

Prospective study of transforaminal lumbar interbody fusion



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degree of
M.Ch Neurosurgery*

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DECLARATION

This thesis titled “**Prospective study of transforaminal lumbar interbody fusion**” is a consolidated report based on a bonafide study of the period from 1st February 2019 to 31 July 2020, done by me under the Department of Neurosurgery, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram.


This thesis is submitted to SCTIMST in partial fulfilment of rules and regulations of MCh Neurosurgery examination.



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CERTIFICATE

This is to certify that the thesis entitled - "Prospective study of transforaminal lumbar interbody fusion" is a bonafide work of Dr. Sawant Ninad Anand and was conducted in the Department of Neurosurgery, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram (SCTIMST) under my guidance and supervision.


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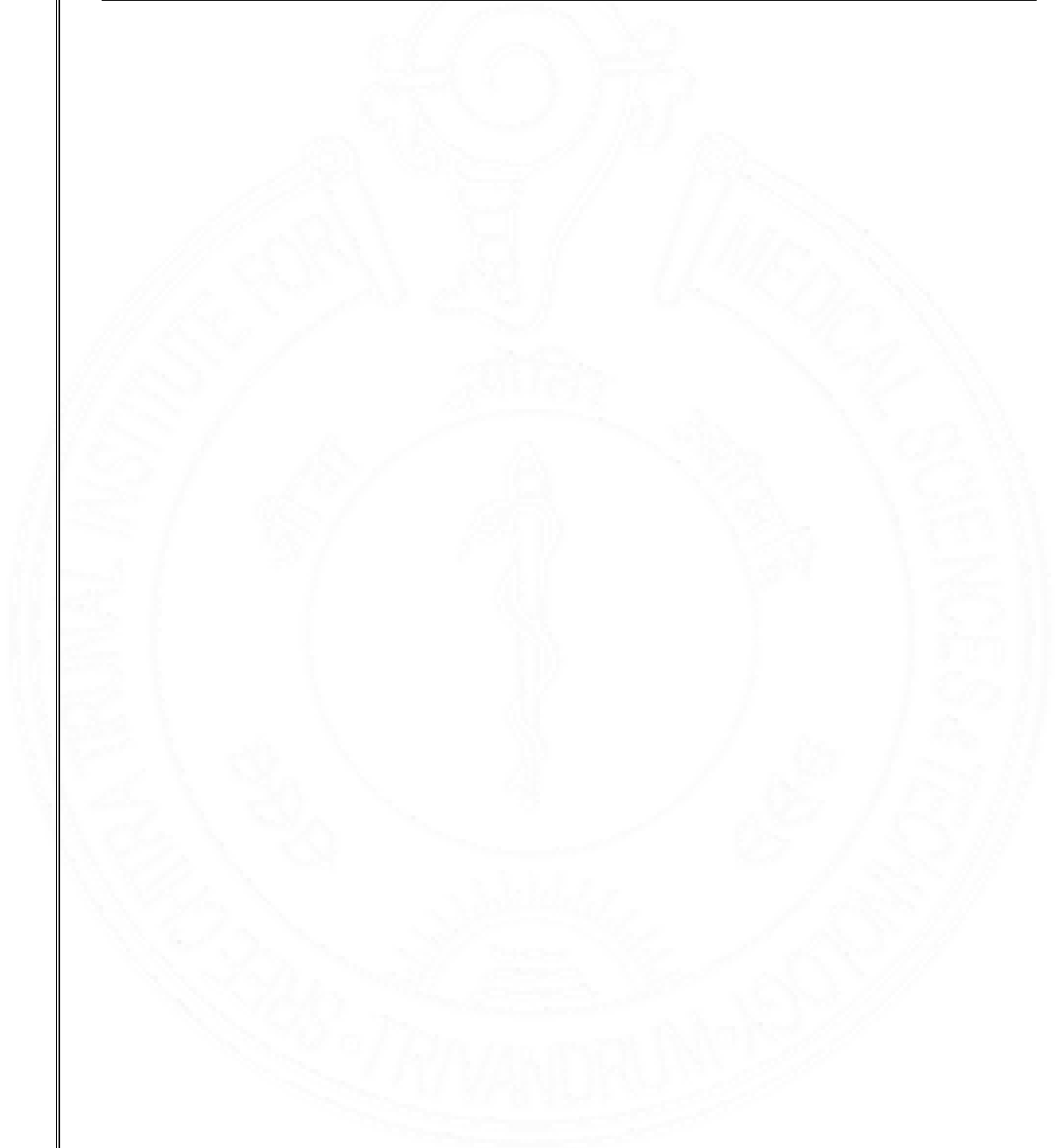
LIST OF ABBREVIATIONS USED

ALIF	Anterior lumbar interbody fusion
BG	Bone Graft
CT	Computed Tomography
PT	Pelvic Tilt
SS	Sacral Slope
SVA	Sagittal Vertical Axis
MRI	Magnetic resonance imaging
ODI	Oswestry disability index
PLIF	Posterior lumbar interbody fusion
PD	Pedicle screw
ALIF	Anterior Lumbar Interbody Fusion
PI	Pelvic Incidence
TLIF	Trans-foraminal interbody fusion
VAS	Visual analogue scale
LL	Lumbar Lordosis
BMI	Body Mass Index
LS	Lumbosacral
ICU	Intensive Care Unit
SD	Standard Deviation
DEXA	Dual Energy X ray Absoptometry
LLIF	Lateral Lumbar Interbody Fusion
TIBFD	Threaded Interbody Fusion Device
PEEK	Polyetheretherketone
HRQoL	Health Related Quality of Life
TS	Translational Slip
PDSH	Posterior Disc Space Height
SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology

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Synopsis

Lumbar spinal instability like spondylolisthesis has been managed surgically by Transforaminal Lumbar Interbody Fusion (TLIF), mainly in cases with unilateral symptoms and who failed nonsurgical management. The aim is to study effectiveness of TLIF procedure by assessing clinical and radiological spinal sagittal parameters pre and postoperatively.

8 patients who underwent TLIF procedure after diagnosis of spondylolisthesis studied prospectively in department of Neurosurgery, Sree Chitra Tirunal Institute for Medical Sciences and Technology in period of 18 months from from 1st February 2019 to 31 July 2020. After recording general information of the patient, symptomatology, functional parameters were evaluated using Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), Short Form 12 (SF 12) and radiological sagittal balance parameters were assessed by calculating Sagittal Vertical Axis (SVA) , Lumbar Lordosis (LL), Pelvic Incidence (PI), Pelvic Tilt (PT), Sacral Slope (SS), preoperatively and postoperatively during follow up at 1 and 3 months.

There were 1 male and 7 female patients in our study with mean age of 51.40years (range: 38-67 years) with average BMI 30.8. We operated 4 (50%) patients at L4-L5 level of degenerative spondylolisthesis, 1(12.5%) patient of degenerative spondylolisthesis at L5-S1 level and 3 (12.5%) patients of isthmic spondylolisthesis at L5-S1 level. All patients were grade 1 spondylolisthesis according Meyerding classification. After surgery all sagittal spinal balance parameters were not found to be statistically changed from the baseline, although there was minimum improvement. Regarding the clinical outcome measures, both VAS (<0.0001), ODI (<0.0001), and SF12 (<0.0001) improved after surgery significantly.

In most case of grade 1 spondylolisthesis, there is only a minimal imbalance of the sagittal spinal balance parameters and so in situ fusion can be done. Even if a complete reduction of spondylolisthesis was not achieved during surgery, there was correction of a few of the parameters of spinal balance which were deranged preoperatively. Improvement in Quality of life could be due to both improvement in spinal balance and reduced abnormal mobility at respective level. Overall TLIF is very good procedure in terms of improvement in clinical and functional parameters in grade 1 spondylolisthesis.

INTRODUCTION

One of the most common factors to missed time at work is low backache and also it is most common reason of work related disability¹. Low back pain may aggravated by activity and which lead to minimizing activity and it further leads to disability. One of the most expensive burdens on the system of health care is low backache. It is one of the common medical problem. In lifetime, there is 50-70% chance of a person getting low backache².

Low back pain can be divided into 3 categories according to duration; chronic if lasting for more than 3 months, subacute if lasting 6 weeks - 3 months and acute if less than 6 weeks. Pain is usually initiated by the result of abnormal movement of vertebral bodies or by instability at single motion segment².

Lumbar spine instability.

Lumbar spinal instability is defined as the “Under physiological load, loss of ability of the spine to maintain its pattern of displacement, with no incapacitating pain, no initial or additional neurological deficit and no major deformity”³.

Motion of spinal segment is defined by biomechanics of ligaments, facets, intervertebral disc, each of which contributes to level of stability to spinal column. Any damage or abnormality of any of above 3 components can alter movement of other 2 and therefore that alters entire motion of particular segment of spine. Generally surgery is considered option when conservative management has failed. Most of the time significant problem is mechanical which reflects as a clinical spinal instability. Mechanical problem refers to inability of carrying spinal load and clinical spinal instability refers to pain or/and neurological deficits³

Causes of instability are as follows¹ –

1. Degeneration of Posterior Elements

Facets are the structure mostly involved whenever we consider pain or posterior element degeneration. Zygapophysial joint (Synovial joint) is joint between inferior articular facets of vertebra which situated above and superior articular facets of vertebra

which is situated below. Articular surfaces of these joints encompassing hyaline cartilage. As age progresses, there is cartilage degeneration which leads to increase in pressure on bone and that ultimately leads to osteophytes formation. All these elements finally affects range of motion of that particular segment and mechanic of adjacent spinal segments.

2. Stenosis

Narrowing of spinal canal is basically called as spinal stenosis. Degeneration of disc and facet joint is the cause for this most of the time. Disc bulge which compressing spinal cord is first mechanism. Other mechanism may be foraminal stenosis because of bone hypertrophy due to increase in stress at facet joints. Foraminal stenosis leads to compression of exiting nerve roots which leads to pain and numbness radiating to legs and buttocks.

3. Disc Degeneration

Intervertebral disc acts as shock absorber which absorbs energy from compression from bodies of adjacent vertebrae and there is controlled distribution of this energy. During degeneration of disc, there is loss of fluid content which loses its shock absorption capacity and this results in high stress at that particular level. Pain signals are transmitted by nerve endings present in outer region of annulus fibrosus. So pain sensations are exaggerated whenever this outer region of annulus fibrosus is irritated. Another result of disc degeneration is instability at that joint and abnormal movement. Pain can be also be the result of higher stresses on dura, nerve roots, endplates, ligaments.

4. Degenerative spondylolisthesis

Rotatory deformity rather than pure translation may distort dura and dural contents and leads to spinal stenosis. Causes of degenerative spondylolisthesis are 1. Disc degeneration and sagittal orientation of facets with secondary changes in facets leading to anterolisthesis. 2. Sagittal orientation of facets that does not prevent anterior translation. 3. Disc degeneration; first disc narrows, then that accelerates arthritic change, secondary remodelling and finally anterolisthesis.

Fusion

Two or more vertebral bodies are fused using a bone graft and some form of stabilizing device like screws and rods is called as spinal fusion. These fusion are done most of the time for pain relief and correction of disc space pathology. Successful fusion procedure depends on multiple factors like individual biological factors of patient, bone graft material, type of instrumentation⁴. Elimination of motion at fusion segment is biomechanical result of successful fusion⁵. Fusion is defined “the newly formed trabecular bone which bridges between two adjacent vertebral bodies”. Presence of this trabecular bone anterior to cage inserted after discectomy in between vertebral bodies is definitive and reliable radiological finding postoperatively⁶.

Mechanics of spine is drastically changed by fusion procedures. Fusion does not change total load on lumbar spine is the main problem. Angular and bending movement contribution executed by particular segment of spine is altered after fusion. This can result in initiation of degeneration of segments adjacent to fused segment⁷. Surgical treatment of low backache has evolved from non instrumented to instrumented fusion over last 25 years⁸.

Successful outcome not always result of increase in fusion rate due to use of instruments because there is factor of adjacent segment disease and loss of motion at fused segment causes discomfort to the patient especially when fusion segment is long. Even though fusion very common surgical armamentarium for multiple spinal pathologies but comes at the cost of deficiencies and risks⁹. Rigid fixation and increasing chances of fusion rate due to transpedicular fixation has revolutionized surgery of spine. Previously intertransverse technique was performed for lumbar fusion requiring wide exposure and iliac crest graft¹⁰. Use of machined allograft or non machined allograft or autograft is an other option for threaded fusion cages¹¹.

Machined allograft spacers allows surgeons to visualize bone incorporation with standard techniques of radiography and requires less bone removal for their insertion. Bone pieces impaction in and around spacers allows maintenance of height of disc space and provide support anterior column. Because of complications and requirement of another incision, iliac crest grafting is not required¹². Bone removed during decompression which can be placed in between vertebral bodies or in intertransverse

spaces lateral to rods along with machined allograft. Quality of bone graft is crucial in achieving solid fusion in terms of both load bearing and biologically¹³. Current practice is to use instrumentation and bone grafting together because it enhances bony fusion success and that results in decrease in chances of hardware failure by reducing long term biomechanical stresses on hardware used.

There are mainly 4 techniques described for lumbar interbody fusion

- 1) PLIF – Posterior Lumbar Interbody Fusion.
- 2) TLIF – Transforaminal Lumbar Interbody Fusion (Open and minimally invasive).
- 3) LLIF – Lateral Lumbar Interbody Fusion.
- 4) ALIF – Anterior Lumbar Interbody Fusion.

TLIF aims to improve both quality of life and low backache. In this study we are interested in assessing effect of TLIF in our group of patients by using pre decided radiological and clinical parameters. Clinical parameters includes pain relief and its reflection into quality of life improvement shall be assessed using scores like SF12, ODI and VAS. Radiological parameters includes Sacral slope, pelvic tilt, lumbar lordosis, pelvic incidence, sagittal vertical axis are to be measured pre and post operatively.

AIMS AND OBJECTIVES

AIM

To study effectiveness of TLIF in the treatment of disabling low backache resulting from spondylolisthesis, discogenic pain syndrome or post discectomy syndromes unresponsive to conservative management by assessing use of clinical and radiological parameters.

OBJECTIVES

Clinical: Overall pain relief and quality of life using a combination of Visual Analogue Scale (VAS), Oswestry Disability Index (ODI) and Short Form 12 (SF 12) questionnaire which shall be assessed both pre and post operatively.

Radiological: Spinal sagittal balance and its parameters i.e. sagittal vertical axis , lumbar lordosis, pelvic incidence, pelvic tilt , sacral slope which shall also be measured pre and postoperatively.

All these parameters are expected to improve postoperatively ultimately improving quality of life.

REVIEW OF LITERATURE

A) RELEVANT LUMBAR SPINE ANATOMY

The spine column consists of 33 vertebrae spreading over 5 main regions; 7 in Cervical region, 12 in Thoracic, 5 in Lumbar, 5 in Sacral and 4 in Coccygeal region. Basic knowledge of neurological structures passing through spinal column along with anatomy of bones and ligaments is essential to understand relative biomechanical stability and treatment of spinal pathologies¹⁴.

The anatomical structures can be broadly classified into two

I. Spinal column.

II. Spinal cord

Embryology:

At onset of trophoblastic stage of embryo, development of human spine starts and ends in 3rd decade of life¹⁵. Sclerotomes of somites forms the vertebral column. Number of somites are formed from segmentation of paraxial mesoderm lie on either side of the developing neural tube. On cross section, somite is triangular structure and has a cavity. There are 3 parts of somites;

- a. Dermatome is lateral part cells of which migrate to deeper surface of ectoderm covering the entire body. Dermis of skin and subcutaneous tissue is formed by these cells.
- b. Sclerotome is ventromedial part, cells of which migrate medially and they surrounds the neural tube forms vertebral column.
- c. Myotome is intermediate part which gives rise to striated muscle.

Mesenchymal cells are distributed uniformly at first then immediately become condensed in part that spread transversely across middle of segment which is called as the Perichondral disc. Fusion of these less condensed part above and below condensed part leads to formation of body of each vertebra. Intervertebral disc is formed from perichondral disc. Same like body, the neural arch and the transverse process also are formed. In the region of vertebral bodies, notochord disappears and in region of intervertebral discs it forms nucleus pulposus.

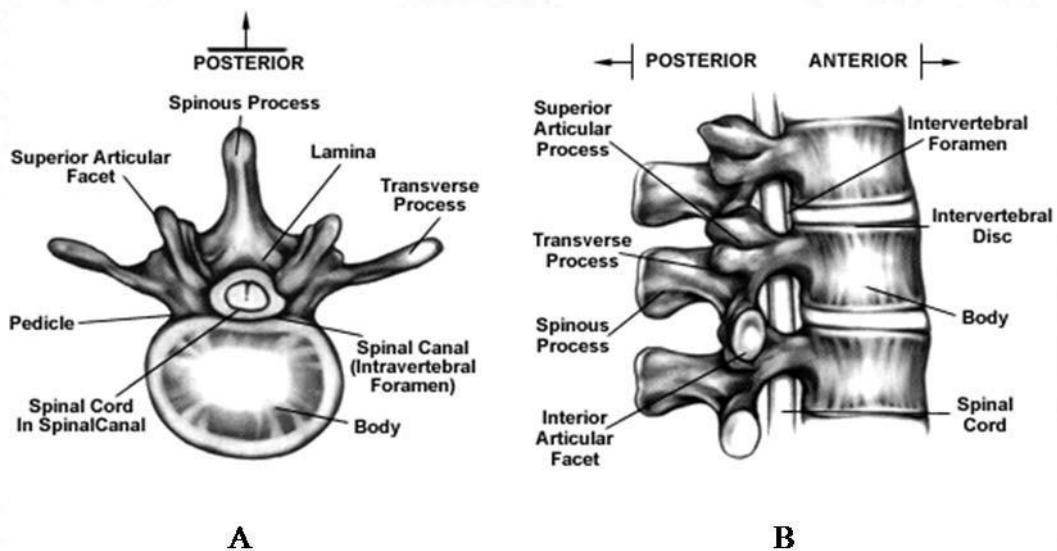
There are 3 primary centres of ossification for each vertebra 1 for greater part of body and two for neural arch. Two halves of the neural arch and the centrum are joined by cartilage at birth. Neural arch forms posterolateral part of body. Neurocentral joints are formed from line of junction between the parts of body derived from the centrum and neural arches.

I. Spinal column:

Spinal column consists of following:

Spinal column consists of posterior elements (spinous process, laminae, transverse process, inferior and superior articular processes, pedicles), intervertebral discs and vertebral bodies¹⁶.

Figure 1: Anatomy of Lumbar vertebral body.



1) Vertebral bodies and intervertebral discs.

There are 5 lumbar vertebrae and intervertebral discs in between. Vertebral bodies and discs are firmly attached together. More stability is added by anterior and posterior longitudinal ligaments. These structures contribute to the anterior and middle columns of Denis which bear 80% of the load applied to the spine in upright position.

2) Posterior elements:

Posterior elements consists of spinous processes, laminae, inferior and superior articular processes, pedicle, transverse process. These structures are connected by facet capsule, ligamentum flavum, intertransverse ligaments, interspinous, supraspinous ligaments. Posterior column of Dennis is formed by all these osseoligamentous structures. These posterior elements are important in terms of posterior stabilization of spine.

3) Ligaments of spine:

These are uniaxial structures. These ligaments are useful in carrying loads along the direction their fibres. They tends to buckle when subjected to compression but they readily resists tensile forces¹⁶.

Two types of ligaments; continuous or segmental.

Segmental ligaments:

Interspinous ligaments

Intertransverse ligament

Ligamentum flavum

Continuous ligaments:

Supraspinous ligament

Anterior longitudinal ligament

Posterior longitudinal ligament

Supraspinous ligament:

Origin is at ligamentum nuchae superiorly and continues downward along tips of spinous processes to attach downward to the sacrum as a round slender strand. This ligament is more broader and thicker in lumbar region

Anterior longitudinal ligament:

Superior most attachment is to anterior aspect of basiocciput and it extends downwards from there to attach anterior edges of vertebral bodies and it is also loosely attached to fibers of intervertebral discs at which level it narrows. Thickness is more in thoracolumbar region.

Posterior longitudinal ligament:

This ligament also superiorly extends from basiocciput to the coccyx while running over vertebral bodies on their posterior surface. Development of this ligament is less in lumbar region compare to anterior longitudinal ligament. Opposite to anterior longitudinal ligament, it narrows at the vertebral body level and wider at disc level.

Intertransverse ligament:

They are rounded cords and connected with muscles of back. They pass between transverse processes of adjacent vertebrae.

Ligamentum flavum:

Extends from posterosuperior border of the lower lamina to anteroinferior border of lamina above. Because of high content of elastin fibres this ligament is called as yellow ligament.

Interspinous ligament:

Attachment of interspinous ligament extends from apex to root of all spinous process. They are thick and broad in lumbar region and elongated and narrow in thoracic region.

Anteriorly the body and posteriorly the facet joints are load bearing structures of vertebral column.

4) Pedicles:

Strongest part of vertebra is bilateral pedicles. For selection of screw and its placement, integrity of the pedicle is important factor¹⁷. Between the neural arch and the vertebral body, pedicles serves as the load transmitting strut. Anterior attachment of pedicles is on body posteriorly at superior and lateral aspect. Posterior attachment

is at pars interarticularis. It consists of inner cancellous medulla and outer cortical bone.

Zendrick et al¹⁸ studied morphometric characteristics of lumbar and thoracic pedicles in 2905 pedicles from T1 to L5 with CT and roentgenograms of individual vertebral specimen. Singel TC et al¹⁹ studied length and width of lumbar pedicles and shown that there is increase in width of pedicles from L1 to L5 and for enabling the weight transmission, width being maximum at L5. Devi et al¹⁷, Krag et al²⁰ also studied pedicle dimensions. Morphometry of pedicle is important to consider in presurgical planning.

Surgical point of view, important morphometric characteristics are

- 1) Transverse pedicle angle.
- 2) Pedicle isthmus width.

Transverse pedicle angle is angle between line parallel to vertebral midline in transverse plane and line perpendicular to transverse isthmus. Largest mean angle from midline was 29.8⁰ and smallest mean angle was 10.9⁰.

Pedicle isthmus width can be measured in transverse and sagittal plane. In transverse plane the widest mean pedicle diameter at L5 was 18.0 mm and narrowest mean pedicle diameter at L1 was 8.7mm. In sagittal plane, narrowest mean width at L5 is 14mm and widest at L1 was 15.4.

RELATIONSHIP TO IMPORTANT STRUCTURES

Knowledge of surrounding structures of pedicles is important for surgeon to avoid breach into the cortex during screw entry so to prevent injury to these structures²¹.

