BIOMECHANICAL STUDY OF LUMBAR LAMINECTOMY VERSUS UNILATERAL LAMINOTOMY, BILATERAL LAMINOTOMY AND BILATERAL LAMINOTOMY WITH POSTERIOR LIGAMENT COMPLEX RESECTION IN A CADAVERIC CALF SPINE MODEL.

SUBMITTED BY

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DISSERTATION SUBMITTED TOWARDS THE FULFILMENT OF THE RULES AND REGULATIONS FOR THE M.S. BRANCH III ORTHOPEDICS EXAMINATION OF THE TAMILNADU M.G.R MEDICAL UNIVERSITY TO BE HELD IN APRIL, 2018.

BONAFIDE CERTIFICATE

This is to certify that this dissertation entitled "Biomechanical study comparing lumbar laminectomy versus unilateral laminotomy, bilateral laminotomy and bilateral laminotomy with posterior ligament complex resection in a cadaveric calf spine model" towards the fulfilment of the requirements of the TamilNadu Dr.M.G.R university , Chennai for MS Branch III Orthopedics examination to be conducted in April 2018,is the bona fide original work by Dr.Febin C Kunnath,Postgraduate student in orthopedics,Christian Medical College ,Vellore.

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DECLARATION CERTIFICATE

This is to certify that the dissertation entitled "Biomechanical study comparing lumbar laminectomy versus unilateral laminotomy, bilateral laminotomy and bilateral laminotomy with posterior ligament complex resection in a cadaveric calf spine model",is my own original work ,done under the guidance of Dr.Kenny S David, Professor and Head of Spinal Disorders Unit, submitted towards the fulfilment of the requirements of the TamilNadu Dr.M.G.R university ,Chennai for MS Branch III Orthopedics examination to be conducted in April 2018 .

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Contents

INTRODUCTION

The benchmark of treatment of lumbar canal stenosis failing conservative management is a facet preserving laminectomy(1).In this surgery, after a midline incision, the paraspinous muscles are detached from the spinous process.It is known that extensive removal of the posterior bone ligaments and muscles will lead to increase in postoperative pain, blood loss, complications like structural instability and length of inpatient stay (2–4)

Disagreement continues about the extent of the bony decompression needed to effectively treat the spinal canal stenosis. The spinal canal narrowing occurs typically at interlaminar region caused by arthrosis of facet joints, bulging of the intervertebral disc and ligamentum flavum.Hence resection of the entire vertebral arch may not be required.On the other hand, soft tissue preserving interlaminar laminotomy may be performed for decompression of lumbar canal (5,6).Many surgical techniques which preserve midline posterior structures have been described recently (2–4,7).Most commonly reported decompressive procedure which preserves the soft tissue is laminotomy.Laminotomy has been shown to be equivalent to laminectomy in the amount of decompression achieved(8)(9) Also, considerable paraspinous soft tissue detachment from the midline bony structures can cause structural instability(10)

Description of the condition

Lumbar canal stenosis is one of the most common diseases of the spine in the geriatric population and is defined as the reduction in diameter of the spinal canal, neural foramina or lateral recess.It is the result of the degenerative process and involves various levels of the lumbar spine.It is caused by osteoarthritis of facet joints, bone hypertrophy,ligamentum flavum hypertrophy, spondylolisthesis, disc protrusion or combination of any of these elements.Central canal stenosis leads to compression of cauda equina, whereas,neuro-foraminal stenosis and lateral recess stenosis leads to the encroachment of nerve roots.Degenerated lumbar canal stenosis most frequently affects L3-L4 and L4-L5 segments (9).Clinical features of lumbar stenosis are numbness, fatigue, pain in the buttocks, thighs, and legs, back pain and muscle weakness.It can also present as radiating pain from buttocks to toes accompanied with parasthesias.The relation between symptoms and function of the patient is considered the pathognomic aspect of lumbar stenosis.Symptoms are aggravated by standing and walking and decreases by sitting or standing with lumbar flexion and lying down. Most characteristically it causes neurogenic intermittent claudication(11).Lumbar canal stenosis is the most common indication for a lumbar surgery in people above the age of 65(12)

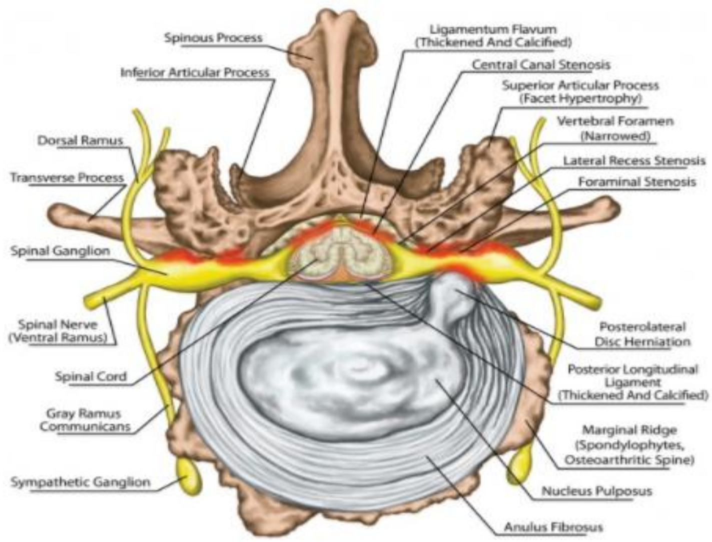


Figure 1 Figure 2 showing the various types and causes of degenerative lumbar canal stenosis

Description of surgery

Conventional laminectomy involves removal of the lamina of the affected level along with the spinous process and the soft tissue attached to it at stenotic levels, preserving the facet joints and pars interarticularis. Alternatively, unilateral laminotomy or bilateral laminotomy and bilateral laminotomy with the posterior interspinous ligaments resection have been developed to reduce the soft tissue trauma and to preserve the integrity of the lumbar spine.In general, compression of the neural structures in lumbar stenosis is classically seen in the interlaminar region.Hence, total resection of the vertebral arch may not be necessary(7,13,14).The back muscles contribute to the larger part of the resistance to load in stabilizing the spine(15,16).The multifidus muscles if detached from the vertebral arches and the spinous processes are associated with muscle atrophy and denervation.(10)

The posterior tension band is provided by the spinous processes and the ligaments(17).Hence, if we are able to minimise the resection of the static and dynamic stabilizers of the lumbar spine, we would possibly be able to minimise the low back pain, muscle weakness and surgically induced instability(13)

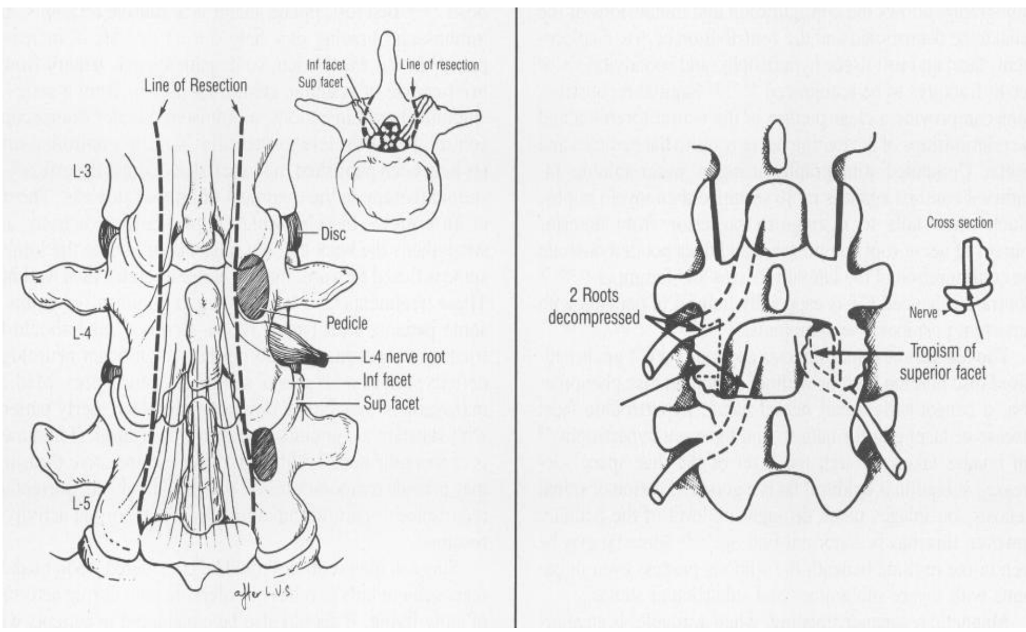


Figure 3 showing the multiple level laminectomy (left) and bilateral laminotomy (right) ***(18)***

Why it is important to do the study

The actual long-term efficacy of laminectomy as compared to the procedures which limit the bony decompression is unclear.Furthermore, surgically induced instability is reduced when the procedure is less invasive with regards to the resection of bony and ligamentous components.Evidence provided so far in the literature for the effects of laminotomy as against a conventional laminectomy is of low quality .(19)Therefore, further research is necessary to establish whether these techniques offer a safe and effective alternative to conventional laminectomy. The goals of this study are to provide a biomechanical assessment of the stability of laminotomy versus a laminectomy and to summarise the conclusions which are relevant to recent clinical practice.

NULL HYPOTHESIS

Conventional laminectomy is comparable with laminotomy in terms of stability

AIMS

To compare the biomechanical effects of unilateral laminotomy, bilateral laminotomy, bilateral laminotomy with interspinous ligament resection and laminectomy in a cadaveric calf lumbar spine model, with particular reference to intradiscal pressures and range of motion.

OBJECTIVES

1) To determine the intradiscal pressure changes in intact specimen and after the 4 procedures - unilateral laminotomy, bilateral laminotomy, bilateral laminotomy with posterior ligament complex resection and laminectomy, are carried out

2) To compare range of motion in all 6 directions- flexion, extension, right lateral bending, left lateral bending, clockwise rotation, and counterclockwise rotation of the biomechanical model between the four procedures.

REVIEW OF LITERATURE

Degenerative lumbar canal stenosis

This condition is commonly caused by a degenerative process wherein stenosis occurs in the spinal canal which ultimately causes pain and dysfunction in the elderly leading on to a negative impact on the quality of life.

Degenerative lumbar canal stenosis was first well described by Verbiest and Epstein in 1954(20). It is defined as narrowing of neural canal and foramina to an extent which leads to the compression of nerve roots and the cauda equina.The articulating facets and the supportive ligamentous structures undergo degenerative hypertrophy and osteophyte formation. These encroach on the nerve roots transiting or exiting the neural canal.

The amount of space available for the nerve roots depends on the anatomic variations. Morphogenesis of the lumbar vertebrae begins after the seventh week of gestation and is completed not before seven years from birth.

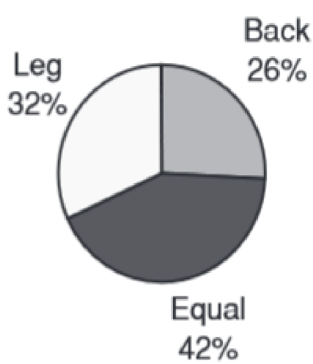
Stenosis can occur in any of the three anatomical sites: central canal which is bordered by vertebral bodies, disc, and the articular processes; the lateral recess or the subarticular canal which extends from thecal sac to pedicle; and intervertebral foramen or the nerve root canal which lies below the pedicle.

Central canal stenosis results from ligamentous/flaval hypertrophy and disc protrusion in addition to a congenitally small spinal canal found in few people.Lateral canal stenosis is due to degenerative ligamentous and the superior hypertrophic facets.

Foraminal stenosis is caused by osteophyte formation at the pars interarticularis where ligamentum flavum is attached, or from a spondylotic defect.The clinical manifestations are similar to all these anatomic sites.

