Navigate and Succeed: MI-Transforminal Lumbar Interbody Fusion with Three-Dimensional Navigation

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Abstract

Introduction: Lumbar Interbody Fusion (TLIF) has become a popular technique for achieving segmental interbody fusion and minimal access approach has its advantages. We have described the various Components in Spine Navigation Systems and how they have evolved in time and also describing our technique in detail. We have discussed on the advantages and disadvantages of the minimal access and use of Navigation.

Method: The authors ventured to assess the impact of 3D navigation in 117 patients that were treated with single level 3D navigated MI-TLIF in evaluating, Navigation setting time , Radiation exposure, Disc space preparation, Cage placement, Accuracy of pedicle screw placement, Cranial facet violation and Evaluation of canal decompression

Result: Total time taken for setting up of navigation was 46.65±9.45 min. Average Radiation exposure was 5.69 mSv. In our study, the amount of disc removed was 75% in the ipsilateral anterior, 81% in ipsilateral posterior, 63% in contralateral anterior and 43% in contralateral posterior quadrants. The cage position was central in 87 patients, contralateral antero-central in six patients and ipsilateral postero-central in eight patients. The mean intraoperative blood loss was 89.65 ± 23.67 ml. Regarding accuracy 95.6% showed grade 0 and 4.4% had Grade 1 pedicle breach. Only 25 out of 408 pedicle screws (6.1%) violated the cranial facet joint. The navigation array probe was utilized to verify the adequacy of decompression and to confirm the anatomical landmarks. In our study, no surgical site infection was seen

Conclusion: We find MIS to be associated with less post-operative infection rates as compared to open techniques. With 3D navigation, MIS becomes safer and highly accurate. MIS-TLIF with 3D navigation have satisfactory clinical outcomes and fusion rates with the additional benefits of less initial postoperative pain, less blood loss, earlier rehabilitation, and shorter hospitalization. MIS–TLIF with 3D navigation is a more cost-effective treatment than MIS-TLIF with fluoroscopy.

Keywords: Lumbar Vertebrae, Minimally Invasive Surgical Procedures, Neuronavigation, Spinal Fusion

Introduction

Over the last decade, Transforminal Lumbar Interbody Fusion (TLIF) has become a popular technique for achieving segmental interbody fusion. The recent advances in minimal access technology havehelped to execute the procedure through a minimally invasive approach and provide adequate decompression with a solid fusion. The minimally invasive technique also helps to avoid many of the disadvantages of the traditional posterior open approach [1, 2]. A study by Schwender et al. [3] reported clinically significant improvements in visual analog scores and Oswestry Disability Index scores along with a 100% fusion rate in a cohort of patients who underwent a minimally invasive TLIF procedure (MIS-TLIF). Visualization is through a smaller and narrower dissection in MIS cases. The presence of complex spine pathologies such as rotated spine in degenerative scoliosis, poor anatomy on fluoroscopy, asymmetric, and abnormally shaped pedicles can pose serious challenges in MIS TLIF, resulting in incorrect placement of pedicle screws and cages [4]. Image guided navigation during spinal surgery can be of an invaluable assistance to MIS surgeons as it allows for a larger area of visualization of bony and soft tissues through a smaller area of surgical dissection.Pedicle screw placement by freehand techniques is primarily based on anatomical landmarks, and various methods have been described so far based on cadaveric

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Figure 1: On table patient positioning.

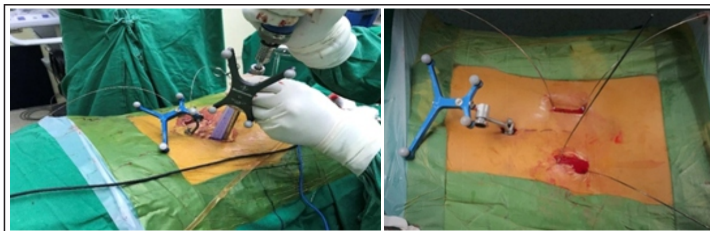

Figure 2: 3D Navigation with guide wire placement.

studies. The high variability in the morphology of pedicles makes it more challenging in complex spinal deformities. Fluoroscopy can assist screw placement; however, it increases the operative time and radiation exposure to the surgeon and operating room personnel. Misplacement rates of up to 30% in the lumbar spine and up to 50% in the thoracic spine have been reported with freehand and fluoroscopic guided pedicle screw placement. Mal-positioned screws risk potential damage to the spinal cord, nerve roots and great vessels; and also decrease the stability of the fixation. Medico-legal concerns over patient safety have further reinforced the need for image-guided screw placements to improve accuracy [5].

Computer-assisted spine surgery is a discipline that uses novel computer-based technologies, including stereotaxy, navigated surgery and robotics. Navigation assisted spine surgery is a group of technologies, which allow the surgeon to access real-time, three dimensional and virtual images of the spine in relation to the surgical instruments intraoperatively. This is a combination of image acquisition and processing that is followed by intra-operative navigation. The primary goal of navigation is to optimize the surgical intervention by providing the surgeon with advanced visualization of the operative field and to see the exact position of the handheld instrument in relation to the bony anatomy. The overall benefits include accurate and safe instrumentation, minimal radiation exposure to the surgical team, reduction of surgeon fatigue, and surgical duration. Spine navigation was initially used to improve the accuracy of pedicle screw placement. However, over the years, its use has extended into minimally invasive surgical techniques, cervical spine surgery, revision surgery, and spine tumor surgery [5].

Components in Spine Navigation Systems [5]

There are numerous navigation systems available commercially now. The basic fundamentals, however, remain the same and include the following.

Image acquisition and processing unit

The first step in spinal navigation is to acquire high-resolution images of the region of interest, either pre-operatively or intra-operatively, which then allows the surgeon to navigate upon these processed images. Intra-operative imaging is currently being used in most navigated surgeries as it involves the acquisition of images after positioning the patient for surgical intervention, and this reduces the rate of errors in matching and registration. Intraoperative imaging can be done either by fluoroscopy, computerized tomography (CT) scan, and late even magnetic resonance imaging.