- 1) Medially: Nerve root, dural sac and epidural space.
- 2) Caudally: Nerve root (exiting) of corresponding level.
- 3) Laterally and superiorly: Nerve root which lies very closely of level above. Lateral to sacral ala, great vessels and their branches lies at sacral level.

4) Anteriorly: Common iliac vein and artery lies at L3 and L4 levels. Sacral artery can lie directly anteriorly in the sacral region.

5) Inferior and superior articular process and facet joint: Projection of superior articular process is from junction of pedicles and lamina. Superior articular process articulates with inferior articular process of vertebra above to form facet joint. Direction of the movement possible between adjacent vertebrae is determined by direction of alignment of joint surface.

6) Laminae: It lies medial and behind the pedicles and these are broad plates of bone.

7) Spinous process: Lumbar spinous processes pass backward and downward from where two laminae meet posteriorly. These provide attachment to muscles and ligaments helping in maintenance of stability of the spine.

8) Transverse process: There are one transverse process on each side. From junction of lamina and pedicle, they project laterally.

SURGICAL LANDMARK TO THE PEDICLE

For transpedicular screws, many strategies for entry point were studied. Most widely used are mentioned below:

- a) *Roy Camille*: The pedicle centre lies at intersection of horizontal line through middle of the transverse process and vertical line through facet joint.
- b) *Weinstein*²²: At inferior and lateral corner of superior articular facet.
- c) *Sreffee*²³: He called the entry point as the “forced nucleus” of the vertebra. It lies at the convergence of ridge on the transverse process, ridge on superior articular process and the ridge on the pars interarticularis.
- d) *Zindrik*²⁴: Proposed a “pedicle approach zone”. Before entering the pedicle, this funnel shaped area should be decorticated.

II] SPINAL CORD:

50% of canal in thoracolumbar segment is filled with spinal cord and remainder is with meninges, epidural fat and cerebrospinal fluid. Grey and white matter structure remains constant in terms of their spatial arrangement and it is consistent throughout length of spinal cord, but there may be change in its proportion.

Termination of spinal cord is at L1-L2 disc level. Spinal and vertebral level do not match with each other. Conus medullaris is located dorsal to L1 and L1-L2 disc and it contain sacral and coccygeal myelomeres.

B] BIOMECHANICS

Although described as a single functional unit, lumbar spine consists of 5 vertebrae to form a “motion segments” which connected in series. 2 adjacent vertebral bodies and connecting ligaments forms each motion segment. Biomechanical characteristics of entire spine is similar to spinal motion segment which is smallest segment of the spine. At each motion segment, rotation and translation can occur. One vertebra moves parallel to the adjacent vertebra due to shear force results in translation. Spinning of one vertebra relative to adjacent vertebra about a stationary axis caused by torque is called as rotation. At each motion segment during lumbar spine movements, translation occurs in any of the cardinal body planes. During movements, there is requirement of stability maintenance so that requires the co ordinated movements of multiple motion segments. In lumbar segment, instability can occur in either translational or rotational movements or both.

Unilateral facet resection especially more than medial half of facet along with extensive discectomy may lead to instability so there is requirement of instrumented fusion. Compare to other posterior fixation techniques, pedicle screw system allows 3 column stabilization which exerts stronger grip force. For pedicle screw fixation, there is no requirement of intact posterior elements, preserves adjacent normal motion segment and prevent deformity progression so ultimately reduce mechanical pain syndromes and encourage immediate ambulation⁶.

Valid treatment for spinal instability is fusion of posterior lumbar elements combines with instrumentation results in solid fusion in nearly 95% cases. Anatomical

interbody space and neural foraminal area is restored by placing interbody device or cage which leads to potential correction of overall spinal alignment and balance⁹.

Compare to posterolateral fusion, interbody fusion has many advantages. In Interbody fusion, graft is compressed by 4 times as much load, more vascular space and graft occupy 9 times as much load so there is higher success and faster fusion. Mechanics of spine is drastically changed by fusion. But the problem regarding this is there is no change in total amount of load upon the lumbar spine and also there is affection of coordination between angular and bending movements of spine so it results in enhancement of speed of degeneration especially segments adjacent to fusion site^{25, 26}.

Spinal sagittal balance parameters

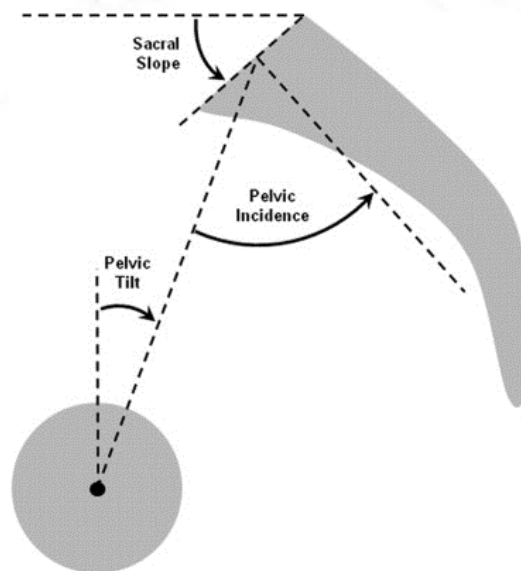
Spinopelvic sagittal parameter measurements including: Pelvic Incidence (PI), Sagittal Vertical Axis (SVA), Sacral Slope (SS), Pelvic Tilt (PT), Lumbar Lordosis (LL). Definition of PI : Angle between bicoxo-femoral axis and line perpendicular to upper endplate of S1 and a line joining centre of the upper endplate of S1. Anatomical relationship between the S1 endplate and acetabulum is demonstrated by PI. Increases from early age to reach its maximum value to represent pelvis's mature morphology. Actually during adulthood, PI is thought to be stable but there is recent research which suggest that there is gradual increase in PI with age through sacroiliac joint anatomy modification^{27,28}. Normal PI value is in between 35° – 85° asymptomatic patients. High PI refers to large pelvis and low refers to narrow pelvis.

Rotational positioning of pelvis around femoral head indicated by PT. PT is angle between line joining middle of S1 endplate and bicoxo-femoral axis and a vertical line. $13 \pm 6^{\circ}$ is the mean PT²⁹. According to Schwab classification for adult spinal deformity³⁰, a value of 20° or less is considered the reference range for “normal” PT. PT measures the position of hip joints when femur in vertical in standing position to balance the pelvis- spine system. Hip extension increases, of the balance needs more PT. Whenever there is need of increase in PT that require more hip extension which ultimately lead to tilting of femoral shaft through flexion of knees. This flexion of knees disappears after surgical correction of increased PT results in normal standing posture of patient.

Sacral slope (SS) is angle formed by horizontal line and endplate of S1³¹. According to sagittal balance requirements, SS may change throughout life. Orientation of L5 and whole spine above is guided by orientation of SS. SS is always in positive increasing values. SS may even reach the horizontal line in pathological situations (SS=0°).

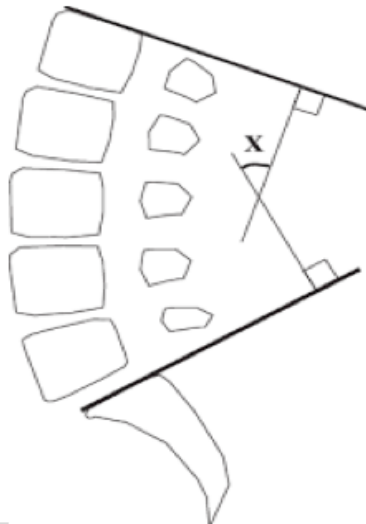
SS, PI and PT are represented by equation $PI = PT + SS$. PT starts equalising PI, when SS tends to reach 0°. Pelvic retroversion (lower SS, higher PT) or pelvic anteversion (increase SS, lower PT) are physiologic strategies that enable humans to assume a bipedal posture in more energy efficient manner. One of the most important compensation mechanism of sagittal balance is ability to position the pelvis in rotation around femoral head³².

Figure 2 : Schematic diagram showing sacral slope, pelvic tilt and pelvic incidence.



Lumbar lordosis (LL) is angle between the upper endplate of first sacral vertebra and first lumbar vertebra³³. Schwab et al³⁴ suggested geometrical formula for $LL = PI \pm 9^\circ$. This formula was correlated to better surgical outcomes in terms of quality of life. During someone's life LL is positional and vert variable parameter. Surgical strategies to control the LL correction have recommended by many authors recently.

Figure 3: Schematic diagram showing lumbar lordosis



Offset between C7 plumb line and posterior superior corner of endplate of first sacral vertebra is called as Sagittal Vertical Axis (SVA)³³. To evaluate global sagittal balance, SVA is widely used. According to Schwab et al³⁵, SVA should be maintained less than 5 cm. SVA can be positive or negative. Positive SVA means C7 plumb line is anterior to posterosuperior corner of the first sacral vertebra end plate and negative SVA means C7 plumb line is posterior to posterosuperior corner of S1 end plate.

Figure 4: Schematic diagram showing Sagittal Vertical Axis (SVA)



C) Spondylolisthesis

Spondylolisthesis is dorsal or ventral displacement of one vertebra over other which leads to malalignment at particular spinal segment. Spondylolisthesis often causes disturbed global spinal alignment especially in sagittal plane that results in disability³⁶.

CLASSIFICATION OF SPONDYLOLISTHESIS

The two most commonly used classification systems are the Wiltse-Newman³⁷ and Marchetti-Bartolozzi³⁸.

Table 1 :Wiltse-Newman classification :

1	Congenital
2	Isthmic; 2A – Stress fracture of pars 2B – Elongated pars 2C – Acute fracture of pars
3	Degenerative
4	Traumatic (involves fracture other than pars)
5	Pathologic

Table 2:Marchetti-Bartolozzi classification :

2 types developmental and acquired. Developmental again divided into 2 types and acquired further divided into 4 types

Developmental
Low grade dysplasia
High grade dysplasia

Acquired
Degenerative
Iatrogenic
Traumatic
Pathological

The Meyerding system is the most widely used grading method³⁹ which grades according to degree of slip present. 4 grades with increasing severity as follows:

Table 3: Meyerding Classification of spondylolisthesis

Grade	% of Slippage	Terminology used
Grade 1	0 to 25	Low grade
Grade 2	26 to 50	
Grade 3	51 to 75	High Grade
Grade 4	76 to 99	
Grade 5	Complete or 100 %	Spondyloptosis

Pathophysiology of spondylolisthesis

Predisposing factors

- Congenital pars articularis weakness
 - Genetic predisposition
 - Dysplastic changes
- Connective tissue defects
- Defects in growth plate
- Abnormal sacropelvic alignment

Environmental factors

- Repetitive lumbosacral spine loading
- Erect posture

Pars elongation and lysis

Pain leading to postural changes

Degeneration of disc and soft tissue

Altered biomechanics

Dysplastic changes

Growth plate remodeling

Etiopathology of spondylolisthesis:

Lumbar spondylolisthesis is often multifactorial. Basically this vertebral slippage is due to slippage of shared defect or loss of normal structural support which constitutes intervertebral discs, pedicles, pars, lamina, interarticular facets.

Of all spondylolisthesis cases, dysplastic type accounts for 14-2% with female to male ratio of 2:1⁴⁰. It results from congenital dysplasia of L5 neural arch including facet joints and pars interarticularis or whole of the sacrum⁴¹. Ultimate result of this is pars interarticularis lysis or elongation. There is normal appearing L5 vertebra and S1 superior end plate without hyperlordosis or retroversion in low grade dysplastic spondylolisthesis. There is trapezoidal L5, pelvic retroversion, a dome shaped superior end plate of first sacral vertebra and hyperlordosis in high grade spondylolisthesis⁴¹. Lumbosacral kyphosis also can be often observed.

The most common type of spondylolisthesis is isthmic spondylolisthesis and most common level is L5-S1 followed by L4-L5⁴². Abnormality of pars interarticularis results in isthmic spondylolisthesis. In lower lumbar spine, due to repetitive forces across the vertebral column develops into fatigue fracture over time. In development of isthmic spondylolisthesis, anatomical factors like pelvic incidence are also thought contribute⁴³⁻⁴⁶. Subtype A is most common type of isthmic variety of spondylolisthesis that results from unhealed bilateral pars interarticularis defects which are replaced by fibrous tissue. These is partial bony healing in subtype B results in callous formation that can occur with pars interarticularis in an distracted abnormal position. Acute traumatic fracture of pars interarticularis results in subtype C of isthmic spondylolisthesis.

Degenerative spondylolisthesis is more common in females compared to males and frequently occur at the L4-L5 level^{47,48}. More than 30% slip is rare in degenerative spondylolisthesis^{47,49}. Intervertebral disc and facet complex deterioration without lytic defect in dorsal element results in degenerative spondylolisthesis⁴⁹⁻⁵². The ability of disc to provide ventral column support decreases as disc degenerates and then as stress increases facet complex begins to fail leading to a ventral slip^{50,52}.

Fracture of part of vertebra other pars interarticularis results in traumatic spondylolisthesis. In type C isthmic spondylolisthesis there is fracture of pars interarticularis.

Pathologic spondylolisthesis occurs when metabolic disease or tumours damage the dorsal elements (i.e. facets, pedicles, pars interarticularis) resulting in vertebral slip. Disruption may be caused by primary or metastatic tumours. Other reported causes includes hyperthyroidism, osteoporosis, syphilis, tuberculosis, Paget disease.

Aggressive surgical decompression can result in iatrogenic spondylolisthesis especially if more than half facet is removed or if extensive pars interarticularis has been done.

D) Transforaminal Lumbar Interbody Fusion (TLIF)

TLIF is similar to PLIF but the difference is that from the unilateral approach cage is placed in anterior portion of the intervertebral space. Discectomy and implantation of graft and cage is done by resecting facet on one side⁵³. TLIF is less risky procedure because it is unilateral procedure and it is easier to manoeuvre around spinal nerves. The posterior fixation is transpedicular screw and rod, same as PLIF.

Fig 5

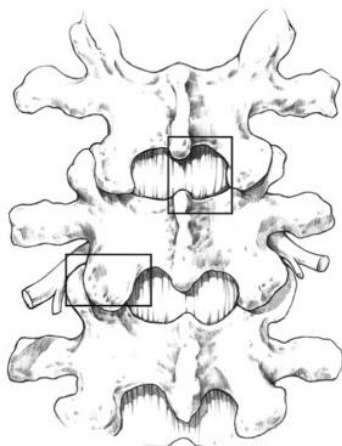


Fig 6

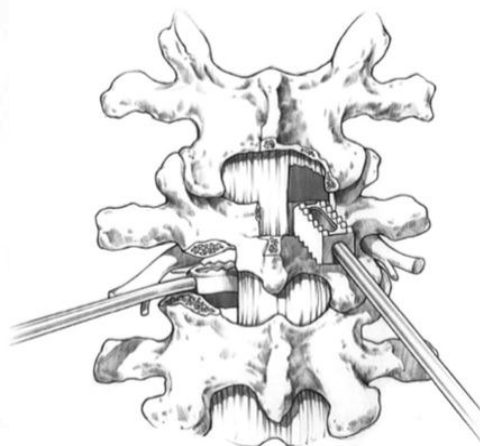


Fig. 5. Picture showing route of access to the intervertebral body space and area of bone removal. Access for PLIF procedure shown at top medial box; Area and access for the TLIF procedure is shown in (bottom) lateral box⁵⁴.

Fig. 6. Picture showing the angle of interbody graft insertion for TLIF procedure (bottom, lateral) and the PLIF procedure (top, medial)⁵⁴.

Comparison done by several nonrandomised and one small randomised controlled trial comparing PLIF and PLIF suggests TLIF procedure is having shorter hospital stay and operative time, less blood loss, fewer complications leading to an improvement of quality of life and lower hospital health care cost⁵⁵⁻⁵⁸.

E) Interbody cages and pedicle screw and rod system:

I) Interbody Cages:

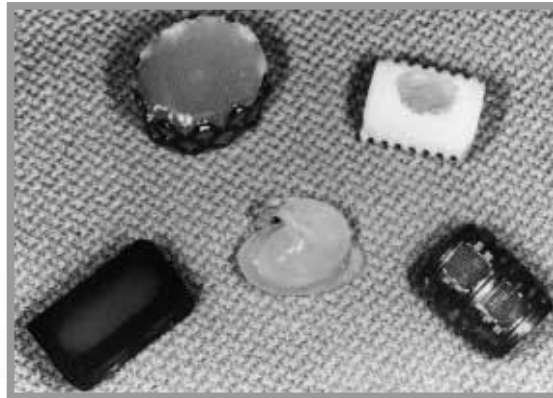
The purpose of interbody cage is to bridge the gap between two vertebral bodies. Reason for placing cage after discectomy is that there may be degenerative changes in disc causing pain and instability so fusion is required to stabilize the segment and restore the height. The main purpose is there should be complete fusion of that respective level so stable scaffold for bone to grow through and around is required.

Types of fusion cages:

Currently available types of cages are

- 1) The threaded interbody fusion device (TIBFD; Tennessee, Memphis, Medtronic Sofamor – Danek Group)
- 2) The Bagby-and-Kuslich device (BAK; Minneapolis, Minnesota, Sulzer Spine-Tech)
- 3) The Harms titanium-mesh cage (Ohio, Cleveland, DePuy – AcroMed)
- 4) The Ray cage (Connecticut, Norwalk, U.S. Surgical)
- 5) The Brantigan rounded and rectangular cages (DePuy – AcroMed).

Figure 7 : Interbody fusion devices (Types)



The BAK devices have been approved only for anterior, posterior or lateral laparoscopic procedures. The TIBFD device only in Exemption studies of Food and Drug Administration. The Ray cage used as a posterior device. The Brantigan cages is only used with posterior pedicle-screw instrumentation. Only Harms cage have unrestricted and widespread use⁶.

3 Main types of cage designs⁵⁹:

- i. Horizontal cylinders
- ii. Open boxes
- iii. Vertical rings

The horizontal cylinders are usually implanted from either posterior or anterior approach bilaterally. Most likely, they will be screwed and threaded into the intervertebral spaces. Open box cage is designed as a rectangular with some grooves and ridges to seat in the endplates securely. Some type of medium can be packed inside the hollow inner space of the all cages to encourage bone growth from one vertebral body to the next. Vertical ring is a mesh cage that will sit on the endplates of vertebra with help of rings on the ends.

Some issues regarding making the cages are that there are efforts to make cage as small as possible to incorporate maximum locally harvested bone graft but that should not be so small that with high stresses will result in its subsidence⁶⁰. Now a days there

are many examples of biconvex cages which are made to nearly match the endplate's concave surface.

Design issues include making the cage volume as small as possible to accommodate the most bone graft but not so small that the high stresses will result in subsidence⁶⁰. Geometry of the cage is an important factor and there are now many examples of biconvex cages which are designed to more closely match concave surfaces of most endplates. Minimum migration, increasing stability of the spacer and its resistance to pullout can be achieved by saw tooth pattern on inferior and superior surfaces which grips the adjacent vertebrae⁶¹. Improvement on allograft bone to act as a spacer or development of biologic spacers which would be incorporated into the healed fusion are the future design considerations.

II. Pedicle Screw and Rod Systems

The pedicle provides a good anchor point for posterior fixation hardware as it is a thick, strong structure on posterior side of vertebral body. Pedicle screws are inserted into vertebral body through pedicle. Rods can sit in the slots on head of the screw. Screws are inserted in desired trajectory through pedicle after aligning spine and then rods is placed through heads of all one side screws then on other side of spine so that 4 screws and 2 rods are used for fixation of one level. For each additional level two more screws should be added and accordingly length of rod will be increased. Most of the time screws are made up of titanium as there is superior MRI resolution post operatively compare to stainless steel. Also titanium screws will have high bioactivity and more flexibility meaning bone growth around the screw will be higher to form a stronger fixation⁶².

There are different types of rods materials available including titanium, cobalt chromium molybdenum alloy, polyether ether ketone (PEEK) with each of them have different advantages and disadvantage. Titanium rods have good biocompatibility but it forms a stiff construct. PEEK rods allows more of the load to be transferred to the anterior spine because that have some flexure so there will be less stress on screws results in lower chances of pullout and breakage, promoting faster fusion at desired levels⁶³.

50-84% is estimated worldwide prevalence of low back pain in lifetime⁶⁴. In India its 6.2-92%. With increase in prevalence with females preponderance and age⁶⁵. After 6-12 weeks of conservative management, surgery may be considered. Lumbar fusion is a treatment of disabling low backache and which is more significant than conservative treatment. This is shown by the Swedish Lumbar study group for the first time in 2001⁶⁶. Harms and Jeszenszky⁶⁷ gave first detailed illustration of TLIF as early as 1998. According to recent research, there is critical role of sagittal spinopelvic alignment maintenance in patients with adult spinal deformity in relieving disability and pain and is primary determinant of health related quality of life (HRQoL) measures⁶⁸⁻⁷³. In this regards TLIF remains a standard care amongst the variety of surgical techniques available. Carbon fiber cage or metallic cage filled with bone for interbody fusion has proven effective treatment of low backache⁷⁴⁻⁷⁷.

Lazennec JY et al⁷⁸ evaluated influence of spinal alignment on pattern of back and leg pain after surgery and its occurrence by conducting radiological analysis before and after fusion procedure. Out of 81 included in study 51 had history of any surgery of back. Exclusion criteria was involved the patients with confirmed or suspected nonunion. In the fusion group of patients residual pain (54 patients) were compared with 27 patients who were with no pain procedure. 18 patients had pain only when they were sitting without any movement, 30 patients when they were standing without any movement and 6 in both positions. Measurements were done with the patient standing as per Duval Beaupere criteria, full-length lateral radiograph (14x36 inch). Post fusion pain subgroup was characterized by a more pelvic tilt ($P < 0.0160$), and less sacral tilt with more vertical sacrum ($P < 0.0062$). The presence of post fusion pain was correlated with PT at a last follow up ($p = 0.0003$). PT was almost double the normal value in patients with post fusion pain. Persistent post fusion pain was also correlated with ST at last follow up (ST fu) in standing position. ($p < 0.0001$) indicating that sacrum remained abnormally vertical in subjects with post fusion pain. Only prognostic factor at last follow up was ST fu, using logistic regression. Both at last follow up and preoperatively, patients with pain in both sitting and standing position or only in standing position were specified at preoperative status by less sacral tilt with more vertical sacrum. They concluded that fusion should not only the goal. To minimize work by muscles during posture maintenance, appropriate position of fused vertebrae is also importance.