Global Epidemiology of the problem

Lumbar canal stenosis is a commonly diagnosed spinal disorder in the elderly population and is the major reason for surgery in them. It is also a major cause of pain and disability especially in people with age more than 60 yrs.Around 5% of people aged above 35 yrs will get sciatica and the incidence of degenerative lumbar canal stenosis is around 1 per 1000 among people older than 65 yrs of age.(21) Distribution of the type of pain in the population is shown below:



(22)

Verbiest had measured the mid sagittal diameter of the lumbar canal and had proposed two types of stenosis using the aid of a CT scan.(23)

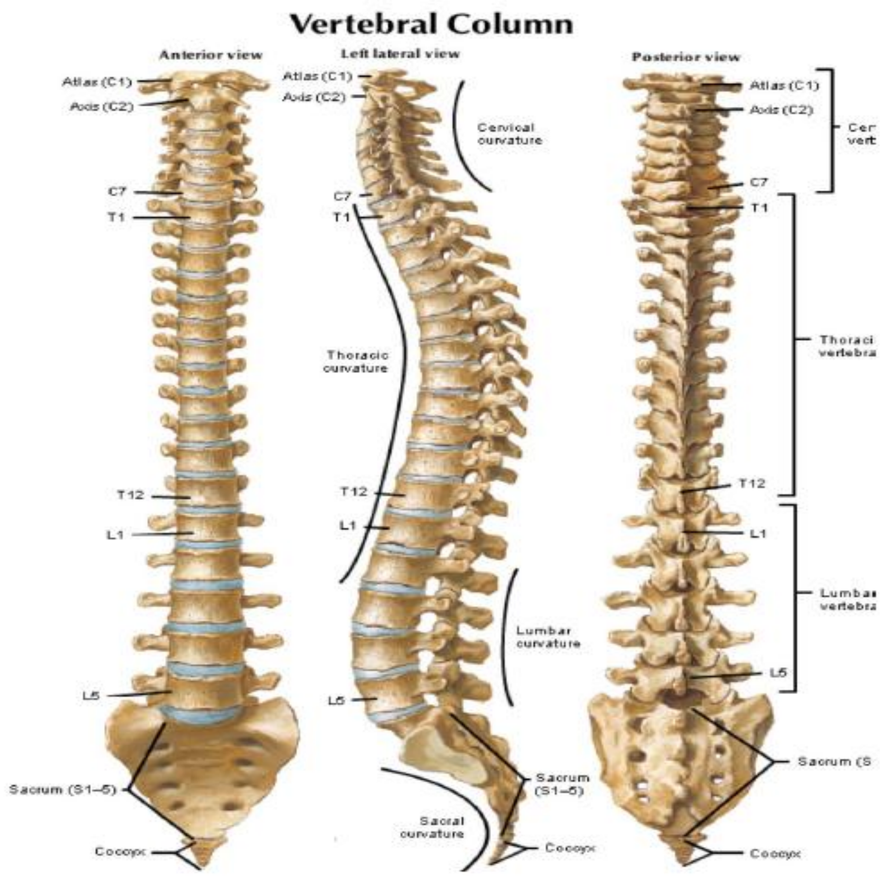
1)Absolute stenosis – with diameter less than 10mm

2)Relative stenosis – with diameter between 10mm to 13mm

In an ancillary project to the Framingham study(24), a cross-sectional study was done to characterize the prevalence of lumbar canal stenosis.The prevalence of relative and absolute degenerative stenosis was found to be 47.2% and 19.4% respectively in the 60-70-year-old age group.This higher prevalence of stenosis in our population warns us about the gravity of the problem and responsibility to treat them with the most effective surgical procedure which will relieve them of the symptoms and at the same time cause less functional disability.

Anatomy of the vertebra

The spinal column has 24 vertebrae and 23 intervertebral discs.Each vertebra consists of a body, lamina, spinous process, lateral costal processes.superior and inferior facet joints.There are 7 cervical 12 thoracic, 5 lumbar,5 sacral, and 1 coccygeal vertebrae.The intervertebral disc consists of outer annulus fibrosus and inner nucleus pulposus.The annulus fibrosus has inner and outer zones.



Morphological differences of discs at different levels:

The intervertebral discs are morphologically different at different vertebral levels.The lumbar intervertebral disc measures 4cm anteroposteriorly and 14mm vertically.The intervertebral discs are diarthrodial joints and the articulate the adjacent vertebrae(25).The lumbar region has got the maximum disc height mainly for distributing the stress and axial deformation(26).The disc height is least in the thoracic region.The thoracic vertebra is more or less stable because of the costovertebral angle and the barrel shape of chest wall(27).The intervertebral disc of the lumbar and cervical region is thicker in the anterior region due to the lordosis and these curves can access extension, flexion and lateral bending(28).The lumbar region has got limited lateral bending but cervical vertebra has got increased rotational range due to the absence intervertebral disc and presence of facet joints at the level of C1-C2(29).The lumbosacral angle over the L5 vertebra is due to the increased thickness of the intervertebral disc in this region.The whole disc height is amounting to one-third of the spinal column.They provide the structural and mechanical support for the intervertebral disc involved in the wide range of movements of flexion and extension at the sagittal plane,lateral-medial bending in the coronal plane and rotational movement.They help to distribute the axial stress.They act as shock absorbers of the vertebral columns when subjected to high energy impacts(25).

The intervertebral disc has mainly three parts:

1)The cartilage end plates 2)The annulus fibrosis and 3)Nucleus pulposus.

1)Cartilage end plates - They are made up of two layers of hyaline cartilage, glycosaminoglycans, type 2 collagen and water and form the interface between the disc and the vertebral body.Collagenous fibers run parallel to the surface of the disc.This collagen is mainly maintained by the chondrocytes in the intervertebral discs.These collagen fibers provide structural integrity of the endplates.The cartilage end plate has

1mm thickness.No direct collagenous connection exists between bone and end plate, but a loose attachment is seen by a thin layer of calcium.(30–32).The periphery of the cartilaginous end plate has higher collagen and lower proteoglycan and water content than at the center close to nucleus pulposus(33).Therefore, the fibers in the periphery bulge on pressure and can guard the nucleus pulposus against protruding into the vertebrae (34).

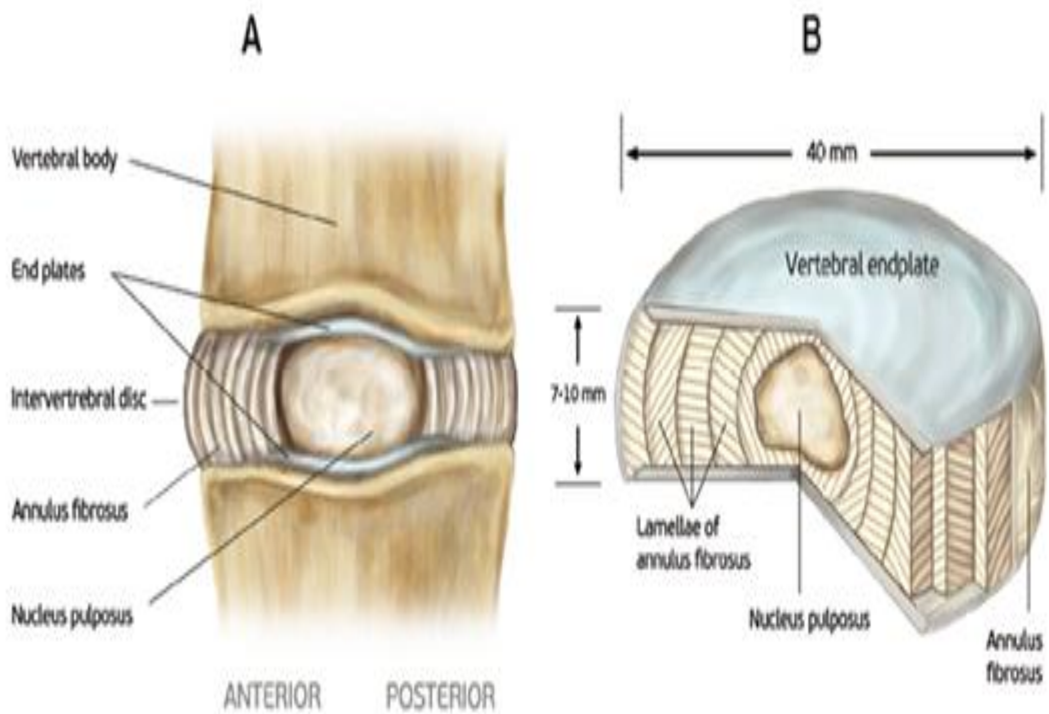
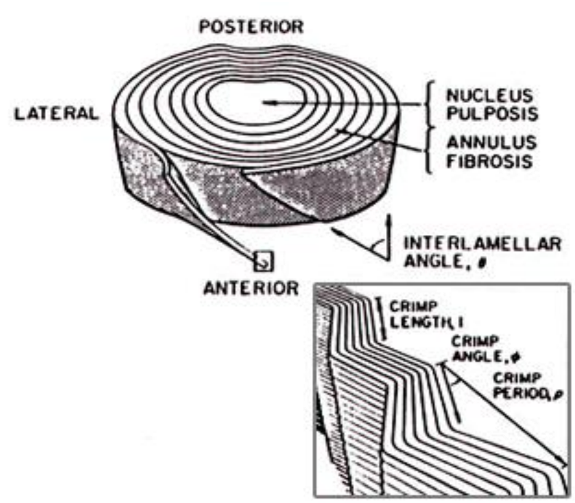
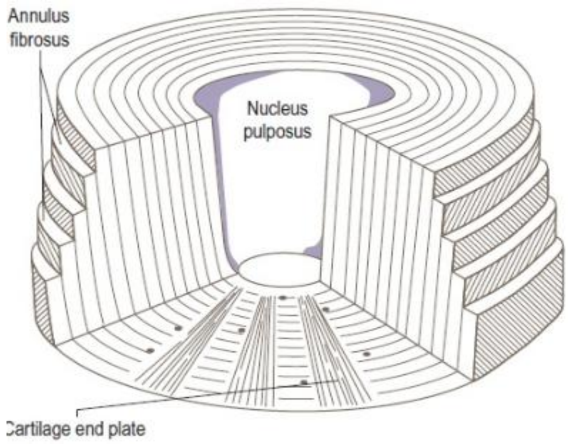


Fig 2





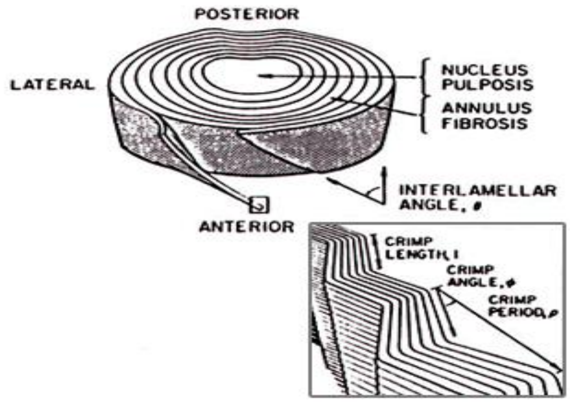


Fig:3 Components of the intervertebral disc.(35)

2)Annulus Fibrosus: This is a fibrous band which consists of 15-25 lamellae of fibers containing mainly type 1 collagen.It functions to contain the nucleus pulposus.It determines the shape of the disc.Lamellae are arranged in 60-degree orientation as parallel fibers alternating left and right to the vertical axis.Sharpey's fibers are the elastic lamellae which attach the outer part of annulus fibrosus to the anterior and posterior spinal ligaments and vertebral bodies.(33,36).

In the majority, tough collagen type1 is seen in the outer fibers whereas, soft type 2 collagen in the inner fibers.Therefore this contributes the compression and recoil of the fibers on application and removal of a force axially.Annulus fibrosus is composed of 65% water,55% collagen(consists of type I, II III, V, VI, and IX),20% proteoglycan and 10%

elastic fibers. The outer zone of annulus fibrosis is composed of cord-like cells network and the inner layer has cytoplasmic processes.The structural integrity of the annulus fiber is maintained by the hydrostatic nature of nucleus pulposus.

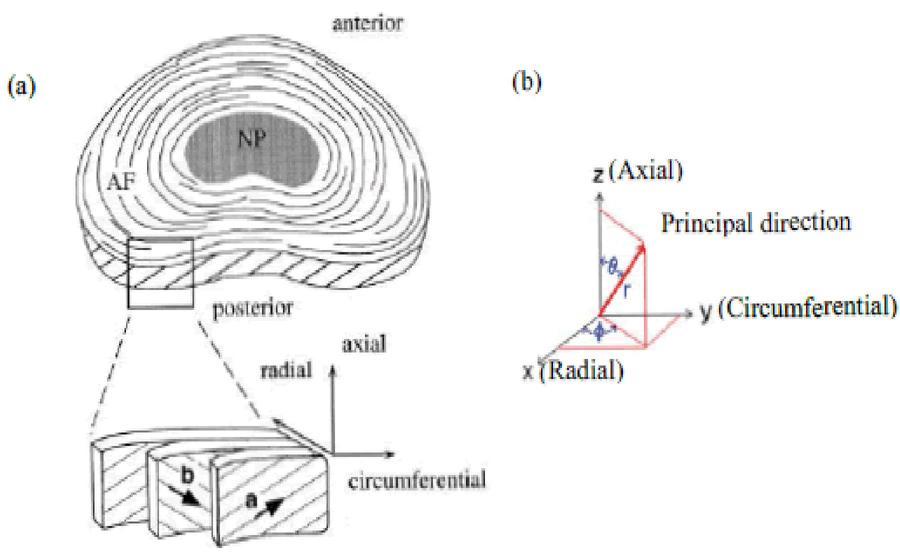


Fig.4: (a)shows the arrangement of annulus fibers with respect to axial, radial and circumferential coordinate.(b) defining angles

Disc structure	**Collagen**	**Consistency**
Healthy nucleus pulposus	4% type II- no type I	gelatinous
Annulus fibrosus-Inner fibers	70% type II	soft
Annulus fibrosus-Outer fibers	90% type I- no type II	tough

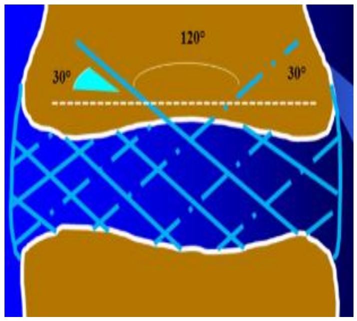
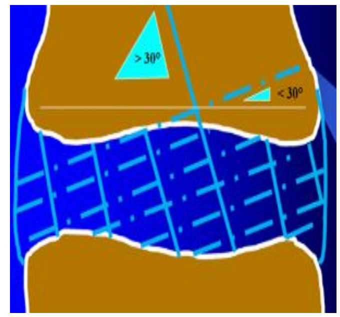
Fig 5(a) 

Fig5(b) 

The strength of annular fibers depends on the type I collagen and its specific cross weaved orientation.In figure 5(a)in each lamella, fibers are arranged parallel to one another and run obliquely between the vertebral bodies at 30 degrees with respect to the horizontal plane of the endplates.Type II collagen bundles in each successive laminae run at an angle 120 degrees to those in the immediate adjacent sheet. In figure5 (b) it shows that while on the torsional movement of the lumbar spine, only 50% fibers (elongated and more horizontal)are put into tension while 50% become slack(shorter vertically oriented ones).As age progresses the annulus fibrosis lose its pliability leading to tears in inner zone followed by protrusion, extrusion, and sequestration.

