Full Percutaneous Transforaminal Lumbar Interbody Fusion Using the Facet-sparing, Trans-Kambin Approach

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Study Design: This was a prospective, multicenter, consecutive case series' study.

Objective: The objective of this study was to evaluate a novel facet-sparing, percutaneous transforaminal lumbar interbody fusion (pTLIF) technique consisting of percutaneous insertion of an expandable interbody cage through an endoscopic cannula with the trans-Kambin approach and complemented with percutaneous transpedicular screws and rods.

Summary of Background Data: Lumbar interbody fusion by open or minimally invasive surgery is the usual treatment for degenerative disk disease but requires a relatively long recovery period. The transforaminal trans-Kambin approach is a standard in endoscopic spine surgery for safe intradiscal access without facet resection.

Methods: Preoperative and postoperative Visual Analogue Scale (VAS) and Oswestry Disability Index scores were quantitatively assessed at 1, 3, 6, and 12 months after surgery and then every 12 months for patients treated with pTLIF between 2009 and 2018 in 2 health care centers. An immediate postoperative control computed tomography scan was performed, whereas conventional postoperative x-ray controls were performed at 1 month and 1 year. Statistical evaluation was performed with the Student t test.

Results: A total of 51 patients (mean age, 59.3 y) were evaluated. The overall mean VAS score for axial lumbar pain improved from 6.6 to 1.8 ($P < 0.01$), mean VAS score for leg pain from 5.5 to 1.2 ($P < 0.01$), and mean Oswestry Disability Index scores from 30.3 to 11.8 ($P < 0.01$) postoperatively with a mean follow-up of 27.9 months (range, 1–77.8 mo). Median estimated blood loss was 103.6 mL. Postoperative complications included 12 (22%) cases with transitory ipsilateral dysesthesia, 2 (4%) cases with transitory ipsilateral muscle weakness, and 3 (6%) clinically asymptomatic cases with radiologic cage subsidence. Median hospital stay was 1.4 days (range, 1–3.2 d).

Conclusions: Postoperative scores for pTLIF significantly improved with minimal blood loss and no long-term complications. On the basis of this experience, the facet-sparing pTLIF is a reliable and safe technique with early hospital discharge, opening the way to outpatient instrumented spine surgery.

Level of Evidence: Level III.

Key Words: expandable interbody cage, endoscopic surgery, trans-Kambin approach, facet-sparing TLIF, percutaneous transforaminal lumbar interbody fusion (pTLIF)

(*Clin Spine Surg* 2019;00:000–000)

Minimally invasive spine (MIS) surgery has obtained similar outcome as conventional surgery but with a lower risk of bleeding, infection, and less scar tissue formation, resulting in faster wound healing, short patient recovery time, and early hospital discharge.[1–4] Because of the limited visual exposition in MIS surgery, intraoperative fluoroscopy is usually required. However, once the learning curve has been mastered, radiation time can be progressively reduced.[5]

The posterolateral, transforaminal approach is a well-known standard in endoscopic spine surgery.[6,7] Progressive tissue dilators and beveled cannulas allow access to the intervertebral disk by safely bypassing the exiting nerve root through Kambin's triangle.[5–7] In the last 2 decades, a variety of devices have been successfully placed into the disk with variations of the trans-Kambin approach.[8–11] Recently, a facet-sparing, percutaneous transforaminal lumbar interbody fusion (pTLIF) has been introduced with promising preliminary results.[12] pTLIF is based on the trans-Kambin approach, using an expandable interbody cage and (optional) foraminoplasty to overcome the intrinsic size (ie, inner diameter) limitations of an endoscopic cannula. Bone and tissue removal is avoided with pTLIF, resulting in the preservation of natural stabilization structures like the facets, ligamentum flavum, and the annulus. The expansion of the interbody cage allows restoring the disk's height and backfilling with bone graft. Combined with a standardized percutaneous posterior fixation, that is, percutaneous transpedicular screws and rods,[13] a 360-degree stabilization can be achieved. Hence, the pTLIF technique offers a broad new array of possibilities with disruptive potential for instrumented, outpatient spinal surgery.

The aim of this work was to evaluate the long-term clinical outcome, complications, risks, and indications of pTLIF with an expandable cage combined with a standard

percutaneous posterior fixation with transpedicular screws and rods. We hypothesized that this full percutaneous approach would result in significant postoperative improvement of patient pain and disability, whereas allowing a rapid recovery of the patient and an early hospital discharge.

