

Clinical and radiological outcomes of open versus minimally invasive transforaminal lumbar interbody fusion

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Abstract

Study design Prospective observational cohort study.

Objective Comparison of clinical and radiological outcomes of single-level open versus minimally invasive (MIS) transforaminal lumbar interbody fusion (TLIF) at 6 months and 2-year follow-up.

Summary of background data There is recognition that more data are required to ascertain the benefits and risks of MIS vis-a-vis open TLIF. This study aims to report on one of the largest currently available series comparing the clinical and radiological outcomes of the two procedures with a minimum follow-up of 2 years.

Methods From January 2002 to March 2008, 144 single-level open and MIS TLIF were performed at our centre, with 72 patients in each group. Clinical outcomes were based on patient-reported outcome measures recorded at the Orthopaedic Diagnostic Centre by independent assessors before surgery, at 6 months and 2 years post-operatively. These were visual analogue scores (VAS) for back and leg pain, Oswestry disability index (ODI), short form-36 (SF-36), North American Spine Society (NASS) scores for neurogenic symptoms, returning to full function, and patient rating of the overall result of surgery. Radiological fusion based on the Bridwell grading system was also assessed at 6 months and 2 years post-operatively by independent assessors.

Results In terms of demographics, the two groups were similar in terms of patient sample size, age, gender, body

mass index (BMI), spinal levels operated, and all the clinical outcome measures ($p > 0.05$). Perioperative analysis revealed that MIS cases have comparable operative duration (open: 181.8 min, MIS: 166.4 min, $p > 0.05$), longer fluoroscopic time (open: 17.6 s, MIS: 49.0 s, $p < 0.05$), less intra-operative blood loss (open: 447.4 ml, MIS: 50.6 ml, $p < 0.05$) and no post-operative drainage (open: 528.9 ml, MIS: 0 ml, $p < 0.05$). MIS patients needed less morphine (open: 33.5 mg, MIS: 3.4 mg, $p < 0.05$) and were able to ambulate (open: 3.4 days, MIS: 1.2 days, $p < 0.05$) and be discharged from hospital earlier (open: 6.8 days, MIS: 3.2 days, $p < 0.05$).

At 6 months, clinical outcome analysis showed both groups improving significantly ($>50.0\%$) and similarly in terms of VAS, ODI, SF-36, return to full function and patient rating ($p > 0.05$). Radiological analysis showed similar grade 1 fusion rates (open: 52.2 %, MIS: 59.4 %, $p > 0.05$) with small percentage of patients developing asymptomatic cage migration (open: 8.7 %, MIS: 5.8 %, $p > 0.05$). One major complication (open: myocardial infarction, MIS: screw malpositioning requiring subsequent revision) and two minor complications in each group (open: pneumonia and post-surgery anemia, MIS: incidental durotomy and pneumonia) were noted.

At 2 years, continued improvements were observed in both groups as compared to the preoperative state ($p > 0.05$), with 50.8 % of open and 58 % of MIS TLIF patients returning to full function ($p > 0.05$). Almost all patients have Grade 1 fusion (open: 98.5 %, MIS: 97.0 %, $p > 0.05$) with minimal new cage migration (open: 1.4 %, MIS: 0 %, $p > 0.05$).

Conclusions MIS TLIF is a safe option for lumbar fusion, and when compared to open TLIF, has similar operative duration, good clinical and radiological outcomes, with additional significant benefits of less perioperative blood

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loss and pain, earlier rehabilitation, and a shorter hospitalization.

Keywords Lumbar fusion · Open · Minimally invasive · Clinical outcomes

Introduction

Lumbar fusion is used to treat various symptomatic spinal deformities and instabilities, and the goal is to achieve stable arthrodeic spinal segments with good disc height and vertebral alignment, thus relieving the pressure on exiting neural structures [1]. There are different techniques and technologies available for fusion, and each operative technique has its inherent benefits and disadvantages [2–5].

Introduced by Cloward [6] more than 50 years ago, posterior lumbar interbody fusion (PLIF) represented a significant evolution in the operative treatment of pathological spinal disorders. Many variations of interbody fusions have since been described including anterior lumbar interbody fusion and transforaminal lumbar interbody fusion (TLIF) [7, 8]. Harms et al. [9] first used TLIF in 1980s, and the procedure has added advantages over PLIF as it allows for far unilateral exposure, decreased neural retraction, and potential neurological injury. The TLIF procedure also preserves the integrity of posterior column through minimizing lamina, facet, and pars resection, which are frequently disrupted during PLIF. Over the last three decades, TLIF has been a proven and safe technique in achieving lumbar fusion, but unfortunately, it is also associated with significant morbidities due to extensive muscle stripping and retraction during the surgical approach [10, 11]. Studies have documented the deleterious effects of extensive and prolonged muscle ischemia adversely affecting both short and long-term patient outcomes [12–15].

