MIS-TLIF: Technical Note, Learning Goals behind Case Selection during Early Part of Learning Curve and Clinical Outcomes in First 150 Cases

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Abstract

Introduction: Minimally Invasive Transforaminal Lumbar Interbody Fusion (MIS-TLIF) has been shown to offer several advantages over conventional (open) TLIF and is being increasingly employed by young surgeons early in their careers. It is important to know the appropriate technique and the correct cases to be selected in the early phase to achieve good outcomes during the learning curve. A detailed and illustrative technical note along with a guide for case selection at different phases of experience has been presented in this article.

Methods: The first consecutive single surgeon series of 150 MIS-TLIF cases done over 4 years between 2012 and 2015 were considered for analysis. Demographic and peri-operative data and previously documented follow-up were collected from case records. Telephonic questionnaire and consultation were done to collect latest status, any procedures/surgeries done elsewhere for issues related to index procedure. Results were stratified as Group 1 – first 25 cases; Group 2 – 26–75 cases; Group 3 – 76–150 cases.

Results: The major indication for surgery in group 1 was either Grade 1 spondylolisthesis or lumbar canal stenosis with concomitant axial symptoms. The incidence of relatively complex cases (Grade 2 or 3 listhesis; Revision cases; Multilevel cases) increased with each successive group. As expected, the operative time (calculated for only single-level cases) improved with time. The overall rate of peri-operative complications was higher in group 2 as compared to groups 1 and 3, predominantly due to an increased incidence of intra-operative dural tears in group 2. Symptomatic screw malposition was detected in five screws, all were managed conservatively. The median duration of follow-up for the entire group was 39 months (Range - 1–119 months). Eighty-two (55%) patients had follow-up of more than 1 year while 31 (20.6%) patients had follow-up of more than 7 years. Around 80–85% of patients at each point of follow-up assessment had a successful outcome (McNab 4 and 5). The re-operation rate for index level problems or adjacent segment was 2.6%, only one of which was done at the author's center.

Conclusions: Minimally invasive TLIF is a safe and effective procedure with favorable long-term results and acceptable complication rates. Though technically challenging in initial phases, a good understanding of the technique and principles of minimally invasive spine surgery along with fulfilling helpful pre-requisites and appropriate case selection as mentioned in this article, will help to smoothen the learning curve and avoid unfavorable outcomes in early stages.

Keywords: Minimally Invasive, transforaminal lumbar interbody fusion, learning curve, long-term outcome, case selection, minimally invasive transforaminal lumbar interbody fusion.

Introduction

Transforaminal Lumbar Interbody Fusion (TLIF) has been the workhorse of any spine surgeon aiming to achieve a successful interbody fusion for a variety of pathologies. It offers the advantages of preserving midline tension band, reducing nerve root and dural sac manipulation to insert a cage whilst accomplishing an adequate direct or Indirect decompression and restoring disc height and segmental lordosis.

With the advent of minimally invasive techniques, and the introduction of Minimally invasive TLIF (MIS-TLIF) in

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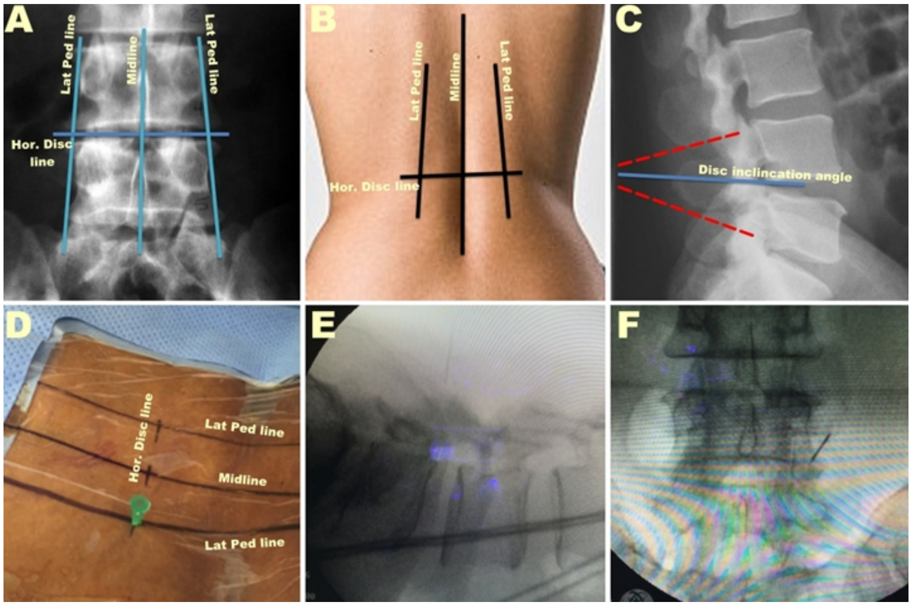

Figure 1: Images illustrating sequential steps to identify the correct entry point and trajectory for performing Minimally Invasive Transforaminal Lumbar Interbody Fusion. (Refer to text for details).

early 2000s [1], it was only prudent that minimally invasive techniques to achieve lumbar interbody fusion would slowly yet progressively become the most appropriate method of performing a lumbar interbody fusion. MIS-TLIF offers several added advantages over a conventional (open) TLIF, basically by reducing approach-related morbidity in terms of lesser tissue injury to the posterior paraspinal muscle groups, especially multifidus, and preserving posterior spinal midline structures. It also offers additional advantages of smaller incisions, lesser blood loss, shorter hospital stay, faster post-operative recovery, earlier return to work, and hence better functional outcomes [2, 3, 4, 5, 6, 7].