Nucleus Pulposus: It is a semi-gelatinous material which is rich in aggrecan.The structural integrity of the nucleus pulposus is contributed by the radially arranged elastin fibers and randomly arranged collagen fibers(37,38).It consists of 80% water and rest with collagen type II and proteoglycan(38).Disc hydration is maintained by proteoglycan(39).The glycation of disc seen in old age and diabetes cause degenerative changes.

Blood supply of intervertebral disc:

The capillaries originating from segmental arteries of aorta pass through vertebral bodies before ending at the endplate(40).Four pairs of lumbar arteries from the aorta and the fifth pair from a median sacral artery, give off branches anteriorly and posteriorly and supply the vertebral segments cranial and caudal to the segment.They anastomose with other segmental arteries also(41).The segmental arteries run anterolateral to the vertebral body and divide into 15 to 20 periosteal branches.These go across the vertebral body as marrow vessels and they end as capillaries at the endplate thus providing the major blood supply to the disc.Small branch vessels from these arteries go to outer annulus fibrosus and provide nutrition(42).Each segmental arteries divide into 2 main branches near intervertebral foramen, in which one supplies posterior vertebral process and the other one enters the spinal canal through the foramen along spinal nerve fiber root and it divides into the dural and radicular artery.The capillaries finally reach the endplate surface.

At the base of the arterioles there exists a sphincter which has muscarinic receptors which regulate blood flow(43)The coiled venules make a network in a subchondral cone.The Vascular bed which is a simple loop like structure become complex at nucleus pulposus.For each cross-sectional 0.1mm^2 there exist 16 vascular buds.The density of the vascular buds decreases from center to periphery.

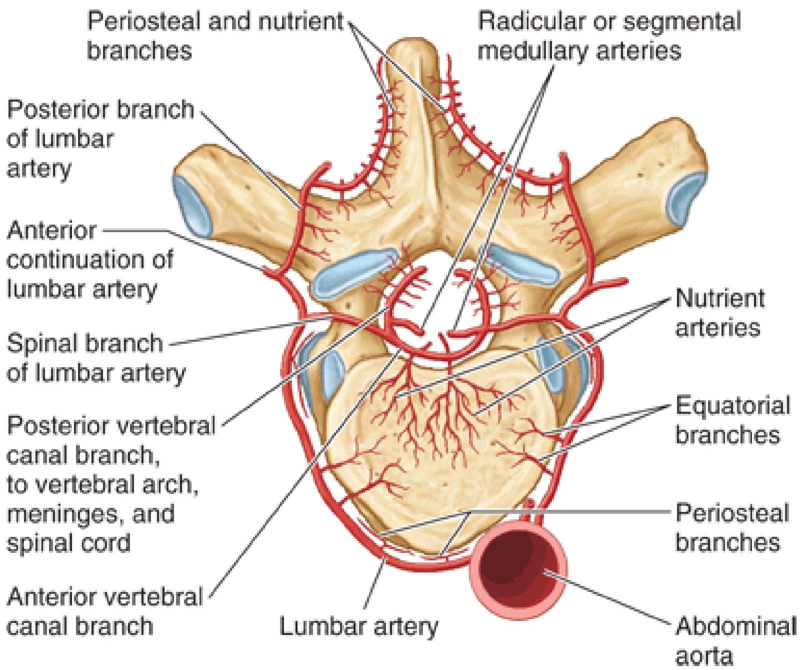


Fig 6a: Blood supply of vertebra

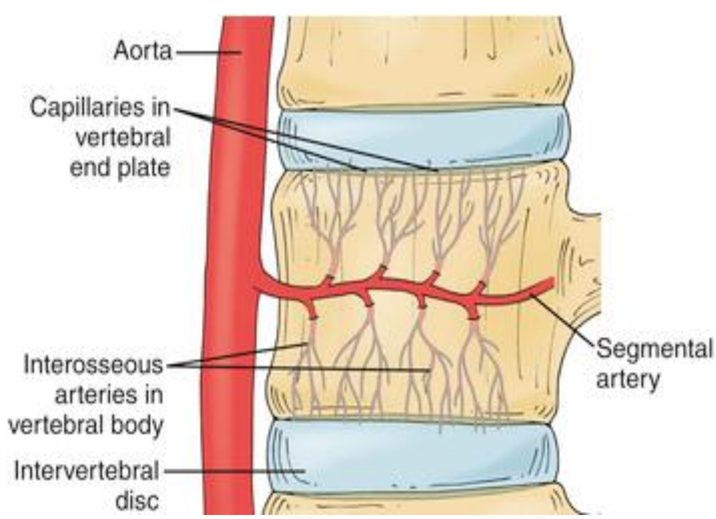
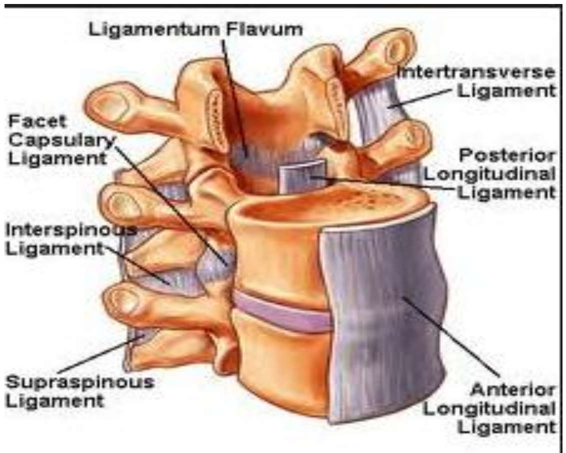


Fig 6b: Capillaries in vertebral endplate (44)

Ligamentum Flavum



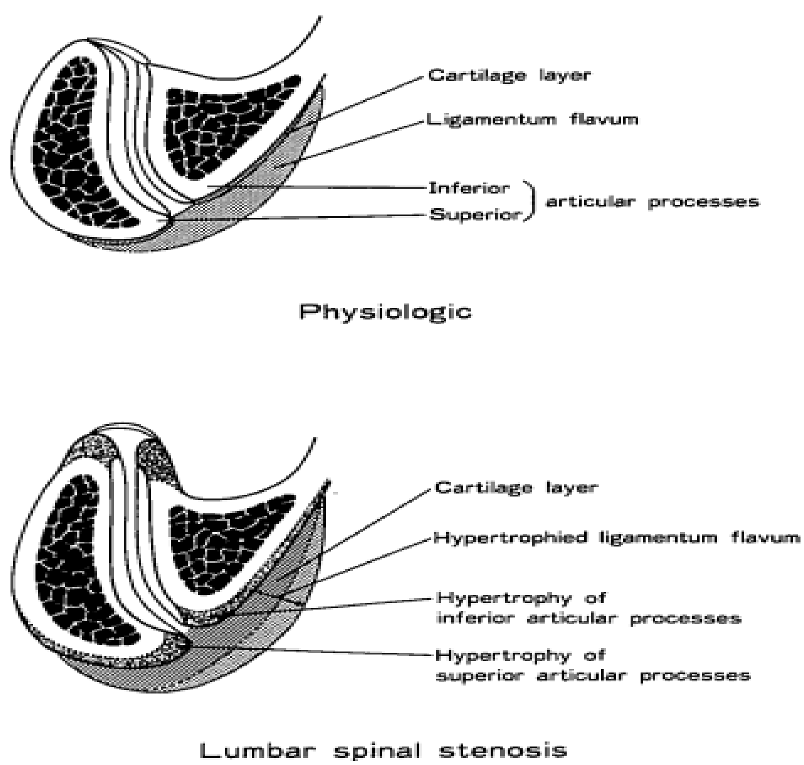
The ligamentum flavum plays a pivotal role in the anatomy of the spinal column, especially since it is the strongest ligament of the spine.It is a yellow colored structure attached to the laminae of the two adjacent vertebrae.It is present all the way from the axis to the first sacral vertebra.

Each ligament consists of 2 lateral portions which start on either side of the base of articular processes and extend posteriorly to a point where laminae meet to form spinous process. It is comprised of elastic tissue and is the thickest in the lumbar region.

One of the contributing factors for lumbar canal stenosis is ligamentum flavum

hypertrophy.The precise cause for hypertrophy is unknown but important etiological factor could be the mechanical stress acting on it.

Recently, many cytokines and growth factors were studied and basic fibroblast growth factor has been documented to play a major role in the hypertrophy of ligamentum flavum. bFGF is a profibrotic factor and plays an important role in the production of fibrotic lesions.(45) The ligamentum flavum is the thickest at l4-l5 level. It consists of 80% elastic fibers and 20 % collagen fibers.In a stenotic canal, the flavum shows degenerative and increase in amount of its collagen fibers.The ligamentum flavum area should be less than 105.90mm square (80.1% sensitivity,76% specificity) and the ligamentum flavum thickness has its upper value as 3.74mm (70.5% sensitivity,66.5% specificity).(46)



(47)

Pathogenesis of ligamentum flavum hypertrophy was divided into three groups:

1) Proliferation of type 2 collagen leading to decrease in elastic fibers

2) Ossification

3) Deposition of calcium crystals.

The hypertrophy is prominent near the medial aspect of the facet joints, more than the interlaminar region.Hence, it is crucial to remove the flavum totally from medial side of superior facet at the capsular region.(48)

Management of lumbar canal stenosis

Degenerative lumbar canal stenosis is a disease which affects the elderly causing a significant impact on quality of life. This is due to the narrowing of the canal space and degeneration of the facet joint cartilage and formation of osteophytes (8,9).All these results in neural compression and lead on to varying degrees of leg and back pain, weakness, numbness and gait disturbances.(10)

Types based on anatomical sites	Caused by	Root affected
Central, subarticular	Listhesis, facet joint hypertrophy, congenital, flavum bulging	Transiting or descending
Foraminal, lateral or extraforaminal	Facet joint bony spurs, bulging disc,flavum hypertrophy	Exiting or emerging

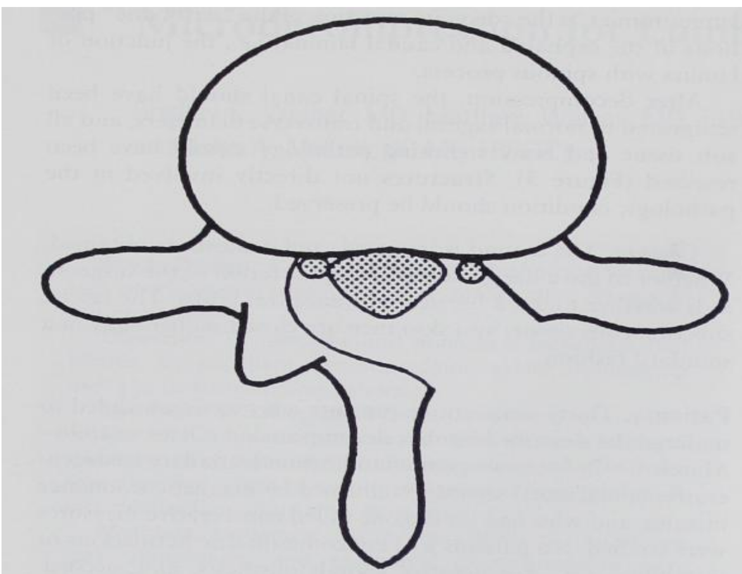
The diagnosis is made from the history and relevant physical examination.The Xrays done are the standing anteroposterior and lateral views.The findings from the Xrays are narrowing of disc space, osteophytes, endplate sclerosis, spondylolisthesis and facet hypertrophy, all these most commonly seen at L4-L5. CT scan can be ordered to look into the extent of the facet arthritis and osteophytes in the foramina.MRI is the gold standard imaging as it can demonstrate disc herniation,ligamentum flavum and facet capsule hypertrophy and the narrowing of the lateral recess and central canal.A uMRI (upright) which is developed in recent times has the ability to film the spine at a position where the clinical symptoms are more severe.(19) Barz et al defined the findings of imaging recently by describing Sedimentation sign of a nerve root or called as Sed sign.In normal supine MRI scans, the lumbar nerve root sink to dorsum of dural sac and in lumbar canal stenosis, it does not sink to the bottom.(49)

The main aim of conservative treatment is to reduce pain and to improve function. This includes a combination of NSAIDS, physiotherapy, and epidural injections. All the patients who fail conservative treatment should go for surgical treatment.There is adequate evidence to suggest that surgically treated patients have a better outcome than the treated by conservative approaches at 2 years follow up.(9,50) Also, there is evidence to show that patients with leg pain rather than back pain have better outcomes after surgery.(22)

Laminectomy

Laminectomy is a conventional procedure for decompressing the lumbar spine in lumbar canal stenosis.In this procedure, the patient is positioned in prone with abdomen free to decrease the intraabdominal and inferior vena cava pressure during surgery. This also reduces the blood quantity in the epidural system. A standard midline posterior incision is used deep down to the fascia. The dissection is performed bilaterally for a central disc.Hemostasis should be maintained from the subcutaneous level till the interlaminar spaces.The vertebral levels are confirmed and then the soft tissues are debrided using nibblers and curettes. The ligamentum flavum is excised after protecting the dura with an elevator.Bilateral laminae are removed using upper cutting Kerrison reongeurs along with the spinous process and the interspinous ligaments.(51)Probes are used to explore each nerve root to make sure it is free of compression.Finally, hemostasis should be achieved and the incision closed in layers under the drain.This standard laminectomy procedure is associated with several complications like paraspinal muscle denervation, large dead space being created and surgical instability.(52)