Rosenberg et al⁷⁹ studied the advantages, safety, surgical efficacy of combination of transpedicular screw fixation with transforaminal approach. Data of 22 patients with grade 2 and grade 1 spondylolisthesis was retrospectively reviewed (age range; 34-63 years with mean of 49 years). All 22 patients underwent TLIF. 3 patients had low backache only and 19 patients had low backache associated with radiculopathy. 8 patients underwent TLIF at L4-L5 level, 11 patients at L5-S1 level, 2 patients at L3-L4 and L4-L5 level, 1 patient at L5-S1 and L4-L5 level. Postoperative follow up was at 1-12 months (mean 5.3 months). According to clinical circumstances, decompression was done. Discectomy followed by placement of interbody cage was done to regain lost disc height. Restoring lumbar lordosis, pedicle rod and screw construct was then compressed. At follow up, it was found that there was moderate pain relief in 5 patients and complete pain relief in 16 patients and no pain relief in one patient. Intraoperative complication was dural tear in one patient. Post operatively 2 patients got wound infection. 1 patient got mild L5 motor paresis. One patient had brachial plexus injury as a result of intraoperative positioning and peripheral neuropathy secondary to prolong blood pressure cuff inflation intraoperatively in 1 patient. So it was concluded that TLIF is effective and safe method of spinal fusion in circumferential way via a single stage procedure. This procedure was particularly helpful in restoring lumbar lordosis and disc space height.

Lowe TG et al⁸⁰ assessed radiological and clinical outcomes of TLIF for degenerative disease of lumbar spine by conducting a prospective analysis of consecutive patients who underwent lumbar fusion using unilateral TLIF procedure. They described the indications and technique of TLIF in degenerative disease of lumbar spine. 40 patients were included in study. Follow up was minimum 3 years (3-3.9 years, mean 3.4 years). Radiological assessment was by using neutral and dynamic radiographs. Clinical outcome was depend on return to work, ability to do daily routine activities and pain relief. Segmental lordosis had increased in all patients at latest follow up and 36 patients had solid fusion. Excellent outcome had seen in 85% patients. Anterior column support on both sides provided by unilateral TLIF. Finally patient satisfaction and high fusion rates were documented with similar complications found in other spinal stabilization and decompression methods.

Kwon BK et al⁸¹ evaluated 35 patients of isthmic type who underwent TLIF with use of 1 or 2 Brantigan carbon fiber cages and pedicle screw instrumentation. Slip angle, disc space height and anterolisthesis were measured in post and preoperative standing neutral radiographs. The author found that height of disc space was increased and anterolisthesis was reduced. The entity not significantly altered was average slip angle. Placement of the interbody cage more anteriorly was correlated with restoration of Lumbar Lordosis across the listhetic disc space. Author concluded, there was restoration of height of disc space and reduced forward shift in patients with isthmic type after TLIF technique was done by using pedicle screw instrumentation and Brantigan cage.

Anterior placement of interbody device was implying improvement in sagittal alignment.

Salehi SA et al⁸² evaluated TLIF procedure by doing retrospective analysis of 24 patients (15 men, 9 women). 42.6 +/- 12.5 years was mean age of patients included in study. Combination of low backache and radiculopathy was original symptom in 17 patients. 10 patients already underwent one spine surgery before. L4-S1 TLIF was done in 11 patients and other remaining patients underwent TLIF at single level. Average floor days and intensive care unit were 5.8 +/- 2.2 and 1.1 +/- 1.0 respectively. 2.8 +/- 1.6 days were number of days required for ambulation. Transient complications were seen in 24 patients. 16 +/- 9.1 was average follow up time. Solid fusions were seen in 22 patients. Clinical outcome was evaluated by using a modified Prolo scale. 16.1 +/- 4.1 was average score. Conclusion of study was TLIF can be performed with excellent clinical outcome and is reliable and safe technique.

Coe JD et al⁸³ evaluated 31 patients of TLIF for primary degenerative indications in terms of clinical and radiographic parameters. Bioabsorbable polymer spacers were used. These spacers were made up of copolymer of 70:30 poly (L-lactide-co-D, L-Lactide) and filled by bone graft harvested from iliac crest autograft. 18 months was mean follow up, 81% patients had excellent outcome, 96.8% patients had attained solid fusion. Out of 3 patients experienced post operative complications, none of that was related to bioabsorbable polymer implant. There was mechanical failure of one implant on insertion, found in 1 patient without any clinical sequelae. 12-18 months was biological life expectancy. Use of biodegradable polymers for interbody fusion was supported by good radiographic and clinical results of this study.

Hackenberg et al⁸⁴ conducted prospective study of 52 patients who of TLIF with minimum follow up of 36 months with mean of 46 months (36-64). Study included 30 patients with degenerative spondylolisthesis and 22 patients with isthmic spondylolisthesis. 2 cases underwent 3 level fusion, 11 cases were 2 level and 39 were one level. Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) was calculated pre and postoperatively for measurement of disability and pain status. Anterior-posterior radiographs were used to evaluate status of bony fusion. Average operative time was 238 minutes for multiple level fusion and 173 minutes for single level fusion. 485 ml and 560 ml was blood loss for single level and multiple level fusions. 4 severe complications were notes: pseudoarthrosis with loosening of implants, symptomatic contralateral disc herniation, persistent radiculopathy, a deep infection. At follow up there was reduction in ODI and pain relief in the VAS ($p < 0.05$). 89% was fusion rate. At last follow up significant differences of ODI neither found between one and multiple level fusions nor between isthmic and degenerative spondylolisthesis. Author concluded potential benefit of TLIF technique were reduction of approach related iatrogenic posterior injury to spinal cord and avoidance of complications related to anterior approach.

Potter BK et al⁸⁵ reviewed consecutive 100 patients of TLIF performed at one institution. The preoperative diagnosis included degenerative adult scoliosis (4), spondylolisthesis (41; 19 degenerative, 22 isthmic), degenerative disc disease (55). There were total 140 levels operated; 1 four – level, 2 three-level, 33 two level and 64 single level TLIF. The fusion was evaluated by using biplanar radiography by independent observers, whereas several established outcome scores were used for assessment of clinical outcomes. Postoperative clinical follow up for all patients was > 24 months and 82% patients were traced after surgery for 34 months (range 24-61 months). $> 50\%$ decrease inpatient's symptoms was reported in 81% of the patients and 76% patients were satisfied postoperatively. Minor complications were seen in 20% patients. No any major complications were observed. In conclusion, author mentioned that TLIF is an effective and safe operative procedure of achieving lumbar fusion with 80% rate of overall patient satisfaction and 93% fusion success but frequently results in incomplete clinical improvement. Complications were generally transient and minor.

Lauber S et al⁸⁶ studied radiographic and clinical results of TLIF as an alternative technique in isthmic and degenerative lower grade spondylolisthesis. There were 1 dysplastic, 19 isthmic and 19 degenerative cases operated on with TLIF. ODI was used for clinical follow up, radiological follow up by using radiographs analysing fusion rate, reduction of spondylolisthesis, segmental lordosis, intervertebral space height. 24 months was minimum follow up, 50 months was mean clinical follow up and 35 months was radiological follow up. In all patients ODI decreased from 23.5 to 13.5, from 20.5 to 10.95 in isthmic spondylolisthesis after 2 years. 94.8% was the radiological fusion rate. There was reduction of sagittal translation from 23% to 15%. Serious postoperative complications were found in 3 (7.6%) patients for which operative revision required. So finally concluded that TLIF theoretically can prevent complications of posterior and ALIF fusion and also it is effective and safe procedure. The results of isthmic spondylolisthesis were better than degenerative spondylolisthesis.

Liu H. Y. et al⁸⁷ studied advantages and effectiveness of TLIF procedure used for upper lumbar disc herniations. Total 18 cases were included in study. Out of 18 patients who underwent TLIF, 6 were females and 12 were males, aged 21-67. 19.8 months (12-54 months) was mean follow up. The complications, outcomes and surgical process were reviewed retrospectively. Bilateral TLIF was performed in 4 cases, unilateral procedure was done 14 patients. 82.4 minutes and 323 ml was mean operation time and blood loss respectively. During the operation, there was no injury to spinal cord or nerve roots. The follow up showed that operation results were fair in 3 cases, good in 4 cases, excellent in 11 cases. There was no relapse or worsening of symptoms present before surgery. Lumbar lordosis and disc spaces were restored satisfactorily. No failure of internal fixation was found. So study concluded that for upper lumbar disc herniations in selected patients, TLIF is one of the effective surgical treatment.

Chastain CA et al⁸⁸ conducted a retrospective study of 42 patients to determine fusion status, disability and postoperative pain after TLIF with long term follow up for 4 and more than 4 years. Pre and postoperative evaluation in terms of VAS and ODI was done of each patient. Statistically significant improvement was seen in both VAS and ODI. Over extended period of time TLIF was effective in alleviating intractable back pain. According to author, for clinical successful outcomes, solid radiographic fusion was unnecessary.

Li B et al⁸⁹ analysed therapeutic effect of TLIF on degenerative disc disease. Total 15 cases included in study. Out of 15 cases, 7 females and 8 males with age range of 33-46 years. All cases were single level degenerative disc disease including 8 cases of L4-L5, 6 cases of L5-S1 and 1 case of L3-L4. Preoperative VAS and ODI was 8.9 +/- 1.8 and 51.4 +/- 8.3 respectively. All patient has no therapeutic effect by conservative management at least for 3 months. Average operation time was 150 minutes (range: 120-180 minutes) and average intraoperative blood loss was 360 ml (range: 200-500 ml). Except for one patient in which power of anterior tibial was reduced to 3/5, there was no major complications were observed postoperatively. That was increase to 4+/5 at 3 month follow up. Total average follow period was 18 months with range of 12-24 months. After 12 months all patients got 100% fusion rate after 12 months. There was significant improvement in VAS and ODI ($p < 0.05$) statistically. In one case there was fair improvement, 8 cases good and 6 cases were regarded as excellent outcome. All patients resumed their normal lives and their jobs. Study concluded that for treatment of degenerative disc disease of lumbar region, TLIF is effective surgical procedure but it is necessary to define indications strictly.

Jagannathan et al⁹⁰ performed retrospective study of 80 patients of TLIF with minimum follow up period of 2 years. Standing X was assessed to look for fusion, restoration of lumbar lordosis, change in segmental and focal kyphosis. 50% patients had sagittal imbalance. Preoperative mean cobb angle was 36.3 +/- 4.5 degrees and 55.1 +/- 6.6 postoperatively. Restoration of lordosis was seen in 33 out of 36 patients with segmental kyphosis. At surgical level, there was improvement in alignment (mean increase in LL, 20 +/- 4.2). The improvement in LL was significantly higher with multilevel TLIFs as compare to single level TLIFs. 75% patients got restoration of normal sagittal balance immediately after surgery. In 91% patients spondylolisthesis was corrected completely. Total 3 patients required reoperation, out of which one for worsening kyphosis and scoliosis above the surgical level and 2 patients for implant malalignment. Pseudoarthrosis was seen in 2 patients. Author concluded that, when appropriate surgical technique in implemented, TLIF surgery is most effective in improving spinal sagittal alignment in degenerative spine pathologies.

Sethi A et al⁹¹ prospectively studied fusion rates and clinical outcomes in implant load construct and of translaminal and unilateral transpedicular screw in TLIF which

reduces cost of posterior implants by almost 50%. 19 consecutive patients were studied. All 19 patients underwent single level TLIF. Out of 19 patients, in 3 patients polyetheretherketone (PEEK) cage was used and in 16 patients TLIF allograft interbody spacer used. Mean follow up of 32 months with range from 15-54 months. A radiological and clinical evaluation was done at the time of multiple follow up and also preoperatively. Overall improvement in VAS and ODI was observed. Radiographic evidence of fusion was observed from 9-26 months (mean 19 months) following surgery. Study concluded that contralateral laminar screw and ipsilateral pedicle screw are viable and cheaper option for single level lumbar fusion.

Cao ZL et al⁹² conducted a study to find out complications and effect of TLIF surgery. This was retrospective review of 40 patients who had underwent TLIF from 2005 to 2007. Total 49 segments were fused. ODI and VAS scoring system was used for pre and 1 year postoperative evaluation. Angle of intervertebral space, disc height and fusion status were also measured as well. 18 months was average follow up with range of 12-24 months. No severe postoperative complications were seen. Mean blood loss and operative time was 510ml and 160 minutes respectively. Final results were fair in cases, good in 7 and excellent in 28 cases with fusion rate of 100%. There was significant reduction of ODI ($p < 0.01$), increased disc height and angle of intervertebral space ($p < 0.05$) and pain relief in the VAS at one year after operation. Low backache to some extent was complained by 15 patients until the last follow up. Author concluded that especially for the failed back surgery syndrome, TLIF can achieve satisfactory radiographic and clinical results.

Ould-Slimane M et al⁹³ studied pelvic and spinal parameters of spinal sagittal balance after TLIF procedures. Study included 45 patients who had underwent TLIF. Spinal sagittal balance parameters were measured at last follow up, immediate postoperatively and preoperatively. 58.4 (± 9.6) years was average age of the patients. 35.1 months (± 4.1) was mean follow up. Anterior imbalance in terms of high pelvic tilt (17.6 ± 7.9) was found in 29 patients. Because of retroversion of pelvis as an adaptive response to loss of lordosis, 22 out of 32 patients had large pelvic tilt. Intraoperatively, there were dural tear occurred in 3 (7%) patients. In 27% cases interbody cage was more posterior than intended. Lumbar lordosis and disc height was significantly increased at fusion level ($p < 0.001$, $p < 0.005$ respectively). Global spinal sagittal balance was not

modified significantly ($p=0.07$) whereas pelvic tilt was significantly reduced ($p=0.01$) postoperatively. Author concluded that reduction of pelvic compensation was found in single level circumferential fusion patients but that does not allow for complete correction of spinal sagittal imbalance.

Gregor Recnik et al⁹⁵ retrospectively studied single level TLIF for patients of isthmic spondylolisthesis to analyse segmental balance. 32 patients were included in study. Lateral neutral radiographs in standing position were studied retrospectively. Translational Slip (TS), Posterior Disc Space Height (PDSH) and Segmental Lordosis (SL) values were compared using paired t test at preoperative, postoperative and final follow up. Using 2-tailed independent t test, change in SL after surgery between groups of next grouping variables: position and type of interbody device and rod contouring was compared. There was no significant change in SL occurred after surgery ($P=0.811$) but mean PDSH increases ($P=0.002$) and mean TS decreased ($P=0.001$). Increase in SL was seen with bending of connecting rods ($P=0.023$) and with ventral positioning of the cage ($P=0.009$). During follow up, there was decrease in PDSH ($P<0.001$) and increase in TS ($P=0.002$). Both postoperatively and preoperatively, lower PDSH was found with more ventral insertion of interbody device. Author concluded that with single level TLIF, restoration of height of disc space and reduction of TS was readily achieved. Increase of SL was consistent with rod contouring and anterior placement of interbody device. Insufficient disc space height restoration was resulted from excessive ventral insertion of the cage.

Alquaroom R et al⁹⁵ studied 56 patients from July 2013 to February 2014 who underwent lumbar fusion surgery at Klinikum Dortmund. There were two groups of patients; 2 level group and 1 level group. Radiological evaluation was done for measurement of following spinopelvic parameters: Sagittal Vertical Axis (SVA), Lumbar Lordosis (LL), Pelvic Tilt (PT), Sacral Slope (SS), Pelvic Incidence (PI). This radiological assessment was done preoperatively and also during follow up at 3 months and 1 year.

Statistically, Pearson correlation coefficient revealed in 1 level group that clinical parameters correlated with SVA ($R=-0.41$) ($p<0.05$), SSA ($R=-0.38$) and PT ($R=0.40$). While clinically mean ODI and VAS was improved significantly as compare to preoperative scores in both groups. Also there was high correspondence between SS and

LL (R= 0.90). This relationship persisted even after year at the same level. The only parameter that was correlated with clinical parameters was SVA in the 2 level group (R=0.49) ($p<0.05$). There was a high interconnection between SS and LL (R= 0.88) even in 2 level group. The study concluded that Clinical improvement in one level patients was possible with only small alteration in spinopelvic parameters. Re-establishment of LL and SVA is require for statistically significant clinical improvement in two level fusion procedure.

METHODOLOGY

We made a prospective non-randomised study of patients with lumbar spine instability. A total of 8 patients were evaluated and assessed during the period from 1st February 2019 to 31 July 2020. The study was conducted in Department of Neurosurgery, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) Thiruvananthapuram.

The indication for surgery was instability, as defined by the criteria for which instrumentation was needed to restore spine stability. The indications for fusion were in cases with combined severe low backache and radicular pain, after failure of conservative treatment. All patients were initially assessed in the outpatient department and underwent a detail evaluation of neurological status; radiographs were taken and underwent treatment as per specific treatment plan.

Inclusion criteria:

- Consenting adult patients with age ≥ 18 years
- Pathology evidenced by CT, MRI LS spine, radiographs.
- Symptomatic backache.
- Able to verbalize pain score
- Glasgow Coma Scale (GCS) – 14,15

Exclusion criteria:

- Nonconsenting patients.
- < 18 years age.
- Pregnancy / Lactation
- ASA (American Society of Anaesthesiology) grade 3,4 and 5.
- Patients who have other pathological problems such as traumatic vertebral fractures, tumours or infectious disease.

When a patient meeting broad inclusion criteria will be admitted, the Principal Investigator will be informed by the admitting team.

PRE-OPERATIVE WORK UP:

Informed and written consent

History

Current intensity and distribution of pain and neurological examination was conducted. Local and systemic examination also was done to assess cause of instability. Pain and instability was graded clinically and radiologically using Visual Analogue Scale (VAS) (0 as no pain to 10 as maximal pain) and Oswestry Disability Index (ODI) of backache (ranging from 0 to 100 with higher scores indicating more disability related to pain) and SF 12 was obtained after brief instruction at least 24 hour before the surgery.

Radiological examination was done using X ray lumbar spine (AP, Lateral and F-E radiographs), X ray whole spine 36 inch lateral view (including C1 and femoral head), CT scan of LS spine plain and MRI LS spine plain. Also spinal sagittal balance and its parameters like sagittal vertical axis, lumbar lordosis, pelvic incidence, pelvic tilt, sacral slope which were measured preoperatively.

- Other investigations– Baseline blood investigations for anaesthesia fitness.
- Post void residual urine was calculated for each patient by doing ultrasound of kidney and urinary bladder. Post void residual urine more than 30 ml was considered significant.
- Diagnosis- Clinical and radiological.
- Surgery- Open Transforaminal Lumbar Interbody Fusion.
- Criteria to select cage will be at the discretion of surgeon.

Patients were posted for surgery electively after preanesthetic check up. Surgeries involved single or multilevel fusion.

Surgical technique to be followed-

In general anaesthesia patient was placed in prone position. The posterior elements of spine were exposed to base of transverse process. After pedicle screw insertion inferior and superior articular processes of one facet joint was resected and disc is exposed in neural foramen. Care was taken to coagulate the epidural veins running superior to the pedicle into the neural foramen before incising the disc. The disc was subtotally resected using rongeurs, shavers and curettes. After discectomy, disc space was progressively distracted via contralateral side. After scraping of the endplates the anterior part of the disc space was filled with autologous bone chips harvested locally. A curved bullet cage was filled with bone graft and inserted into the central or posterior part of the disc space. The 40° angle of the introducer and shape of the cage enable controlled cage positioning. Then rods were mounted with slight compression bilaterally. Decortication of remaining posterior elements was done and bone graft was placed to achieve a posterior fusion. Decompression of the spinal canal was done before discectomy. Resection of the facet joint was done on the same side in cases of unilateral nerve root compression. In cases of isthmic type of spondylolisthesis with nerve root compression on both sides, complete laminectomy was performed to permit adequate nerve root decompression. Resected lamina was used as bone graft. C-arm fluoroscopy confirmation of cage position was done before final tightening of screws and also confirmed that cage was at least 5 mm from the posterior cortical margin. To achieve firm contact between graft material and end plates, gentle compression force was applied over adjacent screws after proper position was obtained. Pedicle screw fixation was carried out to improve the bony union and to obtain the stability immediately after surgery. Wound closure was done on layers after confirming haemostasis.

Intraoperative pictures:

Figure 8: SHOWING DISSECTION FOR ENTRY POINT FOR PEDICLE SCREW



Figure 9: FINAL VIEW AFTER PEDICLE SCREW INSERTION AND ROD FIXATION

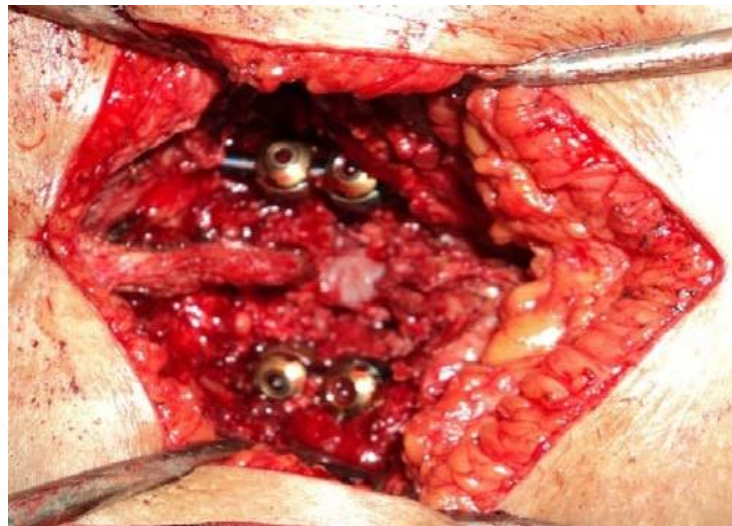


Figure 10: AUTOLOGOUS BONE GRAFT

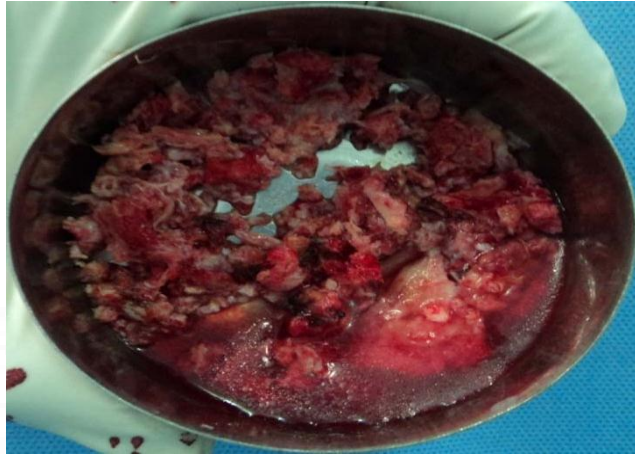


Figure 11: SHOWING INTERBODY FUSION DEVICE CAGE

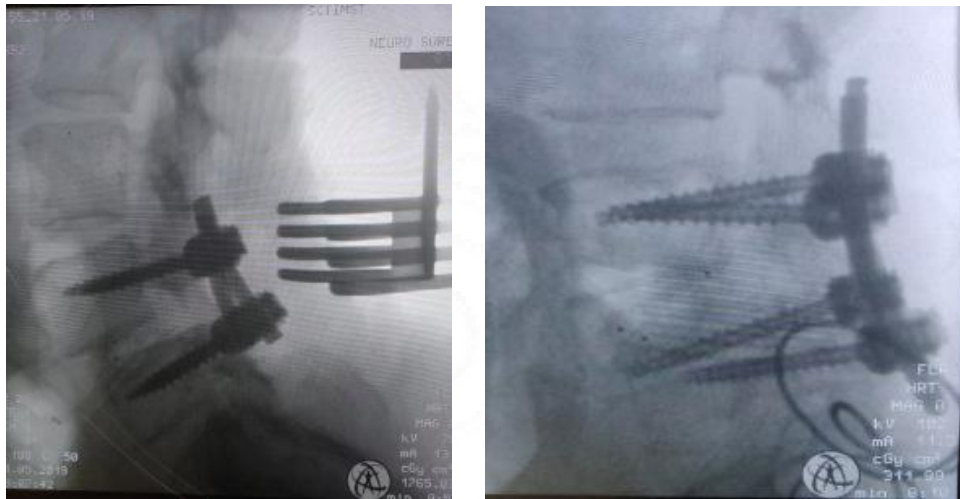


Figure 12: SHOWING INSTRUMENTS USED FOR TLIF





Figure 13: C arm pictures after final tightening of screws



Postoperative management:

Overnight observation in Neurosurgery ICU.