Technical Note

The patient is positioned as for an open (Conventional) TLIF in prone position, either on bolsters across the chest and hip or on a Jackson frame, making sure the abdomen is free and pressure points are adequately padded. Before painting and draping, AP and Lateral fluoroscopic images should be taken to confirm adequacy of imaging, visualizing the pedicles, and making sure there are no radio-opaque table bars or attachments hindering the fluoroscopic view.

Marking skin incision (Fig. 1)

A true anteroposterior (AP) fluoroscopic projection (superior endplate of the inferior vertebral body seen as a single line and the spinous process equidistant from each pedicle) is selected. The midline; bilateral lateral pedicle lines (Line running along the lateral border of the pedicles) and horizontal disc line is drawn on the skin (Fig. 1b) with reference to the true AP fluoroscopic image (Fig. 1a). A vertical incision is marked 1 cm lateral to the intersection of the lateral pedicle line with a horizontal disc line. A needle can be inserted from this point directed towards the disc space and correct trajectory can be confirmed on both AP and Lateral fluoroscopic images (Fig. 1d-f). It is important to know the correct trajectory since a little deviation in the direction from the same entry point can lead to an adjacent level, esp. in the lordotic lumbar spine (Fig. 1c). Alternatively, needles can be inserted to mark the pedicle entry points and the two points can be connected to make the incision.

Docking tubular retractor (Fig. 2)

After skin and fascial incision, the first dilator is passed through the fascia and paraspinal muscle towards the facet joint. At this stage, the first dilator can be used as a dissecting tool to palpate the bony landmarks and enlarge the transmuscular tract, which makes subsequent sequential dilatation easier. It is worthwhile to take some time at this stage to palpate and identify (with the first dilator) the boundaries of the facet joint (pars, Lamina and its inferior edge, lateral border of Superior articular process) (Fig. 2a). One can even use fluoroscopy in initial cases to accurately correlate the position of the dilator with its "feel." Once satisfied, the first dilator is held firmly over the middle of facet joint and sequential dilatation done to place a 22 mm diameter, fixed tubular retractor of appropriate length. One can even use an expandable retractor in initial cases to obtain a relatively larger working space. Once the tube is in place, the operating

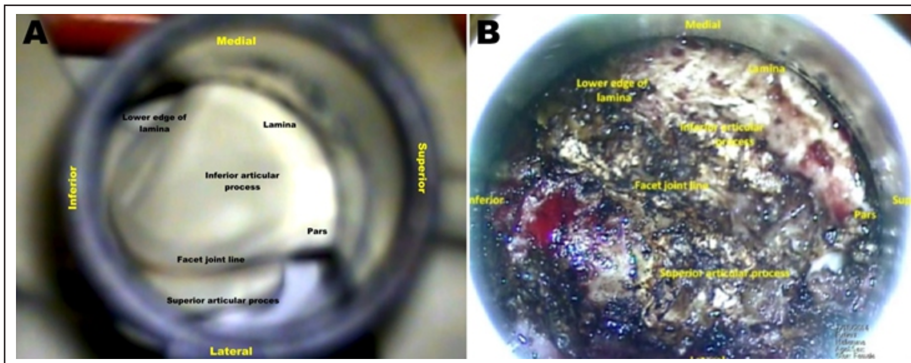

Figure 2: Image illustrating the initial structures to be identified after placement of tubular retractor. (a) Saw-bone model; (b) During surgery after clearing the soft tissue.

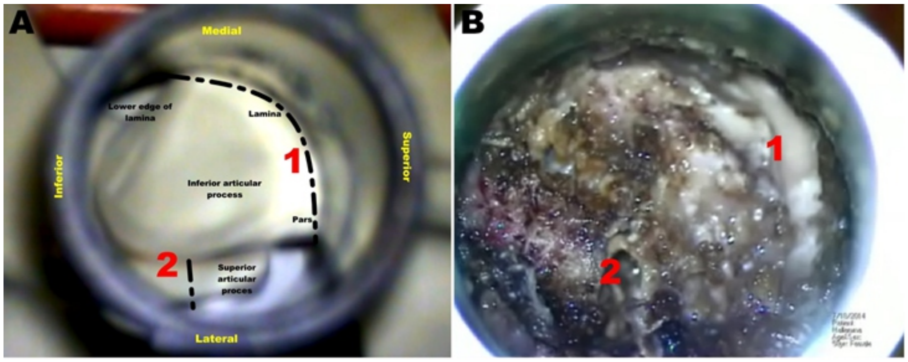

Figure 3: Image illustrating the osteotomies necessary for completing facetectomy – as visualized through the tubular retractor (Refer to text for description).