METHODS

Study Design

This prospective study was conducted in accordance with the Declaration of Helsinki and approved by the institutional ethics committee. Patients were informed about the characteristics of the operation, risks, and potential complications. Written informed consent was obtained from all patients.

Population

Consecutive patients aged 18 years or older presenting between 2009 and 2018 in 2 health care centers, in Europe and the United States, with low back pain and/or associated unilateral or bilateral leg pain were evaluated. Inclusion criteria required a corresponding degenerative alteration confirmed by imaging of the lumbar spine, such as degenerative disk disease, spondylolisthesis up to grade II (Meyerding), and central, recess, and foraminal stenosis. Exclusion criteria comprised patients with previous surgery of the lumbar spine, spondylolisthesis grade > II (Meyerding), drug abuse, neoplasm, trauma, infection, and systemic diseases. Preoperative assessment followed a standard protocol, which included preoperative magnetic resonance imaging, computed tomography (CT) scan of the lumbar spine, and electromyography of peripheral nerves.

General Versus Local Anesthesia

General anesthesia was complemented with neuromonitoring with somatosensory evoked potentials and motor evoked potentials to monitor the involved peripheral nerves. If required, direct probe stimulation was performed. Nerve root distance was considered acceptable at signal intensities ≥ 15 mA.

Alternatively, local anesthesia (bupivacaine and lidocaine solution at 1%) was used upon a patient's request in surgeries with an expected duration of <2 hours. Moderate intravenous sedation, analgesia, and cardiopulmonary monitoring were supervised by an anesthesiologist present during the whole surgery.

Surgical Technique

The pTLIF technique was performed, as described,[12] inserting an expandable cage (Opticage; Interventional Spine Inc., Irvine, CA; RISE; Globus Medical Inc., Audubon, PA; Concorde Lift; Depuy-Synthes Inc., Raynham, MA) using the trans-Kambin approach.[4–7] Patients were operated upon in a prone position. Patient positioning on the surgical table was controlled with C-arm fluoroscopic control. To facilitate the approach, especially for level L5–S1, forward hip flexion was increased while avoiding lumbar kyphosis. A discography of the affected level was performed with an 18-G needle. Tissue was progressively dilated (Optiport; Interventional Spine Inc. or equivalent instrumentation), and, optionally, a foraminoplasty

was performed to progressively enlarge the caudal part of the foramen with manual reamers (Max and More; Hoogland Spine Products GmbH, Unterföhring, Germany) (Figs. 1A–C). A beveled cannula was inserted until reaching contact with the annular wall. A clockwise rotation of the bevel allows protecting the exiting nerve root. Through this percutaneous working channel to the intervertebral disk, a standard nucleotomy was performed (Fig. 1D). Endplate cartilage was scratched with curettes and rasps (Fig. 1E). Thereafter, demineralized bone matrix (DBM) was placed into the anterior and lateral recesses of the intervertebral disk (Fig. 1F). The expandable interbody device was filled with DBM and inserted through the beveled cannula and expanded under C-arm fluoroscopic control (Figs. 1G and 2). In an eventual case of kyphotic deformity, the cage was collapsed, repositioned, and reexpanded until the correct sagittal alignment was achieved. Once the cage had been placed in its final position (Fig. 1H), additional backfilling with DBM of the cage and intervertebral space was performed.

In a second step, a percutaneous posterior spinal fixation system consisting of percutaneous transpedicular screws and rods (REVOLVE; Globus Medical Inc.; LONGITUDE; Medtronic Inc., Fridley, MN) was percutaneously placed according to the standardized procedure.[13] The sagittal alignment was controlled with fluoroscopy and adjusted accordingly.

In cases with severe central stenosis, an additional decompression with a mini-open, microscopic midline approach was performed. Finally, fascia, subcutaneous tissue, and skin were sutured (Figs. 1H and 3).

Outcome Measurement

Both clinical and radiographic outcome analysis was performed: preoperative and postoperative scores were quantitatively assessed at 1, 3, 6, and 12 months after surgery and then successively every 12 months. Lower back and radiating leg pain intensity were separately measured with a Visual analogue Scale, whereas disability was evaluated with the Oswestry Disability Index.[14] A CT control scan was taken in the immediate postoperative period (within 24 h after surgery) (Fig. 3). Conventional radiologic x-ray controls were performed at 4 weeks and 1 year after surgery.

Statistical Analysis

The Student t test was used to statistically compare the preoperative and postoperative results. Statistical significance was defined at P-value <0.05.

