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Original Research Article

Stand-alone XLIF: 22 consecutive patients with degenerative scoliosis and foraminal stenosis in a 2-year follow-up



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ABSTRACT

Introduction: Adult thoracolumbar degeneration is an increasing challenge in the aging population. With age the progressive degeneration of the discs leads to an asymmetric collapse and a thoracolumbar coronal plane deformity, a degenerative scoliosis (DS).

Aim: To evaluate the complication rate and clinical/radiological results in 22 patients treated with XLIF procedure for DS or degenerative disc disease (DDD).

Material and methods: 22 consecutive patients with DS underwent surgery with the XLIF stand-alone procedure, with follow-up of 24 months. Clinical outcome scores were collected. Complications were recorded.

Results and discussion: 22 patients, mean age of 65 years (48–81), underwent surgery on 49 levels (1–4) between L1 and L5. VAS for leg pain improved from 5.94 to 3.5 ($P < 0.05$) and back pain from 5.91 to 3.7 ($P < 0.05$). EQ 5D-3L improved from 0.29 to 0.62 ($P < 0.05$). Seven patients (31.8%) underwent revision surgery. Fusion was achieved in 53% (25/49) at 1-year follow-up. Anterior thigh pain was reported in 12 patients postoperatively, and in 2 patients at 1-year follow-up.

Conclusions: The XLIF stand-alone procedure improves clinical outcome scores significantly after 1- and 2-year follow-up, with a 31.8% revision rate. Due to the high revision rate we recommend supplementary posterior instrumentation, to achieve a higher fusion rate. When considering XLIF-stand-alone procedure for DS or DDD without supplemental posterior instrumentation, only single-level disease should be advised, taking sagittal parameters into account.

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1. Introduction

Adult thoracolumbar degeneration is an increasing challenge in the aging population. With age the progressive degeneration of the discs leads to an asymmetric collapse and a thoracolumbar coronal plane deformity, a degenerative scoliosis (DS).¹

DS in the aging population is a surgically demanding problem since the patients are suffering from chronic back pain, neurogenic symptoms and a loss of body control which lead to poor balance in both standing and walking positions. The cumulative incidence of DS has in a recent study from Japan been estimated to be 17%, predominantly in females, and increasing with age.²

Previously the surgical solution to this problem was posterior spinal fusion with pedicle screws and a correction of the sagittal balance, with different osteotomy techniques combined with anterior support. The patients in this age group are vulnerable, suffers from osteoporosis and medical multimorbidities which often lead to severe bleeding during the surgery and a high risk of complications and reoperations.

The introduction of the XLIF procedure, with an extreme lateral approach through the psoas muscle to the concave side of the spine, was an attractive alternative to more extensive fusion techniques used previously on patients with DS. The advantages are described as promising, the reported risk of bleeding is limited, the procedure is relatively short and the reported hospital stay is shorter than with traditional techniques.^{3,4}

The concept with a large footprint cage in the disk space should provide a stable construction that allows the load forces to be spread over the entire endplate and the surgeon achieves an indirect decompression of the foraminal space after insertion of the cage. The cages are provided in different sizes and angulations, which allow the surgeon to correct the coronal deformity, during the procedure. This novel technique was first introduced in 2006.

In an attempt to solve a major surgical challenge in treating patients with DS, this technique was introduced in February 2011 in the Sector for Spine Surgery and Research in Middelfart.

In total 22 patients were treated with this procedure for DS. This is a case series with the results of our first 22 patients treated with the XLIF procedure, after 2-year follow-up.

2. Aim

The purpose of this study is to evaluate the complication rate and clinical/radiological results in 22 patients treated with XLIF procedure for DS or degenerative disk disease.

3. Material and methods

3.1. Study design

The study is a case study of patients with adult DS treated by a total of 4 surgeons at a single surgical center. During the study

period, 22 consecutive patients underwent XLIF stand-alone procedure. Validated clinical outcome scores, X-rays and/or CT-scan were obtained preoperatively and at 1-year follow-up. Complications were recorded.