Laminotomy



(53)

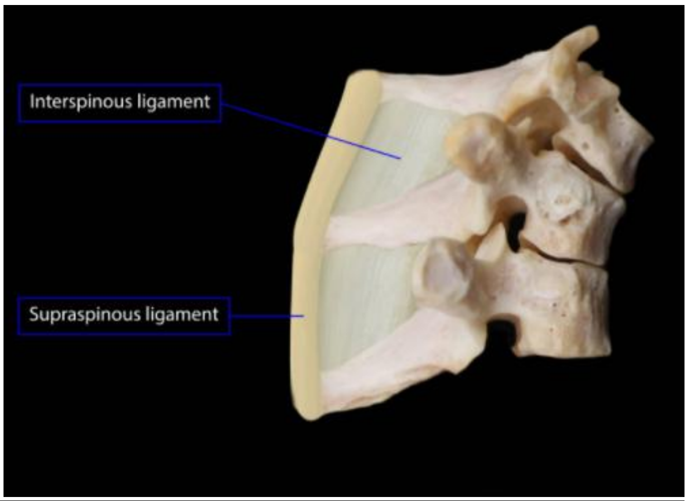
The spine is approached through a midline incision with unilateral retraction of multifidus to allow entry to the canal through a partial laminectomy. This allows decompression of the lateral recess ipsilateral side first. A malleable copper retractor is used to protect the neurological structures. A high-speed burr is used to scallop the inferior aspects of the adjacent spinous processes so that midline can be crossed and careful undercutting of the opposite side of the canal can be performed with Kerrison punches. Safety is ensured by the use of operating microscope, saline irrigation, and fine suction to allow clear visualization. The malleable copper retractor is placed carefully beneath the bony overhang to protect the dura and nerves during the decompression.(54)

In addition to the bilateral stripping causing muscle denervation, removal of midline structures as mentioned above can lead to instability after surgery.(55) Lumbar decompression through many laminotomies has been documented to be an alternative to laminectomy.(56) The spinous process and the interspinous ligaments are left untouched in this and only a small region of the lamina is sacrificed. The surgery has got a bigger learning curve due to the available working space being limited. Postoperative back pain may be reduced more by this technique. Not only the spinous process but also the ligaments and the muscles are preserved in order to give a better outcome than the conventional laminectomy.

Another technique which preserves the soft tissues is a spinous process splitting approach by osteotomising the junction between lamina and the spinous process.

The spinous process is retracted along with the paraspinal muscles and decompression done.(57)A success rate of as high as 64% is reported by Turner et al for surgical decompression in spinous process splitting approach.(58) Post op success rate of lumbar decompression done for lumbar stenosis decreases over time(88% at 6 weeks versus 71% at 5 yrs.)(59)

Laminotomy with ligament resection



The interspinous ligaments are sheets of fibrous tough tissues which extend between the spines of vertebrae throughout the length of the vertebral column. They are thin in the cervical segment, rounder in the thoracic region, broader and thicker in the lumbar segment. During the movements of the spine, these ligaments are seen stretched and hence playing a definitive role in the stability of the spine. Full flexion at the lumbar spine causes maximum tension at these ligaments. In the upper lumbar vertebrae, the fibers are more horizontal and imply that these were not designed for resisting flexion but not preventing posterior translation. Ligaments at L3-L4 and L4-L5 levels are

directed more obliquely preventing extra flexion and also a posterior translation of the vertebrae. At L5-S1, the fibers are vertical and it functions for resisting excessive flexion at this level (60). Although interspinous ligaments are the first to rupture in flexion beyond physiologic limits, the primary constraints of flexion are the intervertebral discs, facet capsules and the ligamentum flava.

The decompression including posterior ligamentous complex, ie, interspinous and supraspinous ligaments can affect the spinous integrity and alters the pathological biomechanic milieu. It causes loss of lordosis, disc degeneration with instability of the spinal segment, alters facet joint biomechanics, capsular laxity and insufficiency of paraspinal musculature. All these make the role of the posterior ligamentous complex even more important in preserving the postoperative spinal stability.

Effects of intervention in lumbar canal stenosis

There are many clinical studies comparing the effects of laminotomy and laminectomy in the literature, but all these have failed to give adequate evidence to prove one as superior over another. (19)Different studies have compared various outcomes to compare the two procedures. These are:

Primary outcomes:

1) Disability – It was calculated qualitatively using disability questionnaires like Oswestry disability index(3), Japanese orthopedic association score(61–63), and

Roland-Morris disability questionnaire(2). None of these could give significant evidence.

2) Recovery – In an article by Fu et al,(64) he assesses recovery using a structured interview evaluating leg pain and back pain, walking disability and restriction from routine activities. Conventional laminectomy group reported 63% excellent/good results compared to the 89% in the bilateral laminotomy group.
3) Leg pain – Thome et al (2)concluded in his study that statistically significant difference was found favoring bilaterally laminotomy. 74% reported improvement in leg pain compared to 68% in the laminotomy group.

Secondary outcomes

1) Length of hospital stay – Unilateral laminotomy had significantly shorter duration of hospital stay compared to conventional laminectomy (4 days in laminotomy group versus 13 days in laminectomy group) (62)
2) Complications – Procedure-related complications were reported by most of the studies.No mortality was documented. The dural tear was the most common complication reported. Thome et al reported a lower incidence of a dural tear in the bilateral laminotomy group.(2)Other complications mentioned were iatrogenic neurological deficits, wound infection and epidural hematoma. But there was no significant difference between the groups.

3) Surgically induced spinal instability – After laminectomy, one-third of surgically treated patients have a bad outcome and are not satisfied.(65) In a study by Yang et al(66), he assessed spondylolisthesis and segmental angulation on lumbar spine after laminectomy. Flexion-Extension Xray views were used to determine these factors. Associated factors like age, sex, smoking, bone mineral density, narrowing of disc space, facet joint tropism, lordotic angle, the volume of paraspinal muscle were taken into consideration. Postoperative spondylolisthesis was defined as 3mm of slippage. Segmental angulation was defined as more than 15° of rotation in the sagittal plane. Cobb's method was used to assess the lordotic angle with a normal range between 31° to 50°. An asymmetry of left and right facet angles is called facet joint tropism. It is regarded as a 10° difference between the facet joint angles of either side. The volume of paraspinal muscles was described as cross-sectional area, width, and thickness of the muscles on MRI. The asymmetry was defined as more than 10° difference between both sides paraspinal muscles. The occurrence of spinal instability was 35.7%(66). It was prevalent more in patients having facet joint tropism, the disc space narrowing, and asymmetric paraspinal muscle volume. This paper concluded by saying bilateral laminotomy was found to be associated with less surgically induced instability than a conventional laminectomy.(66)

4) Muscle atrophy and muscle cell injury – Many studies reported paraspinal atrophy or denervation as an outcome of decompression surgeries. Yagi et al got 35% of atrophy after laminectomy compared to 13% in laminotomy group. He calculated the muscle ratios between the multifidus and the erector spinae. This difference was statistically significant but quality of evidence was low.(62)
5) Walking distance – Gurelik et al assessed walking distance using a treadmill where all the patients were made to walk on it. He did not find significant result in which unilateral laminotomy group walked 288m while laminectomy group of patients walked 203m.(3)
6) Back pain – Many papers have reported low back pain post surgery which was evaluated with Visual Analogue Score(3,61,62,64). Most of these studies found a significant difference between laminotomy and laminectomy. Laminectomy group had VAS of 0.05 whereas the laminectomy group had VAS of 0.63 on an average.(3)
7) Length of surgical procedure – Thome et al documented a significant increase in duration of bilateral laminotomy which is 90 mins compared to 73 mins for laminectomy and 77 mins in unilateral laminotomy.(2) Celik et al reported a longer duration for laminectomy, ie,107mins compared to 64 mins in unilateral laminotomy.(3) But these data were found to be of low-quality evidence.

8) Blood loss – Yagi et al got statistically significant data in favor of laminotomy compared to a laminectomy, ie, a blood loss of 177ml versus 227 ml. The quality of evidence is again low regarding this.(2,62)

9) Analgesics – Requirement of analgesics was considered of having no significance statistically as stated by various authors like Yagi et al and Watanabe et al. The latter compared the use of NSAIDS among treated with laminotomy and laminectomy till the third postoperative day.(63)

Biomechanics

Biomechanics is a study of science which deals with the mechanical properties of living tissues. This branch of science gives us the idea of how the living tissue would behave in real life during the various stages of treatment or after the various surgeries undergone on a human body. The spine is composed of a complex arrangement of tissues that allow it to perform its 3 basic functions: 1) transmit and withstand loads 2) allow for segmental motion 3)protect the spinal cord. The underlying mechanics that make these functions possible are very complex, but a basic comprehension of these principles is crucial in order to understand how the spine works, how it fails, and how it is affected by our interventions.

Biomechanics of lumbar spine

Specific types of the mechanical loading on lumbar spine will cause typical injuries to the lumbar spinal tissues.(67)

Compression: Compressive loading will act along the axis of spine and perpendicular to the intervertebral disc and arises from the tension in the paraspinal muscles and longitudinal muscles of the abdomen. The weakest point of the spine is the vertebral body during compression and almost always fails first even with the injured discs(68). In the vertebral body, end plates are the first structure to give way(68). Vertebral body collapse leads on to adjacent disc degeneration and stress shielding of the anterior margin of the body. This weakened bone after compression loading will lead to fracture. Dowager's hump is a kyphotic deformity seen due to anterior wedge fracture in people with osteoporosis or weak bone.(68)

Bending: Flexion of the spine is counteracted by the ligaments. The supraspinous and the interspinous are the first to fail if the physiological load limit is exceeded. Further flexion causes tearing of capsular ligaments and then the posterior annulus along with a chip of bone from the vertebral body. Extension of the spine is counteracted by the compaction

of the vertebral arches. The first structures to be damaged in extremes of extension are the joints and the capsules. Alternating flexion and extension beyond limits can lead on to the forces acting on the pars interarticularis, ultimately causing the defect called as spondylolysis.

Axial rotation: Lumbar spine can take 1°-3° of rotation beyond which the compaction occurs. The vertebral ligaments and anterior margins of the discs are the ones which fail when the axial loading crosses the limit.(69)

Combination of bending and compression loads can occur while lifting weights from the floor. If these loads are regularly applied to the spine, radial fissures can occur in the disc, especially in the posterolateral corner of the disc leading to the expulsion of the nucleus pulposus.

How does back pain occur?

Anatomical evidence:

Each spinal nerve has a dorsal ramus which divides into 3 branches: the medial, intermediate and the lateral. Lateral branch supplies the iliocostalis lumborum and the skin. Intermediate branch supplies longissimus muscle and apophyseal joints and medial branch supplies apophyseal joints at the same level and one below. The end plates of the vertebral bodies also have sensory innervations. Nerve plexus endings are found in the posterior longitudinal ligaments. The posterior and the posterolateral annulus

fibrosis has also got nerve supply from a mixed nerve called as the sinuvertebral nerve formed by the grey rami communicans from the lumbar sympathetic trunk and ventral rami from the lumbar spinal nerves. So, outer few mm of the annulus fibrosis has free nerve endings and this region has got only little compressive stress.

It has been studied that the back pain is from the annulus fibrosis or the facet joint capsule, also known as facet syndrome and the leg pain is due to the inflammation or mechanical compression of a nerve root.

Aging, degeneration, and pain:

Various studies have proved that by the biological changes of aging, the structure of a disc is never disrupted. Disruption is caused by the structural disruption which prevents discs from balancing the load on a vertebra. This unnatural load is acting on the annulus which is innervated and thus is painful. From the MRI scans of patients with back pains, it has also been proved that the back pain is associated with various injuries to the disc like radial fissures, endplate fracture, disc prolapsed and vertebral height collapse. Hence, there is growing evidence from the literature to show that the pain is arising from the degenerated disc and not the aged dehydrated disc.

Genetic predisposition :

Recent studies have shown that 70 % of disc degeneration is related to the genetic makeup of the individual. Few of the genes which are responsible for the degeneration are identified, eg: genes which code for vitamin d receptors,

proteoglycans and collagen type IX.

Loading history:

The phenomenon of fatigue failure is because of repetitive loading which creates microscopic damages in a tissue which cumulatively causes gross structural failure. It affects those tissue more which has poor blood supply and low rate of metabolism. So, the intervertebral discs are more affected since it is considered the largest avascular tissue in the human body.