RESULTS

### Patient Demographic Characteristics

Demographics and preoperative diagnosis of 51 included patients are shown in Table 1.

Outcome and Results

The surgical characteristics of the operated patients can be found in Table 2. Mean axial lumbar pain, leg pain, and Oswestry Disability Index scores significantly improved postoperatively (Figs. 4A, B, Table 3). DBM was used for all cases as bone graft material.
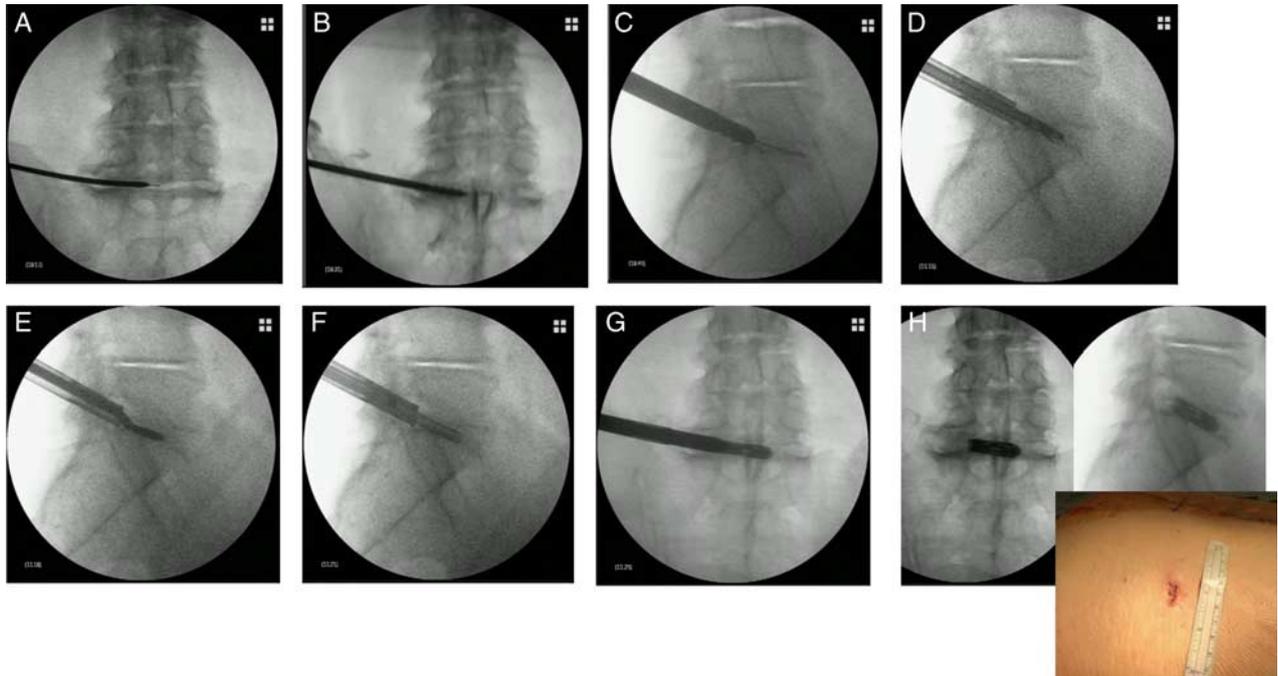
FIGURE 1. Percutaneous transforaminal lumbar interbody fusion approach on a 74-year-old male patient with an extremely collapsed L5/S1 disk with severe right foraminal stenosis. The figure depicts consecutive fluoroscopic anteroposterior and lateral images of the operative sequence: A, Anteroposterior view of a small dilator and a Kirschner wire placed inside the intervertebral disk. B, Anteroposterior view of a small 3-mm manual drill through the right neuroforamen. C, Lateral view of a 9-mm manual drill (guided by a Kirschner wire) through the caudal aspect of the right neuroforamen; lateral view of a nucleotomy punch passing through a cannula placed in the intervertebral disk. D, Lateral view of a paddle rasp scratching the upper endplate of the sacral vertebra through the placed cannula. E, Lateral view of a special instrument for graft injection in the disk. F, Anteroposterior view of the interbody cage's expansion in L5/S1. G, Final anteroposterior and lateral controls of the expanded interbody cage in place centered in the intervertebral disk. Note the opening of the foramina of L5/S1 in comparison with (H). On the bottom right side: photograph of the sutured surgical incision of ~12 mm length. [full color online]