3.2. Subjects

The study group (22 patients) was followed for 2 years. Inclusion criteria were back pain and/or symptoms of foraminal stenosis according to MRI, and DS detected on standing X-rays. The patients were included if traditional decompression surgery was not sufficient, or if conservative treatment had failed. Exclusion from the study was prior spinal fusion surgery, instrumented or uninstrumented, history of malignancy or motor-weakness in the lower extremities.

3.3. Surgical technique

Patients were placed on the operating table in a true lateral decubitus position, and the surgical table was flexed to increase the distance between the lower ribs and the iliac crest. The patient's legs were placed on top of each other, with the hips and knees flexed, to achieve relaxation of the psoas muscle. Under fluoroscopic guidance, the levels were marked before the skin incision was made and the spine was always approached from the concave side of the scoliosis. The retroperitoneal space was reached, after a blunt dissection through the border between the erector spinae muscles and the abdominal oblique muscles, without perforating the peritoneum. When passing through the psoas muscle nerve monitoring was performed, to avoid damage to the lumbar nervus plexus, and a dilator was used to minimize the damage to the muscles. When the disk level was reached, the dilator was placed and removal of the disk was performed. The posterior structures were left intact, and a spreader was used to ensure space mobility for the implant. The cage was prepared with bone allograft, and inserted in the disk space. No bone enhancing products were used in this study. After placement of cage, X-rays were taken, before the insertion was closed. No drains were required in our 22 patients. A total of 49 levels from L1 to L5 (range 1-4 levels) were treated with the XLIF procedure.

3.4. Clinical outcome scores

Validated clinical outcome scores were collected preoperatively, at 12- and 24-months follow-up. EQ 5D-3L and visual analog score (VAS) for back and leg pain were obtained. Complications during surgery were recorded. During follow up osseous fusion and subsidence were assessed at the 12-month follow-up on X-rays and/or CT-scan.

3.5. Statistical analysis

Patient demographics and treatment variables were characterized with frequency statistics. Clinical outcome scores were evaluated with paired t-tests as the data were normally distributed. We used STATA version 13 as the statistical analysis tool. Results are presented in box-and-whisker plots. Statistical significance was defined as $P < 0.05$.

4. Results

All patients were treated with the XLIF stand-alone procedure for DS and back pain with or without foraminal stenosis. The primary goal of surgery was to relieve the back and leg pain; the surgeons did not attempt to correct the deformity of the spine, during this procedure. The mean age of the patients was 65 years (range 48–81), 17 women and 5 men were treated. In the study group, 9 patients had undergone prior surgery with laminectomy, and had recurrent symptoms; 4 patients were active smokers at the time of surgery. All patients stopped their consumption of NSAID 7 days prior to surgery, in an attempt to enhance the bone formation and osseous healing. The average BMI was 24.8 (range 17–35). In total 5 patients suffered from Parkinson's disease, but had a normal posture and gait.

The mean operating time was 114 min (range 45–240). Blood loss was recorded less than 100 mL in all patients in this series. One perioperative complication occurred, and during the transpoas approach in 1 patient the L4 nerve of the lumbar plexus snapped during preparation of the disk space despite visualization of the L4 nerve. Mean admission time after surgery was 5.5 days (2–22 days).

VAS score for back pain (0–10) decreased from 5.91 preoperative (0–9.8) to 3.94 (0–9.1) at 1 year, and 3.7 (0–9.0) at 2-year follow-up (Fig. 1). Both values were significant with a *P*-value more than 0.05. VAS score for leg pain decreased similar from 5.94 (0–9.8) to 3.11 (0–9.3) at 1 year and 3.5 (0–8.4) at 2-year follow-up (Fig. 2).

The EQ5D scores (0–1.0), increased from 0.29 (from –0.07 to 0.69) to 0.63 (from –0.08 to 1.0) at 1 year and 0.62 (0.08–1.0) at 2-year follow-up. Both 1-year and 2-year follow-up scores improved significantly with a *P*-value more than 0.05 (Fig. 3). The results in Figs. 1–3, the above-mentioned, results are depicted in box-and-whisker plots with the mean value as a solid line through the boxes, and each end of the whiskers marking the range of the observations.