Testing criteria for spinal implants

As the number of spinal surgeries is widely increasing day by day, the need to check the biomechanical stability of the procedures are gaining importance. Therefore these surgical procedures should be tested for stability in standardized labs using standardized equipment and tests before being implemented into clinical use.(70)Under standard calibrated loading conditions, in vitro testing can be done to study structures like a disc, ligaments, vertebral bodies in all the six degrees of motion of a spinal column. To standardize testing criteria for spinal procedures, the German society of spinal surgery created a recommended standard for testing in 1996.(71)

Few terminologies:

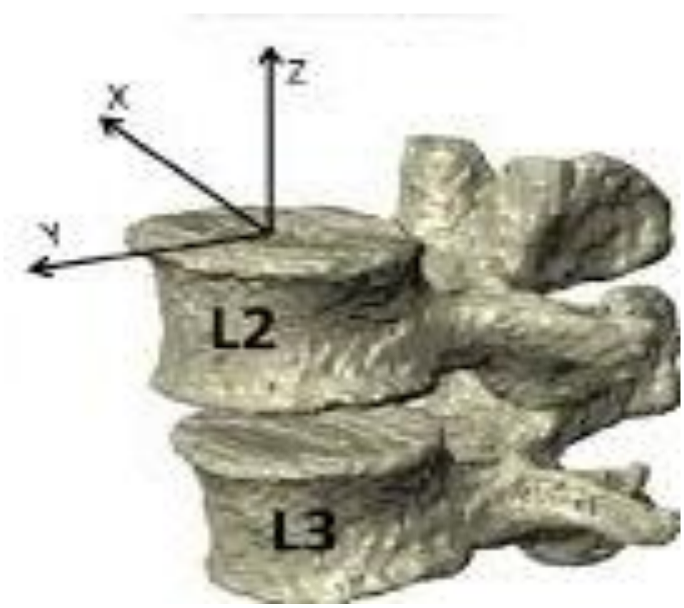
1) A functional spine motion unit is defined as 2 adjacent vertebrae having intervening ligaments and discs intact.

<u>2)</u> The intact specimen is defined as a new fresh spine with totally intact disc and ligaments with at least 1 functional spinal unit.

<u>3)</u> A contruct is defined as a spine unit consisting of the instrumented or post-procedure specimen

<u>4)</u> A spinal loading simulator is an apparatus on which the testing specimen is mounted and tested using standard loading conditions.

<u>5)</u> A coordinate system is a 3d orthogonal coordinate system with the following axis –X, Y, Z.



X -axis – right and left lateral bending

Y-axis – flexion and extension

Z-axis – axial rotations(72)

A spinal loading simulator should satisfy all the following criteria:

1) The testing specimen should be able to move in all 6 degrees of movements.
2) It should be able to simulate the 6 loading components individually.

3) All loading combinations should be provided.
4) Loading should be applied continuously or by stepwise manner.
5) The specimen should be loaded through negative and positive directions so as to obtain load-displacement curves which reflects the cycle of movements in one direction

Specimens from other species are considered for testing in vitro due to the limitation of availability of human cadaveric specimens. The use of calf spines is accepted as human spine models if the parameter we are checking is range of motion.

Specimen should be stored frozen at -20° to -30° and should be thawed for many hours before the test. It is reported that freezing and thawing has very less effect on biomechanical properties of bone and the disc.(73)

A standard loading is described as a pure moment which is applied at the end of the specimen (cranial or caudal).If a pure moment loading is used in the lumbar spine amplitude of +/- 7.5Nm is recommended, especially complex loading can be applied by different force simulators(pneumatic / hydraulic), which acts through cables and pulleys attached to the bone structures.(74)

Data sources:

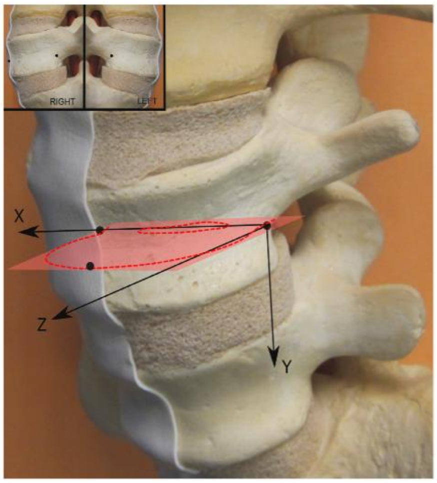
Universal Testing Machine

This is also known as universal tester or materials test frame and is used to test tensile strength and the compressive strength of various materials. It can perform any kind of standard compression and tensile tests on different materials and structures. The components of this machine are:

1) Load frame – consists of 2 supports of the machine
2) Load cell – this is a force transducer which measures the load
3) Crosshead – this is the movable head of the machine which can be programmed to move at the desired speed

The specimen is placed in between the machine and the desired force is set to deform the specimen. Once the setting is made, the machine continues to apply an increasing force on the construct. The desired torque when attained, the moving arm is made to stop. The moving head descends down to cause the desired torque. The machine can record the load-displacement curve by itself. The slope of the load-displacement curve can be used to calculate the stiffness of the construct.

3D Motion Sensor



G4(Polhemus, 40 Hercules Drive • PO Box 560 • Colchester, Vermont 05446-0560 US & Canada)is a wireless motion tracking system that delivers full 6DOF (6 Degree-Of-Freedom) tracking, providing both position and orientation without hybrid technologies. Allowing the user complete freedom of movement, the entire system can be set up in minutes. As with all Polhemus tracking systems, G4 utilizes AC electromagnetic technology. This means G4 tracks through most walls, as no line-of-sight is required for continuous tracking.

KEY FEATURES:

- Wireless Tracking

  Tetherless tracking utilizes a wireless data transmitting system. Position and Orientation are sent wirelessly to the PC via RF links.

- 10+ Hours of Battery Life.
- Portability

  The G4 system is compact and portable, and the system electronics unit (hub) can be belt worn.

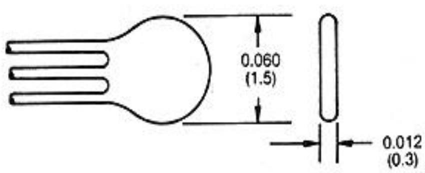
- Auto Tracking Recognition

  The G4 system has auto tracking capability, meaning G4 will re-acquire the signal as a tracked subject walks back into the field of tracking range.

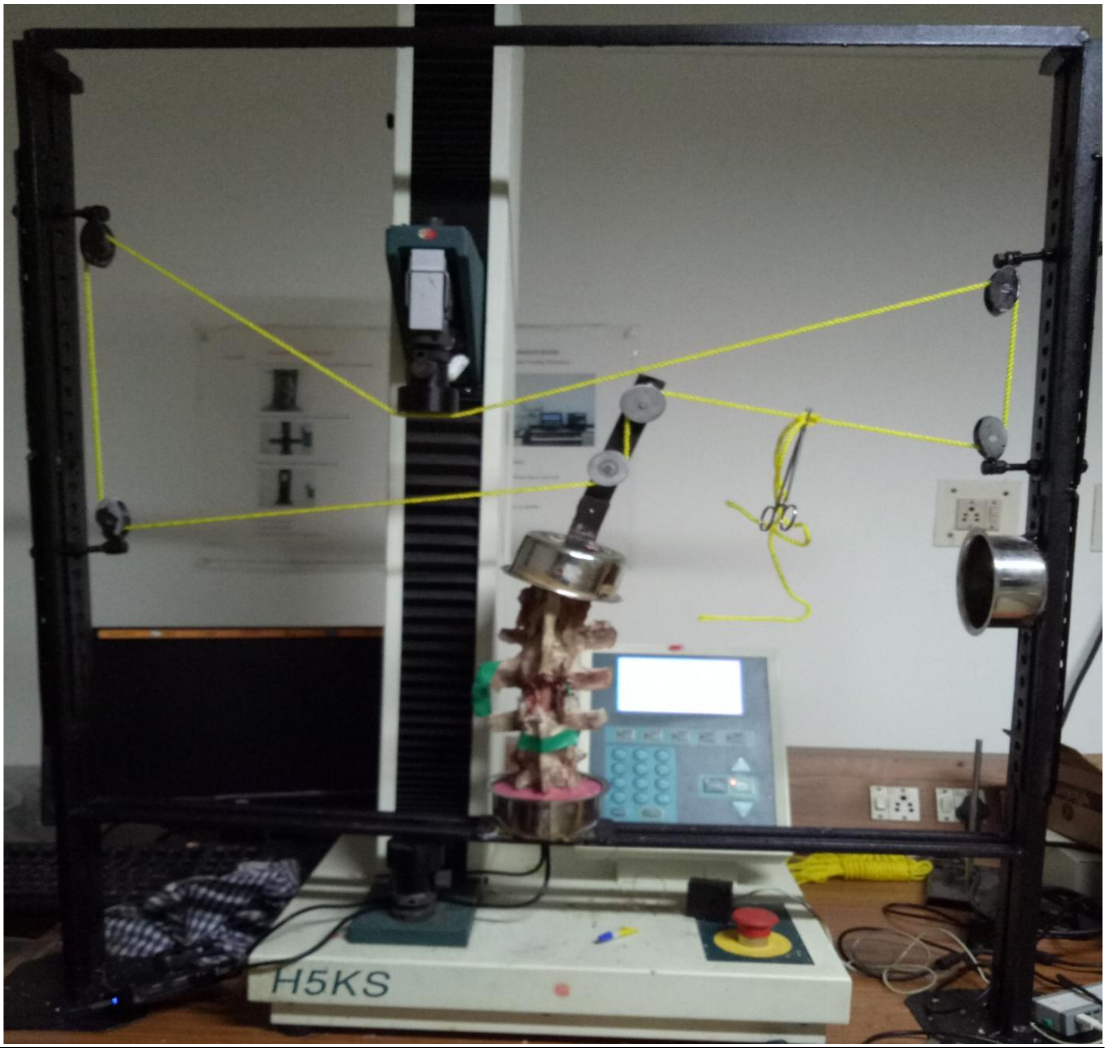
- The standard G4 system includes one hub, one source, and one sensor

Micro tip pressure transducer

The model 060 miniature pressure transducer(Precision Measurement Company, P.O box 7676 Ann Arbor, MI 48107) is the ultimate in pressure sensor miniaturization. It is designed for critical biological or medical applications where an absolute minimum intrusion volume is required and is the smallest pressure sensor commercially available. This transducer utilizes a 350-ohm foil strain gauge carefully attached to the substrate for maximum stability. It is furnished with 1.0 meter 3 conductor 36 stranded copper lead wire, Teflon coated. Model 060 is also made of stainless steel.



Modified Crawford pulley system



This apparatus is used to apply a pure moment to the spine specimen in intro testing and remains uniform throughout the length of the testing specimen.(75) In this model, the pure moment is non-constraining with no interference. This frame consists of a mounting frame with 4 pulleys, 2 placed on either side,2 potting fixtures- bottom one fixed to the frame and the upper ones which are designed for rotations and the other four degrees of motion. The first type of upper mounting fixture has an upright limb with 2 pulleys and the second type has a horizontal limb with equidistant holes. A commercial rope is used to form the circuit including the pulleys and the mounting fixture. The UTM machine applies a force on the upper part of the rope and this causes the construct to deform in the desired direction. The pure moment or the torque required is calculated using the force applied and the vector of displacement happening at the point of contact of the moving limb of UTM and the rope.

METHODOLOGY

This is a biomechanical study done in collaboration with Vellore Institute of Technology (VIT). The apparatus used in this study are the Universal testing machine H5KS, a modified Crawford pulley system with frame, Polhemus G4 3d motion sensor, miniature series pressure transducer model 060 and CMC data acquisition system.

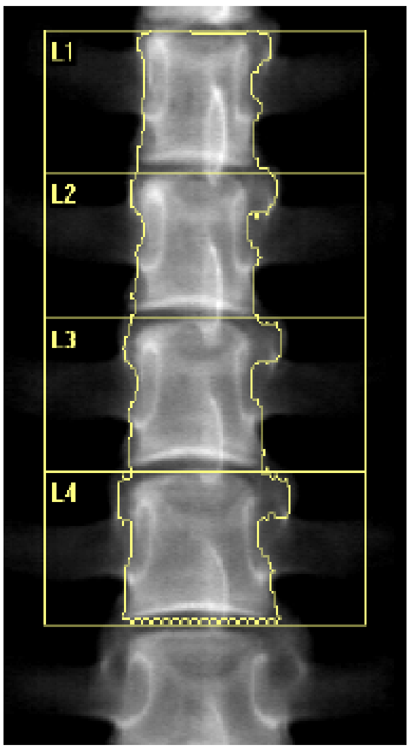
Six fresh calf lumbar spines including L1 to L5 vertebrae were harvested from 6-9 months old calf cadavers. These were bought from the nearby slaughterhouses. Each specimen was weighed and investigated with X-rays and bone mineral density scans to make sure they have no morphological defects or deformity.

Then the specimens were cleared of all the muscles and other soft tissues retaining the disco-ligamentous structures. These were then packaged within double thickness plastic bags and stored at -20°C in a deep freezer.

Only one specimen was tested at a time. The specimen to be tested was taken out of the deep freezer and thawed overnight at room temperature. The lab test was done in medical physics laboratory of VIT. The end vertebrae of the specimen were trimmed and mounted on the modified Crawford frame using dental acrylic powder which sets in 15 mins from the time of mixing. For the lateral bending, flexion and extension movements, an upright mounting bowl was used; for the testing of rotation movements, the mounting bowl with a horizontal limb was used. This was connected to the pulley and rope system.