Routine antibiotics and analgesics/anti-inflammatory were used during preoperative, immediate and late postoperative period. Post operatively patients were ambulated with a lumbar corset generally on the second day after surgery.

Post operatively, spinal sagittal balance and its parameters i.e. sagittal vertical axis, lumbar lordosis, pelvic incidence, pelvic tilt, sacral slope were measured and compared both preoperatively and postoperatively. ODI, SF12, VAS were also measured postoperatively and compared to look for any improvement.

5. Clinical follow-up was done at 1 month and 3 months.

Evaluation of functional outcome in terms all parameters of spinal sagittal balance were calculated by repeating 36 inches X ray whole spine before each follow up. ODI, SF12, VAS were measured during each follow up.

Table 4: Data collection schedule

EVALUATION		Pre-op	Post-op	1 month	3months
X ray whole spine		+	+	+	+
T2 weighted MRI/ CT		+			
Lateral neutral extension & flexion		+			
Neurological examination		+	+	+	+
Data forms	SF-36	+		+	+
	VAS	+		+	+
	ODI	+		+	+

Figure 14: Pre and postoperative radiographic measurement Sagittal Vertical Axis (SVA)

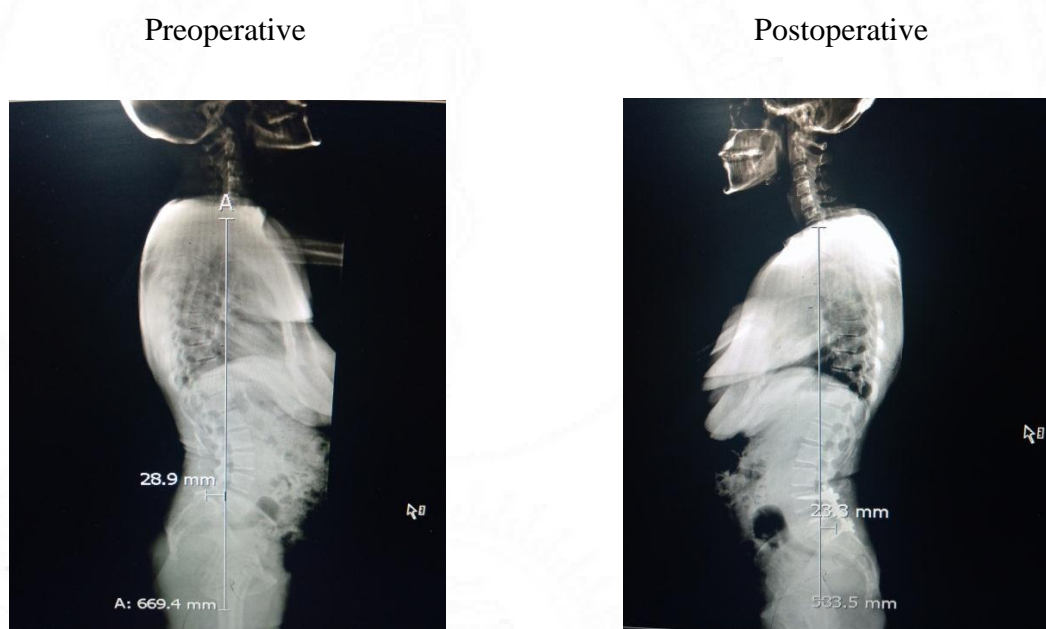


Figure 14: Showing preoperative SVA was 28.9 mm and postoperatively reduced to 23.3mm

SVA was measured as offset between the C7 plumb line and posterior superior corner of S1 endplate.

Figure 15: Pre and postoperative radiographic measurement of lumbar lordosis (LL).

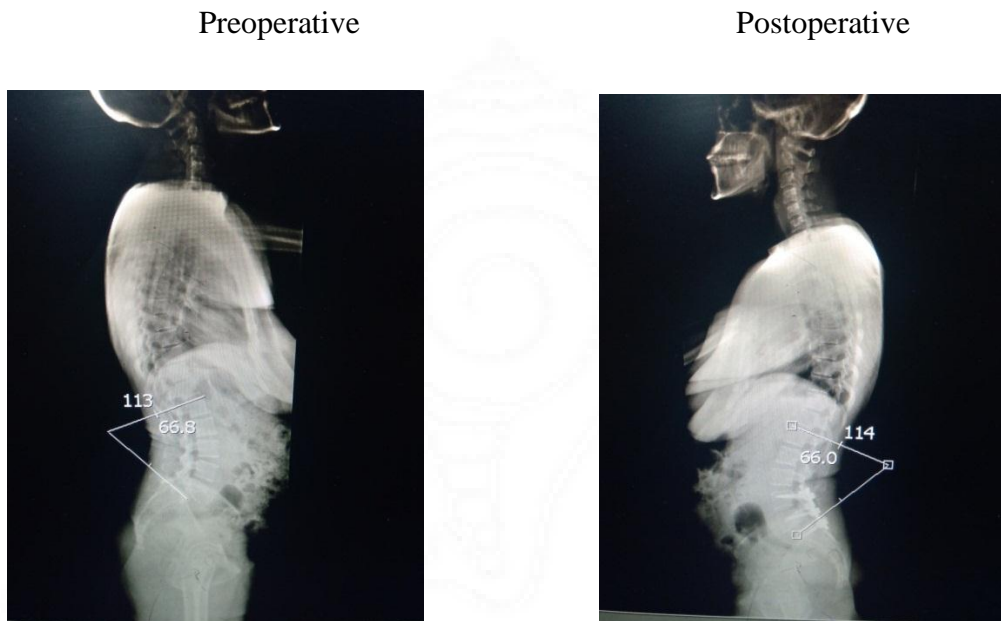


Figure 15: Showing preoperative LL was 66.8° and postoperatively its 66.0° .

LL was measures as an angle between the upper endplate of S1 and L1.

Figure 16: Pre and postoperative radiographic measurement of PI (Pelvic Incidence), SS (Sacral Slope), PT (Pelvic Tilt)

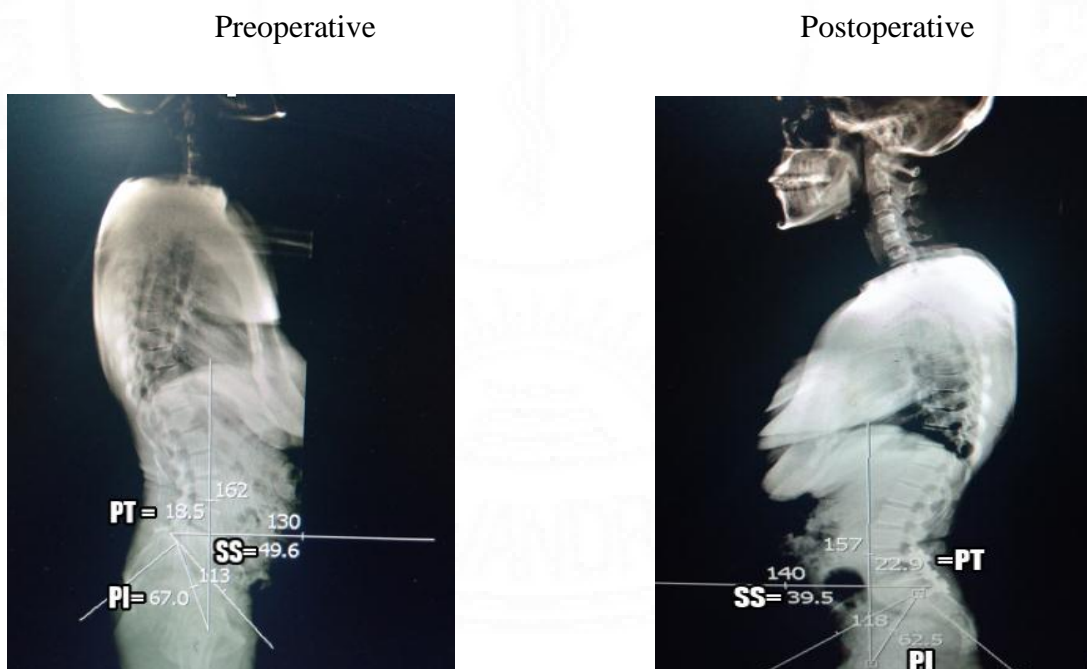


Figure 16: Preoperative PI, PT and SS was 67° , 18.5° and 49.6° respectively and post operatively PI, PT and SS was 62.5, 22.9 and 39.5 respectively. Pelvic incidence (PI) was measured as angle between bicoxo-femoral axis and line perpendicular to upper endplate of first sacral vertebra and a line joining centre of the upper endplate of first sacral vertebra. PT was measured as angle between line joining middle of first sacral vertebra endplate and bicoxo-femoral axis and a vertical line. Sacral slope (SS) was measured as angle formed by a horizontal line and endplate of S1.

Statistical analysis:

Qualitative data were presented using frequency, percentage and quantitative data using descriptive statistics i.e. Mean \pm SD. Shapiro-Wilk's test was used to test whether the data is following normal distribution. Means were compared between the different time points using the repeated measures ANOVA test or paired t-test. Spearman or Pearson's correlation coefficient was performed to assess correlation between parameters. Statistical significance was set at 0.05. Results were represented graphically. Descriptive statistics were used for parameters which did not need statistical analysis. MS Excel and GraphPad softwares (SPSS Inc., Chicago, IL, USA) were used for data entry and analysis.

RESULTS

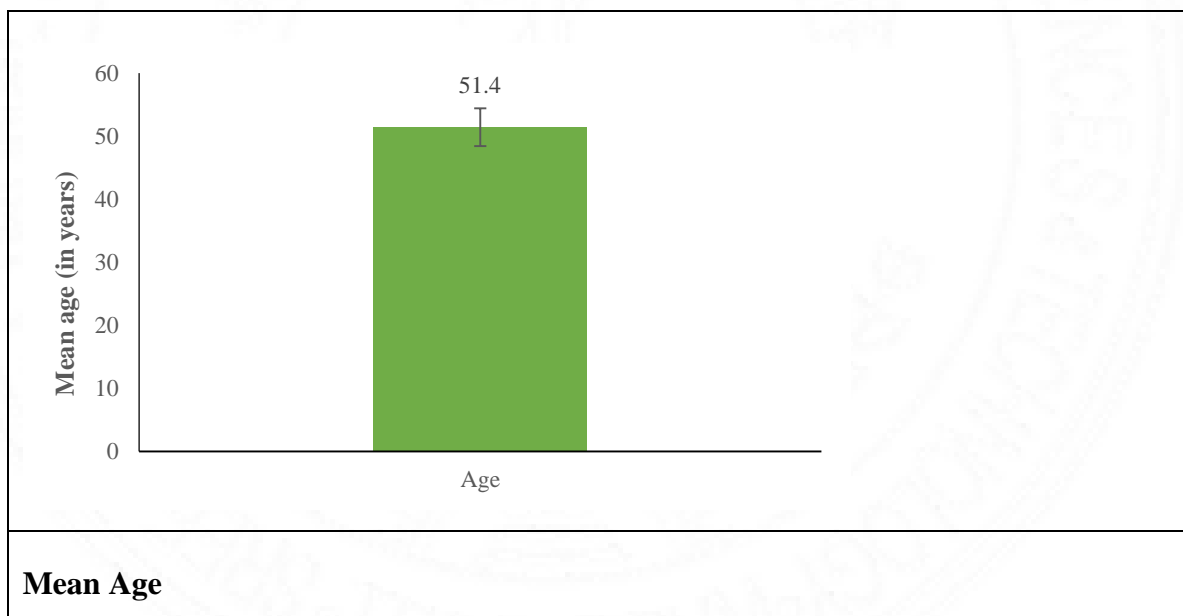
Our study comprises of clinical and radiological evaluation of patients who underwent Transforaminal Lumbar Interbody Fusion. Functional outcomes were measured using different scales of pain and overall quality of life parameters. Radiological outcome was measured using parameters of spinal balance.

- **Age and sex distribution:**

Average age of patients were 51.40 with range of 38-67. The youngest patient was aged 38 years and the oldest was 67 years old.

Table 5 :Mean Age

	Mean	SD	Range
Age (in years)	51.40	8.35	38 – 67

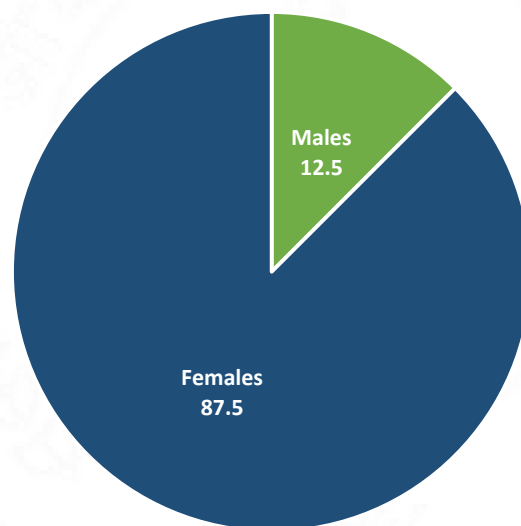


- **Gender distribution**

In our series, 8 patients were included, 1 (12.50%) was male and 7 (87.50%) were females. Overall sex ratio was male: female was 1:7.

Table 6: Gender distribution

Gender	No. of patients	% of patients
Males	1	12.50
Females	7	87.50
Total	8	100

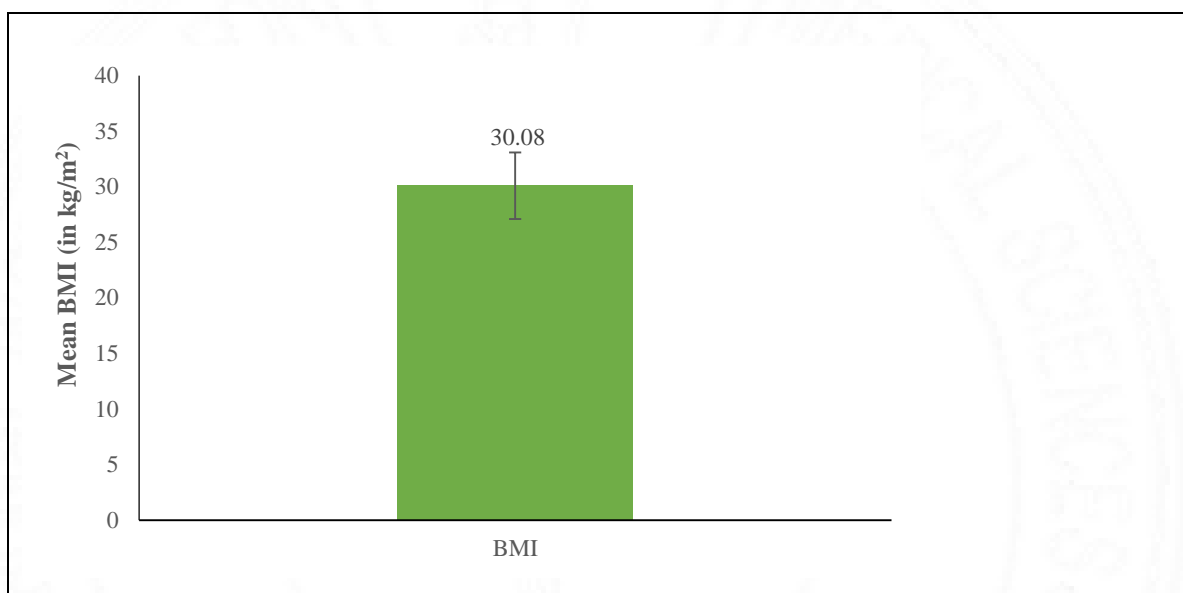


Gender distribution

- **Body Mass Index**

Table 7: Body Mass Index

BMI parameters	Mean	SD	Range
Height	158.64	6.96	146.6 – 170
Weight	74.13	7.28	60.6 – 82
BMI	30.08	3.59	24.22 – 35.10



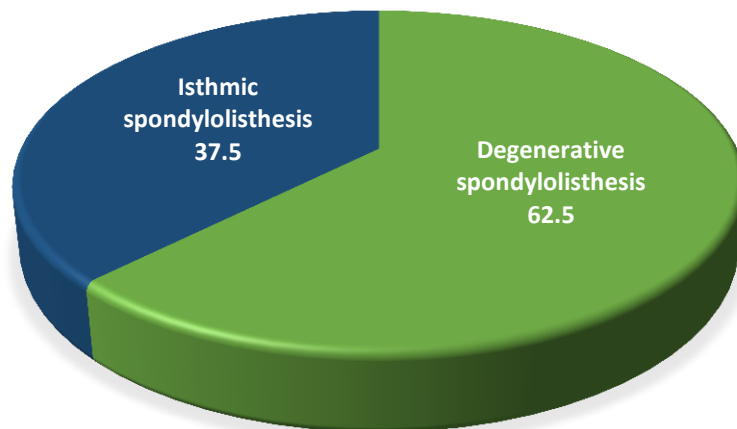
Body Mass Index

The mean height of our study patients was 158.64 ± 6.96 cm, ranging from 146.6 cm to 170 cm. Their average weight was 74.13 ± 7.28 kgs, and ranged between 60.6 kgs to 82 kgs. The mean body mass index of our patients was 30.08 ± 3.59 kg/m² (range: 24.22-35.10 kg/m²).

- **Pathology**

Table 8: Pathology of spondylolisthesis

Pathology	No. of patients	% of patients
Degenerative spondylolisthesis	5	62.5
Isthmic spondylolisthesis	3	37.5
Total	8	100



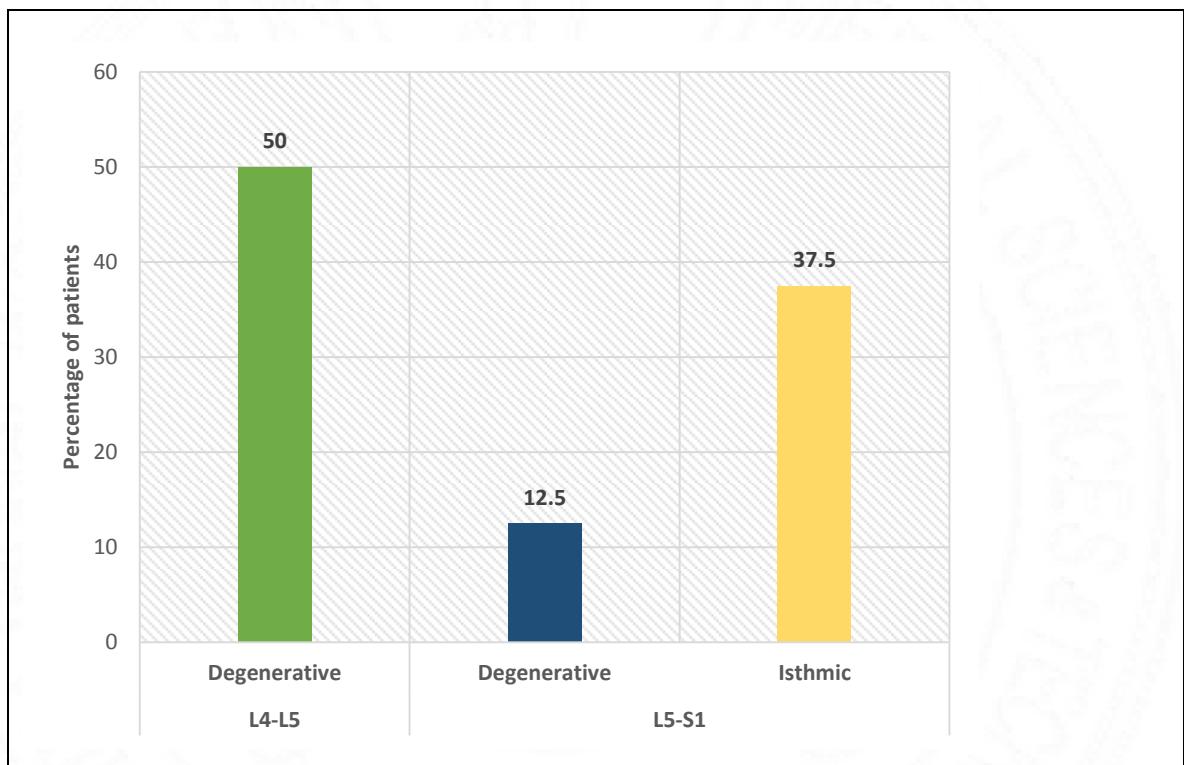
Pathology

Out of the 8 patients included, 62.5%, i.e. 5 patients had degenerative spondylolisthesis, while 37.5%, i.e. 3 patients had isthmic spondylolisthesis.

