patients with scoliosis, over grade II Meyerding spondylolisthesis, degenerative spondylolisthesis, infection, tumor, a prior fusion surgery or a fusion greater than two-levels were excluded.

Surgical technique

The morphology and location of pre-vertebral vascular structures were preoperatively analysed by a 3D angioCT scan with a special interest on relationships between iliac veins and intervertebral discs [7].

Patients were positioned supine, legs in abduction and the lumbar spine slightly hyper-extended, on a standard operating table. Through a midline abdominal incision, retroperitoneal exposure of the disc level(s) was performed. Following radiographic verification of the correct level, the intervertebral disc was removed. All cartilaginous material was removed from the endplates. Normal disc height was re-established (compared to adjacent levels) and an appropriately sized, lordotic, PEEK cage was selected (Antelys™, Scient’x-Alphatec, Carlsbad, USA) filled-up with recombinant human bone morphogenic protein (2rhBMP-2). Radiographic verification of correct positioning of the cage was finally obtained.

Under the same anaesthesia, patients were then repositioned in ventral decubitus. They underwent single- or double-level instrumented arthrodthesis using mono- and poly-axial pedicle-screws with pre-lordosed rods (Aladyn™, Scient’x-Alphatec, Carlsbad, USA). In case of symptomatic lumbar stenosis with radicular pain, a recalibration of the lumbar canal was realized. Bone obtained from the spinous process and the arthrectomy was morselized and applied as graft material between lamina and facet joints.

Finally, a one-step 360° arthrodthesis was obtained with optimal biomechanical stabilization of the spinal segment (Fig. 1). Surgical time for the anterior, posterior and total procedure was calculated from the initial skin incision to closure, the second skin incision to closure and the initial anterior incision to the posterior dressing, respectively.

Clinical evaluation

Visual analog scores (VAS) for back and leg pain, Oswestry Disability Index (ODI) and Rolland–Morris score were prospectively collected preoperatively and at last follow-up by another surgeon than the operator. Hospital charts and medical records were independently evaluated for operative and postoperative complications, estimated blood loss and surgical time.

Radiological evaluation

Each patient had preoperative and 1 year postoperative full length standing radiographs with the EOS
system (Biospace, Paris, France) [8]. Measured parameters were:

- pelvic incidence (PI): angle between the perpendicular to the sacral plate at its midpoint and the line connecting this point to the femoral heads axis;
- pelvis tilt (PT): angle between the vertical line and the line through the midpoint of the sacral plate to femoral head axis;
- lumbar lordosis (LL): angle between L1 superior endplate and S1 endplate;
- segmental lordosis (Lseg): angle between upper endplate of the vertebra above the instrumented disc and lower endplate of the vertebra below the instrumented disc (for L5S1 disc, we considered S1 endplate). Lseg was measured for the levels fused with cages only.
- sagittal vertical axis (SVA): distance between C7 plumb line and S1 top margin posterior corner [9];
- C7plumbline/sacro-femoral distance ratio (C7/CSFD): ratio between the C7 plumb line and the sacro-femoral distance (i.e. the horizontal distance between the vertical bi-coxo-femoral axis and the vertical line passing through S1 endplate posterior corner) (Fig. 2). C7/CSFD evaluates the global sagittal alignment of the spine above the pelvis (normal value \(-0.9 \pm 1\) [10];
- disc height (DH): as reported by Drain et al. [11], for the levels fused with cages (Fig. 3).

Two independent observers assessed the quality of the fusion on the 1 year CT scan, evaluated according to the Spine Interbody Research Group criteria [12].

Statistical analysis

Statistical analyses were conducted using SPSS version 12.0 (SPSS Inc, Chicago, IL, USA). Paired-samples t-tests were

Figure 1 Oblique view of the construct demonstrating anterior interbody PEEK cage associated with pedicle-screw-based posterior stabilization.

Figure 2 C7 plumbline/sacro-femoral distance ratio. [10]. C7/CSFD = AB/CD. used to compare the preoperative and postoperative radiological parameters. A P value inferior to 0.05 was taken as significant.