DEXA scan of a specimen to make sure all specimens are structurally similar:

eferring Physician: DR.FEBIN STUDY



k = 1.164, d0 = 73.0
101 x 164

Scan Information:

Scan Date: 06 July 2017 ID: A07061718
Scan Type: a Lumbar Spine
Analysis: 06 July 2017 14:35 Version 13.4.2:3
Infant Spine
Operator:
Model: Discovery A (S/N 83624)
Comment:

DXA Results Summary:

Region	Area (cm^2)	BMC (g)	BMD (g/cm^2)	T - score	PR (%)	Z - score	AM (%)
L1	14.65	10.78	0.736				
L2	15.98	11.54	0.722				
L3	18.15	12.48	0.687				
L4	19.82	12.72	0.641				
Total	**68.62**	**47.52**	**0.692**				

Total BMD CV 1.0%, ACF = 1.039, BCF = 1.010, TH = 0.093

The study motion segment is taken as L3-L4 level. Hence the intradiscal pressure transducer was inserted into the L3-L4 disc. This was done using a 14G iv cannula which was inserted 1.5cm into the disc and fixed at that position for the rest of the experiment. The miniature pressure sensor was then threaded through the 14G catheter and made sure the sensor tip was outside the catheter. The position of the pressure sensor was confirmed to be in the nucleus pulposum of the disc.

The 3d motion tracking sensors were attached to the L3 and L4 vertebrae to record the range of motion in different test directions.

The specimen was loaded in 6 degrees of motion, ie, flexion, extension, right lateral bending, left lateral bending, clockwise rotation, and counterclockwise rotation. Each specimen underwent 5 procedures in a sequential manner – intact, unilateral laminotomy, bilateral laminotomy, bilateral laminotomy with resection of L3-L4 posterior ligamentous complex and finally a conventional laminectomy. So, a total of 4 types of lumbar spine decompression procedures were put to test.

Pure unidirectional bending moments were applied in each test direction at a rate of 5mm/sec and torque of 7.5 Nm. Force was applied to the pulley system with the moving limb of the UTM. Three preconditioning loading cycles were applied to take the slack out of the system. The coordinates were recorded at the resting position and at the end of the 4^{th} loading cycle. The resultant values were converted to degrees using mathematical calculations. The intradiscal pressure readings were also recorded in the same manner, once at rest and then at maximum loading.

The biomechanical testing was repeated using the same test protocol and the values were recorded for each surgical procedure.

Laminotomy was defined as resection of 5mm of lamina without disturbing interspinous and supraspinous ligaments and facet joint capsules. Laminectomy was defined as resection of the entire lamina along with the spinous process and posterior ligament complex sparing the facet joints. The procedure with posterior ligament complex resection removed both the interspinous and supraspinous ligaments. The instruments used to perform the surgical procedures were Kerrison's rongeur, bone nibbler, heavy toothed tissue forceps and bone cutter.

The increase in the range of movement and the intradiscal pressure variations were measured and statistically evaluated using single tailed paired student t-test and analyzed for any significant variation.

Figure 4

This shows the set up with laminectomy specimen in flexion.

Figure 5

This figure shows the set up with the intact specimen in extension

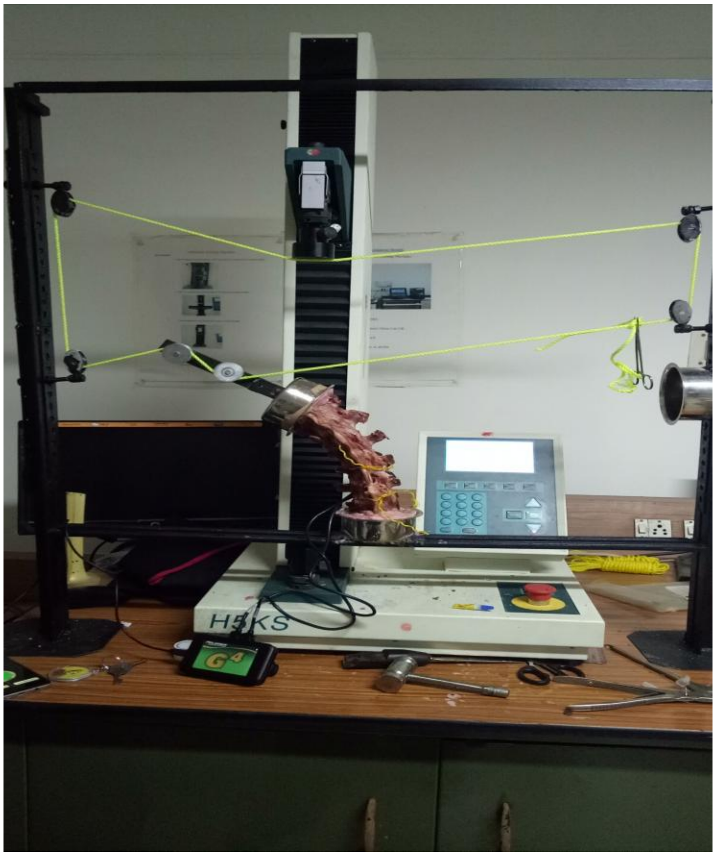


Figure 6

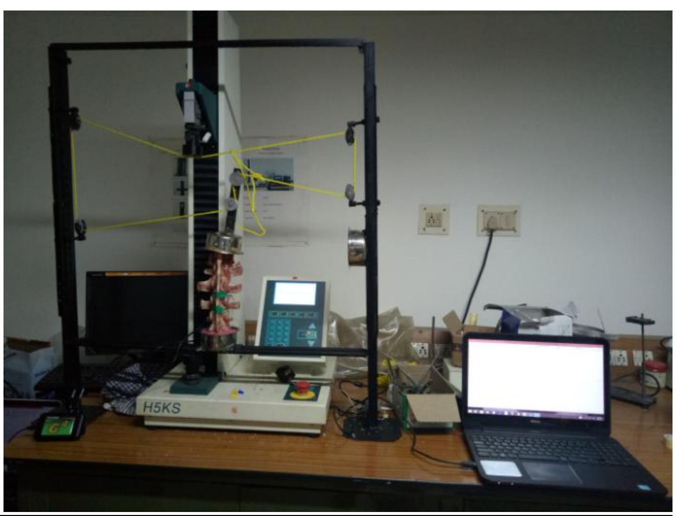


Figure 7

Figure 3 shows laminectomy specimen in left lateral bending and figure 4 shows intact specimen in right lateral bending.

Figure 8a Figure 5b

Figure 5a shows a unilateral laminotomy at L3-L4 level with 3d motion sensors attached at L4 and L3 levels and also pressure sensor inserted into the L3-L4 disc.

Figure 5b shows a bilateral laminotomy specimen in a counterclockwise rotation.

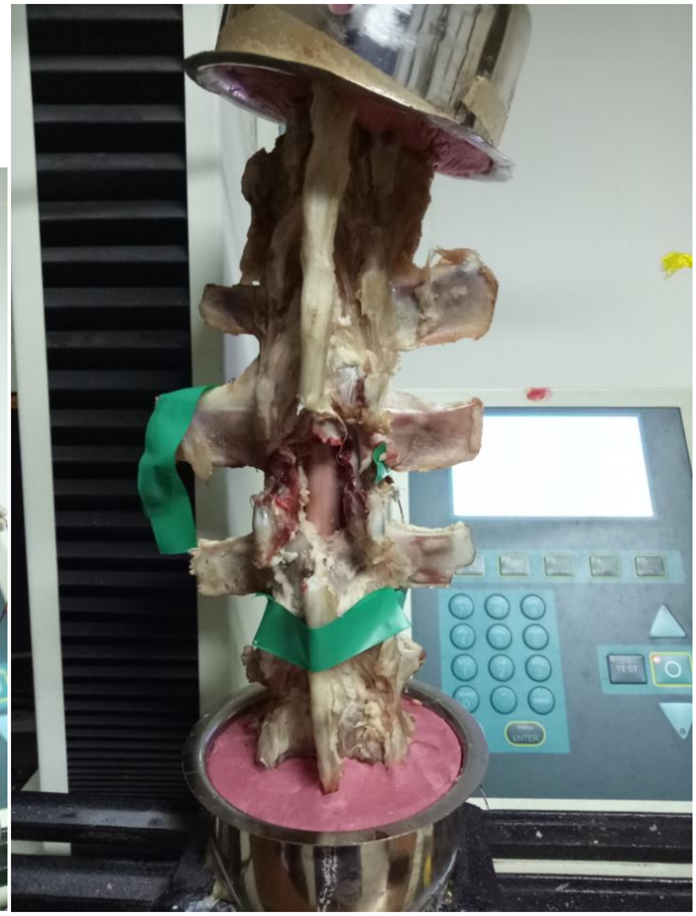


Figure 9a figure 6b

Figure 6a shows a bilateral laminotomy with posterior ligament complex resection specimen and figure 6b shows a laminectomy specimen at L3 vertebra.

Figure 10

Figure 7 shows unilateral laminotomy specimen at L3 vertebra with the pressure transducer inserted at L3-L4 level.

RESULTS

The final laboratory values were analyzed using Wilcoxon signed-rank test. Each of the four procedures done on the calf lumbar spine was compared with the values of the intact specimen. Final values were confirmed to be significant if the p-value was below 0.05.

Abbreviations used:

RLB – Right Lateral Bending

LLB – Left Lateral Bending

FLE – Flexion

Ext – Extension

CW - Clockwise rotation

CCW - Counterclockwise rotation

Unilam – Unilateral laminotomy

Bilam - Bilateral laminotomy

Ligres – bilateral laminotomy with ligament resection

Laminec – Laminectomy

Intradiscal pressure:

subgrp			Mean	N	Std. Deviation	Std. Error Mean	p-value
L4 RLB	Pair 1	Intact	.0852	6	.01613	.00658	0.176
		Uni Lam	.1008	6	.03639	.01486	
L4 LLB	Pair 1	Intact	.0867	6	.05715	.02333	0.138
		UniLam	.1212	6	.07057	.02881	
L4 FLE	Pair 1	Intact	.0817	6	.03656	.01493	0.680
		UniLam	.0842	6	.03666	.01497	
L4 EXT	Pair 1	Intact	.0717	6	.04401	.01797	0.136
		UniLam	.0887	6	.03713	.01516	
L4 CW	Pair 1	Intact	.0672	6	.03699	.01510	0.345
		UniLam	.0813	6	.05541	.02262	
L4 CCW	Pair 1	Intact	.0547	6	.07139	.02914	0.114
		UniLam	.0743	6	.08367	.03416	

Above seen table compares unilateral laminotomy with the intact specimen values in all 6 degrees of motion. The p values are all found to be nil significant.

subgrp			Mean	N	Std. Deviation	Std. Error Mean	P values
L4 RLB	Pair 1	Intact	.0852	6	.01613	.00658	
		BiLam	.1300	6	.04195	.01713	0.028
L4 LLB	Pair 1	Intact	.0867	6	.05715	.02333	
		BiLam	.0767	6	.01751	.00715	0.752
L4 FLE	Pair 1	Intact	.0817	6	.03656	.01493	
		BiLam	.0917	6	.01602	.00654	0.336
L4 EXT	Pair 1	Intact	.0717	6	.04401	.01797	
		BiLam	.0983	6	.02858	.01167	0.102
L4 CW	Pair 1	Intact	.0672	6	.03699	.01510	
		BiLam	.1150	6	.06595	.02693	0.104
L4 CCW	Pair 1	Intact	.0547	6	.07139	.02914	
		BiLam	.0907	6	.08022	.03275	0.207

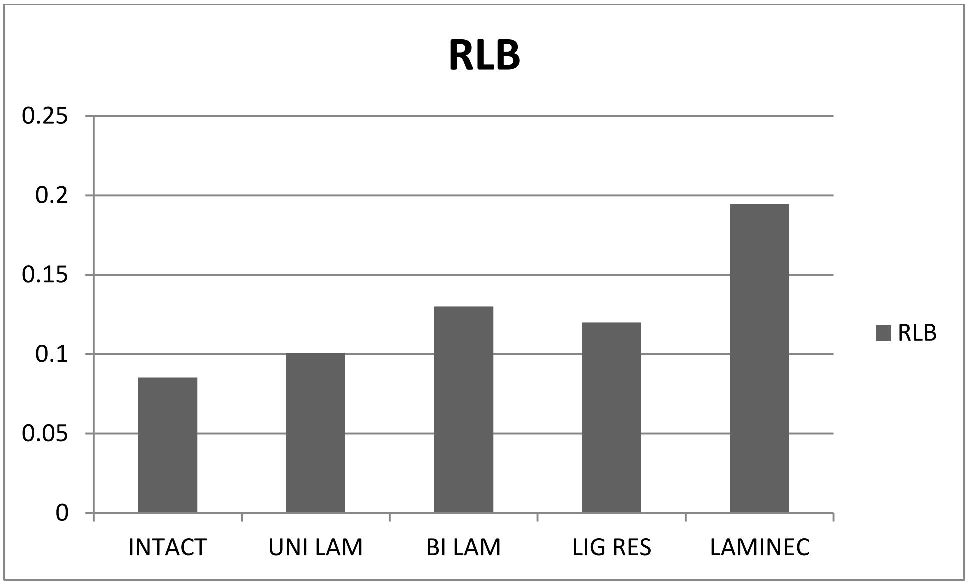
Above seen table compares bilateral laminotomy with the intact specimen values in all 6 degrees of motion. The p values are all found to be nil significant except for right lateral bending with p-value of 0.028.

subgrp			Mean	N	Std. Deviation	Std. Error Mean	P value
L4 RLB	Pair 1	Intact	.0852	6	.01613	.00658	
		LigRes	.1200	6	.04690	.01915	0.075
L4 LLB	Pair 1	Intact	.0867	6	.05715	.02333	
		LigRes	.1033	6	.06121	.02499	0.340
L4 FLE	Pair 1	Intact	.0817	6	.03656	.01493	
		LigRes	.1067	6	.01506	.00615	0.093
L4 EXT	Pair 1	Intact	.0717	6	.04401	.01797	
		LigRes	.1200	6	.04648	.01897	0.028
L4 CW	Pair 1	Intact	.0672	6	.03699	.01510	
		LigRes	.1300	6	.05020	.02049	0.046
L4 CCW	Pair 1	Intact	.0547	6	.07139	.02914	
		LigRes	.1100	6	.06033	.02463	0.075