- Level of spondylolisthesis

Table 9 : Level of spondylolisthesis

Level of spondylolisthesis	Type of spondylolisthesis	No. of patients	% of patients
L4-L5	Degenerative	4	50
L5-S1	Degenerative	1	12.5
	Isthmic	3	37.5
Total		8	100



Level of spondylolisthesis

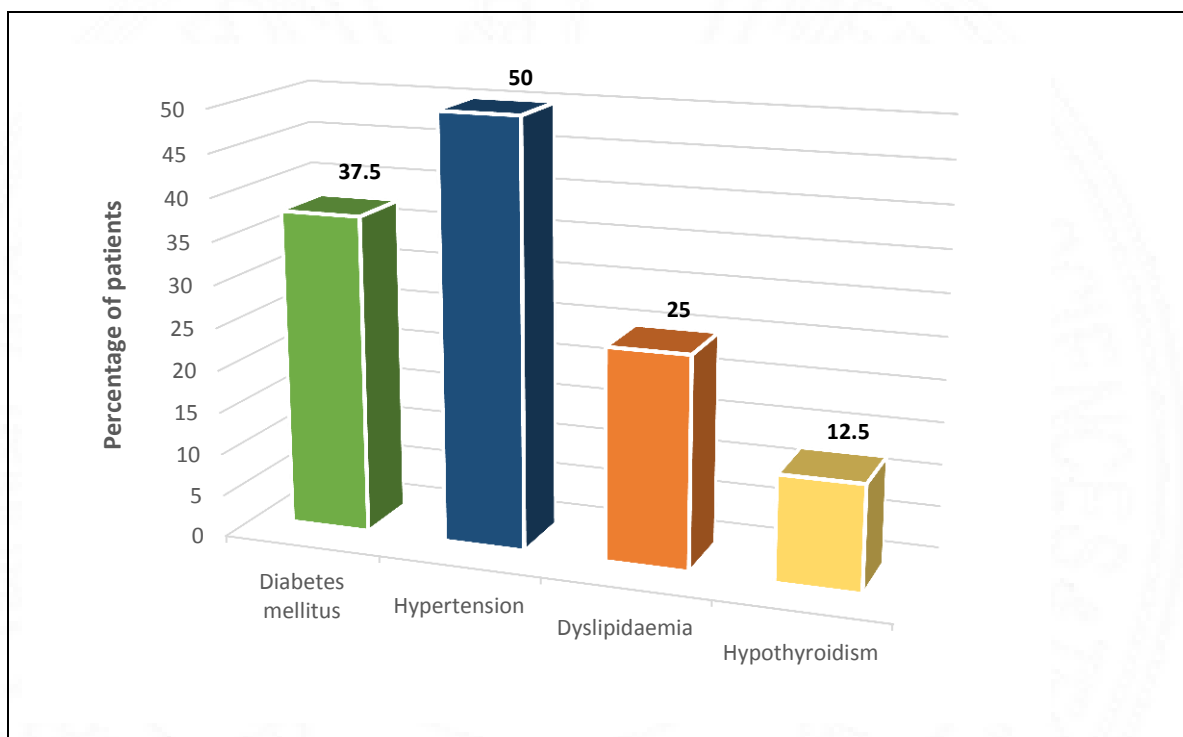
Of the 8 patients included in our study, the level of spondylolisthesis (degenerative spondylolisthesis) was L4-L5 in 50% (4/8) patients and L5-S1 in the remaining 50% (4/8) patients (degenerative spondylolisthesis, 12.5%, 1/8; isthmic spondylolisthesis, 37.5%, 3/8).

All patients in our study were of grade 1 spondylolisthesis according to Meyerding classification³⁹.

- **Co-morbidities**

Table 10: Comorbidities

Co-morbidities	No. of patients	% of patients
Diabetes mellitus	3	37.5
Hypertension	4	50
Dyslipidaemia	2	25
Hypothyroidism	1	12.5



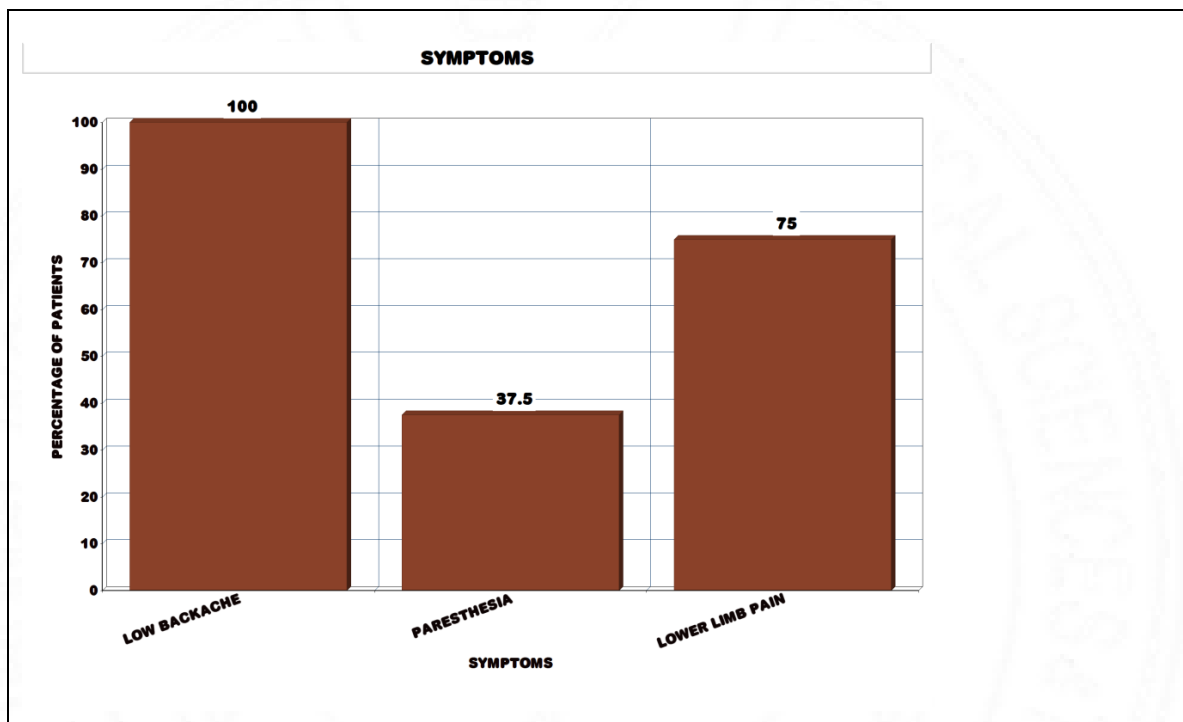
Co-morbidities

In our study population, 50% (4/8) patients had hypertension, 37.5% (3/8) patients had diabetes mellitus, 25% (2/8) patients had dyslipidaemia, and 12.5% (1/8) patients had hypothyroidism.

- Symptoms

Table 11: Symptoms

Symptoms	No. of patients	% of patients
Low back ache	8	100
Paresthesia	3	37.5
Lower limb pain	6	75

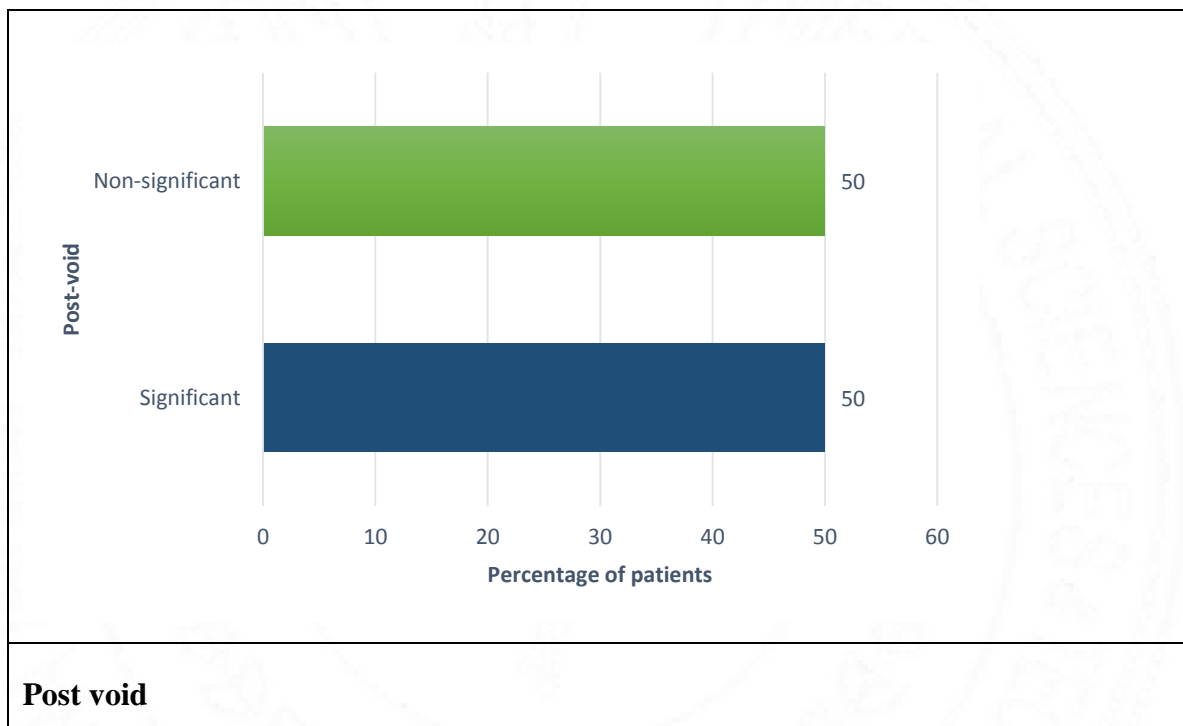


In the current study, the most common symptom experienced by our patients was low back ache (100%; 8/8), followed by lower limb pain in 75% of patients and paresthesia in 37.5% patients. Right lower limb pain (50%; 4/8), paresthesia left lower limb (25%; 2/8), left lower limb pain (25%; 2/8), and right lower limb paresthesia (12.5%; 1/8). That means unilateral lower limb radiculopathy was there in 75% (6/8) of patients. Neurological deficit in terms of unilateral lower limb paresthesia in 37.5% (3/8) of our patients.

- **Post void residual urine volume**

Table 12: Post void residual urine volume

Post void	No. of patients	% of patients
Significant	4	50
Non-significant	4	50
Total	8	100

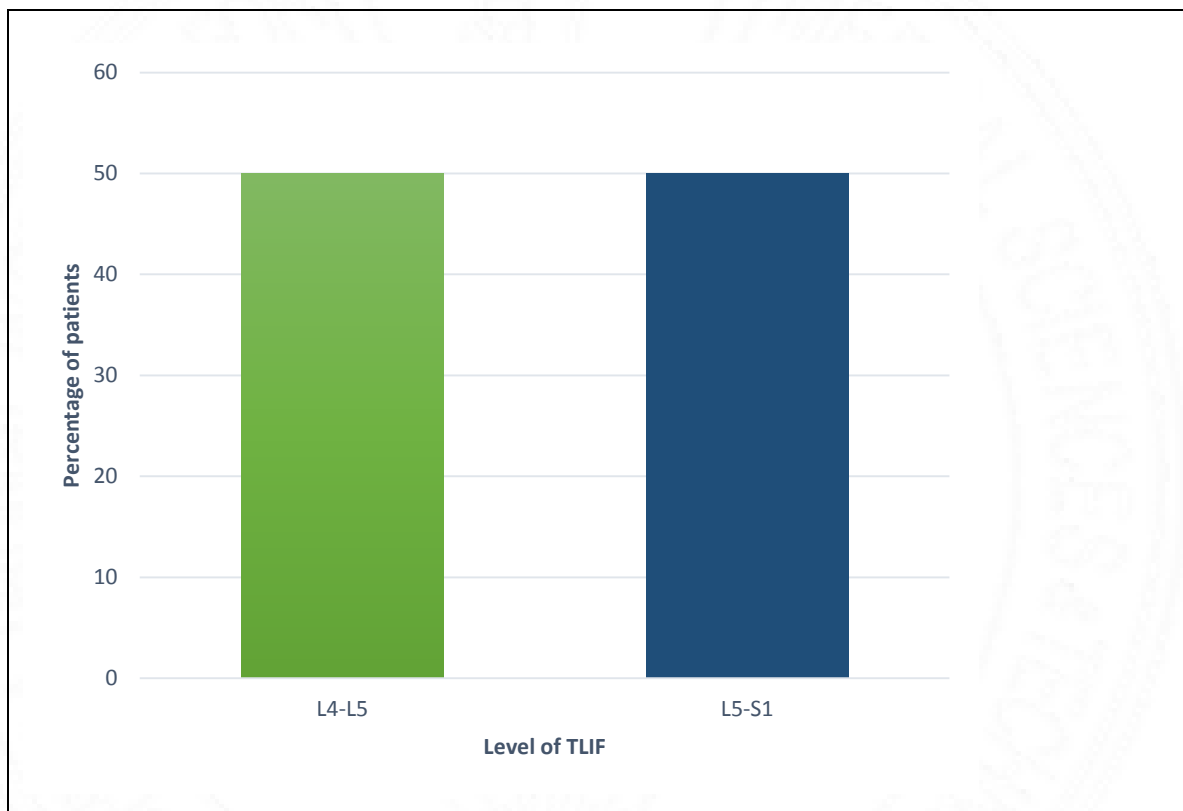


In this study, post void was significant in 50% (4/8) patients and non-significant in the remaining 50% (4/8) patients.

- Level of TLIF

Table 13: Level of TLIF

Level of TLIF	No. of patients	% of patients
L4-L5	4	50
L5-S1	4	50
Total	8	100



Level of TLIF

Titanium cage filled with bone graft and mixed with MASTERGRAFT (resorbable ceramic granules made of hydroxyapatite and b-tricalcium phosphate) was used in all of our patients during surgery.

Half the patients in our study underwent TLIF at L4-L5 level and the other half at L5-S1 level. In the this study, average operative time was 147.5 ± 22.5 minutes.

- **Blood transfusions**

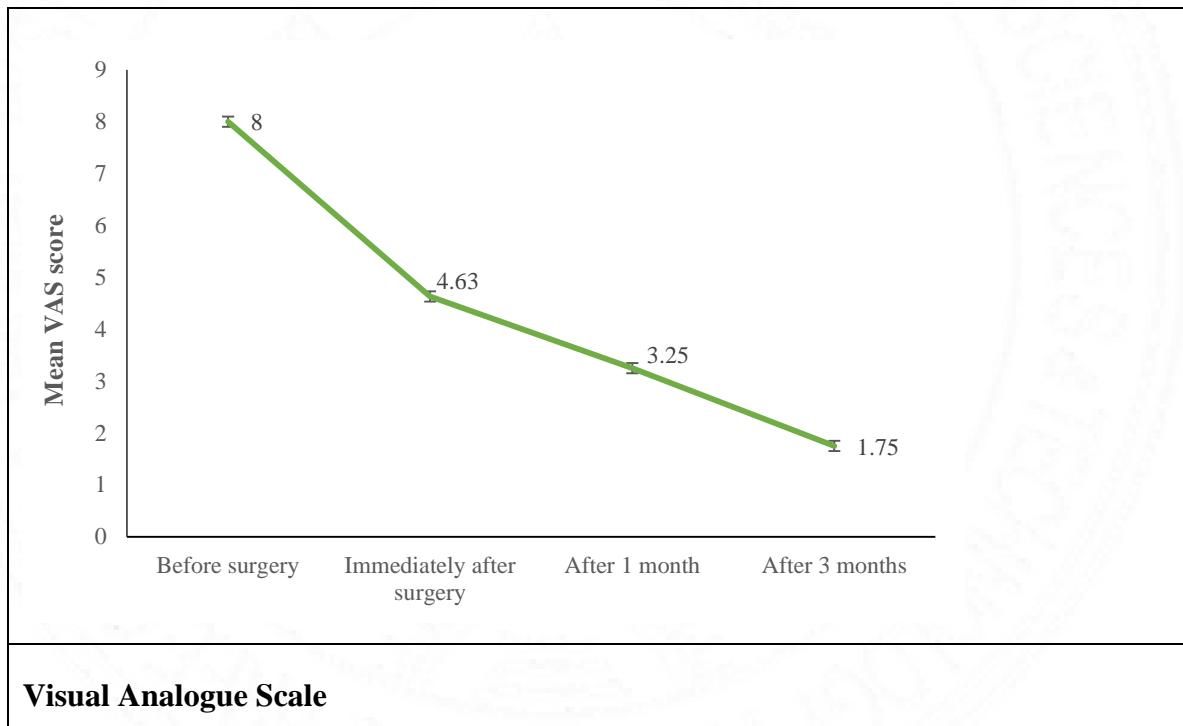
In this study, blood transfusion was not needed in any patient. The average intraoperative blood loss of our study patients was 437.5 (range: 300-550 mL).

- **Visual Analogue Scale (VAS)**

Table 14: Visual Analogue Scale (VAS)

Visual Analogue Scale	Mean	SD	Range	p-value*
Before surgery	8.0	0.76	7 – 9	<0.0001
Immediately after surgery	4.63	0.74	4 – 6	
After 1 month	3.25	0.71	2 – 4	
After 3 months	1.75	0.71	1 – 3	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



In this study, the average VAS score prior to surgery was 8.0 ± 0.76 (range: 7-9), which reduced to 4.63 ± 0.74 (range: 4-6) immediately post-surgery, 3.25 ± 0.71 (range: 2-4) after 1 month of surgery, which further decreased to 1.75 ± 0.71 (range: 1-3) 3

months postoperatively. The one-way ANOVA test revealed a statistically significant difference in the VAS score among the different time points.

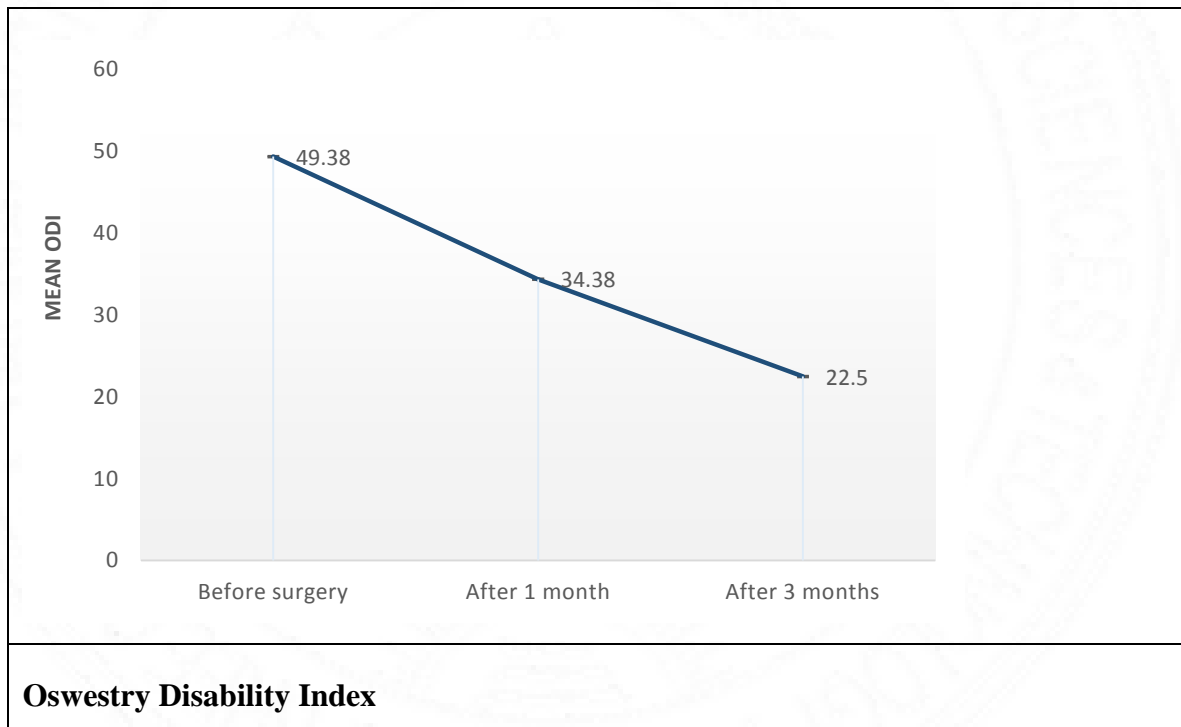
Also 2 of the patients in our study showed improvement in paresthesia in the immediate post operative period and also on 1 and 3 month follow up.

- **Oswestry Disability Index (ODI)**

Table 15: Oswestry Disability Index

Oswestry Disability Index	Mean	SD	Range	p-value*
Before surgery	49.38	4.44	42 – 55	<0.0001
After 1 month	34.38	4.31	29 – 42	
After 3 months	22.50	2.62	19 - 27	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



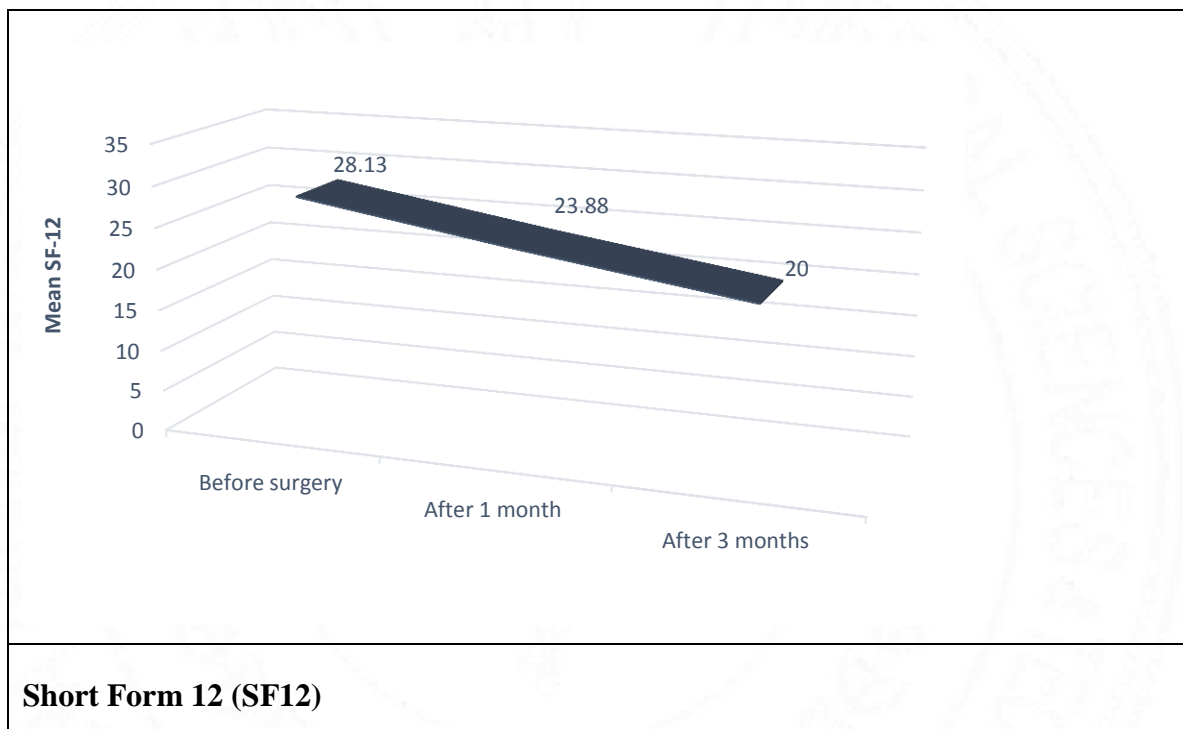
In the this study, the average ODI before surgery was 49.38 ± 4.44 (range: 42-55); it reduced to 34.38 ± 4.31 (range: 29-42) one month after surgery, which further decreased to 22.50 ± 2.62 (range: 19-27) three months post-surgery. The one-way ANOVA test demonstrated a statistically significant difference ($p < 0.0001$) in the ODI at various points in time.