Minimally invasive (MIS) TLIF is made possible with the advancements in spinal instrumentation and radiological imaging. Foley et al. [16] first described this novel technique which utilized tubular retractors inserted serially under radiological guidance via a muscle-dilating approach, thus reducing the amount of iatrogenic muscle and soft tissue injuries. A paper by Schwender in 2005 affirmed the feasibility of performing MIS TLIF safely and effectively in 49 patients with an average of 2-year follow-up. All the patients had better post-operative outcomes in terms of lesser blood loss, shorter hospitalization stay, and reduced clinical symptoms [17].

Currently, there are few studies that perform head-on comparisons of the long-term outcomes between MIS and open TLIF [18, 19, 21]. In 2008, Peng et al. analyzed the outcomes in 29 pairs of MIS and open TLIF, and concluded that MIS TLIF had similar good clinical outcomes and high

fusion rates as open TLIF with additional benefits of less pain, early ambulation, and shorter hospitalization. However, the study was limited by the relatively small number of patients, different operating surgeons and inconsistent instrumentation used [18]. In 2010, Villavicencio et al. [19] compared the outcomes of 63 open and 76 MIS TLIF patients, and they reported comparable good clinical outcomes between the two groups, but with a higher neurological complication rate in the MIS group. In a meta-analysis by Wu et al. of 16 open TLIF studies consisting of 716 patients and eight MIS TLIF studies consisting of 312 patients, the authors reported similar fusion and complication rates in both groups, but the study did not analyze the differences in clinical outcomes between the two procedures [20].

There is still a need for more studies to ascertain the benefits and risks of MIS vis-a-vis open TLIF. We hope to contribute to this by reporting on one of the largest currently available series comparing the clinical and radiological outcomes of the two procedures with a minimum follow-up of 2 years.

Materials and methods

After obtaining Institutional Review Board's approval, consecutive patients undergoing TLIF between January 2002 and March 2008 in our institution were studied.

Inclusion criteria included: (1) single-level TLIF (open or MIS) and (2) MIS cases utilizing Sextant ITM (Medtronic, MN) pedicle screw-rod instrumentation and Capstone (Medtronic MN) interbody cage. Exclusion criteria included: (1) previous spinal instrumentation, (2) tumor spinal pathologies, (3) spinal infections, and (4) acute spinal trauma.

All the patients had preoperative evaluation with detailed neurological examination and radiological imaging, which involved static (anterior-posterior and lateral) and dynamic (flexion and extension) plain lumbar spine radiographs, magnetic resonance imaging (MRI), and/or computed tomography (CT). The indications for surgery were symptomatic spondylolisthesis (grades 1 and 2), recurrent prolapsed disc, spinal stenosis requiring resection of more than 50 % of either facet joint in order to achieve adequate decompression and degenerated collapsed disc requiring disc-space height restoration in order to achieve adequate neuroforminal decompression. All patients presented with radicular pain refractory to medical therapy of at least 6 months duration.

The details of the operative techniques for both open and MIS TLIF were described in a previous publication [18]. *All open and MIS patients had decompression of the affected neural structures as part of the procedure, and in*

the MIS patients, direct decompression was achieved through the same paravertebral incision. Using a high-speed drill, the surgeon will perform facetectomy from lateral to medial to expose the posterolateral aspect of the disc. Discectomy will then be performed for cage placement, with the lateral margin of the ligamentum flavum resected to expose the ipsilateral exiting and traversing nerve roots. And if more extensive stenosis were present, the tubular retractor will be angled medially with the patient tilted laterally to facilitate direct decompression of the central canal and contralateral stenosis.