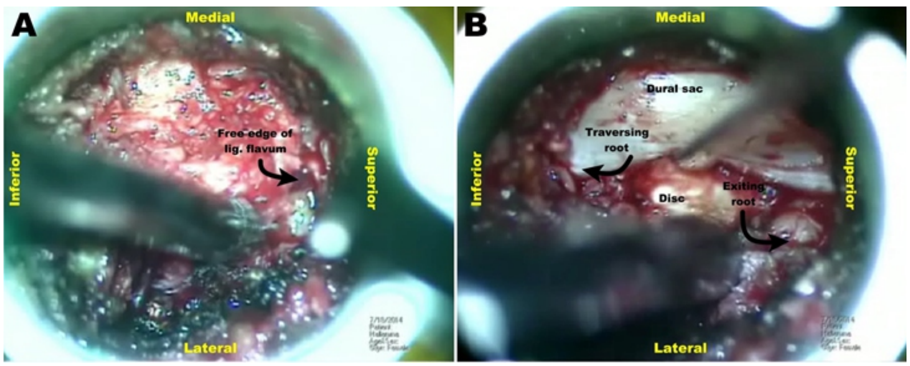

Figure 4: Image illustrating the steps for identifying the upper free edge of ligamentum flavum (a), complete ipsilateral flavectomy and structures visualized after ipsilateral decompression (b).

microscope is taken and soft tissue over the facet joint is cleared with a monopolar cautery and bony landmarks mentioned above (Boundaries of facet joint) are identified (Fig. 2b).

The most important part of MIS-TLIF (for a surgeon already accustomed to doing Open TLIF) is the above two steps – to select the correct incision, place the tube in correct position and identify bony landmarks. Once this is accomplished, the remainder of the surgical steps is similar to an open TLIF.

Facetectomy (Fig. 3) and flavectomy (Fig. 4)

Complete facetectomy is then performed by sequentially removing the inferior articular process by making an osteotomy from the inferior edge of the lamina to the pars along the supero-medial extent of the tube (Fig. 3, line marked 1) and extending superiorly up to the free edge of the ligamentum flavum underneath (Fig. 4a). The overhanging portion of the superior articular process (SAP) is then removed flush with the upper edge of the lower pedicle (Fig. 3, line marked 2) to completely deroof the kambin's triangle (Fig. 4a). It's important to identify the upper border of the lower pedicle to avoid inadvertently extending the osteotomy into the pedicle and hence compromising on the subsequent screw integrity. One can use either a high-speed drill or an osteotome to perform the osteotomy. The ligamentum flavum is then resected, making sure its lower attachment to the upper border of the lower lamina and medial lip of SAP is also removed, thus adequately decompressing the ipsilateral dural sac and traversing nerve root, and identifying the disc space (Fig. 4b). The exiting nerve root, esp. in cases of listhesis can be identified in the upper part of the foramen.

Discectomy, endplate preparation, and cage insertion (Fig. 5)

The traversing root is retracted, block

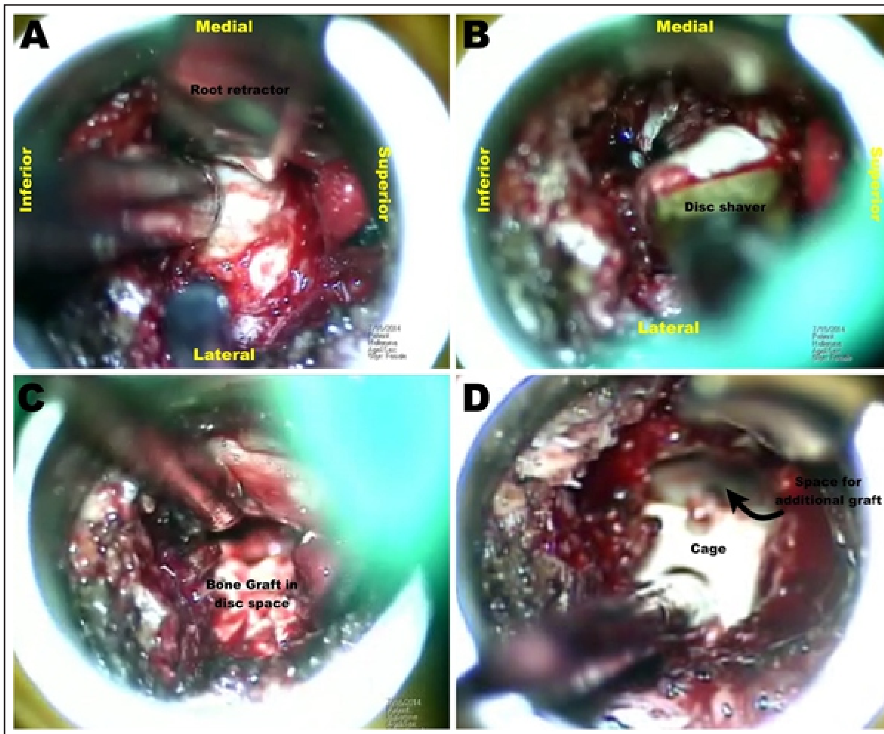

Figure 5: Images illustrating the steps for annulectomy after retracting the traversing root (a), endplate preparation with a shaver (in this case) (b), placement of bone graft (c) and oblique placement of the cage (d). In many cases additional space can be available for graft medial to the cage (d). Initial graft can be placed and pushed to the contralateral side followed by cage insertions in many cases.