Referencing system

This includes dynamic reference frame/array (DRA), light emitting diodes (LED), and Tracking system.

DRA

The DRA is usually attached to fixed anatomical landmarks, such as the spinous process. The accuracy of the navigation depends on the stable fixation of this DRA, and, therefore, it must be left undisturbed throughout the surgery.

Light-emitting diodes

DRA has provisions for attaching three or more spheres known as LED. These LEDs emit light, which is tracked by an electro-optical camera and are known as active arrays. Specialized surgical instruments are used, which also have LEDs attached to them and are called passive arrays as they reflect the infra-red rays emitted from the camera and gives the surgeon a real-time tracking of the exact location of these devices over the surgical field. The three-dimensional

Figure 3: Planning tube placement-navigated probe.

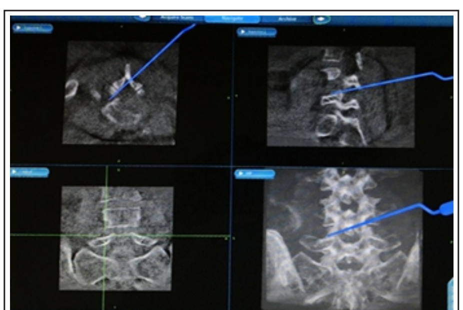

Figure 4: Evaluation of decompression.

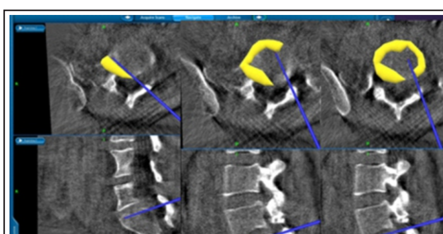

Figure 5: Cage placement.

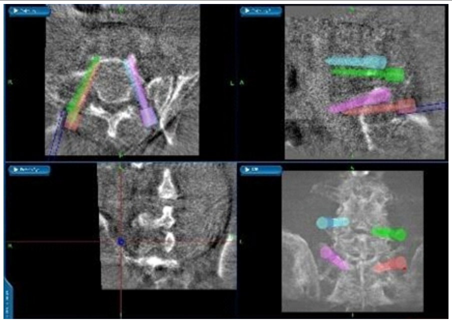

Figure 6: Pedicle screw placement.

(3D) orientation between these active and passive LEDs thus facilitates navigation.

Tracking system

Various tracking systems are available that include optical, mechanical, acoustic or electro-magnetic systems. Optical tracking systems are the most frequently used due to superiority in terms of accuracy. They use infrared camera devices to actively track the light emitted or reflected from the LEDs, which are attached to the DRA and surgical instruments which requires the "line of

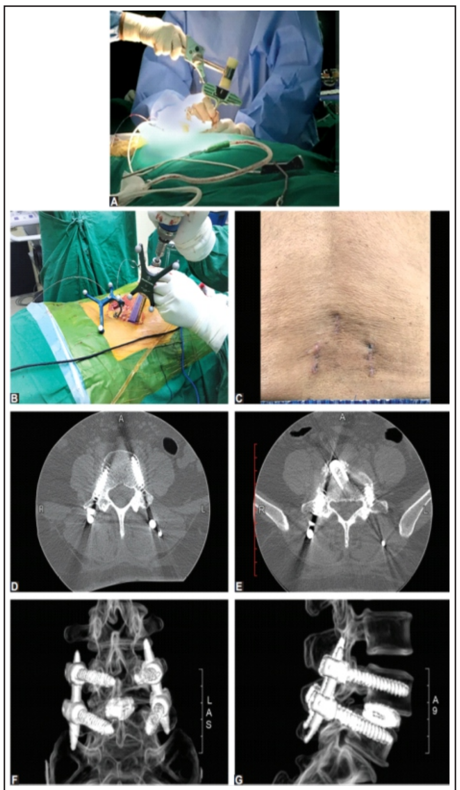

Figure 9: (a-g) (a and b) Set up of navigation apparatus (band c) healed scar area; (d-g) CT scan showing good alignment of pedicle screws with interbody cage.

Figure 7: Placement of screws and rods.

sight" maintenance between the LEDs and cameras at all times.

Registration process

The process of establishing the synchronization between virtual images and the real anatomy is called registration. Once the image is acquired, the data aretransferred to the navigational system, which then performs an automated registration eliminating the need for manual registration.

Evolution

The methodology of pedicle screws insertion techniques in spine fusion surgery is the most significant advancement, extending from conventional open procedures to accurately placed percutaneous pedicle screws. Numerous studies in the literature have highlighted clinically significant sequelae from inaccurate

Figure 8: Scar at 6 weeks post single level 3D navigated MIS TLIF.

implant placement. For achieving a safe and ideal screw placement, a number of imaging methods and image guidance systems have been used. The use of stereotactic navigation based intra-operative CT is a promising modality offering the benefits of highly accurate pedicle screw placement reduced operative radiation exposure, and seamless integration into minimally invasive spine surgery (MISS). Recently, extensive minimally invasive spinal systems have surged, almost all based on the principle of using a series of dilators of different lengths and increasing diameters to create a path between