4.1. Complications

Only 1 patient (4.6%) suffered from a L4 nerve lesion during surgery, despite nerve monitoring. The patient had knee

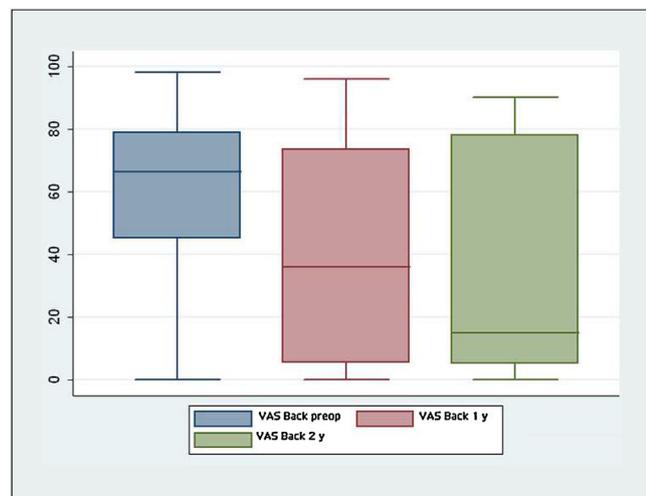


Fig. 1 – Back pain measured on a VAS scale (0–100).

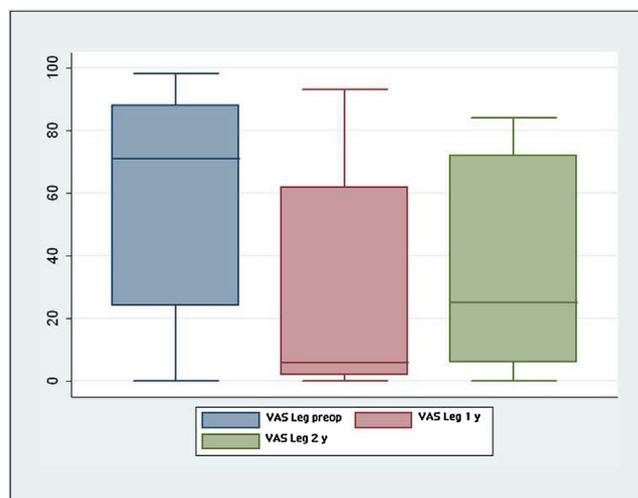


Fig. 2 – Leg pain measured on a VAS scale (0–100).

extension paralysis, persistent after 12-week rehabilitation therapy. Anterior thigh pain and/or weakness postoperatively during hospital admission were experienced by 12 patients (57.0%). At 1-year follow-up only 2 patients complained of continuous anterior thigh pain.⁵

A total of 7 patients underwent revision surgery, all within the first year postoperatively (31.8%). The indications for revision surgery were lack of osseous fusion and recurrence of symptoms. Revision rate was 20.0% (1:5) on single level surgery, and 35.0% (6:17) on multilevel surgery. The revisions included decompression and supplemental posterior fusion, either with bilateral pedicle screws and rods (3 patients) or with posterolateral uninstrumented fusion (4 patients).

The osseous fusion was recorded at 1-year follow-up, either with standing X-rays in 8 patients (36%) or with CT-scan in 14 patients (64%). In total, 25 levels were evaluated as fused (53%), 12 partially healed (26%) and 8 levels without fusions (17%); 2 levels (4%) were not evaluated because of poor visualization in X-rays.