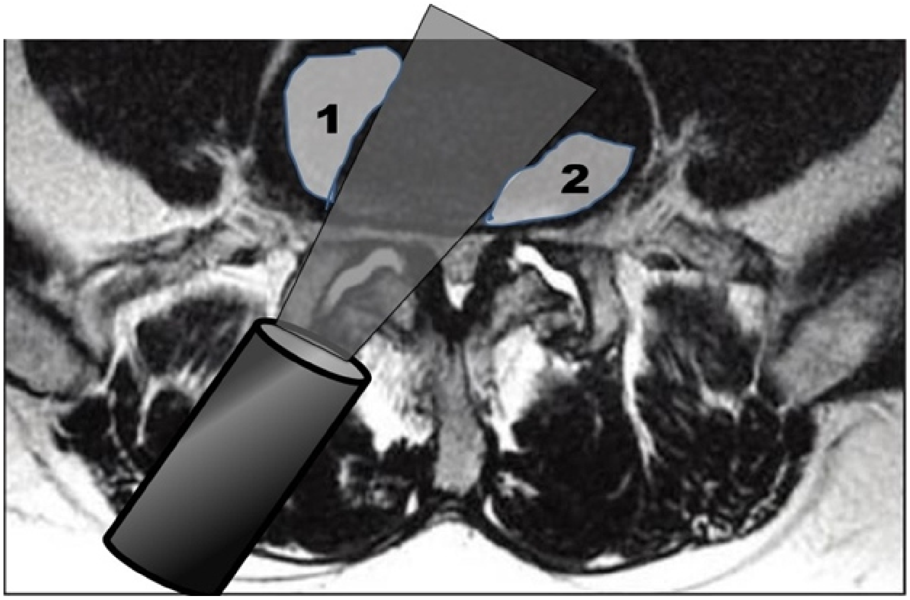

Figure 6: Schematic representation of the angulation during minimally invasive transforaminal lumbar interbody fusion. The tube angulation combined with a lateral entry point facilitates median and contralateral intradiscal visualization. In cases needing more disc preparation, Area marked 1 can be accessed by reducing the angulation of the tube and area marked 2 can be accessed with a forward angle disc forceps used cautiously in a sub-annular fashion.

annulectomy performed, disc space distracted using blunt disc distractors, and endplate preparation done using shavers and/or scrapers. It is important to note that the lateral to medial angulation of the tube will favor discectomy and endplate preparation towards the midline and contralateral (Fig. 6). One has to decrease the tube angulation to do more ipsilateral disc preparation. Once disc preparation is completed, appropriate sized cage with bone graft (both within the cage and on either side outside the cage) is inserted and position confirmed with fluoroscopy. It is important to protect the traversing and (in some cases) exiting nerve roots with a root retractor while inserting the cage.

Percutaneous pedicle screw insertion

The details of technique of percutaneous pedicle screw fixation (PPSF) is not covered in this article. However, the timing of PPSF in MIS-TLIF is important. Due to obvious reasons of extender towers in PPSF systems coming in the way, pedicle screws cannot be inserted on both sides before facetectomy and endplate preparation. However, guidewires can be placed within the pedicle at the beginning of the surgery on both sides, which will still allow for the placement of tubular retractor. In cases where reduction or distraction maneuver involving the screw is not required, PPSF on both sides can be simultaneously performed after the interbody work and cage placement. In cases where reduction requires screw manipulation, PPSF can be done on one side and interbody work for the other side followed by PPSF on the second side.

Guide for Case Selection and Learning Goals in MIS-TLIF

Owing to its biomechanical and clinical advantages to the patient and the cosmetic attraction of effectively performing a spine surgery with small incisions, minimally invasive spine techniques are being employed increasingly by novice surgeons early in their career. This could be either due to