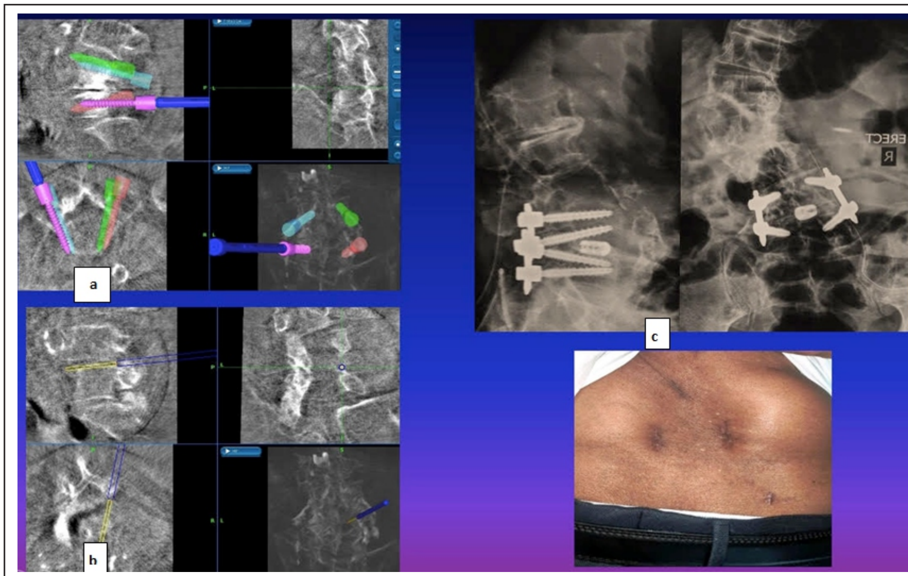

Figure 10: (a)Accurate placement of screws across rotated pedicles with malformed anatomy due to advanced degenerative arthritis is seen. (b)The cage can be placed optimally using navigation. (c) Post-operative X-ray and healed scar of MI-TLIF.

Table 1: Comparison between various navigation systems

Image acquisition	2D fluoroscopy	3D fluoroscopy	Preoperative CT	Cone Beam CT	Intraoperative CT
Generation	2nd	2nd	1st	2nd	3rd
Registration	Automated	Automated	Manual and time consuming	Automated	Automated
Registration duration	Short	Short	Long	Short	Ultra-Short
Image display	2D (AP and Lateral)	3D	3D	3D	3D
Scan time	Only AP and lateral radiographic images	2 min	30 s	40 s	30 s
Number of vertebrae in single scan	3–5 vertebrae	3–5 vertebrae (working corridor 12×12 cm)	Whole spine	6–8 vertebrae (working corridor 30x40 cm)	Whole spine
Bone image quality	Poor	Poor	Good	Good	Good
Imaging in severe deformities	Not possible	Not possible	Possible	Possible	Possible
Carbon table and carbon head clamp fixation	Not necessary	Required	Not necessary	Required	Required
Ideal area of the spine	Lumbar spine	Whole spine	Whole spine	Whole spine	Whole spine
Minimally invasive spine surgery	Difficult	Possible	Not possible	Possible	Possible
Real time imaging	Yes	Yes	No	Yes	Yes
Radiation Exposure	Patient↓ OT Personnel↓	Patient↓ OT Personnel↓	Patient↑↑ OT Personnel↓	Patient↑ OT Personnel↓	Patient↑↑ OT Personnel↓

muscle fascicles to access the posterior spinal elements [6, 7, 8]. Initial surgeries using these access portals involved simple decompressive procedures; however, over the last decade, these systems have been expanded to facilitate interbody and posterolateral arthrodesis in addition to the placement of pedicle screws in a less invasive fashion in traumatic to deformity correction cases [9]. Spinal navigation is closely related to intra-operative 3D imaging providing an imaging dataset for navigational use and the opportunity for immediate intra-operative assessment of final screw position giving the option of immediate screw revision if necessary.

Generations of Navigation System [5]

The history of spine navigation systems can be considered to have undergone three generations of evolution as shown in Table 1.

First generation spine navigation

First-generation spine navigation systems employed image acquisition using thin-slice CT scan pre-operatively.

Second generation spine navigation

Second generation spine navigation managed to overcome the shortcomings noted in the first generation. They offered intra-operative reconstruction images of the spinal anatomy using two-dimensional (2D) and 3D fluoroscopy. The 2D fluoroscopy system provided images in two planes. Axial reformatting was not available. The advantage of this system was that the computer software and image acquisition system could be paired with routinely used fluoroscopy units available in the operating room. Further improvement was seen in the form of cone-beam CT that used basic multiplane fluoroscopy to reconstruct 3D CT like images. The drawbacks were that limited segments of the spine could only be scanned during the process. This made multiple level fixation spanning long segments difficult as multiple scans needed to be performed for a single procedure, increasing the radiation exposure, and operative time.

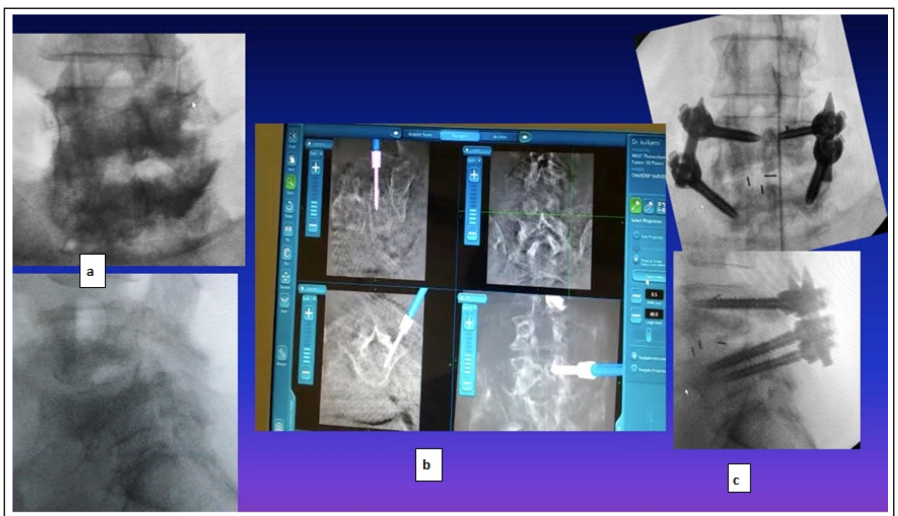

Figure 11: (a) Poorly defined anatomy on 2D fluoroscopy images. (b)Pedicle screw insertion using 3D navigation. (c) Post-operative X-ray of MI-TLIF

3D C-arm navigation system

This system depends on the concept of isocentricity. The fluoroscopy unit is coupled with a special reference system and computer software to provide axial, sagittal, and coronal reformatted images. The fluoroscopy unit moves through an arc of 180° while focusing on a solitary point in the spine. The system can be calibrated to a high spatial resolution protocol, which takes multiple fluoroscopy images while the arc moves through the 180° or lower resolution protocol, which may take fewer images during the process. The system allows for automatic reference. The advantage of the system was that it did not require a pre-operative CT scan. Intra-operative image acquisition allowed for a post-operative scan to assess the accuracy of the screw position possible. The 3D C-Arm can be used as a routine fluoroscopy unit and can be paired with image guidance surgery software to work as a navigation system for complex spinal surgery.