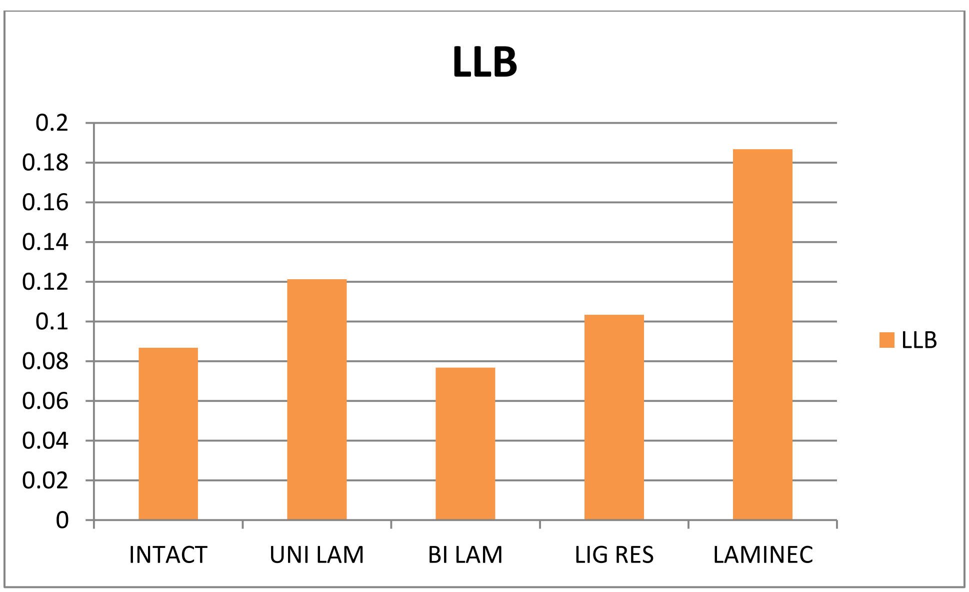
Above seen table compares bilateral laminotomy plus interspinous ligament resection procedure with the intact specimen values in all 6 degrees of motion. The p values are found to be significant only in extension and clockwise rotational direction.

subgrp			Mean	N	Std. Deviation	Std. Error Mean	P value
L4 RLB	Pair 1	Intact	.0852	6	.01613	.00658	
		Laminec	.1945	6	.06275	.02562	0.028
L4 LLB	Pair 1	Intact	.0867	6	.05715	.02333	
		Laminec	.1867	6	.03983	.01626	0.042
L4 FLE	Pair 1	Intact	.0817	6	.03656	.01493	
		Laminec	.1492	6	.04079	.01665	0.027
L4 EXT	Pair 1	Intact	.0717	6	.04401	.01797	
		Laminec	.2000	6	.06099	.02490	0.027
L4 CW	Pair 1	Intact	.0672	6	.03699	.01510	
		Laminec	.1963	6	.06147	.02509	0.028
L4 CCW	Pair 1	Intact	.0547	6	.07139	.02914	
		Laminec	.1605	6	.08943	.03651	0.027

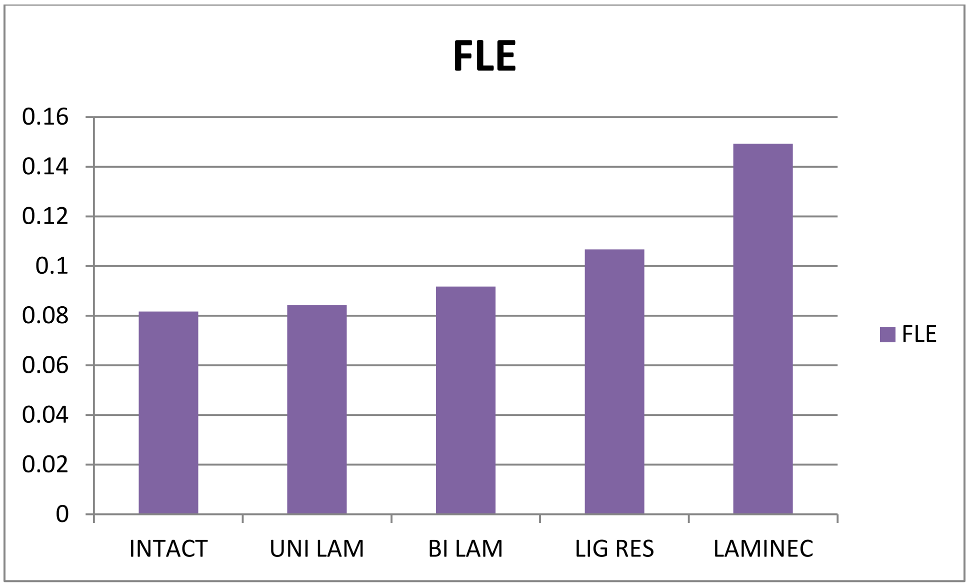
Above seen table compares laminectomy with the intact specimen values in all 6 degrees of motion. The p values are found to be significant in all test directions in terms of intradiscal pressure.



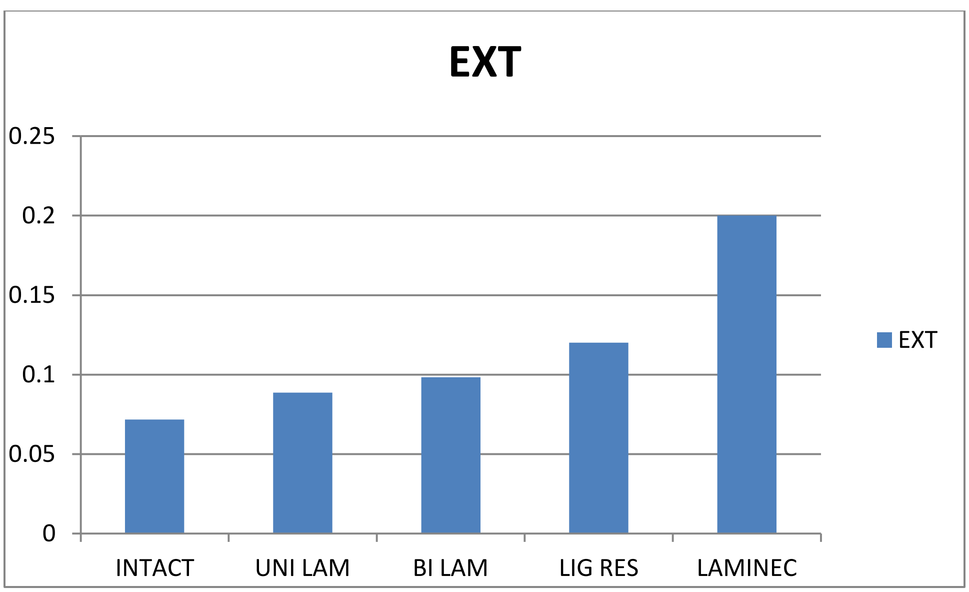
The average intradiscal pressure of each procedure in right lateral bending is shown above. The pressure almost doubled in the laminectomy specimen.



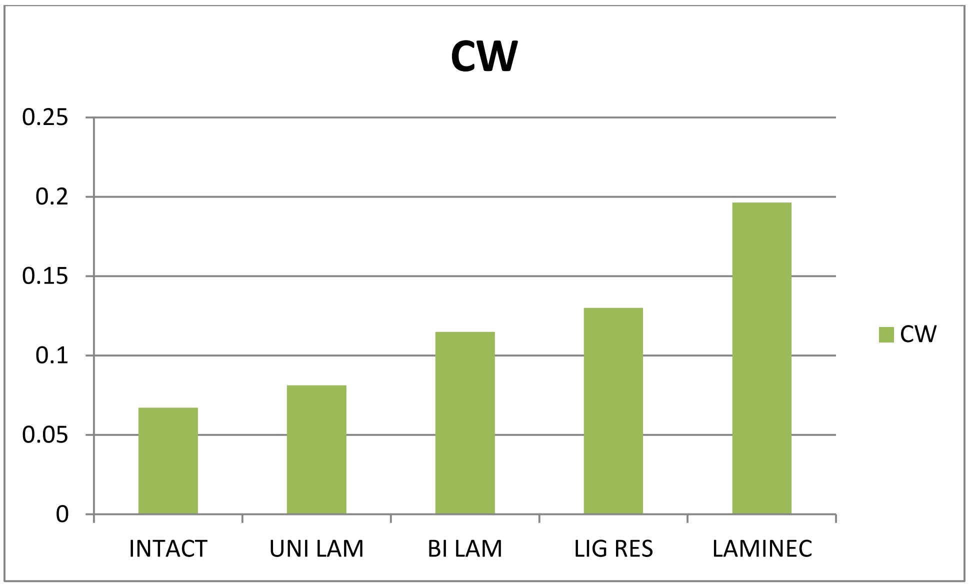
The average intradiscal pressure of each procedure in left lateral bending is shown above. The pressure almost doubled in the laminectomy specimen



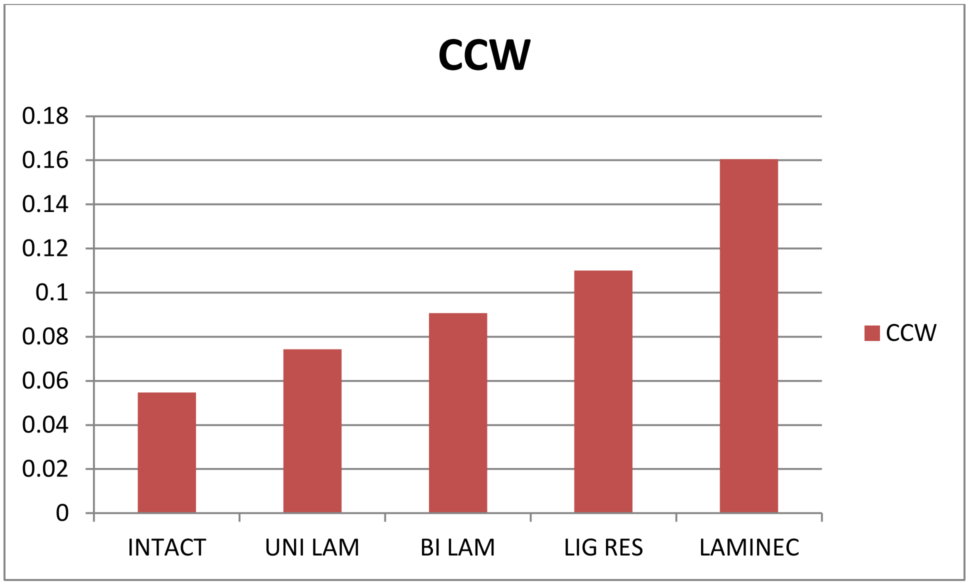
The average intradiscal pressure of each procedure in flexion is shown above. The pressure almost doubled in the laminectomy specimen.



The average intradiscal pressure of each procedure in extension is shown above. The pressure almost tripled in the laminectomy specimen.



The average intradiscal pressure of each procedure in the clockwise rotation is shown above. The pressure almost doubled in the laminectomy specimen.



The average intradiscal pressure of each procedure in a counterclockwise direction of motion is shown above. The pressure became more than 3 times in the laminectomy specimen compared to the intact specimen.

The range of motion (in degrees):

subgroup			Mean	N	Std. Deviation	Std. Error Mean	UniLam – Intact P value
L4 RLB	Pair 1	Intact	15.3185	6	23.03572	9.40429	
		Uni Lam	18.0156	6	25.69445	10.48972	0.028
L4 LLB	Pair 1	Intact	7.1270	6	6.87476	2.80661	
		UniLam	7.5190	6	6.95962	2.84125	0.600
L4 FLEX	Pair 1	Intact	76.5770	6	8.62571	3.52143	
		Uni Lam	76.3301	6	9.32091	3.80525	0.917
L4 EXTN	Pair 1	Intact	37.1195	6	26.19441	10.69382	
		Uni Lam	36.4536	6	24.63527	10.05731	0.599
L4 CW	Pair 1	Intact	23.2002	6	15.89040	6.48723	
		Uni Lam	23.8582	6	16.18670	6.60819	0.249
L4 CCW	Pair 1	Intact	17.8265	6	13.54706	5.53056	
		Uni Lam	17.6527	6	13.08467	5.34179	0.753

The above-mentioned table shows that p-value (0.028) is significant only in the right lateral bending motion when unilateral laminotomy was compared with the intact testing specimen.

subgroup			Mean	N	Std. Deviation	Std. Error Mean	BiLam - Intact
L4 RLB	Pair 1	Intact	15.3185	6	-1.787[a]	9.40429	
		Bi Lam	17.3119	6	.074	10.07891	0.074
L4 LLB	Pair 1	Intact	7.1270	6	-1.992[a]	2.80661	
		Bi Lam	8.5865	6	.046	3.20466	0.046
L4 FLEX	Pair 1	Intact	76.5770	6	-.734[a]	3.52143	
		Bi Lam	77.9587	6	.463	4.00062	0.463
L4 EXTN	Pair 1	Intact	37.1195	6	-.524[a]	10.69382	
		Bi Lam	36.7933	6	.600	10.28133	0.600
L4 CW	Pair 1	Intact	23.2002	6	-2.201[a]	6.48723	
		Bi Lam	26.1123	6	.028	7.02732	0.028
L4 CCW	Pair 1	Intact	17.8265	6	-2.201[a]	5.53056	
		Bi Lam	19.4097	6	.028	5.62209	0.028

The above-shown table tells us about the significance of motion in left lateral bending, clockwise and counterclockwise motions when the intact specimen was compared with bilateral laminotomy specimen.