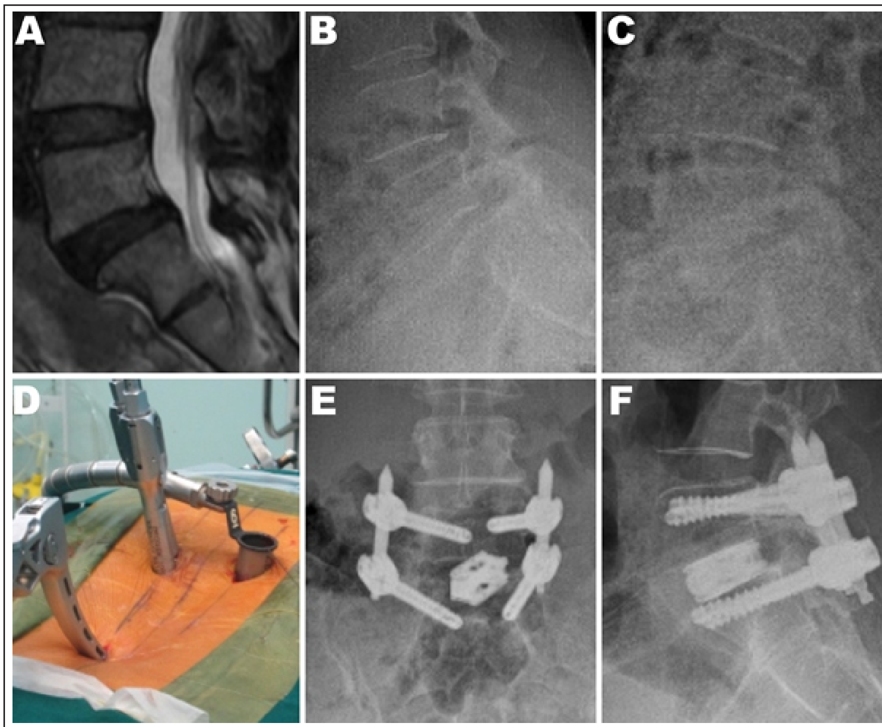

Figure 7: Illustrative case example for an ideal case for a beginner, A case of Gr 1 listhesis (a and b) without any significant canal stenosis or neural compression, which achieves near-complete reduction on Extension ©. Unilateral percutaneous screws can be initially placed to achieve complete reduction and interbody cage is placed form the other side (d). Post-operative anteroposterior (e) and Lateral (f) radiograph images showing the cage and screws in place.

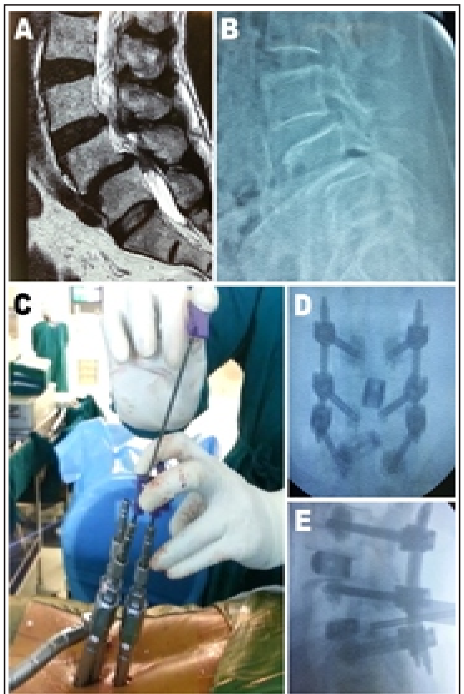

Figure 6: Illustrative case example for an ideal case for a surgeon with Intermediate level experience-A case of 2 level degenerative listhesis with facet hypertrophy, canal stenosis and severe osteoporosis (a and b). Patient underwent 2 level minimally invasive transforaminal lumbar interbody fusion with augmented fixation (fenestrated screws with cement injection) (c). Final Implant position on anteroposterior (d) and Lateral (e) fluoroscopy images at end of surgery.

the surgeons' well-deserved enthusiasm to learn and adopt the latest technique and upcoming trend in spine surgery or more guardedly because the patient demanded it and the surgeon couldn't refuse. In either case, though this is a promising trend, it's also imperative that these young surgeons have a clear understanding about appropriate case selection in early stages so that it helps them to tide through their learning curve in a smooth manner without having to face the undesirable situation of having an avoidable complication, early in their learning curve. Selecting simple cases, in early phase, and avoiding complications will also go a long way in convincing the surgeon of the efficacy of the procedure 'in his hands' and adopt, with increasing regularity, such a technique in his routine practice.

There are certain helpful pre-requisites that will enable the surgeon to perform his/her first few cases of MIS-TLIF with relative ease. Having performed vertebroplasty or PPSF for trauma cases would make placing percutaneous case during MIS-TLIF easier and effortless so that the surgeon can concentrate on the other essential steps of facetectomy, decompression, and cage placement during their first few cases. It is also advisable that the surgeon has tried minimally invasive technique for simpler cases (Lumbar discectomy) to develop his/ her skills of operating through the tube. The type of cases suitable for a surgeon according to his level of expertise, along with the learning goals at each step has been enumerated in Table 1.