Complications

Transitory, ipsilateral dysesthesia was reported for 12 (22%) cases. Dysesthesia usually presented 2–3 days after surgery with radiating leg pain in the corresponding dermatome of the operated level. In 11 (92%) dysesthesia cases, the affected nerve root was L4. All dysesthesia cases occurred under general anesthesia with perioperative neuromonitoring and were fully resolved after an average of 7.4 weeks with oral pregabalin treatment. Two cases required an additional L4 nerve root block with cortisone and local anesthesia. Transitory, ipsilateral

FIGURE 2. Image of the surgical setup: an expandable cage filled with bone graft is held by a handle (left side) immediately before being inserted into the disk. Note the access cannula (right side) that had already been placed in a lumbar disk under fluoroscopic control.

muscle weakness was additionally observed in 2 (4%) dysesthesia cases, both with an ipsilateral dorsiflexion weakness grade 3/5, respectively. Both cases fully recovered after an average of 8.2 weeks with an initial daily 4 mg intramuscular dexamethasone treatment for 12 days and physiotherapy. A total of 3 (6%) cases presented sacroiliac joint pain during the postoperative follow-up and required an ambulatory, intra-articular sacroiliac joint infiltration with corticoid steroids and 2% lidocaine solution.

In 3 (6%) cases routine postoperative radiologic controls at 12 months showed moderate subsidence of a cage into the endplates. All 3 cases were clinically asymptomatic. No cases of infection, dural tear, permanent nerve damage, or pseudoarthrosis have been reported. No interbody cage migrated, had to be revised, extracted, or required replacement.

DISCUSSION

In this study, we have detailed our clinical experience with pTLIF in combination with a percutaneous posterior fixation to achieve a 360-degree percutaneous instrumented stabilization of the lumbar spine for primary lumbar surgery. Our postoperative outcome with > 2 years of mean follow-up does not differ from reported results for conventional transforaminal lumbar interbody fusion (TLIF) surgery.[1–3] To our

FIGURE 3. Percutaneous transforaminal lumbar interbody fusion case example of a 75-year-old woman with a grade I spondylolisthesis: upper row: 4 weeks postoperative x-ray control anterior/posterior and lateral views; lower row: immediate postoperative computed tomographic scan axial, lateral, and coronal views of a monosegmental stabilization of L4–L5 with transpedicular screws and rods and an expanded cage. Note in the axial computed tomographic scan projection how the cage is positioned over the midline of the disk. Upper right picture: it was taken 18 hours after surgery showing a total of 4 small wounds for the percutaneous transpedicular screws and a small wound on the patient's right side for the percutaneous insertion of the expandable cage. The patient shown here resumed walking 4 hours after surgery and was discharged early morning the next day after surgery. [full color online]

best knowledge, this is the first report on pTLIF with a long-term follow-up and an extensive cohort of patients. The pTLIF technique, as presented here, allows a fast patient recovery and hospital discharge with minimal blood loss and a skin incision of only ~15 mm length (Figs. 1H, 2 and 3) and sparing the facets. Lateral recess stenosis was resolved in most cases by restoring the disk's height with the cage's expansion, as the consequent ligamentotaxis facilitated an indirect decompression of the lateral recess. In cases with severe foraminal and lateral recess stenosis, enhanced decompression of the foramen and the lateral recess was achieved with

additional foraminoplasty using manual reamers with a progressive increase of up to 9 mm of outer diameter. pTLIF may also be of interest in revision surgery cases,

TABLE 1. Demographics and Characteristics of the Operated Patients

Category	Overall (N = 51) [n (%)]
Age [mean (range)] (y)	59.3 (26.1–82.4)
Female individuals	33 (65)
Preoperative diagnosis*	
Degenerative disk disease	43 (84)
Type of stenosis	
Foraminal stenosis	23 (45)
Central stenosis	4 (8)
Lateral recess stenosis	7 (14)
Spondylolisthesis (Meyerding)	16 (31)
Grade I	13 (25)
Grade II	3 (6)

*Multiple diagnoses per case may apply.