However, there are a few disadvantages to this navigation system. It scans patients based on the selected isocenteric point. Therefore, all the images obtained are from a segment of the spine in the field of the scan. This limits the scan to 6-7 vertebral segments. Although the images generated by the 3D C-Arm are similar to a reformatted CT scan, the image quality is inferior to conventional pre-operatively performed CT scans.

Cone beam CT (CBCT)

Plenty of CBCT devices are available commercially, and again they can be used either pre-operatively or intraoperatively. The image quality is superior to 3D C-Arm, and the time for image acquisition is also shorter. Intra-operative CBCT devices allow automatic registration and have a larger field of scan and, therefore, can screen more vertebral segments in a single scan when compared to the 3D-C Arm system. They can provide both routine fluoroscopy images and reformatted CT images in the axial, sagittal and coronal sections. The radiation dose of the CBCT devices, however, is lower than a conventional CT scanner, and it may be used to assess the accuracy of placement of screws intraoperatively.

Third generation spine navigation systems

Third generation spine navigation systems are considered the most recent developments in the field. These navigation systems can perform an intra-operative CT scan with subsequent automatic registration. They provide excellent CT images with a scan field that can screen the entire spinal column. It offers an opportunity to use the navigation in conjunction with minimal access surgical procedure. The radiation exposure to the patient with the use of such CT based systems can be much higher than fluoroscopy-based navigation systems. These imaging devices have adjustable radiation density thresholds, which provide good images even when the density is reduced by 25–50% of the maximum dosage.

Senior author's (SA) MIS navigation surgical technique

The SA MIS surgical technique is centered around navigation when performing specific portions of his operations. We will outline the operating room setup, data acquisition for tracking, registration of instrumentation/patient, and operative steps while performing navigated MIS TLIF.

Indications

- Degenerative spondylolisthesis with difficult facet morphology
- Grade I-III spondylolytic spondylolisthesis and spondyloptosis with narrow pedicles
- Degenerative scoliosis with an indication for selective fusion with rotated pedicles
- Revision spine surgery - adjacent segment disease.

Operating room setup

The SA sets up the operating room with the patient prone in the center of the operating room. The image intensifier comes in from the right side of the room (as seen from the foot of the patient). The monitor with the navigation guide stays above the right side of the patient's right shoulder. The registration camera is above the head of the bed.

Anesthesia

General anesthesia is used for navigated TLIF.

Positioning

The patient is placed prone on a radiolucent operating table following intubation which allows tilting in all directions and is secured with tapes/belts. The elbows are placed at 90° to decrease traction on the brachial plexus and pads are placed under the ulnar and peroneal nerves. In addition, pillows are placed under the lower extremities (Fig.1). After positioning, the mobility of the Foley catheter is checked, the endotracheal tube is secured and the fluoroscopic machine is draped into the operative field. Reverse Trendelenburg position is given to make the involved level as vertical as possible to the floor and avoid prolonged abnormal postures with microscope usage.

3D navigation registration

Following standard skin preparation and sterile draping, navigation reference frame is docked on the adjacent spinous process (usually one level above). The 3D C-arm is triggered to spin around the patient and the procured images get formatted into images in all planes (sagittal, coronal, and axial). These images are then transferred to the Stealth monitor. The Stealth™ camera can detect and track anatomy using infra-red rays to whichever part/instrument the tracker is attached and registered. At the time of spinning the 3D C-Arm, operating team are off the operating room to avoid radiation.The total time taken from draping to registering patients data to 3D navigation takes approximately around 45 min. Authors noticed that anchoring reference frame, static position of patient, and temporary suspension of ventilation to sidestep respiratory movements (generally for a minute) at the time of image capture by the C-arm play a key role to minimize anatomical (registration) errors [10, 11]. Literature suggests that error margins were positive in <1 mm translation and 5° rotation of the patient reference array in all regions of spine [12].

As a first step following verification, navigated Jamshedi needle is registered and tracked to the optical system following which pedicle cannulation is performed using real time visualization in all the three-planes. Percutaneous guide wires are then passed into the pedicles through the Jamshedi needle (11 G) (the authors prefer to place the pedicle guide wires first followed by interbody cage and finally pedicle screws with interconnecting rods. This is because of the change in the real anatomy as a result of disc-space preparation and insertion of the cage vs. the virtual anatomy that was captured earlier). Once the placement of the navigated Jamshedi needle within the vertebral body at an appropriate orientation is confirmed, a blunt-tipped threaded guidewire is passed through the cannulated center of the entry needle. Care should be taken not to advance the guide wire to within 10 mm from the anterior wall of the vertebral body. Following confirmation by lateral view from navigated images, tip of the guidewire from the navigated Jamshedi needle is withdrawn. The steps are repeated for rest of the pedicles and all the guide wires are bent away from the operative field securing them to the draping without introducing sharp bends into them (Fig.2).