The patients were not pre-selected for either group; the type of operation undertaken was based on surgeon's and patient's preferences. All the MIS cases were performed by a single surgeon (WMY), whereas for open TLIF cases were performed by the two most senior spine surgeons in the department, one of which was the same surgeon who performed all the MIS cases. In our study, the open cases were performed by the two most senior surgeons after their learning curve, and their techniques were equivalent. The MIS cases were performed by a single surgeon who decided to explore this technique and included his learning cases. Unfortunately, the other surgeon decided not to pursue MIS TLIF due to various reasons. There were very few MIS cases in the first 3–4 years of the study period, as the author was still exploring the technique, with case observations and cadaveric work, in addition to a few actual surgeries. As he became more familiar with MIS TLIF, the number of cases increased and in the last 2 years of the study period, there were more MIS cases compared to the open ones. The point of time chosen to begin the analysis of data was decided upon when the two groups became comparable in number, with the aim of analyzing three main types of outcomes: perioperative, clinical, and radiological outcomes.

After discharge from hospital, the patients were followed up regularly by the surgeon (2 weeks, 3 months, 6 months, 1 year, and annually thereafter) and monitored closely for complications, and plain lumbar spine radiographs; if indicated MRI or CT scans, were ordered to assess and confirm the complications. The complications were categorized into clinical and technical aspects; clinical complications included new or worsening neurological deficit(s) and wound infections, and technical complications included cage migrations and malpositioned screws.

For clinical outcomes, the patients were evaluated by independent assessors at the Orthopaedic Diagnostic Centre (ODC) before surgery, and at 6 months and 2 years post-surgery. For all elective spine surgeries, ODC has been systematically tracking and administering patient-reported outcome measures at the various time-points since August 1998. When patients did not return, follow-up was obtained through personal telephone calls. The following

patient-reported outcome measures were evaluated: visual analogue scores (VAS) for back and leg pain, Oswestry disability index (ODI), short form-36 (SF-36), North American Spine Society scores for neurogenic symptoms (NASS), returning to full function and patient rating of the overall result of surgery. With the results collected and stored in standardized digital formats, future data retrieval and analysis on prospectively collected data can be performed.

For radiological outcomes, static and dynamic plain lumbar radiological films taken at 6 months and 2 years post surgery were utilized to assess fusion. The fusion criteria were based on Bridwell interbody fusion grading system (Table 1), and the assessments were performed by two independent assessors, with a third assessor available for adjudication.

All data were collected prospectively. Statistical analysis was performed with SPSS version 17.0. The χ^2 contingency table was used to compare categorical data (gender, level of fusion, fusion grading at 6 months and 2 years post-surgery, cage migration, return to full function, and patient rating of overall result of surgery). Student's *t* test for independent samples was used to compare continuous variables (age, length of operation, length of stay, fluoroscopy time, intra-operative blood loss, post-operative blood loss, amount of patient-controlled analgesia and time to ambulation). Tests of between-subject effects were used to evaluate the differences in VAS, ODI, SF-36 and NASS. In all analyses, significance was defined as $p < 0.05$.

Results

One hundred and forty-four patients met the study inclusion criteria, with 72 consecutive eligible patients in both open and MIS TLIF groups. Data with patients' demographics and lumbar levels fused are presented in Table 2. In terms of demographics, the two groups were similar in terms of patient sample size, age, gender distribution, BMI and spinal levels operated, with no statistical difference. For fusion enhancers, only local bone grafts and

Table 1 Bridwell interbody fusion grading system

Grade	Description
I	Fused with remodeling and trabeculae present
II	Graft intact, not fully remodeled and incorporated, but no lucency present
III	Graft intact, potential lucency present at top and bottom of graft
IV	Fusion absent with collapse/resorption of graft

Table 2 Patient demographics

	Open	MIS	<i>p</i>
No. of patients	72	72	1.000
Gender (male/female)	22/50	20/52	0.714
Age (years)	56.6 ± 14.6	52.2 ± 13.8	0.061
BMI (kg m ⁻²)	27.1 ± 4.5	25.7 ± 4.5	0.081
Spinal level fused			
L34	4	6	0.627
L45	54	49	
L5S1	14	17	

Table 3 Perioperative parameters

	Open	MIS	<i>p</i>
Fluoroscopy time (s)	17.6 ± 20.0	49.0 ± 33.9	0.000
Intra-operative blood loss (ml)	447.4 ± 519.2	50.6 ± 161.0	0.000
Length of operation (min)	181.8 ± 45.4	166.4 ± 52.1	0.062
Post-operative blood loss (ml)	528.9 ± 241.6	0 ± 0	0.000
Patient-controlled analgesia (IV morphine—mg)	33.5 ± 38.6	3.4 ± 10.1	0.000
Time to ambulation (days)	3.4 ± 1.1	1.2 ± 0.6	0.000
Length of hospitalization (days)	6.8 ± 3.4	3.2 ± 2.9	0.000

demineralized bone matrix (DBM)—Osteofil (Medtronic, MN) were utilized in MIS group. In open group, the fusion enhancers utilized were similar less one patient who had recombinant human bone morphogenetic protein-2 (rhBMP-2—Infuse, Medtronic, MN).