- **Short Form 12 (health survey) (SF12)**

Table 16: Short Form 12 (health survey) (SF12)

SF12	Mean	SD	Range	p-value*
Before surgery	28.13	2.23	23 – 30	<0.0001
After 1 month	23.88	1.55	21 – 26	
After 3 months	20.0	1.51	17 – 22	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



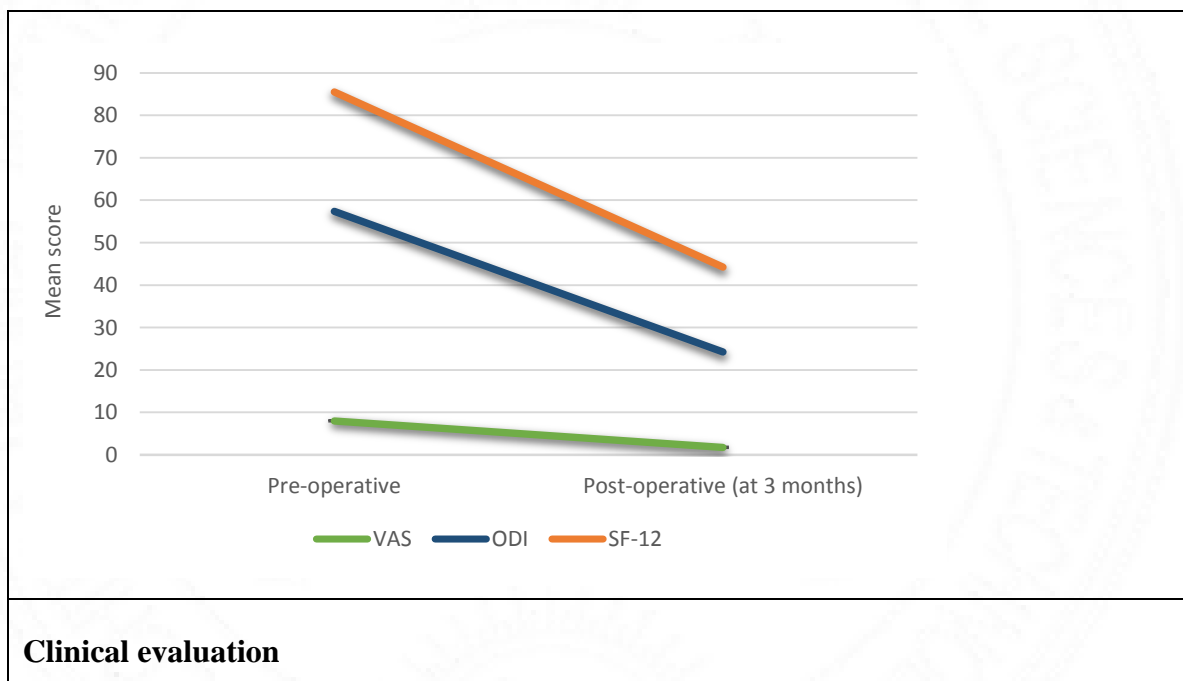
In the current study, the average SF-12 score before surgery was 28.13 ± 2.23 (range: 23-30) that decreased to 23.88 ± 1.55 (range: 21-26) one month after surgery, which further reduced to 20.0 ± 1.51 (range: 17-22) three months post-surgery. The one-way ANOVA test demonstrated a statistically significant difference ($p < 0.0001$) in the SF-12 scores at various points in time.

- **Clinical evaluation**

Table 17 : Clinical evaluation using VAS ODI and SF12

Parameter	Pre-operative	Post-operative (at 3 months)	p-value*
VAS	8.0 ± 0.76	1.75 ± 0.71	<0.0001
ODI	49.38 ± 4.44	22.50 ± 2.62	<0.0001
SF-12	28.13 ± 2.23	20.0 ± 1.51	<0.0001

*Calculated using the paired t-test. P<0.05 considered statistically significant.

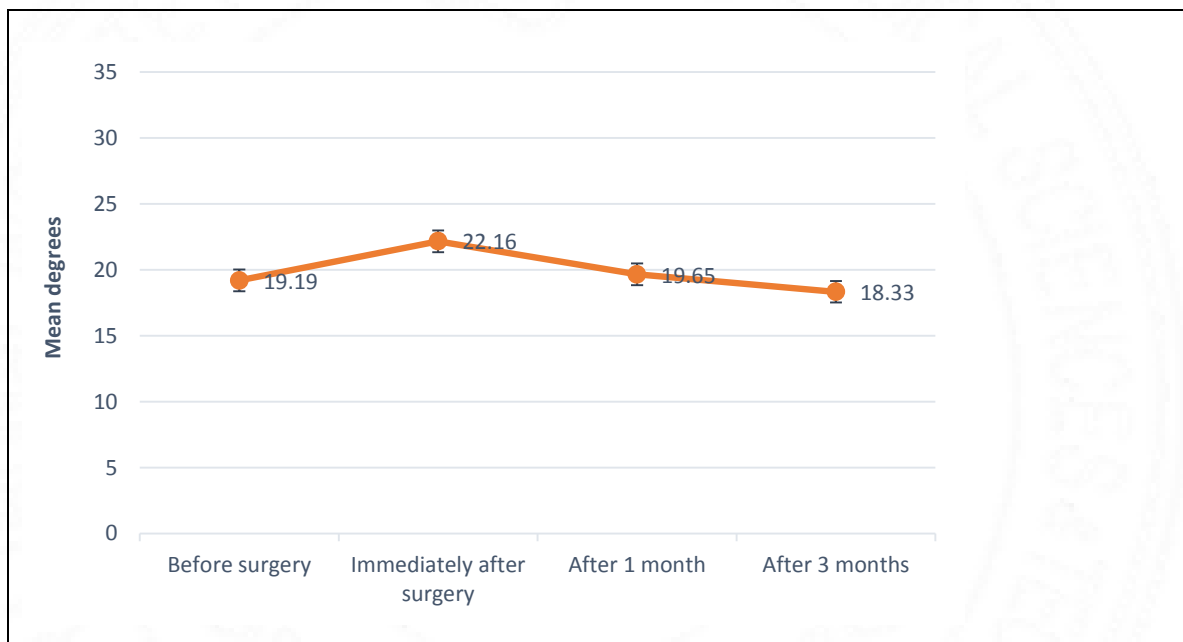


- Pelvic Tilt (PT)

Table 18: Pelvic Tilt

Pelvic Tilt	Mean	SD	Range	p-value*
Before surgery	19.19	6.33	8.8 – 31.2	0.5134
Immediately after surgery	22.16	6.28	13.10 – 33.0	
After 1 month	19.65	4.85	15 – 28.3	
After 3 months	18.33	2.82	14.1 – 22.3	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



Pelvic Tilt

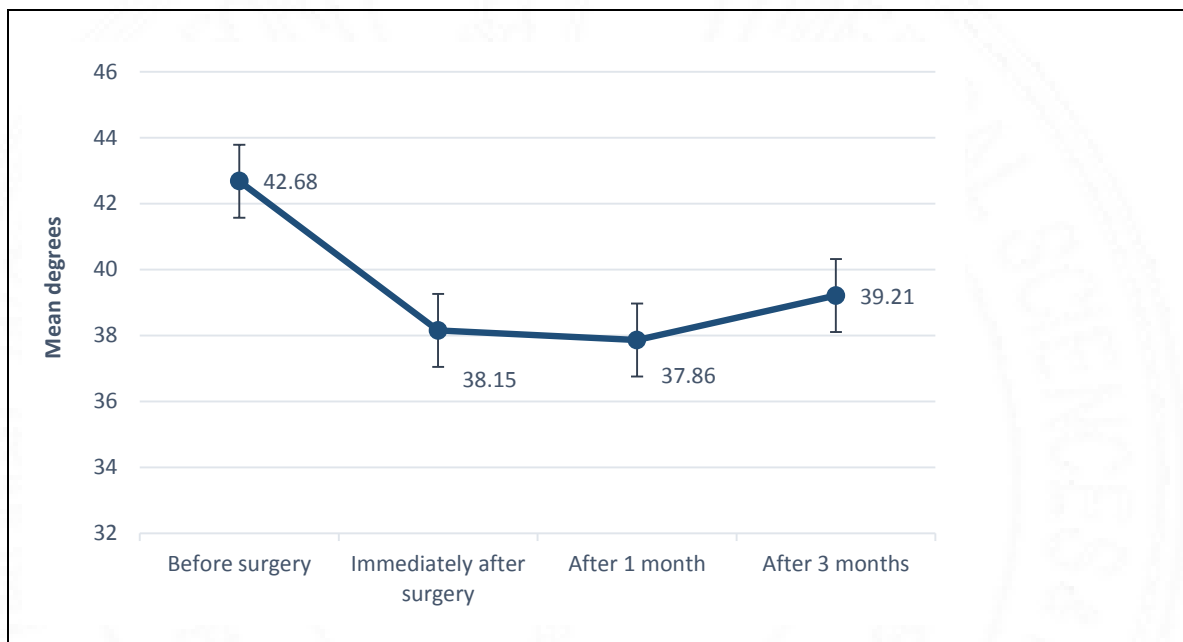
In this study, the average pelvic tilt prior to surgery was $19.19^{\circ} \pm 6.33^{\circ}$ (range: 8.8° - 31.2°), $22.16^{\circ} \pm 6.28^{\circ}$ (range: 13.1° - 33°) immediately after surgery, $19.65^{\circ} \pm 4.85^{\circ}$ (range: 15° - 28.3°) one month after surgery, and $18.33^{\circ} \pm 2.82^{\circ}$ (range: 14.1° - 22.3°) three months post-surgery. The one-way ANOVA test demonstrated no significant difference ($p=0.5134$) in the angle of pelvic tilt between the different time points.

- Sacral slope (SS)

Table 19: Sacral Slop (SS)

Sacral slope	Mean	SD	Range	p-value*
Before surgery	42.68	9.43	30.1 – 57.3	0.4226
Immediately after surgery	38.15	4.39	30.6 – 45.5	
After 1 month	37.86	5.52	29.5 – 47.1	
After 3 months	39.21	4.82	28.7 – 45.4	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



Sacral slope

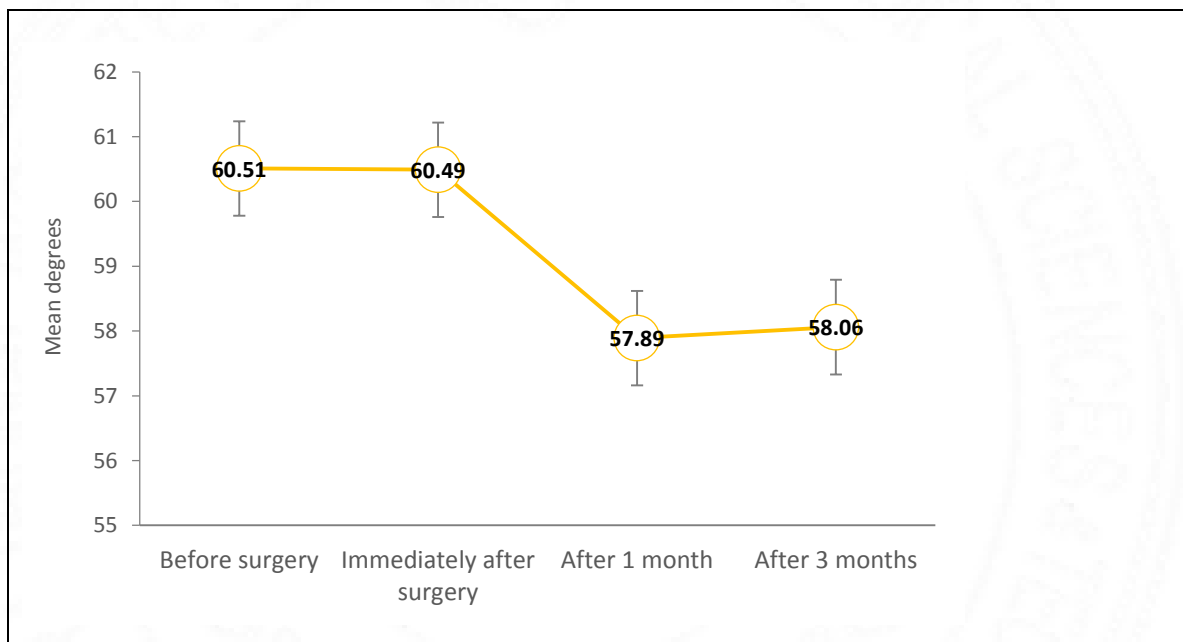
In this study, the average sacral slope prior to surgery was $42.68^{\circ} \pm 9.43^{\circ}$ (range: $30.1^{\circ} - 57.3^{\circ}$), $38.15^{\circ} \pm 4.39^{\circ}$ (range: $30.6^{\circ} - 45.5^{\circ}$) immediately after surgery, $37.86^{\circ} \pm 5.52^{\circ}$ (range: $29.5^{\circ} - 47.1^{\circ}$) one month after surgery, and $39.21^{\circ} \pm 4.82^{\circ}$ (range: $28.7^{\circ} - 45.4^{\circ}$) three months post-surgery. The one-way ANOVA test demonstrated no significant difference ($p=0.4226$) in the angle of sacral slope between the different time points.

- Pelvic incidence (PI)

Table 20: Pelvic incidence (PI)

Pelvic incidence	Mean	SD	Range	p-value*
Before surgery	60.51	10.36	41 – 75.4	0.8191
Immediately after surgery	60.49	7.45	50.1 – 69.5	
After 1 month	57.89	5.68	48.8 – 65.2	
After 3 months	58.06	5.10	48.3 – 64.5	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



Pelvic Incidence

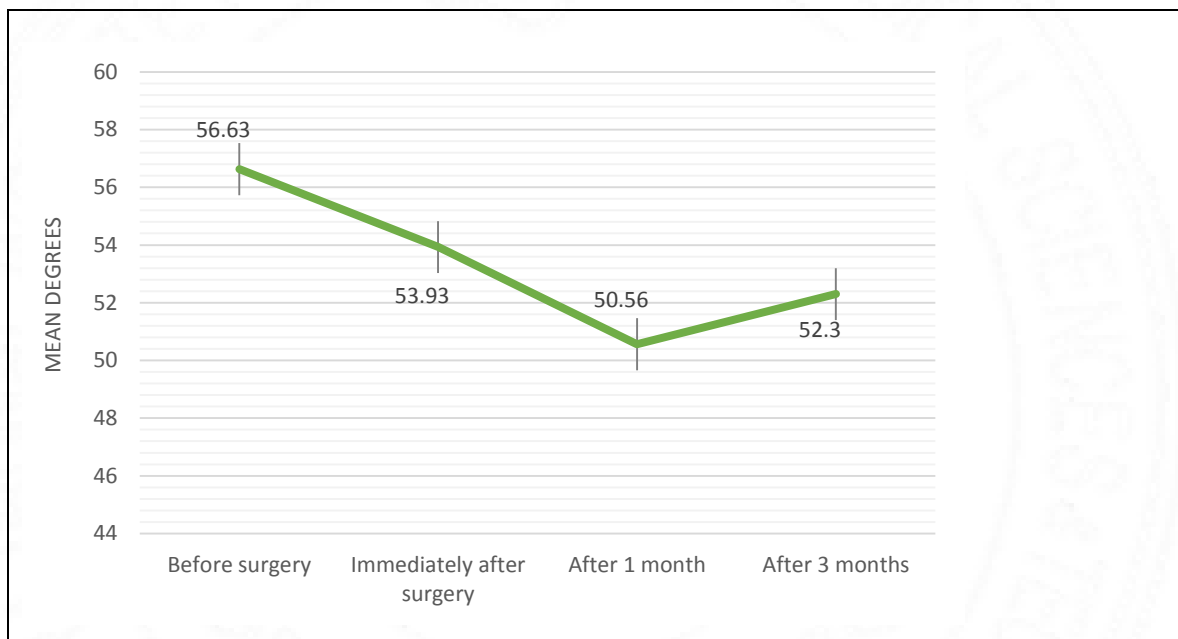
In present study, the average PI prior to surgery was $60.51^{\circ} \pm 10.36^{\circ}$ (range: 41° - 75.4°), $60.49^{\circ} \pm 7.45^{\circ}$ (range: 50.1° - 69.5°) immediately after surgery, $57.89^{\circ} \pm 5.68^{\circ}$ (range: 48.8° - 65.2°) one month after surgery, and $58.06^{\circ} \pm 5.10^{\circ}$ (range: 48.3° - 64.5°) three months post-surgery. The one-way ANOVA test demonstrated no significant difference statistically ($p=0.8191$) in the angle of pelvic incidence between different points in time.

- Lumbar lordosis (LL)

Table 21: Lumbar lordosis (LL)

Lumbar lordosis	Mean	SD	Range	p-value*
Before surgery	56.63	9.87	39.1 – 65.9	0.5948
Immediately after surgery	53.93	9.08	36.5 – 64.0	
After 1 month	50.56	8.58	39.2 – 66.9	
After 3 months	52.30	8.83	39.2 – 69.9	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



Lumbar lordosis

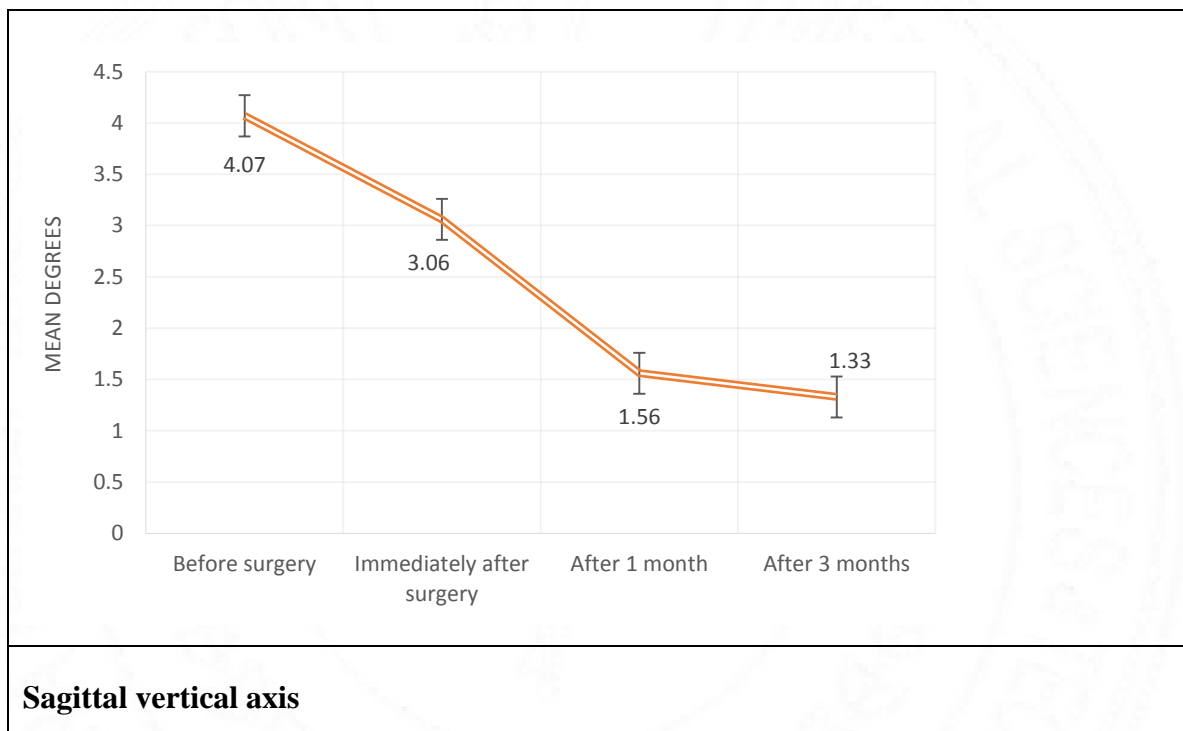
In present study, the average lumbar lordosis before surgery was $56.63^{\circ} \pm 9.87^{\circ}$ (range: $39.1^{\circ} - 65.9^{\circ}$), $53.93^{\circ} \pm 9.08^{\circ}$ (range: $36.5^{\circ} - 64^{\circ}$) immediately after surgery, $50.56^{\circ} \pm 8.58^{\circ}$ (range: $39.2^{\circ} - 66.9^{\circ}$) one month after surgery, and $52.30^{\circ} \pm 8.83^{\circ}$ (range: $39.2^{\circ} - 69.9^{\circ}$) three months post-surgery. The one-way ANOVA test demonstrated no significant difference statistically ($p=0.5948$) in the lumbar lordosis angle between different points in time.