Decompression

Using the Wiltse's approach, with 3D navigation, successive serial dilators of increasing diameters till 22mm are inserted. The tubular retractor of appropriate length (5/6/7 cm) is placed over the dilator and accurately docked on the lamina-facet complex (Fig.3). After removal of dilators, the final retractor system can be a fixed rigid tube (METRx), or a split blade tubular retractor (QUADRANT, MARS 3 retractor, etc.) that can be expanded. The surgical microscope is then moved into the field and decompression and interbody fusion is performed through the tubular retractor with variations in the operative steps as per the demands of the indication. The soft tissue over the facet is removed with a long monopolar cautery and Kerrison rongeur. The facet–lamina junction is delineated using navigated curette. Using an angled curette, the space between the lamina and the ligamentum flavum is defined after thinning out the lamina with a high-speed navigated burr. Using the Kerrison rongeur, the lamina-facet junction is removed. If there is no stenosis, then a small laminotomy can be done to allow the visualization of the neural elements in close proximity to the facet joint. If the patient has stenosis on the ipsilateral side, a complete laminectomy should be performed. In cases of bilateral stenosis, the spinous process is undercut and a contralateral laminectomy and medial-facetectomy accomplished by tilting the tube. If stenosis is severe or there is a significant foraminal component on the contralateral side, we suggest decompressing the lateral recess down to the exit zone by wanding the tube caudally [13]. For confirming adequate decompression, navigated probe is checked into spinal canal and foramina in both ipsilateral and contralateral sides (Fig.4). A navigated burr may be used to drill the lamina and the facets, but this decreases the quantity of bone graft, since the surgeon relies on locally excised bone for fusion.

Disc space preparation

The next step is identifying the disc space. In general, the traversing root is medial to the pedicle and only minimal retraction is justified. The exiting nerve root hugs the superior pedicle as it exit the neural foramen and is generally cephalad to the level of the disc in the foramen. Although we do not necessarily dissect out the exiting root, it may be protected by placing a patty directed toward the cephalad pedicle in the foramen. Discectomy and disc space preparation is performed with the help of disc forceps, Kerrison rongeurs, bayonetted curettes, and rotating end plate shavers. The completeness of excision of the intervertebral disc is evaluated by introducing the navigation array probe in all directions contralateral posterior, anterior and ipsilateral anterior, posterior quadrants of disc space (Fig.5) [14]. Once disc space is cleared of the remnant disc, superior, and inferior cartilaginous endplates are curetted till superficial bleeding appears on the bed of endplates to promote fusion. In certain complex situations such as high-grade spondylolisthesis, conditions with collapsed disc spaces identification of the posterior annulus and intervertebral disc may be difficult and the navigation probe has a role in identifying the precise anatomy.

The appropriate size trial interbody cage is then placed into the disc space. After confirming proper placement on navigated screen, the trial is removed and any fragment of bone and cartilage is removed. Autologous bone graft is then packed into the anterior disc space using a funnel and checked with navigated probe for equal distribution of graft. The interbody structural device (cage filled with bone-graft) is then advanced into the disc space. The size and position of the cage to be placed werecalculated using calibration applications on the Stealth monitor. Interbody fusions are performed using either titanium/PEEK cage and autograft, the cage being precisely positioned, and verified with navigation assistance.

Percutaneous pedicle screw and rod fixation

The skin and underlying fascia are dilated by means of sequential dilators to create a pathway for the pedicle screws over the initially placed guide-wires. The largest dilator is left in place to protect surrounding soft tissue. Using navigation assistance tracker attached to the handles of cannulated tap, advanced over the guidewire down to the pedicle. Depth and diameter of pedicle can be calculated using navigated measurement software at the end of tapping. Care should be taken to prevent the guidewire from advancing or backing-out. Once the pedicle is tapped, the tap and tissue dilator sleeve are withdrawn while the screwdriver and tower assembly are placed over the guidewire. The pedicle screw is advanced with the navigated assistance polyaxial screwdriver avoiding cranio-facet joint violation until the appropriate depth is achieved (Fig.6). Coronal, axial, and sagittal images are checked intraoperatively to confirm the screw's placement within the pedicle, orientation and overall depth. Care should be taken to avoid advancing the screw head to bone, which would limit the ability to seat the rod. The guidewire is withdrawn as the screw enters the pedicle in-order to avoid it getting bent ahead of screw tip and trapped. The screwdriver is withdrawn from the tower assembly. Subsequent pedicle screws are placed with this same technique. It is important to note that all screw tower assemblies should line up in the same orientation and height before the next step of the procedure (Fig.6).

A rod measurement guide is placed to facilitate measurement of the rod size. The rod is passed percutaneously through a separate stab incision (SEXTANT) or placed free-hand in other designs leaving adequate lengths at both ends. Once the rod is seated, a cap inserter is placed in the tower assembly. Subsequent screw caps are now placed. Compression can be achieved by system specific methods. Final tightening of the construct is performed with an anti-torque stabilizer and torque-limited driver. The screw tower assemblies are loosened and removed. Final radiograph is obtained to confirm proper positioning of screws, cage and rod (Fig.7). Dorso-lumbar fascia is approximated with absorbable No. 2-0 Vicryl and subcuticular running closure with Monocryl 3–0 done.

Post-operative care

Ambulation usually begins on post-operative day 1. The average hospital stay is 2 days to longer for patients who have additional medical comorbidities with most patients being discharged on POD 4 with assisted ambulation. The scar at 6 weeks follow-up is cosmetic (Fig.8).

Advantages of MIS

The conventional open posterior approach contributes to wide soft-tissue dissection and leads to localized denervation of muscles, extensive blood loss,fibrous tissue(dead space), persistent back pain, and muscle spasm after the procedure[15, 16, 17]. Kawaguchi et al.[18] demonstrated that the duration of muscle retraction during spine surgery, pressure of the retractors, and the number of levels exposed directly correlate with the post-operative elevation of serum creatinine phosphokinase isoenzymes, a marker of muscle injury. The MIS TLIF procedure has overt advantages over open TLIF in reducing blood loss (intraoperative and post-operative) thus abolishing need for transfusion, reduced infection rates[19, 20]. These specific advantages can be attributed to fall back of the dilated muscles in the tracts thus collapsing the dead-space, which in turn helps to hasten post-operative recovery and early rehabilitation in MIS-TLIF.