Results of Author's Case Series

Methods

The first 150 consecutive cases of MIS-TLIF operated by a single surgeon (U.S) over a period of 4 years from 2012 to 2015 were selected for analysis. Patients' demographic data, clinical symptoms, indications for surgery, operative time, blood loss, peri-operative complication profile, duration of follow-up and imaging details (X-ray, computed tomography (CT), Magnetic resonance imaging scan, if any) were noted form the hospital records. All patients were contacted over a telephonic interview to determine their latest status, any complications or surgeries done elsewhere for sequelae or complications related to index surgery were noted. For

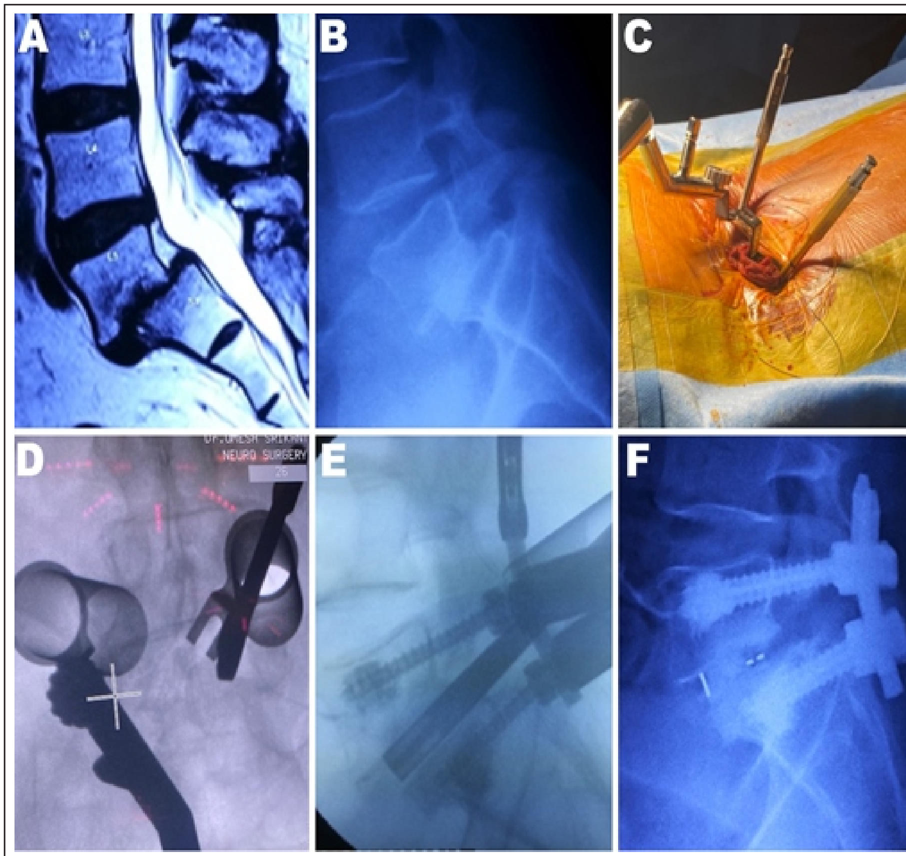

Figure 9: Illustrative case example for an experienced surgeon, A case of Gr 2 listhesis with disc space collapse and bilateral severe facet hypertrophy and foraminal stenosis (a and b) along with osteoporosis (T-score -2.8). Such cases, where unilateral decompression is not sufficient to release and reduce the listhesis need bilateral ports for decompression, release and distraction (c and d), following which unilateral screws are used to reduce the listhesis, maintaining distraction from the other side (e) and cage inserted. Follow-up post-operative X-ray showing good fusion mass with slight loss of disc height (f) compared to immediate post-operative X-ray.

Table 1: Essential pre-requisites prior to performing MIS-TLFI and guide for case selection along with learning objectives according to surgeon experience

Helpful Pre-requisites		• Percutaneous pedicle screw fixation for Trauma cases • Kyphoplasty/ Vertebroplasty • Tube assisted microlumbar discectomy (min 10–15 cases) • Observed/ assisted cases of MIS-TLIF (at least 10) • Hands-on cadaver course (at least one)	
Level of expertise	Timeline	Case selection criteria	Learning Goals
Beginner (Fig. 7)	First 10–15 cases	• Single level disease • Reducible low grade listhesis with relatively preserved disc height and no significant compression with mechanical LBP • LCS with axial symptoms • Moderate facet hypertrophy	• Accurately positioning the tubular retractor • Identification of facet anatomy with first dilator and through the tube • Making osteotomy or drill cuts in facets • Passing larger instruments (shavers, curettes etc.) through the tube • Cage placement
Intermediate (Fig. 8)	Amongst the next 20-30 cases	• LCS with severe facet hypertrophy/ degen listhesis • Gr 1 listhesis with foraminal stenosis/ disc space collapse • 2 level disease	• Dealing with hypertrophied facets which extend beyond tube margins • Achieving adequate decompression (ipsilateral and contralateral) • Reducing operative time in routine cases
Expert (Fig. 9)	Include after 40-50 cases	• Gr 2 or 3 listhesis • Fully Collapsed disc spaces • TLIF after prior laminectomy (Dural repair) • Degenerative deformity • Osteoporosis with deformity/ listhesis	• Using percutaneous reduction maneuvers in difficult/ tight listhesis • Dissection through previous adhesions with the tube and perform dural repair if necessary • Tackling intra-op complications like Screw pullout in osteoporosis

LBP: Low back pain, LCS: Lumbar canal stenosis, Gr: Grade, TLIF: Transforaminal lumbar interbody fusion, MIS-TLIF: Minimally Invasive Transforaminal Lumbar Interbody Fusion

patients who had expired at the time of telephonic calling (and the call was answered by a relative), the patients date of expiry and any complaints related to primary spine surgery before that were noted. Results were tabulated in groups of cases according to the timeline – Group 1 - Case no 1-25; Group 2 – case no. 25-75; Group 3 – case no. 75-150.