- **Sagittal vertical axis (SVA)**

Table 22: Sagittal vertical axis (SVA)

Sagittal vertical axis	Mean	SD	Range	p-value*
Before surgery	4.07	3.56	0.97 – 11.9	0.1979
Immediately after surgery	3.06	3.78	0.4 – 11.56	
After 1 month	1.56	1.89	0.3 – 6.11	
After 3 months	1.33	1.37	0.3 – 4.5	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



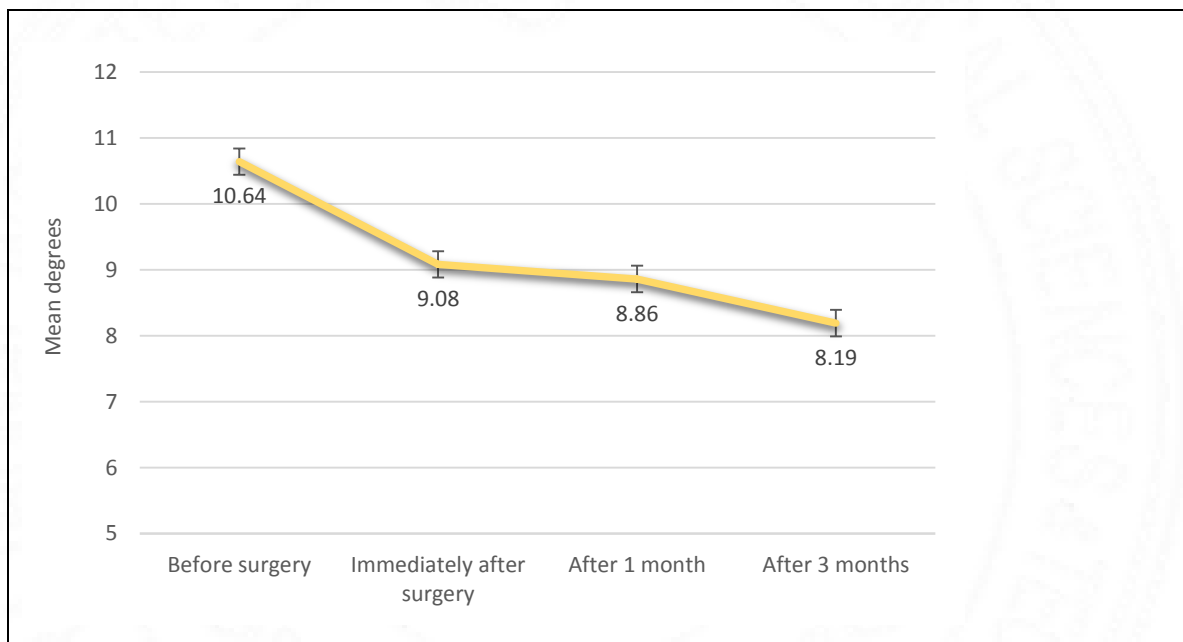
In present study, the average sagittal vertical axis before surgery was $4.07^\circ \pm 3.56^\circ$ (range: $0.97^\circ - 11.9^\circ$), $3.06^\circ \pm 3.78^\circ$ (range: $0.4^\circ - 11.56^\circ$) immediately after surgery, $1.56^\circ \pm 1.89^\circ$ (range: $0.3^\circ - 6.11^\circ$) one month after surgery, and $1.33^\circ \pm 1.37^\circ$ (range: $0.3^\circ - 4.5^\circ$) three months post-surgery. The one-way ANOVA test demonstrated no significant difference statistically ($p=0.1979$) in the sagittal vertical axis between different points in time.

- **PI-LL difference**

Table 23: PI-LL difference

PI-LL difference	Mean	SD	Range	p-value*
Before surgery	10.64	6.84	1.4 – 19.8	0.7386
Immediately after surgery	9.08	4.45	1.8 – 15.3	
After 1 month	8.86	2.72	6.1 – 14.5	
After 3 months	8.19	2.71	3.6 – 12.5	

*Calculated using the One-Way ANOVA Test. P<0.05 considered statistically significant.



PI-LL difference

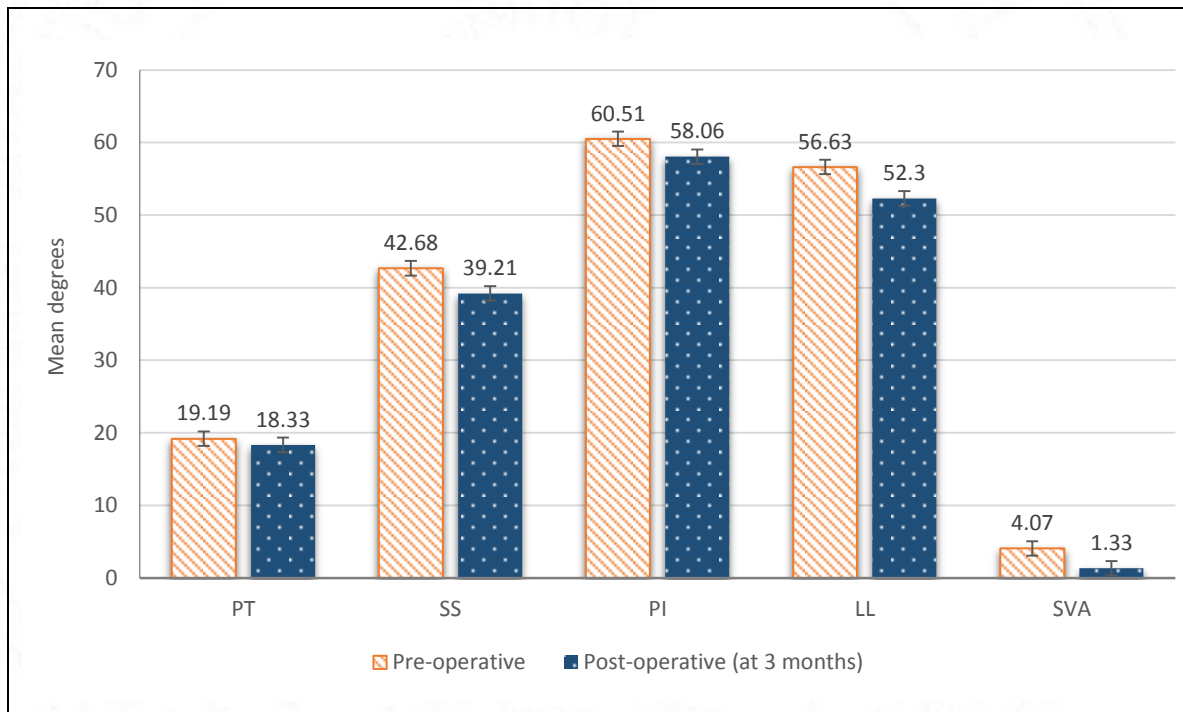
In our study, the average PI-LL difference before surgery was $10.64^{\circ} \pm 6.84^{\circ}$ (range: $1.4^{\circ} - 19.8^{\circ}$), $9.08^{\circ} \pm 4.45^{\circ}$ (range: $1.8^{\circ} - 15.3^{\circ}$) immediately after surgery, $8.86^{\circ} \pm 2.72^{\circ}$ (range: $6.1^{\circ} - 14.5^{\circ}$) one month after surgery, and $8.19^{\circ} \pm 2.71^{\circ}$ (range: $3.6^{\circ} - 12.5^{\circ}$) three months after surgery. The one-way ANOVA test demonstrated no significant difference statistically ($p=0.7386$) in the PI-LL difference between different points in time.

- Comparison of all spinal balance parameters

Table 24: Comparison of all spinal balance parameters

Parameter	Pre-operative	Post-operative (at 3 months)	p-value*
PT	19.19° ± 6.33°	18.33° ± 2.82°	0.5762
SS	42.68° ± 9.43°	39.21° ± 4.82°	0.3244
PI	60.51° ± 10.36°	58.06° ± 5.10°	0.4456
LL	56.63° ± 9.87°	52.30° ± 8.83°	0.1866
SVA	4.07° ± 3.56°	1.33° ± 1.37°	0.1244

*Calculated using the paired t-test. P<0.05 considered statistically significant.

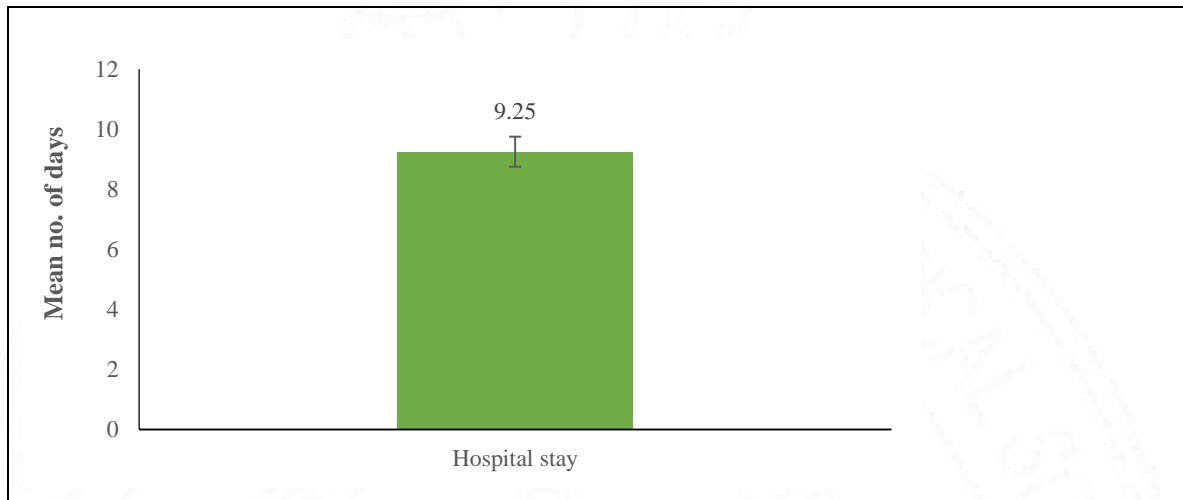


Comparison of all spinal balance parameters

- **Hospital stay**

Table 25: Hospital Stay

	Mean	SD	Range
Hospital stay (in days)	9.25	2.49	6 – 14



Hospital stay

The average hospital stay of our study patients was 9.25 ± 2.49 mL, and ranged between 6 days and 14 days.

There were no complications during or immediate after surgery and also during 1 month and 3 months follow up period. None of our patients (100%; 8/8) needed any revision surgery.

Figure 17: Pre and postoperative lateral neutral X ray lumbosacral spine

Preoperative X ray



Post operative X ray



DISCUSSION

Various techniques for fusion of lumbar spine have been reported over the past 90 years. The trend has been changed from fusion without instrumentation to the use of one of following viz. Metallic cages, carbon fiber cage, autograft, allograft, bone morphogenic protein and supplemental instrumentation. Lumbar fusion is generally offered after a trial of conservative treatment or failure of non surgical treatment. TLIF is a commonly done operative procedure for lumbar fusion especially patients suffering from unilateral symptoms.

In our study, all patients had a low grade spondylolisthesis i.e. grade 1 (Meyerding classification³⁹). Studies have shown a good radiological and clinical outcome in symptomatic low grade spondylolisthesis with transforaminal lumbar interbody fusion⁹⁶⁻⁹⁹. However, we couldn't find any study which looked at outcomes of TLIF in patients with a grade 1 spondylolisthesis only, which is most common grade of spondylolisthesis (75%).¹⁰⁰ In a study on 3990 chinese patients, Lai-Chang He¹⁰¹ et al found the most common grade prevalent among the population was grade 1.

In our study, we had only two types pathologies, one being degenerative spondylolisthesis (type 3) and the other isthmic spondylolisthesis (type 2) (Wiltse classification³⁷). Out of 8 cases 37.5% cases were isthmic spondylolisthesis and 62.5% cases were degenerative spondylolisthesis. In a study by Keyvan Eghbal et al⁹⁶ 58% of the patients were operated for degenerative spondylolisthesis and 42% patients were operated for Isthmic spondylolisthesis. In another study by Raship Khan et al¹⁰² 60% of the patients were operated for degenerative spondylolisthesis and 40% patients for Isthmic spondylolisthesis.

Out of 8 patients in our study, we had 12.50% males and 87.50% females and average age of patients 51.40 years. Keyvan Eghbal et al⁹⁶ in their patient population found 16 % males while 84% were female. The mean age in their study was 54.1 years. Female preponderance in spondylolisthesis was also found in a study done by Ramdas Maloth et al.¹⁰³

Average BMI in our study was 30.08 with a standard deviation of 3.59. In study by Mourad Ould-Slimane et al³¹ the average BMI was 27 ± 3.6 , while Gregor Recnik et al⁹⁴ in their study found the average BMI was 27.9 ± 4.1 .

50% patients underwent TLIF at L4-L5 while the rest had it at L5-S1 level. In a study done by Gregor Recnik et al⁹⁴, 43.75% patients underwent TLIF at L4-L5 level and 37.5% patients underwent TLIF at L5-S1 level. In a study by Mourad Ould-Slimane et al³¹ 62% patients underwent TLIF at L4-L5 level and 20% at L5-S1 levels. The commonest pathology in both these studies was degenerative spondylolisthesis. This was similarly to our study where 4 out of 5 patient with degenerative spondylolisthesis underwent surgery at L4-L5, which is most common level involved in degenerative spondylolisthesis¹⁰⁴. The most common level involved in isthmic spondylolisthesis is L5-S1 level^{100,105}. All patients with isthmic type of spondylolisthesis in our study had a listhesis at L5-S1 level.

In our study, amongst patients undergoing TLIF, 50% patients had hypertension, 37.5% patients had diabetes mellitus, 25% patients had dyslipidaemia, 12.5% patients had hypothyroidism and no patient had osteoporosis on a DEXA scan. According to meta-analysis by M. Formica et al¹⁰⁶, preoperative assessment of patient related risk factors like osteoporosis, diabetes mellitus, obesity, smoking was critical as these factors directly contributed to increasing rates of non union. In our study average BMI of all patients is 30.08. 37.5% patients were also diabetic. Thus these patients would require a long term follow up and also suggestions for life style modification for better post operative outcomes.

All patients in our study had low back ache, 75% patients had unilateral radicular pain and 37% patients had neurological deficit in terms of unilateral lower limb paresthesia, these findings are comparable with finding of study by Hamid Reza Abdollahpour et al⁹⁶ in which majority of patients that is 92% had back ache, 86% patients had radicular pain and 10% patients had neurological deficit. Also study by C Joney Mandice et al¹⁰² there was 100% patients had low backache and 30% patients had sensory deficits which is comparable with our study.

In our study, there was no significant change in the spinopelvic parameters postoperatively at 3 months compared to preoperative measurements. In study by Brice Ilharreborde et al³¹ only PT and LL significantly improved post operatively while SVA, PI and SS did not significantly change postoperatively. In study by Keyvan Eghbal et al⁹⁶, only lumbar lordosis changed significantly, all other parameters not significantly changed.

Mean PI-LL (difference of pelvic incidence and lumbar lordosis) in our study was 10.64 preoperatively which decreased to 8.19 postoperatively. Yasuchika Aoki et al¹⁰⁷ studied influence of PI-LL mismatch on surgical outcomes of short-segment transforaminal lumbar interbody fusion and suggested that efforts should be made to reduce PI-LL to 10° or less whenever feasible. In study by Schwab et al³⁴ advised simple formula of “LL= PI ±

9°” based on study of lumbar lordosis and pelvic incidence relationship. In our study mean PI-LL is 8.19 in follow up which is comparable with these studies.

50% of our patient had insignificant postvoid residual urine that is less than 30 ml. According to Anastasios D. Asimakopoulos et al¹⁰⁸ currently there is no universally accepted definition of a significant residual urine volume. For clinical practice, PVR <30 ml can be considered insignificant.

In this study, blood transfusion was not needed in any patient. The average intraoperative blood loss of our study patients was 437.5 (range: 300-550 mL). In prospective study by Yang, E., Xu, J. Liu, X. et al¹⁰⁹ average blood loss in TLIF procedure is 432.5 ml and there was no requirement of blood transfusion in most of the patients which is similar to our study. In the study by Mourad Ould-Slimane³¹, average blood loss was 570 (±360) mL and no blood transfusion was necessary. These results are comparable with our study.

Average operative time in our study was 147.5 minutes which is comparable with other studies. In studies by Mourad Ould-Slimane³¹ and Yang et al¹⁰⁹, average operative time was 124 (±37) minutes and 90-160 minutes respectively.

In our study, the average hospital stay was 9.25 days which is comparable with a study by Hwee Weng Dennis Hey et al¹¹⁰ where range of hospital stay was 5-11 days. In a meta-analysis by Ahmed Hammad et al¹¹¹ the hospital stay in open TLIF ranged from 3-19 days with a mean of 6.92 days in 25 different studies, which is comparable to our study.

Leg and back pain measured by VAS along with ODI and SF 12 were significantly improved in our study. This findings correlates with others studies. In study done by Hamid Reza Abdollahpour et al⁹⁶, there was decrease in VAS and ODI with significant p value like in our study. Also in comparative study done by Scott L. Parker et al¹¹², there was decrease in VAS, ODI and SF12 with significant p value (<0.001). Also in meta analysis by Ahmed Hammad et al¹¹¹ mean VAS score at follow up was 2.88 and mean ODI at follow up was 20.62 which is also comparable with our study findings.

In spite of no significant change in spinal balance parameters there was clinical and quality of life parameters. This would be due to subtle changes in spinopelvic parameters. We found pelvic tilt in our patients largely unchanged after surgery. Interestingly in our patients there was minimal improvement the SS postoperatively which then translated into an incremental improvement in pelvic incidence. This reduction in pelvic incidence lead to a further reduction in the SVA. While the SVA in our patient subset was normal to begin with, the final SVA was only within 1.33cm. We believe that in addition to the intraspinal space created by decompression, discectomy, foraminotomy and amenable increase in disc height due to insertion of a cage, decrease in SVA too has contributed to improvement in overall quality of life parameters.

Limitations of study:

- Patients with grade 1 spondylolisthesis only.
- Follow period was 3 months only. Most studies have included those with at least 2 years. Long term follow up required generally to evaluate adjacent segment disease, pseudoarthrosis and implant stability.
- Fusion status and fusion rate were not examined in this study. Post operative thin cut CT is required to see fusion rate that was not done in the follow period in our study.
- Required number of 10 patients set out in the proposal could not be achieved due to the COVID 19 pandemics.

Conclusion

- Spondylolisthesis is more common in the 4th & 5th decade of life with female predominance, the commonest level of instability being L4-L5 in case of degenerative spondylolisthesis and L5-S1 in case of isthmic spondylolisthesis.
- Obesity was the most common risk factor for spondylolisthesis requiring fusion procedure like TLIF which is done especially in cases with predominantly unilateral symptoms.
- Most of the patients undergoing surgery will have comorbidities which should be managed to avoid complications postoperatively.
- Significant improvement was seen clinically in terms of VAS for back and leg pain and functionally in terms of ODI and SF12 scores after TLIF procedures for spondylolisthesis.
- Measurement of sagittal spinal balance parameters is mandatory before any fusion procedure preoperatively and postoperatively to predict outcome and decide management plan according to that.
- In most case of grade 1 spondylolisthesis, there is only a minimal imbalance of the sagittal spinal balance parameters and so in situ fusion can be done.
- Even if a complete reduction of spondylolisthesis was not achieved during surgery, there was correction of a few of the parameters of spinal balance which were deranged preoperatively. Improvement in Quality of life could be due to both improvement in spinal balance and reduced abnormal mobility at respective level.

Overall TLIF is very good procedure in terms of improvement in clinical and functional parameters in grade 1 spondylolisthesis.

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ANNEXURE

PATIENT PROFORMA

Sree Chitra Tirunal Institute for Medical Sciences & Technology

“Prospective study of transforaminal lumbar interbody fusion”

A. General information

- Hospital ID
- Age
- Gender
- Co-morbidities
- Height
- Weight
- Body mass index

B. Preoperative Clinical details and Sagittal balance parameters

- Symptoms at presentation :
- Pathological type of spondylolisthesis
- Grade of spondylolisthesis (Meyerding classification)
- Post void urine residue
- Visual analogue score:
- Oswestry disability index:
- SF-12 score:
- Pelvic tilt:

- Sacral slope :
- Pelvic incidence:
- Lumbar lordosis :
- Sagittal vertical axis :
- Pelvic incidence-lumbar lordosis difference:
- Pelvic tilt + Sacral slope

C. Intraoperative details

- Type of surgery
- Type of cage
- Operative time
- Blood loss
- Blood transfusions required
- Intraoperative complications

D. Immediate postoperative details (Before Discharge)

- Visual analogue score:
- Pelvic tilt:
- Sacral slope :
- Pelvic incidence:
- Lumbar lordosis :
- Sagittal vertical axis :
- Pelvic incidence

- lumbar lordosis difference:
- Pelvic tilt + Sacral slope
- Any complications :
- Improvement in VAS: yes/no
- Improvement in ODI: yes/no
- Improvement in SF-12: yes/no
- Correction of spinal parameters: yes/no
- Hospital stay

E. STATUS ON FOLLOW UP ON 1 MONTHS

- Visual analogue score:
- Oswestry disability index:
- SF-12 score:
- Pelvic tilt:
- Sacral slope :
- Pelvic incidence:
- Lumbar lordosis :
- Sagittal vertical axis :
- Pelvic incidence-lumbar lordosis difference:
- Pelvic tilt + Sacral slope
- Any complications :
- Improvement in VAS: yes/no

- Improvement in ODI: yes/no
- Improvement in SF-12: yes/no
- Correction of spinal parameters: yes/no

F. STATUS ON FOLLOW UP ON 3 MONTHS

- Visual analogue score:
- Oswestry disability index:
- SF-12 score:
- Pelvic tilt:
- Sacral slope :
- Pelvic incidence:
- Lumbar lordosis :
- Sagittal vertical axis :
- Pelvic incidence-lumbar lordosis difference:
- Pelvic tilt + Sacral slope
- Any complications :
- Improvement in VAS: yes/no
- Improvement in ODI: yes/no
- Improvement in SF-12: yes/no
- Correction of spinal parameters: yes/no
- Revision surgery required: yes/no

Informed consent

Hospital Number: _____ **Participant's name:** _____ **Age:** _____

Mr./Mrs./Miss. _____ son/daughter/husband/wife, ____ of _____ suffering from _____ has been planned for _____ after personally verifying and discussing the data obtained from your clinical history, examination and imaging. You have also expressed your willing for surgical management of your disease condition.

What if you consent for the trial?

You will undergo the surgery for your lumbar spinal region (lower back) pathology. You will be assessed at admission, intraoperatively, immediate postoperatively and at 1 month and 3 months postoperative follow up as detailed in the patient information sheet. If you have any further questions, please ask **Dr. Ninad Anand Sawant, Senior Resident, Department of Neurosurgery, SCTIMST (Ph: 9892408495, Email: ninad.sawant321@gmail.com).**

What if you do not consent for the trial?

Even if you do not consent for this study, you will undergo surgery as usual without any change in the timing or plan of surgery you were supposed to undergo.

I _____, _____ of _____ declare that

I have read the above information provide to me regarding the study: **“Prospective study**

of transforaminal lumbar interbody fusion” and have clarified any doubts that I had.