Perioperative data for both groups are presented in Table 3. Fluoroscopy time was significantly longer for MIS compared to open cases, about three times longer. Blood loss was significantly less in MIS compared to open patients, about 12 % that of open patients. The mean operative time in MIS was shorter than open cases by an

average of 15.4 min, but the difference was not statistically significant. Post-operative drains were not used in all the MIS cases with no adverse outcome, while the open cases had significant drainage. The MIS patients used about 10 % of intravenous morphine used by open TLIF patients. Open patients generally took about three times as long to start walking, and they stayed about twice as long in the hospital. All these differences were significant.

In this study, we managed to achieve a high percentage of patient follow-up. At 6 months, all open patients returned while MIS had 95.8 % follow-up attendance (three patients were foreigners and had returned to their countries). At 2 years, the percentage in open group was still high at 91.7 % (six patients were lost to follow-up with one patient passing away due to unrelated causes and five foreigners returning to their countries), while in MIS it remained steady at 95.8 %.

Analysis of SF-36 and VAS for both back and leg pain revealed the scores improving post-operatively at all time-points, with the most significant improvement (≥50 %) occurring at 6 months post-surgery. However, there was no significant difference in SF-36 and VAS between both groups at 6 months and 2 years. For ODI and NASS, both groups showed similar significant improvements (≥50 %) at 6 months post-surgery, and the improvement as compared to preoperative status was maintained up to 2 years. Similarly, there was no significant difference between the two groups (Table 4).

For patients returning to full function at 6 months, both groups had a good proportion of patients achieving pre-morbid functional status (open: 33.3 % (*n* = 23), MIS: 44.8 % (*n* = 30), *p* = 0.171) and they showed continual improvements up to 2 years (open: 50.8 % (*n* = 33), MIS: 58.0 % (*n* = 40), *p* = 0.403). When rating the overall result of surgery at 6 months, there were 10.5 % more MIS than open patients rating their experiences very favorably (*p* = 0.533). At 2 years, both groups had similar proportion of patients rating their experiences favorably (*p* = 0.711).

Table 4 VAS (back and leg pain), SF-36 physical function, ODI, NASS

	Preoperative	6 months	2 years	<i>p</i>
VAS back (open)	6.3 ± 2.9	2.7 ± 2.8	2.4 ± 2.7	0.826
VAS back (MIS)	6.3 ± 2.9	3.1 ± 2.8	2.3 ± 3.0	
VAS leg (open)	6.2 ± 3.1	2.0 ± 2.9	2.0 ± 2.8	0.354
VAS leg (MIS)	5.8 ± 3.3	1.8 ± 2.6	1.6 ± 2.7	
SF36 physical function (open)	42.8 ± 27.0	63.0 ± 23.7	65.4 ± 25.4	0.679
SF36 physical function (MIS)	43.1 ± 26.8	64.6 ± 24.5	68.1 ± 26.8	
ODI (open)	44.4 ± 18.0	20.6 ± 17.2	20.7 ± 16.5	0.252
ODI (MIS)	48.1 ± 18.8	24.6 ± 18.2	21.4 ± 20.9	
NASS (open)	45.5 ± 26.2	16.9 ± 20.2	18.7 ± 23.0	0.567
NASS (MIS)	50.6 ± 28.3	17.7 ± 23.7	18.5 ± 26.3	

In terms of bony fusion, at both 6 months and 2 years, the MIS group was able to achieve comparable high fusion rates as the open group with no significant difference between the two groups. At 6 months, 52.2 % of open and 59.4 % of MIS patients achieved Grade 1 fusion, and 40.6 % of open and 36.2 % of MIS patients achieved Grade 2 fusion ($p = 0.608$). At 2 years, 98.5 % of open and 97 % of MIS patients achieved Grade 1 fusion ($p = 0.551$).

There was one major clinical complication in open group with the patient suffering an intra-operative myocardial infarction, while MIS had none. No intra-operative conversion of MIS to open TLIF was documented.