Results: (Tables 2 and 3)

The clinical profile, indications for surgery, surgical details, and peri-operative complication profile is enumerated in Table 2. The incidence of major co-morbidities was similar and did not vary significantly between the groups. The major indication for surgery in Group 1 was either Grade 1 spondylolisthesis or lumbar canal stenosis with concomitant axial symptoms. The incidence of surgeries done for Grade 2 or Grade 3 spondylolisthesis increased progressively in groups 2 and 3, so did the number of cases with prior laminectomy or discectomy at same level. A larger number of patients with 2 or 3 level disease were treated in groups 2 and 3 as compared to group 1. As expected, the operative time (calculated for only single-level cases) improved with time. There was no significant difference in the intra-operative blood loss between the groups. No patient was switched over from MIS to conventional (open) technique in our series.

The overall rate of peri-operative complications was higher in group 2 as compared to groups 1 and 3, predominantly due to an increased incidence of intra-operative dural tears in group 2. The incidence of dural tears in group 3 was lesser (and similar to group 1).

Routine post-operative CT scan to evaluate the integrity of the pedicles and accuracy of pedicle screws was not followed in our institution. Screw adequacy was assessed based on AP and lateral radiographic image for all patients on Post-operative day 1. One patient in group 1 and 2 patients each in groups 2 and 3 who remained persistently symptomatic for post-operative radicular symptoms underwent CT scans which showed Pedicle breach (all at L5). Patients who developed transient post-operative radicular symptoms whose X-rays looked satisfactory were not evaluated with CT scan for any minor pedicle breaches.

The median duration of follow-up for the entire group was 39 months (Range - 1–119 months). Eighty-two (54.6%) patients had follow-up of more than 1 year while 31 (20.6%) patients had follow-up of more than 7 years. The percentage of patients who had a successful outcome (McNab grade 4 and 5) and unsuccessful outcome (McNab grade 1-3) at 1 year, 3 years, 5 years, and 7 years' cross-sectional points are enumerated in Table 3. Three patients had cage retropulsion, all detected on routine follow-up radiographs in the 2nd post-operative month. All the three patients were asymptomatic and were managed conservatively. Two patients had screw loosening, both were advised revision surgery but they refused and were lost for further follow-up. Within the follow-up available, four patients (2.6%) had undergone re-operation, only one at authors center for an adjacent segment disease. The exact reason and the type of re-operation was not available in the other three patients operated elsewhere, but based on telephonic information, it was probably due to adjacent segment disease. Six patients underwent surgeries at distant levels unrelated to the primary surgery and five underwent either a facet or nerve root block at the authors center. Nine patients from the series had expired at the time of writing this paper, either due to natural causes or disease unrelated to that of the primary surgery.

Discussion

Minimally invasive spine surgery, including its wide gamut of Tubular retractor assisted and various endoscopic surgeries, are increasingly being adopted for routine practice by young and experienced spine surgeons likewise. Thought to have a steep learning curve, minimally invasive spine surgeons need patience, perseverance, and dedication to be able to perform these technically challenging surgeries with ease. Several reports have pegged the learning curve for MIS-TLIF to be around 30–45 cases [8, 9, 10, 11], with one study commenting that 50% of learning milestones can be completed around the

Table 2: Clinical profile, surgical details and peri-operative complication profile

Parameter assessed	Group 1	Group 2	Group 3
	First 25 cases	25–75 cases	75–150 cases
Age (Median ± Interquartile variation)	51.2 (46–70)	55.3 (49–68)	53.7 (41–68)
Sex (M:F)	7:18	1:01	10:09
Major Co-morbidities			
IHD	5	12	22
Uncontrolled DM/ HT	2	5	14
COPD/ Cor pulmonale	0	2	3
Indications			
Gr 1 listhesis	15	28	35
Gr 2 listhesis	2	8	9
Gr 3 listhesis	0	2	3
LCS with axial symptoms/severe facet arthropathy	5	7	16
Recurrent PIVD	1	3	4
Bilateral foraminal stenosis with disc space collapse	1	2	1
Spondylodiscitis	1	0	4
Previous laminectomy/ discectomy	1	3	9
Operative time (single level) (in min)	226 (192–274)	198 (160–226)	166 (138–204)
Blood loss (in ml)	130 (108–145)	148 (104–176)	126 (98–144)
Retractor type			
22 mm fixed	18	38	72
26 mm semi-Expandable (X-tube)	7	12	3
Levels			
Single	21	28	52
2 level	4	18	16
3 level	0	4	7
Peri-op Complication profile			
Overall	4 (16%)	12 (24%)	13 (17%)
Dural tear	2 (8%)	8 (16%)	6 (8%)
Root injury	0	1	0
Fresh post-op deficit	0	2	2
Symptomatic screw malposition	1 (L5)	2 (both L5)	2 (both L5)
Superficial wound infection	2	0	1
Deep op-site infection	0	0	3
Other (non-spinal/ Systemic/ General)	0	1	1