TABLE 2. Surgical Characteristics of the Operated Patients

Category	Overall (N = 51) [n (%)]	P
Operated levels (interbody cages)		
L2/L3	1 (2)	
L3/L4	8 (14)	
L4/L5	34 (62)	
L5/S1	12 (22)	
Total levels	55 (100)	
Number of levels operated with interbody cages (cases)		
One level	47 (92)	
Two levels	4 (8)	
Anesthesia		
General anesthesia with neuromonitoring	49 (96)	
Local anesthesia with sedation	2 (4)	
Median estimated blood loss (mL)	103.6	
Anterior disk height (mm)		
Preoperative (mean)	9.64	
Postoperative (mean)	13.21	0.018
Posterior disk height (mm)		
Preoperative (mean)	6.95	
Postoperative (mean)	10.45	0.007
Postoperative time until first walking [median (range)] (h)	4.7 (3–23)	
Time of hospital stay [median (range)] (h)	33.6 (25–77)	
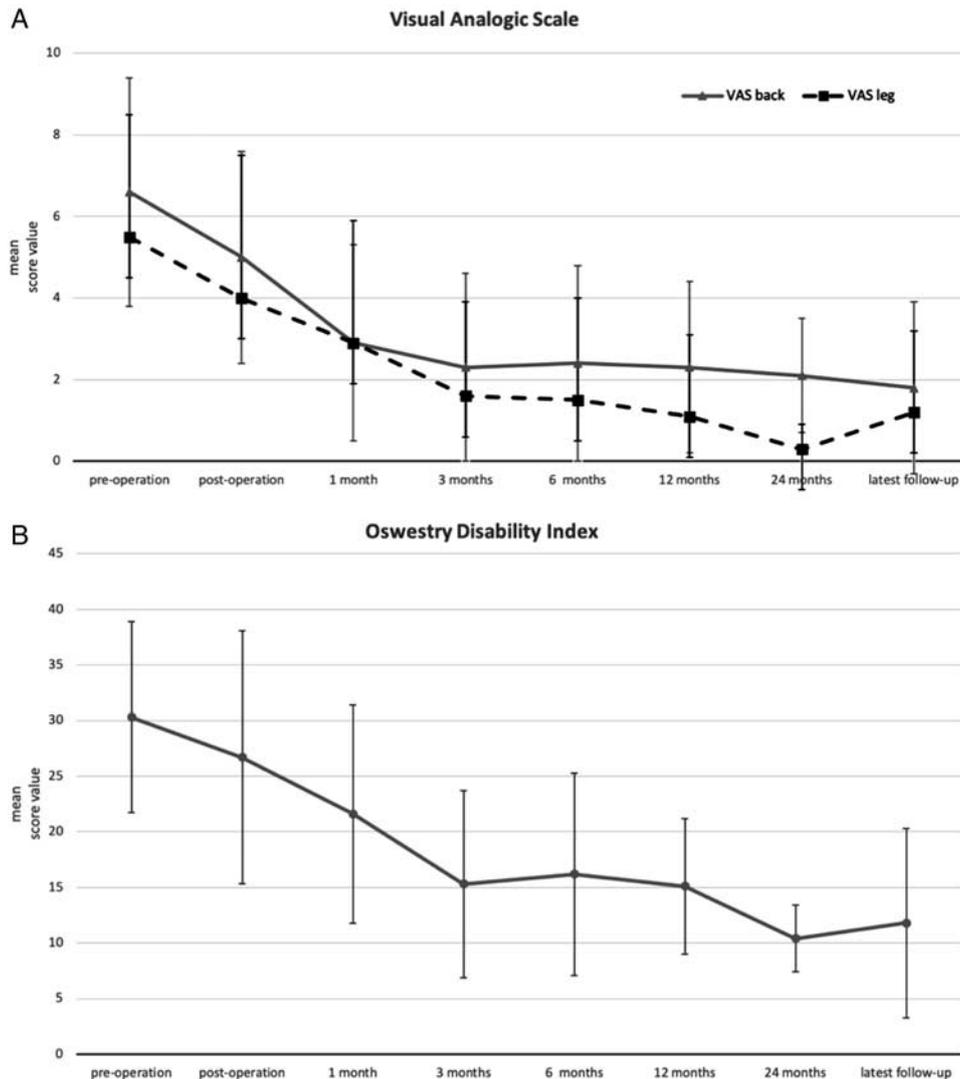
FIGURE 4. Evolution over time of mean score values (with SDs depicted as error bars) for Visual Analogue Scale (VAS) of back and leg, respectively (A), and Oswestry Disability Index scores (B) for the follow-up controls at the immediate postoperative 1, 3, 6, and 12 months and latest follow-up for the reported case series.

as the trans-Kambin approach allows bypassing posterior scar tissue of previous surgeries, decreasing the risk of infection and dural tears.[12,15]