I also understand that my participation in this study is entirely voluntary. I am free to withdraw permission to participate at any time without affecting my usual treatment/ legal rights

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree for this access

I understand that my identity will not be revealed in any information released to third parties or published

I voluntarily agree to take part in this study

Patient's name & sign

Witness's name & sign

Date

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him/ her in nontechnical terms all of the information contained in this informed consent, including any risks and adverse reactions that may reasonably be expected. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Name and Signature of Person Obtaining Consent

വിവരം ബോധ്യപ്പെടുള്ള സമ്മതം

ഹോസ്പിറ്റൽ നമ്പർ: _____ പങ്കാളിയുടെ പേര്: _____ വയസ്സ്: _____

നിങ്ങളുടെ ക്ലിനിക്കൽ ചരിത്രം, പരിശോധന, ഇമേജിംഗ് എന്നിവയിൽ നിന്ന് കരസ്ഥമാക്കിയ ഡാറ്റാ വ്യക്തിപരമായി പരിശോധിക്കുകയും ചർച്ച ചെയ്യുകയും ചെയ്ത ശേഷം, _____ മൂലം പ്രയാസപ്പെടുന്ന _____ എന്റെ _____ (മകൻ/ മകൾ/ ഒർത്താവ്/ഭാര്യ/ അച്ഛൻ/ അമ്മ) ശ്രീ / ശ്രീമതി / കുമാരി _____ ചെയ്യാൻ പദ്ധതിയിട്ടിരിക്കുകയാണ്.

നിങ്ങളുടെ രോഗാവസ്ഥയുടെ ശസ്ത്രക്രിയാ മാനേജ്മെന്റിനുള്ള നിങ്ങളുടെ സന്നദ്ധത നിങ്ങൾ പ്രകടിപ്പിക്കുകയും ചെയ്തിട്ടുണ്ട്.

ട്രെയിൻ നിങ്ങൾ സമ്മതിച്ചാൽ എന്താവാം?

നിങ്ങൾ പിനിയൽ റീജിയൻ ട്രൂമറിനുള്ള ശസ്ത്രക്രിയയ്ക്ക് വിധേയമാകുന്നതാണ്. രോഗിക്കുള്ള വിവര പുതികയിൽ വിശദീകരിച്ചിട്ടുള്ളതു പോലെ നിങ്ങളെ പ്രാവശ്യത്തിലും, ശസ്ത്രക്രിയാ വേളയിലും, ശസ്ത്രക്രിയാ കഴിഞ്ഞ ഉടനെയും, ശസ്ത്രക്രിയാനന്തര തുടരവേഷണത്തിന്റെ 3-6 മാസങ്ങളിലും നിങ്ങളെ വിലയിരുത്തുന്നതാണ്. നിങ്ങൾക്ക് കൂടുതൽ എന്തെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ, ദയവായി ഡോ. നിനാദ് ആന്റ് സാവന്ത്, സീനിയർ റെസിഡന്റ്, ഡിഫർട്ട്മെന്റ് ഓഫ് ന്യൂറോസർജറി, എസ്.സി.ടി.ഐ.എം.എസ്.ടി. (ഫോ: 9892408495, ഇമെയിൽ: ninad.sawant321@gmail.com) യോട് ചോദിക്കുക.

ട്രെയിൻ നിങ്ങൾ സമ്മതിക്കുന്നില്ലെങ്കിൽ എന്താവാം?

ഈ പാനത്തിന് നിങ്ങൾ സമ്മതിച്ചില്ലെങ്കിൽ പോലും, നിങ്ങൾ വിധേയമാകുമെന്ന് പ്രതീക്ഷിക്കപ്പെട്ടിരിക്കുന്ന ശസ്ത്രക്രിയയുടെ സമയത്തിലോ പദ്ധതിയിലോ ഒരു വ്യത്യാസവും കൂടാതെ സാധാരണഗതിയിൽ നിങ്ങൾ വിധേയമാകുന്നതാണ്.

_____ നിന്നുള്ള _____ എന്ന ഞാൻ ചുവടെ പറയും പ്രകാരം പ്രസ്താവിക്കുന്നു

- [] “ട്രാൻസ്ഫോറമിനൽ ലുംബാർ ഇന്റർബോഡി ഫ്യൂഷന്റെ ഗുണപ്രതീക്ഷയുള്ള പാനം” എന്ന പാനത്തെ സംബന്ധിച്ച് എനിക്ക് പ്രദാനം ചെയ്ത മുകളിൽ നൽകിയിരിക്കുന്ന വിവരങ്ങൾ ഞാൻ വായിക്കുകയും എനിക്കുണ്ടായിരുന്ന ഏത് സംശയങ്ങളും നിവൃത്തിക്കുകയും ചെയ്തു.
- [] ഈ പാനത്തിലെ എന്റെ പങ്കാളിത്തം പൂർണ്ണമായും സാമയധാർമ്മ്യമാണ് എന്നു ഞാൻ മനസ്സിലാക്കുന്നു. പങ്കെടുക്കുന്നതിനുള്ള അനുമതി ഏത് സമയത്തും, എന്റെ പതിവ് ചികിത്സയെ/ നിയമപരമായ അവകാശങ്ങളെ ബാധിക്കാതെയും പിൻവലിക്കുന്നതിന് എനിക്ക് സ്വാതന്ത്ര്യമുണ്ട്.
- [] ട്രെയിനിൽ നിന്ന് ഞാൻ പിന്മാറാൻ പോലും എന്റെ ആരോഗ്യ രേഖകൾ പരിശോധിക്കുന്നതിന് പാന സ്റ്റാഫിനും ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ സമ്മതം ആവശ്യമില്ല എന്നു ഞാൻ മനസ്സിലാക്കുന്നു. ഈ പ്രാപ്യതയ്ക്ക് ഞാൻ സമ്മതിക്കുന്നു.

[] മൂന്നാം കക്ഷികൾക്ക് പ്രകാശനം ചെയ്യുന്നതോ പ്രസിദ്ധീകരിക്കുന്നതോ ആയ ഒരു വിവരങ്ങളിലും എന്റെ വ്യക്തിത്വം വെളിപ്പെടുത്തുന്നതല്ല എന്നു ഞാൻ മനസ്സിലാക്കുന്നു.

[] ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് ഞാൻ സാമേയയാ സമ്മതിക്കുന്നു.

രോഗിയുടെ പേരും ഒപ്പും

രോഗിയുടെ പേരും ഒപ്പും

തീയതി

ഈ പത്രത്തിൽ വിശദീകരിച്ചിരിക്കുന്ന വൈദ്യ ഗവേഷണ പ്രോജക്ടിനുള്ള വിവരം ബോധ്യപ്പെടുള്ള സമ്മതത്തിനുള്ള ആവശ്യകതകൾ പൂർത്തീകരിച്ചിട്ടുണ്ട് എന്നു ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു. ഗവേഷണ പ്രോജക്ട് ഞാൻ പങ്കാളിയുമായി ചർച്ച ചെയ്തുകയും, ന്യായമായും പ്രതീക്ഷിക്കാവുന്ന ഏത് അപകടസാധ്യതകളും പ്രതികൂല പ്രതിപ്രവർത്തനങ്ങളും ഉൾപ്പെടെ ഈ വിവരം ബോധ്യപ്പെടുള്ള സമ്മതപത്രത്തിൽ അടങ്ങിയിരിക്കുന്ന എല്ലാ വിവരങ്ങളും സാങ്കേതികമല്ലാത്ത പദങ്ങളിൽ അദ്ദേഹത്തിന്/അവർക്ക് വിശദീകരിച്ചു നൽകുകയും ചെയ്തു. ചോദ്യങ്ങൾ ചോദിക്കാൻ പങ്കാളിയെ ഞാൻ പ്രോത്സാഹിപ്പിച്ചു എന്നും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകി എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതം കരസ്ഥമാക്കുന്ന വ്യക്തിയുടെ പേരും ഒപ്പും

Questionnaire

1) Oswestry Low Back Pain Disability Questionnaire

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

SECTION 1 - PAIN INTENSITY

- I can tolerate the pain I have without having to use painkillers.
- The pain is bad but I manage without taking painkillers.
- Painkillers give complete relief from pain.
- Painkillers give moderate relief from pain.
- Painkillers give very little relief from pain.
- Painkillers have no effect on the pain and I do not use them.

SECTION 2 - PERSONAL CARE (washing, dressing etc.)

- I can look after myself normally, without causing extra pain.
- I can look after myself normally, but it causes extra pain.
- It is painful to look after myself and I am slow and careful.
- I need some help, but manage most of my personal care.
- I need help every day in most aspects of self-care.
- I do not get dressed, wash with difficulty and stay in bed.

SECTION 3 - LIFTING

- I can lift heavy weights without extra pain.
- I can lift heavy weights, but it gives extra pain.
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned (e.g., on a table).
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- I can lift only very light weights.
- I cannot lift or carry anything at all.

SECTION 4 - WALKING

- Pain does not prevent my walking any distance.
- Pain prevents me walking more than 1 mile.
- Pain prevents me walking more than ½ of mile.
- Pain prevents me walking more than ¼ mile.
- I can only walk using a stick or crutches.
- I am in bed most of the time and have to crawl to the toilet.

SECTION 5 - SITTING

- I can sit in any chair as long as I like.
- I can sit in my favourite chair as long as I like.
- Pain prevents me sitting more than 1 hour.
- Pain prevents me from sitting more than ½ an hour.
- Pain prevents me from sitting more than 10 minutes.
- Pain prevents me from sitting at all.

SECTION 6 - STANDING

- I can stand as long as I want without extra pain.
- I can stand as long as I want but it gives me extra pain.
- Pain prevents me from standing for more than 1 hour.
- Pain prevents me from standing for more than 30 minutes.
- Pain prevents me from standing for more than 10 minutes.
- Pain prevents me from standing at all.

SECTION 7 - SLEEPING

- Pain does not prevent me from sleeping well.
- I can sleep well only by using tablets.
- Even when I take tablets, I have less than 6 hours sleep.
- Even when I take tablets, I have less than 4 hours sleep.
- Even when I take tablets, I have less than 2 hours sleep.
- Pain prevents me from sleeping at all.

SECTION 8 - SEX LIFE (If applicable)

- My sex life is normal and causes no extra pain.
- My sex life is normal but causes some extra pain.
- My sex life is nearly normal but is very painful.
- My sex life is severely restricted by pain.
- My sex life is nearly absent because of pain.
- Pain prevents any sex life at all.

SECTION 9 - SOCIAL LIFE

- My social life is normal and gives me no extra pain.
- My social life is normal, but increases the degree of pain.
- Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
- Pain has restricted my social life and I do not go out as often.
- Pain has restricted my social life to my home.
- I have no social life because of pain.

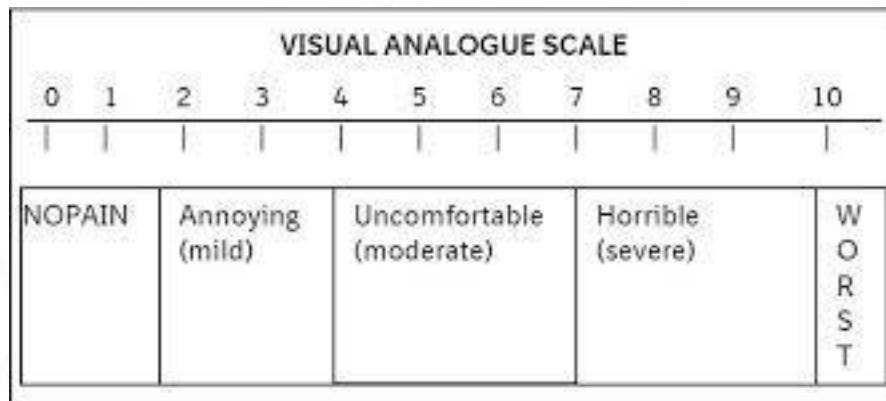
SECTION 10 - TRAVELLING

- I can travel anywhere without extra pain.
- I can travel anywhere but it gives extra pain.
- Pain is bad but I manage journeys over 2 hours.
- Pain restricts me to journeys of less than 1 hour.
- Pain restricts me to short necessary journeys under 30 minutes.
- Pain prevents travel except to the doctor or hospital.

Interpretation of ODI scores:

0% to 20%: minimal disability :	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
21%-40%: moderate disability :	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60%: severe disability :	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled :	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%:	These patients are either bed-bound or exaggerating their symptoms.

2) Visual Analogue Scale (VAS)



SF-12: Patient Questionnaire

This information will help your doctors keep track of how you feel and how well you are able to do your usual activities. Answer every question by placing a check mark on the line in front of the appropriate answer. It is not specific for arthritis. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

1. In general, would you say your health is:

Excellent (1) Very Good (2) Good (3) Fair (4)

-----Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:

Yes, Limited A Lot (1) Yes, Limited A Little (2)

No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:

Yes, Limited A Lot (1) Yes, Limited A Little (2) No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:

Yes (1) No (2)

5. Were limited in the KIND of work or other activities:

Yes (1) No (2)

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like

_____ Yes (1) _____ No (2)

7. Didn't do work or other activities as CAREFULLY as usual:

-----Yes (1) -----No (2)

8. the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work the home and housework)?

-----Not At All (1)
-----A Little Bit (2) Moderately (3) -----Quite A Bit (4) -----Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS.

9. Have you felt calm and peaceful?

_____ All of the Time (1) _____ Most of the Time (2) _____ A Good Bit of the Time (3) _____
Some of the Time (4) _____ A Little of the Time (5) _____ None of the Time (6)

10. Did you have a lot of energy?

_____ All of the Time (1) _____ Most of the Time (2) _____ A Good Bit of the Time (3)
_____ Some of the Time (4) _____ A Little of the Time (5) _____ None of the Time (6)

11. Have you felt downhearted and blue?

_____ All of the Time (1) _____ Most of the Time (2) _____ A Good Bit of the Time (3)
_____ Some of the Time (4) _____ A Little of the Time (5) _____ None of the Time (6)

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

_____ All of the Time (1) _____ Most of the Time (2) _____ A Good Bit of the Time (3) _____
Some of the Time (4) _____ A Little of the Time (5) _____ None of the Time (6)

KEY TO MASTERCHART

SN – Serial Number

S - Sex

M – Male

F – Female

A – Age

H – Height

W – Weight

BMI – Body Mass Index

P – Pathology of Spondylolisthesis. D – Degenerative I - Isthmic

G – Grade of spondylolisthesis

L – Level of spondylolisthesis

C – Comorbidities

1: Diabetes Mellitus.

2: Hypertension.

3: Dyslipidemia

4: Hypothyroidism

SYM – Symptoms

1: Low backache

2: Left lower limb paresthesia

3: Right lower limb pain

4: Right lower limb paresthesia

5: Left lower limb pain

PV – Post Void residual urine volume

S* – Significant (≥ 30 ml)

NS- Nonsignificant (< 30 ml)

VAS – Visual Analogue Scale

ODI – Oswestry Disability Index

SS – Sacral Slope

PI – Pelvic Incidence

PT – Pelvic Tilt

SVA – Sagittal Vertical Axis

LL – Lumbar Lordosis

SF 12 – Short form 12 (Health Survey)

PLD – PI LL difference

PT SS – PT + SS

TOS – Type Of Surgery

TS – Transpedicular Screw

OT – Operative Time

BL – Blood Loss

NT – Number of blood transfusions

IC – Intraoperative Complications

POC – Post Operative Complications

HS – Hospital Stay

Ca – Cage

T – Titanium

RS – Repeat surgery

MASTERCHART

													Before surgery									
SN	A	S	H	W	BMI	P	G	L	C	SYM	PV	VAS	ODI %	SF12	PT	SS	PI	LL	SVA	PLD	PT SS	
1	67	F	159	79	35.1	D	1	L4-L5	1,2,3	1,2	NS	7	42%	30	8.8	32.2	41	60.8	3.94	19.8	41	
2	50	F	164	77.4	28.9	D	1	L5-S1		3 1, 3	S*	9	54	23	19.7	37.7	64.5	65.9	2.23	1.4	57.4	
3	38	F	158	81	32.5	I	1	L5-S1		4 1, 3	S*	8	52	28	21.4	30.1	54.1	47.5	11.9	6.6	51.5	
4	55	M	170	70	24.2	I	1	L5-S1		1 1, 5	NS	7	46	29	31.2	57.3	75.4	60.9	0.97	13.7	88.5	
5	46	F	158	82	32.9	D	1	L4-L5		2 1, 3	S*	8	50	28	16.4	41.5	56.3	39.1	1.16	17.2	57.9	
6	54	F	161	68.9	26.9	D	1	L4-L5		2 1, 3, 4	NS	8	46	28	19	43.8	59.7	65.9	5.68	6.2	62.8	
7	53	F	147	60.6	28.5	I	1	L5-S1		1 1, 5	NS	9	55	30	21.2	46	67.1	62.9	4.4	4.2	67.2	
8	48	F	153	74.1	31.7	D	1	L4-L5		2 1, 2	S*	8	50	29	15.8	52.8	66	50	2.3	16	68.6	

Intraoperative						Immediately after surgery									
TOS	Ca	OT	BL	NT	IC	VAS	PT	SS	PI	LL	SVA	PLD	PT SS	POC	HS
L4-L5 TLIF	T	140	500	0	no	5	13	35.5	50.7	59.6	0.4	8.9	48.6	no	14
L5-S1 TLIF, L4-S1 TS	T	160	400	0	no	4	17	41.5	62.2	64	2.08	1.8	58.6	no	9
L5-S1 TLIF	T	125	300	0	no	6	26	36.2	63.3	54.7	1.27	8.6	62.5	no	11
L5-S1 TLIF, L3-S1 TS	T	175	350	0	no	4	33	38.1	69.5	54.2	11.56	15.3	71.1	no	7
L4-L5 TLIF, L2-L5 TS	T	160	550	0	no	5	20	30.6	50.1	36.5	1.29	13.6	50.8	no	6
L4-L5 TLIF	T	130	500	0	no	4	26	38.2	65.1	55.2	0.7	9.9	64.2	no	9
L5-S1 TLIF, L4-S1 TS	T	140	400	0	no	5	23	45.5	67.4	61.9	5.5	4.2	68.7	no	10
L4-L5 TLIF, L4-S1 TS	T	150	500	0	no	4	18	39.6	55.6	45.3	1.7	10.3	58	no	8

After 1 months												After 3 months												
VAS	ODI	SF12	PT	SS	PI	LL	SVA	PLD	PT	SS	POC	VAS	ODI	SF12	PT	SS	PI	LL	SVA	PID	PT	SS	POC	RS
2	36%	25	15	35.2	53.5	46.8	0.3	6.7	50.2	no		1	27%	20	14.1	38.1	53.5	47.8	0.3	5.7	52.2	no	no	
3	30	21	17	41.5	60.8	66.9	1.1	6.1	58.5	no		2	23	21	18.2	41.2	60.2	69.9	0.98	9.7	59.4	no	no	
3	32	23	19.8	33.7	52.8	43.3	1.03	9.5	53.5	no		2	22	20	19.5	38.7	57.2	53.6	0.5	3.6	58.2	no	no	
4	35	24	28.3	35.5	63.6	49.1	6.11	14.5	63.8	no		3	21	19	22.3	39.5	61.6	49.1	4.5	12.5	61.8	no	no	
4	42	25	17	29.5	48.8	39.2	1.3	9.6	46.5	no		2	25	22	18.2	28.7	48.3	39.2	1.44	9.1	46.9	no	no	
3	33	23	25.8	38.8	65.2	57	0.5	8.2	64.6	no		1	19	17	20.9	41.9	64.5	57	0.5	7.5	62.8	no	no	
4	38	26	18.5	41.6	58.9	49.1	0.6	9.8	60.1	no		2	23	20	18.8	40.2	58.7	49.1	0.75	9.6	59	no	no	
3	29	24	15.8	47.1	59.5	53.1	1.5	6.5	62.9	no		1	20	21	14.6	45.4	60.5	52.7	1.7	7.8	60	no	no	



PLAGIARISM REPORT



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INTRODUCTION One of the most common factors to missed time at work is low backache and also it is most common reason of work related disability¹. Low back pain may aggravated by activity and which lead to minimizing activity and it further leads to disability. One of the most expensive burdens on the system of health care is low backache. It is one of the common medical problem. In lifetime, there is 50-70% chance of a person getting low backache². Low back pain can be divided into 3 categories according to duration; chronic if lasting for more than 3 months, subacute if lasting 6 weeks - 3 months and acute if less than 6 weeks.

Pain is usually initiated by the result of abnormal movement of vertebral bodies or by instability at single motion segment². Lumbar spine instability. Lumbar spinal instability is defined as the "Under physiological load, loss of ability of the spine to maintain its pattern of displacement, with no incapacitating pain, no initial or additional neurological deficit and no major deformity"³. Motion of spinal segment is defined by biomechanics of ligaments, facets, intervertebral disc, each of which contributes to level of stability to spinal column.

Any damage or abnormality of any of above 3 components can alter movement of other 2 and therefore that alters entire motion of particular segment of spine. Generally surgery is considered option when conservative management has failed. Most of the time significant problem is mechanical which reflects as a clinical spinal instability. Mechanical problem refers to inability of carrying spinal load and clinical spinal instability refers to pain or/and neurological deficits³.



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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Institutional Ethics Committee (IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1372/APRIL-2019

15.05.2019

Dr. Ninad Anand Sawant
Senior Resident
Department of Neurosurgery
SCTIMST, Thiruvananthapuram

Dear Dr. Ninad Anand Sawant,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "PROSPECTIVE STUDY OF TRANSFORAMINAL LUMBAR INTERBODY FUSION (IEC/1372)" on 12th April, 2019.

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 15.03.2019 with checklist
2. TAC Approval Letter
3. IEC Application Form
4. Project Proposal
5. Proforma
6. Patient Information Sheet and Informed Consent Form in English and Malayalam
7. CV of Principal Investigator and Co- Principal Investigators

Revised submission

1. Covering letter from Prof. Mathew Abraham, Head, Department of Neurosurgery, SCTIMST addressed to the Chairperson, IEC, SCTIMST, Recommended by the Member Secretary, TAC (Clinical studies), SCTIMST dated 06.05.2019
2. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 06.05.2019 with checklist
3. TAC Approval Letter
4. IEC Application Form
5. Project Proposal
6. Proforma
7. Questionnaire in English and Malayalam
8. Patient Information Sheet and Informed Consent Form in English and Malayalam
9. CV of Principal Investigator and Co- Principal Investigators

Page 1 of 2

The following members of the Ethics Committee were present at the meeting held on 12th April, 2019 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
5.	Dr. Harikrishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
6.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
7.	Dr. S S Giri Sankar	LL.M. Ph.D.	Male	Legal Expert	No
8.	Dr. Aneesh V Pillai	BA, LLB (Hons.), LLM, Ph. D, SET (Law)	Male	Legal Expert	No
9.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
10.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
11.	Dr. Anand Kumar A	MD, DM	Male	Clinician	No
12.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

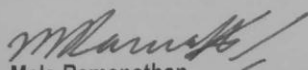
The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,


Mala Ramanathan
Member Secretary, IEC