There were two minor complications in each group. In the open group, one patient suffered post-operative anemia and wound abscess requiring surgical intervention within 3 months of discharge, while the other patient suffered from post-operative pneumonia, which resolved with intravenous antibiotics. In the MIS group, one patient had incidental durotomy which was promptly repaired intra-operatively with no deleterious outcome, while the other patient had post-operative pneumonia, which resolved with intravenous antibiotics.

In both groups, a small percentage of patients had technical related complications. 8.8 % (6) of open and 6.0 % (4) of MIS patients had asymptomatic cage migrations, but these patients did not require revision surgery. In addition, MIS group had one patient with a misplaced pedicle screw requiring revision and this incident happened during the early phase of the surgeon's experience and was placed by his resident on the contralateral side.

Discussion

In 1980s, open TLIF was first introduced by Harms et al. [9] as a modification to PLIF and the technique has been a proven and safe technique to achieve lumbar fusion. Unfortunately, open TLIF is also associated with extensive iatrogenic lumbar soft tissue and muscle injuries [8–15]. At the turn of century, MIS TLIF represents the latest evolution of TLIF through its minimally invasive approach to achieve lumbar fusion [16, 17]. With its paramedian and muscle-dilating approach, MIS TLIF was able to minimize iatrogenic soft tissue and muscle injuries, and posterior midline spinal structures were preserved. Previous publications have reported the benefits of such an approach, and early results were promising. However, currently there are few studies that directly compare the clinical and radiological outcomes of open versus MIS TLIF with large patient numbers [18, 19, 21]. Acknowledging the lack of randomized control trials comparing the outcomes between the two techniques, Wu et al. performed a meta-analysis on

24 open and MIS TLIF studies involving 1,028 patients and noted comparable fusion and complication rates in both groups. Clinical outcomes were not analyzed due to the heterogeneity in clinical outcome measures in the various studies [20]. With our study, we aim to further elucidate the efficacy of MIS TLIF by analyzing one of the largest available comparison series.

To reduce the number of confounding factors in the study, one senior surgeon performed all the MIS cases using only one type of pedicle screw-rod instrumentation (Sextant ITM, Medtronic, MN,) and one type of interbody cage (Capstone, Medtronic, MN), and only single-level TLIF patients were included in this single centre study. To further reduce bias, independent assessors performed the data collection and analysis, and the surgeons were not involved in the process.

Compared to open TLIF, MIS TLIF is technically more challenging as the surgery involves a much smaller operative field and requires more radiological imaging assistance in the placements of screws and cages. As such, early papers on MIS TLIF reported longer operative timing with MIS TLIF [18, 19, 21], but in the current study, the surgeon managed to achieve shorter operating timing for MIS cases. Even though the difference in operating time between the two groups is not significant, the difference could be enhanced as the MIS cases included the surgeon's initial learning cases, whereas the open TLIF technique is familiar to both surgeons. Therefore, as with all new surgical techniques, the initial steep learning curve can be overcome with dedicated repetition and experience.

MIS TLIF requires additional specialized instrumentation to achieve minimal tissue disruption, but the greater financial cost can be off-set against the benefits of MIS superior perioperative outcomes, namely earlier ambulation, less analgesic requirement and shorter hospitalization stay [22]. MIS patients generally have minimal post-operative blood loss, and they use about 10 % of analgesia used by open TLIF patients. Open patients generally take three times as long to start walking, and they stay twice as long in the hospital.

There are limitations in this study. Firstly, it is an observational cohort comparison study and not a randomized controlled trial, thus to further validate the efficacy of MIS TLIF, future randomized controlled studies may be warranted.

Secondly, it is not a true historic cohort study, and the results could be biased due to the differing level of surgical expertise prevalent in each study arm. Ideally, both groups should include the learning cases, but unfortunately, the objective data for the first open TLIF cases were not captured as the cases happened prior to the establishment of ODC. *Hence this disparity could potentially favor the outcomes in open group. Conversely, the surgeon started*

performing MIS TLIF after mastering the principles of TLIF via the open method, and with his improved general skills, the outcomes in the MIS group could be favored. However, considering both points in totality, one cannot assume one bias cancels out the other, rather the uncertainty is increased.

In conclusion, MIS TLIF provides patients a safe option for lumbar fusion, and the technique is comparable to open TLIF with similar operating time; equivalent clinical and radiological outcomes; and comparable complication rates. In addition, MIS TLIF patients do have significant advantages over open TLIF patients in terms of perioperative outcomes, such as less blood loss and pain, earlier ambulation and discharge from hospital.

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