Results

Thirty-nine patients (21 female women and 18 men, mean age of 46 ± 10.1-year-old) were operated by a single surgeon for a lumbar degenerative disc disease (n = 29, 74%) or an isthmic spondylolisthesis (n = 10, 26%). The distribution of levels fused were (Fig. 4):

- for 1-level fusion: 13 for L5S1 (33.3%), 2 for L4L5 (5.1%);
- for 2-level fusion: 10 for L4S1-ALIF L5S1 (25.6%), 14 for L4S1-2 ALIF (L4L5 and L5S1) (35.9%).

Mean surgery time was 95 ± 24.8 min, 111.9 ± 25 min and 227 ± 41.4 min for anterior, posterior and total procedure,
respectively. Mean blood loss was $62.2 \pm 96.3 \text{ mL}$, $246 \pm 154.7 \text{ mL}$ and $308 \pm 179.2 \text{ mL}$ for the anterior, posterior and total procedure, respectively (Table 1). Mean follow-up was $22.5 \pm 8.7$ months.

There are no dural tears, no postoperative infection and no neurologic deficit observed postoperatively. During an anterior approach, one vascular wound of the right external iliac artery was encountered, needing the intervention of a vascular surgeon with no secondary side effects. There was no revision surgery.

**Clinical outcome**

Pre- and postoperative scores are reported in Table 2. VAS, ODI and Roland–Morris/24 significantly decreased postoperatively at 1 year.

**Radiological outcome**

Preoperative and postoperative parameters are reported in Table 3. No instrumentation breakage, cage migration/subsidence or implant failure was observed. DH, Lseg and LsegL5S1 significantly increased postoperatively (Fig. 5). Mean correction was $8.5 \pm 5$ [0–21] regardless of the level. At L5-S1, mean gain of lordosis was calculated to $11.6 \pm 6$ [3–21].

All levels instrumented with cages were considered as fused on the last-time follow-up CT scan (Fig. 6). The sagittal balance global analysis (PT, SVA, C7/SFD, LL) showed no significant modifications postoperatively.

**Discussion**

Lumbo-sacral arthrodesis is one of the commonest surgical procedures for the management of lumbar degenerative disease. Its objectives are to stabilize the spinal segment, restore lordosis, obtain intervertebral fusion, and perform decompression of the neurological structures when required. We assessed a specific approach for lumbar fusion, a one-step ALIF using rhBMP-2 and PEEK cage combined with posterior pedicle-screw fixation.

Many authors studied fusion success following combined anterior/posterior arthrodesis procedures. El Masry et al. [13] reported an overall fusion success of 97% in 47 patients treated by ALIF, using autogenous iliac crest bone combined with posterior pedicle fixation. Anterior arthrodesis and posterior instrumentation succeeded in 95% of the 58 patients [14]. Finally, a radiographic fusion rate of 100% and 93% for single- and two-level procedures was reported in 43 patients who underwent ALIF followed by a posterior instrumented fusion [15]. This high successful fusion is probably due to:

- the ALIF procedure permitting thorough discectomy, large bone grafts and the use of osteoinductive agent rhBMP-2 [16,17];
- the posterior approach providing a rigid stabilization [18], the ability to realize a 360° graft and a recalibration of the vertebral canal, when necessary [19,20].

Even though iliac crest remains the gold-standard bone graft in spinal surgery to fill up the cage, we preferred rhBMP-2. Indeed, the harvest of autogenous iliac crest is hampered by the donor’s site morbidity, with a complication rate reported from 2.8 to 39%, and long-term pain of the graft site persisting for 31% of the patients [21]. Many surgeons have accepted the use of rhBMP-2 since it offers an excellent fusion rate in anterior procedures and avoid iliac crest graft morbidity [22,23].