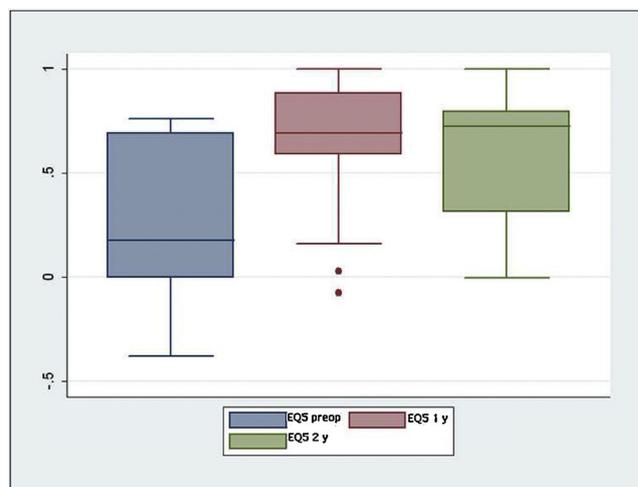


Fig. 3 – Quality of life measured with EQ5D questionnaire (–0.5 – 1.0).

5. Discussion

The stand-alone XLIF procedure is a novel surgical solution, for instrumented fusions in elderly patients with DS. Previous studies with stand-alone XLIF are few, but the complication and revision rates are similar to our findings.⁶⁻⁸ The challenge in this population is to achieve a significant decompression and solid fusion with better success rates and less invasive than standard ALIF or PLIF techniques.^{7,9} When reviewing decompression surgery as an alternative in patients with lumbar degeneration, several studies including the study of Yamada et al., show an immediate pain relief in both back and leg pain. However recurrence of leg symptoms within the first year occurs in patients with degenerative lumbar scoliosis, due to the continuing degenerative deformation.¹⁰

Reviewing the clinical results in this study, a significant decrease in VAS score both regarding leg and back pain is observed. VAS back pain decreases from 5.91 to 3.94 at 1 year, and VAS leg pain from 5.94 to 3.11, at 1 year. These findings are similar to the ones reported by Malham et al.,¹¹ who report an improvement of 63% in back and 59% in leg pain. Their mean follow up was 11 months, and they included 26 patients in their study, but only 13 patients were treated with stand-alone XLIF.

Reviewing fusion rates, our fusion rate of 53% is similar to the findings of Phillips et al., who achieved 58% solid fusion in a group of combined surgical approaches with only 20% stand alone cases.⁶ Malham et al. reported a 77% fusion rate, in a true stand-alone XLIF cohort, and 92% in the group with combined fixation, after 12 months. This high fusion rate was achieved with the use of BMP2, peek cages and other fusion enhancing products.¹¹ Our fusion rates are achieved with the use of allograft only, which might decrease the fusion rates in comparison. About 31.8% of our patients were revised to achieve a solid fusion.

The improvement in EQ5D from 0.29 to 0.63 after 1 year, and 0.62 after 2 years, is better than reported by Malham et al., with an 51.3% increase in physical quality of life.¹¹ The improvement is highly significant and consistent in our study with a 24-month follow-up period.

A main disadvantage of the extreme lateral approach through the psoas muscle is the anterior thigh pain, and weakness in the hip flexion and knee extension, reported in several studies.^{5,12} Transient anterior thigh pain during the first days after surgery was reported by 12 patients (54.5%), but only 3 (13.6%) reported thigh pain at 1 year follow up. A complete paralysis in the knee extension, which did not improve during the rehabilitation phase, was observed in 1 patient (4.5%). These finding are equal to other studies, and in summary the XLIF procedure seems to have less complications than reported in PLIF, TLIF and ALIF trials in this patient group.⁹

6. Conclusions

Stand-alone XLIF is a relatively safe and minimal invasive procedure, for elderly patients with spinal stenosis with or

without DS. The XLIF procedure improves both back and leg pain and EuroQol scores significantly, after 1 and 2 years, in our patient population, with a complication rate similar to other procedures with a more open/invasive approach.

Following this study when reviewing the revision rate of 31.8% in our patient series, we recommend supplementary posterior instrumentation, in multilevel disease or in patients with sagittal imbalance. In our department single level procedures in patients with degenerative disk disease and with normal sagittal parameters are still performed. However more studies are needed to investigate the full potential of the stand-alone procedure.

Conflict of interest

None declared.

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