Advantages of Navigation Assisted Surgery

Although MIS-TLIF with fluoroscopy causes lesser damage to the patients, the intra-operative challenges faced by surgeons in inserting percutaneous pedicle screw are spinal alignment, quality/quantity of multifidus muscle, and depth of screw entry point. Furthermore, the pedicle dimensions, facet joint arthritis, screw location (ipsilateral and contralateral), screw length, screw diameter, cortical encroachment, frank penetration, and screw trajectory angle are all uncertainty screw-related variable[4].

Accuracy

Navigation assisted screw positioning has reported lower misplacement rate compared to the freehand placement. Rajasekaranet al. in a recent article have analyzed pedicles and documented an accuracy rate of 96.2% using intraoperative CT based navigation[21]. In addition, to pedicle screw placement, navigation helps to classify these non-negotiable pedicles and prevents the surgeon from attempting to instrument it. Navigation has resulted in pedicle perforation rates as low as 1–5%. The accuracy of 3D navigation system is considered to be superior to virtual fluoroscopy and 2D navigation[22]. A meta-analysis of 9019 thoracic pedicle screws established the superiority of CT navigated instrumentation over fluoroscopic guidance[23]. Castro et al. noted a 40% pedicle breach following free hand pedicle screw placement in fluoroscopy assisted surgery inspite of anatomic visualization of entry points[24]. MISS is likely to have much higher misplacement rates.Navigated spine surgery has the potential to create phantom screw trajectories and helps the surgeon to apply stab incision at the appropriate level through which screws can be placed with ease in correlation with these phantom images. Baaj et al. used intraoperative navigation to apply percutaneous pedicle screws in short constructs in degenerative spine[25]. Kim et al. observed an accuracy rate of 96.6% in MISS using computer aided navigation and intraoperative CT[26].

Radiation safety

It has been noted that for the spine surgeons, radiation exposures is up to 10–12 times greater than in other orthopedic procedures and may approach or exceed guidelines for cumulative exposure[27]. MISSinvolve notoriously high amount of radiations to the surgeon and other operating room staff due to the non-visualization of anatomical landmarks for free hand placement of screws. In such a scenario, navigation-assisted surgery reduces the radiation exposure for the operative team, as all members are protected during the scanning procedure. They also found 87% less exposure time to radiation while using intraoperative CT in comparison to fluoroscopy used in MIS procedures[28]. From the patient's perspective, the radiation exposure for CT based navigation systems is significantly higher when compared to fluoroscopy-based systems, yet they fall within permissible limits.

Surgical site infection

A review of MIS-TLIF studies suggests an infection rate of 0–10%[26]. Similar experience has been highlighted by the author's team [20]. O'Toole et al. found that the incidence of surgical wound infection was significantly lower after MIS–TLIF (0.6%) than after open TLIF (4.0%)[29]. To reduce the rate of infection with MIS-TLIF, it is recommended to avoid placing fingers into the surgical wound, which may increase the risk of surgical wound infection if there are microscopic breaks in the surgeons gloves. Nassr A also concluded that MIS-TLIF is associated with lower incidence of surgical site infection than open TLIF[30].

Facet joint preservation

There is also a high chance of facet joint violation in MISS which in turn results in adjacent segment degeneration. The real advantage of navigated MIS TLIF lies in the fact that precise facet joint sparing entry can be taken and optimal trajectory in axial plane can be made with maximal screw length to achieve a near perfect and extremely safe pedicle screw with maximum possible pull-out strength (Fig. 9). Lau et al. observed lesser facet joint violations in MISS while using intraoperative navigation[31].

In obese/osteoporotic patients

Instrumentation using MISS in obese patients and frail osteoporotic patients is challenging as manual tactile feel of the pedicles would not be possible, and spinal navigation comes to the rescue in such scenarios.

Concerns with Spine Navigation

Operative time

The older generation of navigation systems employing manual point matching registration did lead to increased operative times. This drawback has been overcome with newer generation navigation systems that allow for automatic registration and a larger field of scan (BRAINLAB) extending to multiple vertebral segments. Improvement in quality of virtual images, reduction in acquisition time, and automatic registration process has contributed to the reduction in the duration of a surgery over the years. The overall duration is set to improve steadily as the experience of the surgeon and operating room personnel rises resulting in a systematic workflow in the long run.

Wobbling and motion related artifacts

Whilst the entry points and trajectories of instrumentation are clearly defined by image-guided surgery, the wobble created by manually tapping or inserting screws across the trajectories involved might result in inaccuracies due to the maximal radial movement from its center of axis[10]. This is best avoided by postponing the screw insertion process after creating trajectories of all planned screws. Nowadays, powered pedicle screw drive systems are available which enhance surgeon experience with faster, accurate screw insertions. In lean and poorly built patients, ventilation related movement of the thoracic spine may hinder the accuracy of navigation. It is better to acquire images in a non-ventilation mode and reduce the tidal volume in such scenarios to reduce motion-related artifacts. More important, all the nursing staff and assisting surgeons who are involved in the handling of instruments around the surgical field must be aware of the fact that the slightest deflection of the fixed reference array might result in severe inaccuracy. In doubtful scenarios, the surgeon needs to re-verify the accuracy. If the tip of the pointer appears to be either underneath the lamina or hanging above in space, one can be sure that there has been a disturbance of the array, and the entire navigation needs to be repeated. Some times in spite of placing the surgical instruments and camera in the "line of sight," navigation might be troublesome. It might be due to bloodstain or debris covering the spherical diodes. Care should be taken to gently clear it to avoid disturbing the position of reference array.