Transitory ipsilateral dysesthesia was the most frequent complication after pTLIF. Dysesthesia is a known, albeit rare, complication in regular endoscopic spine surgery using the trans-Kambin approach.[4–6] Even though placing an endoscopic cannula through Kambin triangle usually allows a safe access to the disk and the spinal canal, the exiting nerve root can be irritated if the cannula

TABLE 3. Preoperative and Postoperative Evolution of VAS and ODI Scores For all Operated Patients

Category	Preoperative Score (n = 51)	Postoperative Score at 1 mo (n = 51)	P^{**}	Postoperative Score at 12 mo (n = 43)	P^{**}	Postoperative Score at 24 mo (n = 38)	P^{**}	Latest follow-up postoperative Score* (n = 51)	P^{**}
VAS back	6.6 ± 2.8 (0–10)	2.9 ± 2.4 (0–8)	< 0.01	2.3 ± 2.1 (0–7)	< 0.01	2.1 ± 1.4 (0–4)	< 0.01	1.8 ± 2.1 (0–8)	< 0.01
VAS leg	5.5 ± 3.0 (0–9)	2.9 ± 3.0 (0–9)	< 0.01	1.1 ± 2.0 (0–6)	< 0.01	0.3 ± 0.6 (0–2)	< 0.01	1.2 ± 2.0 (0–9)	< 0.01
ODI scores	30.3 ± 8.6 (12–47)	21.6 ± 9.8 (7–44)	< 0.01	15.1 ± 6.1 (5–30)	< 0.01	10.4 ± 3.0 (3–18)	< 0.01	11.8 ± 8.5 (2–34)	< 0.01

Scores are displayed as mean ± SD (range).
*Mean follow-up of 27.9 ± 27 months (range, 1–77.8 mo).
**Statistical significance compared with preoperative scores.
ODI indicates Oswestry Disability Index; VAS, Visual Analogue Scale.

is placed too close to neural structures like the neural ganglion, resulting in postoperative, temporary dysesthesia. Our reported rate of dysesthesia for pTLIF is higher than for regular endoscopic procedures. This could be due to a bigger outer diameter of the pTLIF cannula (10–12 mm) compared with regular endoscopic cannulas (7 mm) and the additional manipulation required to place a cage into the intervertebral disk. However, further research is required to understand why the L4 nerve root seems to be particularly vulnerable to dysesthesia. Despite perioperative neuromonitoring, all dysesthesia cases occurred under general anesthesia. In our experience, standard perioperative neuromonitoring falls short of detecting sensitive alterations of the nerve roots and is only useful for monitoring neuronal motor function. None of the pTLIF cases performed here under local anesthesia reported dysesthesia. Hence, local anesthesia with intravenous sedation seems to be safer for pTLIF but is currently limited to surgeries of <2 hours of duration. Yet, novel local anesthesia techniques[16] are being explored for enhanced pain control in long TLIF surgeries. In our learning curve, we were able to progressively reduce the dysesthesia rate by avoiding overdistraction of the operated level with the expandable cage, optimizing the approach's surgical instrumentation (ie, reducing the outer diameter of the endoscopic cannula), avoiding strong vibrations when placing the cannula and inserting the expandable cage (ie, not using a hammer to tap the devices into the disk), and avoiding excessive instrument manipulation close to the nerve root if the approach was difficult (ie, facilitating the approach with a systematic foraminoplasty using manual reamers). It should be noted that the learning curve for the trans-Kambin approach[5] requires appropriate training and should not be underestimated even by experienced spine surgeons,[17] particularly, as accessing level L5/S1 is challenging in male individuals. Moderate cage subsidence was observed and was considered an incidental finding in routine radiographic control, as all 3 patients were clinically asymptomatic and radiologically stable in the follow-up, showing osteointegration of the cage with the endplates.

We also would like to note some limitations of this study: this study reports the clinical experience of 3 surgeons in 2 centers. An extensive cohort and longer term follow-up would be desirable in a blinded, multiarm, randomized study with direct comparison with conventional TLIF techniques. Radiologic evidence of interbody fusion should also be evaluated in a new study with long-term follow-up and postoperative CT scan controls at 12 and 24 months.

In conclusion, we have presented the clinical outcome of a novel, facet-sparing pTLIF technique for full percutaneous stabilization of the lumbar spine. Our outcome does not differ from reported results for conventional TLIF surgery,[1–3] whereas patient recovery with pTLIF was fast, allowing early hospital discharge within 1 day after surgery. This novel technique could complement present surgical options in MIS surgery and open the way to ambulatory, instrumented surgery of the lumbar spine in an outpatient facility.

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