As reported for the TLIF procedure [24], no significant changes in global balance analysis was observed in our study, which can partly be explained by the proper preoperative balance of most patients. Complete correction of sagittal imbalance requires more invasive surgical procedures,
Lumbo-sacral TLIF to approach ALIF

Such as multi-level fusion or osteotomies [11]. By the way, the proper disc height and segmental lordosis restoration allowed by single or two-levels fusion remain of great importance (Fig. 7), improving short- and long-term outcomes [25,26].

The hitcher lordotic cage (on average 13 mm) used in ALIF procedure, more adequate to restore local balance, can explain higher difference of DHL5S1 and DHL4L5 than in TLIF procedure [24]. The surgical sequence is also important to consider, allowing:

- re-aligning the spine during the anterior step facilitated by the patient supine and slightly extension of lumbar spine;
- stabilization during the posterior one.

Otherwise, we noted that the technique by combined approach was highly efficient to restore local lordosis, especially for L5–S1, with a mean gain calculated around 8–12°. In general, restoration of lordosis for others interbody techniques (TLIF, PLIF) is reported to be only 5–6° [24]. This is a clear advantage of the combined surgery considering that restoration of lordosis is a key-factor to prevent adjacent segment degeneration and also to reduce the risk of postoperative low back pain [27].

The high rate of successful fusion and the restoration of an important DH, in this study are more likely to be due to this combined approach. Pradhan et al. [28] reported a high rate of graft collapse and pseudarthrosis following “standalone” ALIF procedures using femoral ring allograft and rhBMP-2. The mechanical stability of the construct is of most importance to prevent collapse of the allograft during the rapid remodelling created by rhBMP-2. Therefore, stable fixation, due to posterior pedicle-screw-based arthrodesis, seems to be part of the success of a lumbar interbody fusion using structural allograft bone and rhBMP-2 [29]. The choice of an open versus percutaneous posterior fixation allows us to realize decompression if necessary and a posterior bone graft with local bone increasing the chance of fusion success.
We reported one vascular approach complication with no secondary side effects. Vascular complications and genital risk encountered at the L5–S1 level in male are known complications for ALIF procedures and are observed in 6.1% of the cases for some authors [30]. A trained surgeon used to anterior procedures is beneficial to avoid and manage those exposure complications. On the opposite, the ALIF procedure allows the placement of the cage without opening the vertebral canal, probably explaining that mean blood loss of $308 \pm 179.2 \text{mL}$ was lower than usually described in open TLIF procedures [31,32]. Limiting the blood loss is an important point since it increases hospital stay, postoperative complication rates and early recovery [33]. The absence of postoperative infections in our series can probably be explained by the shortening of posterior surgery time by the ALIF first procedure [34]. The absence of dural tears and radicular deficit can also be explained by the ALIF procedure to place the cage. The combined approach interest lies in the realization of a unique anaesthesia, allowing a shorter hospital stay and lower postoperative infection rate [35]. Despite the cumulative risks due to the combined approach surgery, the high fusion rate, the restoration of a proper local balance, the absence of dural tears and infections, the limited blood loss in our series make us consider the one-step combined approach as an interesting fusion method.

Further comparative studies will be necessary to evaluate this procedure and demonstrate a significant benefit, even if controlled trial studies seemed to demonstrate the benefits of a combined approach compared to posterior approach [20,36].

Conclusions

Our study demonstrates that one-step combined approach is a safe and efficient technique to achieve fusion with a proper disc height and a correct sagittal balance, leading to acceptable clinical and functional results, while increasing total operative time. Lumbo-sacral fusion achieved by a combined approach offers the benefits of the both ALIF and posterior procedures, with a more thorough discectomy (source of pain), optimal clearing of endplates (promoting fusion), insertion of a large and lordotic cage with a great surface of contact between the bone graft and the endplates, a larger bone graft, no vertebral canal opening limiting dural tears, nerve roots manipulation and blood loss, and more rigid pedicle-screw-based stabilization. These advantages seem to be more pronounced for L5S1 level. Although further comparative studies will be necessary, surgeons might consider the combined approach technique before realizing a lumbar fusion.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References