Distance from reference array

The accuracy of instrumentation is directly proportional to the distance of the level of interest from the reference array. Even though the current systems are capable of imaging the whole spine, the accuracy is questionable at the farthest point from the reference array. This can be solved in two ways. Firstly, when the surgeon requires imaging of the entire spine in case of complex deformity and surgery involves more than 12 segments, it would be appropriate to affix the reference array midway between the ends of the surgical incision. On the other hand, where the surgeon is not able to get an adequate fixation point as in pediatric cervical spine, considering the far distance of iliac crest from the area of instrumentation, it would be better to place the reference array on immobile regions such as Mayfield clamp. Whenever instrumentation is attempted at distal levels, it is better to re-verify the accuracy manually.

Cost-effectiveness

The uptake of navigation technology has been limited by start-up, acquisition, and maintenance costs. The opponents of spinal navigation cite this as one of the major drawbacks. The economical evaluations have recognized limitations and challenges as the cost-effectiveness depends on multiple factors such as the number of surgeries performed, the intricateness of surgical procedures undertaken, complications and the cost of revision surgeries. But a study also concluded that it would actually be a cost-saving surgery for a spine unit that does more than 254 spinal instrumentations yearly[32]. Al-Kouja et al.in his systematic review states that the biggest advantage of image-guided surgery is the prevention of reoperation and four out of seven studies had a zero reoperation rate[33].

Learning curve

As with any new technology and its user experience, navigated spine surgery does have a learning curve. However, here, it requires well-organized operating room personnel to function as a single unit, and the success depends on the learning curve of the entire team. Each of the team needs to understand and execute their roles efficiently to reduce the nuances of surgical duration and technical flaws. Bai et al.in his prospective study analyzed the learning curve of surgeons using image-guided navigation spinal surgery and noticed a steep incline in operating time and screw perforation rate by 6 months and reached a plateau by 12 months[34]. Sasso et al. in his retrospective analysis of 4-year data noted an average reduction of 40 minutes in operative time for lumbar fusion using navigation and image-guided surgery[35]. Ryang et al., in his prospective analysis of the learning curve using 3D fluoroscopy, found a learning curve of 4 months in placing lumbar and thoracic pedicle screws[36].

Senior authors experience

The authors ventured to assess the impact of 3D navigation in MI-TLIF in evaluating

1. Navigation setting time
2. Radiation exposure
3. Disc space preparation
4. Cage placement
5. Accuracy of pedicle screw placement
6. Cranial facet violation and
7. Evaluation of canal decompression.

Results

3D navigation setting time

Total time taken for setting up of navigation including pre- surgical time, that is, scrubbing of the parts, draping, initializing the 3D C-arm and the navigation workstation, mounting reference array on the patient, acquiring scans and transferring the same onto the navigation workstation was 46.65±9.45 min. As displayed in results, the navigation setting up time progressively reduced with increasing experience. Our setting time values were in consensus with a study conducted by Balling et al. Balling [37] recorded an O- arm guided 3D navigation setting time of 46.2±10.1 minin a prospective study of 306 posterior instrumentations. In our study, we experienced navigation error in one case probably due to translation of the reference array while operating. And this caused a medial breach in one patient which was rectified immediately. Rampersaud et al. suggested that error margins were positive in less than 1 mm translation and 5° rotation of the patient reference array in all regions of spine[12]. Furthermore, a study by Rahmathullah et al., with his experience of 1500 cases in navigation commented that turning on the warmers during registration can causes image artifacts leading to error[10]. Again, while registration and setting up of navigation takes additional time, the total operating time may get shorter in patients with complex anatomy, as compared to fluoroscopy-assisted MI-TLIF. To minimize anatomical errors that could be secondary to respiratory movements, the authors temporarily suspend ventilation (generally for a minute) at the time of image capture by theC-arm[11].

Radiation exposure

In author's experience,117 patients were treated with single level 3D navigated MI-TLIF, 15 have lost to follow up. A total of 408 pedicle screws were implanted, the mean time for fluoroscopy usage was 97.6 ± 11.67 and mean amount of radiation from fluoroscopy was 4.43 ± 0.87 which was similar to those found by Mendelsohn et al. reported that radiation exposure to patients using O arm navigation was 2.77 times more when compared to non-navigated surgeries. However, the dose of 5.69 mSv was much lower than a conventional CT (7.5 mSv) and amounts to one-quarter of the total occupational exposure allowed per year. They also found 87% less exposure time to radiation while using intraoperative CT in comparison to fluoroscopy used in MIS procedures. From the patient's perspective, the radiation exposure for CT based navigation systems is significantly higher when compared to fluoroscopy-based systems, yet they fall within permissible limits[28]. Kim et al. has also concluded that the use of navigation-assisted fluoroscopy is feasible and safe for MISS. Radiation exposure is decreased to the patient as well as the surgical team[38].

Volume of disc excised

Adequate disc space preparation is extremely vital for optimum fusion. In our study, the amount of disc removed was 75% in the ipsilateral anterior, 81% in ipsilateral posterior, 63% in contralateral anterior and 43% in contralateral posterior quadrants Following discectomy, Hurly et al. [14] compared the area of empty disc space between two techniques; cone beam navigation and open technique using a navigation probe. Disc removed using cone beam navigation was ipsilateral-anterior = 75 %, ipsilateral-posterior = 81%, contralateral-anterior = 63% and contralateral-posterior = 43%. Rhin et al. showed in his randomized study of 40 lumbar TLIF that the percent disc removed by volume (80% vs. 77%, P = 0.41), percent disc removed by mass (77% vs. 75%, P = 0.55), and percent total disc removed by area (73% vs. 71%, P = 0.63) between the open and MIS approaches were nearly same. The posterior contralateral quadrant was associated with the lowest percent of disc removed compared with the other three quadrants in both open and MIS groups 50% and 60%, respectively. Thus, concluding that navigation can help guide adequate disc space preparation intra operatively and the surgeon should be generous during discectomy from the posterior contralateral corner to minimize the likelihood of pseudoarthrosis[39].