M: Male, F: Female, IHD: Ischemic Heart Disease, DM: Diabetes Mellitus, HT: Hypertension, COPD: Cor pulmonale, Gr: Grade, LCS: Lumbar canal stenosis, PIVD: Prolapsed Intervertebral disc, min: Minutes; ml: millilitres, mm: millimeters

12th case while it takes 39 cases to complete 90% of learning milestones [12]. However, many of these studies have failed to classify the learning objectives based on the type of cases and severity of pathology to be addressed. In this article, the authors have provided a guide for case selection at each category of surgeons experience along with the learning objectives to be kept in mind at each stage. Though the number of cases to reach an "Expert level" has not been reached based on any statistical model in this study, it is advisable to include more complex cases after doing the specified number of routine cases mentioned in Table 1.

We also analyzed the learning curve, peri-operative results, and long-term outcomes of the first 150 cases done over a period of 4 years (2012-2015). Similar to other reports [8, 13], operative time in our series also reduced over time with experience. The incidence of dural tear in MIS-TLIF reported in the literature varies between 3 and 12% [14, 15, 16]. Although the incidence of dural tears in our series was in sync with that of literature in groups 1 and 3, the incidence was noticeably higher in group 2. This was probably due to the increasing complexity of cases in group 2 as compared to group 1 (Grade 2 and 3 listhesis; severe canal stenosis; revision cases; multilevel), requiring more extensive peridural dissection and decompression across the midline and contralateral side.

Consistent with our suggestion in Table 1, the incidence of relatively complex cases (Grade 2 or 3 listhesis; Revision cases; Multilevel cases) increased with each successive group. Since the complication rate rose sharply in group 2, we speculate that including relatively complex cases that were done more frequently in group 2 in an earlier phase would probably have resulted in a further higher rate of complications. One of the complications we advise caution against even in early phase is an intra-operative dural tear. It is advisable that a surgeon is well equipped, both in terms of infrastructure (specific micro-instruments/ dural substitutes or sealants) and expertise to effectively deal with such a situation.

Table 3: Long-term follow-up data

Parameter assessed	> 1 year follow-up (%)	> 3 year follow-up (%)	> 5 year follow-up (%)	> 7 year follow-up (%)
N (no. of patients) *	82 (54.6)	67 (44.6)	53 (35.3)	31 (20.6)
McNab outcome measure#				
1, 2 and 3 (Unsuccessful outcome)	11 (13.5)	9 (13.5)	8 (15)	6 (19.3)
4 and 5 (Successful outcome)	71 (86.5)	58 (86.5)	45 (85)	25 (80.7)
Follow-up complication profile				
Cage retropulsion/ migration	3 (all conservatively managed)			
Screw loosening/ halo/ breakage	2 (advised revision – both refused; lost to f/u)			
Re-operation for index level/ASD	4 (3 elsewhere – no details)			
Re-operation for distant level/ Unrelated	6 (4 cervical; 2 Kyphoplasty)			
Nerve root/ facet blocks	5			

*The percentage in parentheses are with respect to the total number of cases (n=150), #The percentage in parenthesis are with respect to the number of cases in that particular column, ASD: Adjacent segment Disease, f/u: Follow-up

Nearly 45% of the patients in our study had a follow-up of >3 years and 20% of them had a follow-up of more than 7 years. On the downside, 45% of patients did not even complete 1-year follow-up to qualify for long-term outcome assessment. Around 80–85% of patients at each point of follow-up assessment had a successful outcome (McNab 4 and 5). These are consistent with other reports in the literature [17, 18, 19]. In our series, a total of 5 patients (3.3%) had implant-related complications during the course of follow-up. A total of 10 patients underwent re-operation (four of them for conditions related to index level or its adjacent segment and 6 for conditions unrelated to the primary surgery), putting the re-operation rate for index level lesion or ASD at 2.6%. The reported rates of re-operation for MIS-TLIF varies from 0.5% to 5%, significantly less than the reported re-operation rates for open TLIF [19, 20, 21, 22].

Conclusions

Minimally invasive TLIF is a safe and effective procedure with favorable long-term results and acceptable complication rates. Though technically challenging in the initial phases, a good understanding of the technique and principles of minimally invasive spine surgery along with fulfilling helpful pre-requisites and appropriate case selection as mentioned in this article will help to smoothen the learning curve and avoid unfavorable outcomes in early stages.\

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflict of Interest: NIL; **Source of Support:** NIL

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