Cage placement

Transforaminal lumbar interbody fusion entails packing the anterior 1/3rds of disc space with bone graft and navigation allows assessment of the thickness of this mantle of bone-graft using the navigation probe. While the guidelines for exact placement of the cage have not been published, numerous papers show encouraging results with anterior and central placement within the intervertebral disc space[40]. In our study, the cage position was central in 87 patients, contralateral antero-central in six patients and ipsilateral postero-central in eight patients. The Cohen's kappa statistic test for inter observer co-relation was 0.92 for the two examiners with regards to cage placement. Progressive posterior cage migration was noticed in a patient with initial poster-lateral placement of the cage and this was revised. Schupper et al. had employed navigation in his revision L3L4 case, as an adjunct, to help localize the interspace for cage deployment through minimal exposure. The TLIF cage was able to be appropriately placed in the collapsed disk space, as well as the pedicle screws, which allowed for improvement of lumbar lordosis. Similarly, Lian et al. in his 33 cases had determined the size and orientation of the cage by the navigation and after the cage insertion, a second scan was made to verify the accuracy of all the implants. Navigation also allows the surgeons to place and impact the cage in the desired spot and also most importantly avoid mishaps such as accidental penetration of anterior longitudinal ligament and retroperitoneal positioning of the cage[41].

Blood loss

The mean intraoperative blood loss was 89.65 ± 23.67 ml which is lower as compared to Xu et al.[42] and Foley et al.[3].

Accuracy of Pedicle screw placement

Regarding accuracy 95.6% showed grade 0 and 4.4% had Grade 1 pedicle breach. In one case a Grade 3 pedicle screw breach occurred; this was suspected intraoperatively on the C-arm images and confirmed by spinning the 3D C-arm again and extracting images before extubating the patient. The Cohen's kappa statistic test with regards to pedicle screw breach was 0.889 which demonstrated high reproducible accuracy. Free hand screw misplacement rates in spine is much higher than other spinal segments, and it becomes much more challenging in dysmorphic pedicles as seen in deformities and in areas where there is distortion of normal anatomical landmarks such as trauma, revision surgeries, and ankylosed spine. Navigation has resulted in pedicle perforation rates as low as 1–5%. The accuracy of 3D navigation system is considered to be superior to virtual fluoroscopy and 2D navigation[22]. A meta-analysis of 9019 pedicle screws established the superiority of CT navigated instrumentation over fluoroscopic guidance[22, 23]. Similarly, 94.6% had grade 0 and 5.4% demonstrated Grade 1 cranial facet violation as was observed by Lau et al.[31] Thus, 3D-navigation makes sure that the pedicle screw is implanted in the most precise trajectory in all the 3 planes with added benefit of protection against radiation.

Cranio-facet violation

The facet joint cranial to the level of fixation is a critical anatomic structure and protection of this joint is vital in avoiding adjacent segment disease[42,43,44]. Int he current study, only 25 out of 408 pedicle screws (6.1%) violated the cranial facet joint, with 94.6% and 5.4% of pedicle screws demonstrated grade 0 and Grade 1 cranial facet violation, respectively, reinforcing the advantages of navigation-assisted insertion of pedicle screws. Again, the degree of violation in these 6.1% of screws appears relatively inconsequential (Grade 1), based on the classification of Babu et al.[45]. The Cohen's kappa statistic test with regard to cranial facet violation was 0.878 which demonstrated high reproducible accuracy. Ohba et al. [46] reviewed 194 pedicle screws in 28 consecutive patients and found that 87.5% and 94 % of screws inserted using conventional fluoroscopy and 3D navigation group, respectively, did not violate the facet joint. Park et al. [47] reported a high rate of cranial-facet joint violation in fluoroscopic MISS surgery when compared to open surgeries (31.5% vs. 15.2% of all screws, P< 0.001).

Evaluation canal decompression

In our study, the navigation array probe was utilized to verify the adequacy of decompression and to confirm the anatomical landmarks as and when necessary. In their study on 28 patients undergoing MIS TLIF, Lee et al. found that the mean spinal canal cross section area at disc spaces has increased significantly at 12 months postoperatively from 157.5 mm2 to 294.3 mm2, (P= 0.012) leading to a good clinical outcome, which could easily be evaluated intraoperatively using the navigation like in our study [14, 48].

Reduced surgical site infection

In the present study of 117 patients, no surgical site infection was seen. In our another study of 1043 patients treated with MIS techniques, 763 underwent non-instrumented surgeries and 280 underwent instrumented fusion. The overall infection rate after MISS was 0.29%, 0% in non-instrumented cases and 1.07% (3 out of 280 cases) in instrumented cases. Nassr also concluded that MIS-TLIF is associated with lower incidence of surgical site infection than open TLIF[30].

Example 1

Fig. 10 demonstrates the use of navigation in L4L5 MI -TLIF in a patient with adult degenerative scoliosis in which only selective fusion of L4 L5 is indicated.

a. Accurate placement of screws across rotated pedicles with malformed anatomy due to advanced degenerative arthritis is seen

b. The cage can be placed optimally using navigation

c. Post-operative X-ray and healed scar of MI-TLIF.

Example 2

Fig. 11 demonstrates the use of 3D navigation in ill-defined anatomy at L4L5 in advanced degenerative arthritis.

a. Poorly defined anatomy on 2D fluoroscopy images

b. Pedicle screw insertion using 3D navigation

c. Post-operative X-ray of MI-TLIF.

Conclusions

At author's institution, almost all cases requiring fusion are operated with Minimally Invasive Transforaminal Lumbar Interbody Fusion (MIS-TLIF) technique with fluoroscopy and 3D navigation. With vast experience in minimally invasive techniques, we find MIS to be associated with less post-operative infection rates as compared to open techniques. With 3D navigation, MIS becomes safer and highly accurate. MIS-TLIF with 3D navigation have satisfactory clinical outcomes and fusion rates with the additional benefits of less initial postoperative pain, less blood loss, earlier rehabilitation, and shorter hospitalization. MIS–TLIF with 3D navigation is a more cost-effective treatment than MIS-TLIF with fluoroscopy.

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.

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