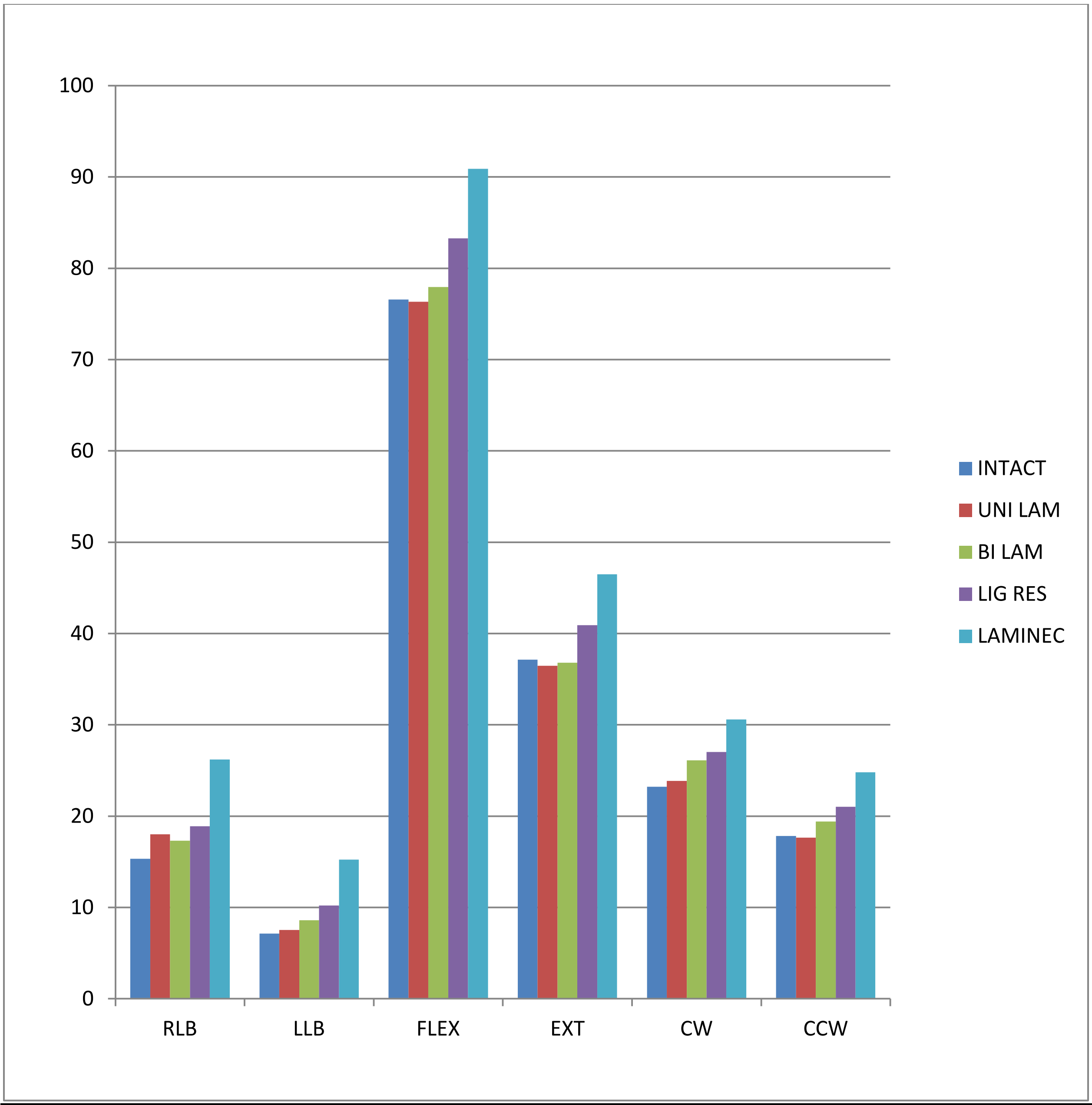
subgroup			Mean	N	Std. Deviation	Std. Error Mean	Lig Res - Intact
L4 RLB	Pair 1	Intact	15.3185	6	23.03572	9.40429	
		Lig Res	18.8856	6	21.65381	8.84013	0.028
L4 LLB	Pair 1	Intact	7.1270	6	6.87476	2.80661	
		Lig Res	10.2107	6	7.20342	2.94079	0.028
L4 FLEX	Pair 1	Intact	76.5770	6	8.62571	3.52143	
		Lig Res	83.2894	6	10.86261	4.43464	0.027
L4 EXTN	Pair 1	Intact	37.1195	6	26.19441	10.69382	
		Lig Res	40.8995	6	25.31971	10.33673	0.046
L4 CW	Pair 1	Intact	23.2002	6	15.89040	6.48723	
		Lig Res	27.0207	6	16.03922	6.54799	0.028
L4 CCW	Pair 1	Intact	17.8265	6	13.54706	5.53056	
		Lig Res	21.0218	6	14.03755	5.73081	0.027

The above table shows that all the difference in the range of motion is significant when the intact specimen was compared with the specimens which underwent bilateral laminotomy plus ligament resection.

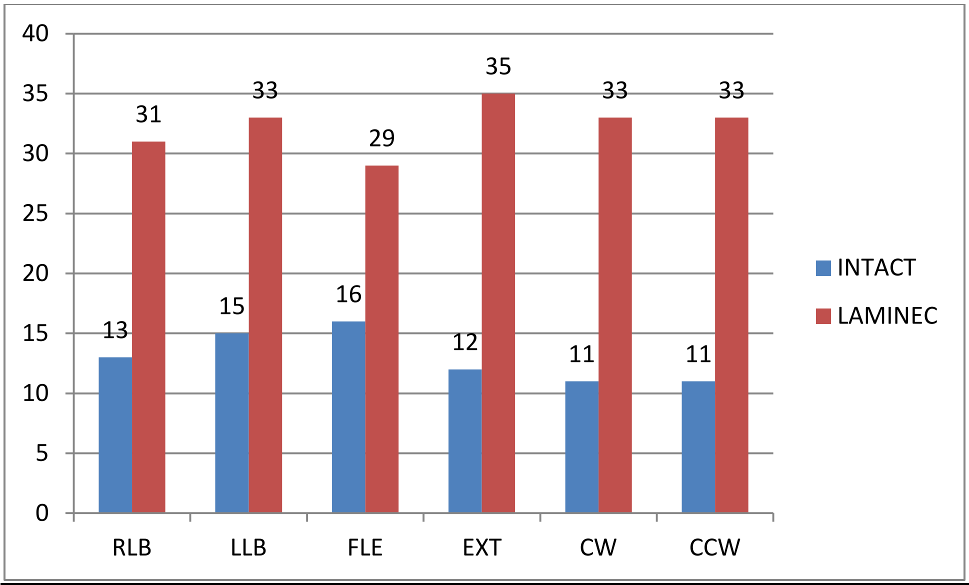
Paired Samples Statistics

subgroup			Mean	N	Std. Deviation	Std. Error Mean	Laminec - Intact
L4 RLB	Pair 1	Intact	15.3185	6	23.03572	9.40429	
		Laminec	26.1906	6	26.76475	10.92666	0.028
L4 LLB	Pair 1	Intact	7.1270	6	6.87476	2.80661	
		Laminec	15.2312	6	7.20474	2.94132	0.028
L4 FLEX	Pair 1	Intact	76.5770	6	8.62571	3.52143	
		Laminec	90.9012	6	11.19765	4.57142	0.028
L4 EXTN	Pair 1	Intact	37.1195	6	26.19441	10.69382	
		Laminec	46.4858	6	26.93307	10.99538	0.028
L4 CW	Pair 1	Intact	23.2002	6	15.89040	6.48723	
		Laminec	30.5709	6	16.53737	6.75135	0.028
L4 CCW	Pair 1	Intact	17.8265	6	13.54706	5.53056	
		Laminec	24.8078	6	14.22826	5.80866	0.028

The above table shows that all the values are significant in all testing directions when laminectomy specimens are compared with intact specimens.

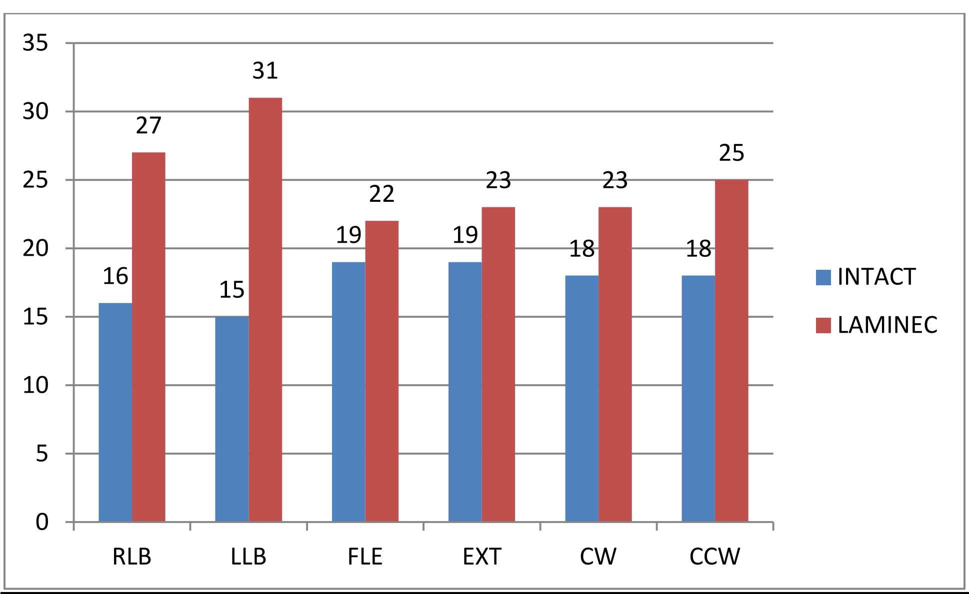


The average range of motion at the surgical level (L3-L4) in all test directions in degrees is shown above. The range of motion is maximum in the laminectomy bar.

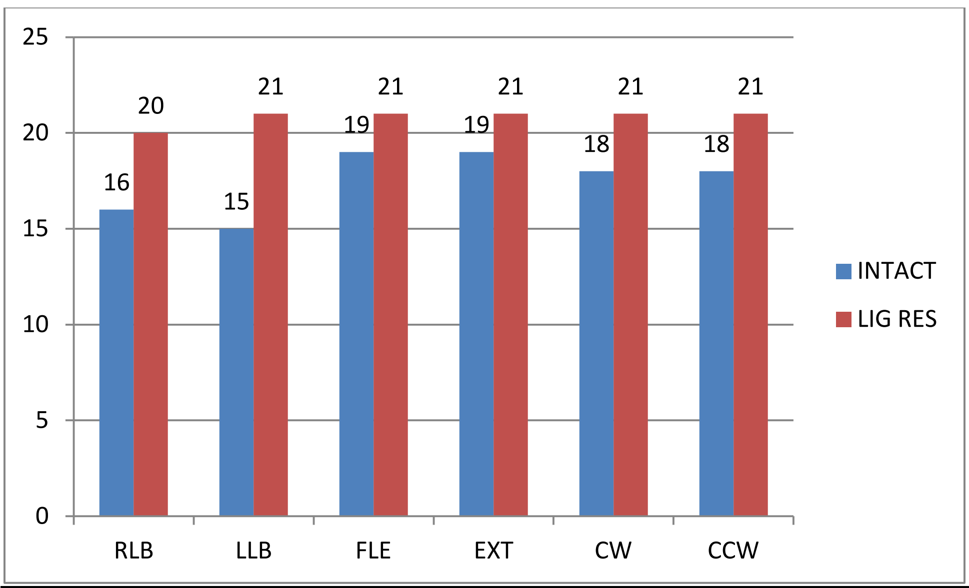


The above bar diagram shows the percentage increase in the intradiscal pressure in the laminectomy group compared to the intact specimens.

Finally, intradiscal pressures were found to be high and statistically significant in laminectomy group in all the 6 testing directions.



This bar diagram shows the percentage increase in the laminectomy specimens compared to the intact specimens with regards to the range of motion.



The above-mentioned bar diagram shows the percentage increase in the bilateral laminotomy ligament resection group compared to the intact specimens with regards to the range of motion.

It is observed that the range of motion becomes significant in all testing directions in both ligament resection group and the laminectomy group.

DISCUSSION

Multiple authors have reported about Surgery Induced Spinal Instability **(SISI)**caused due to the conventional laminectomy for degenerative lumbar canal stenosis. SISI mainly includes spondylolisthesis and segmental angulation after decompressive laminectomy in the lumbar spine. Yang et al analyzed factors contributing to SISI and found that female sex, lordotic angle, facet joint tropism and asymmetrical paraspinal volume are the factors which are significantly associated with the postoperative spondylolisthesis.(76) Bisschop et al looked into factors prognosticating spinal instability after a laminectomy and concluded that the instability is predicted by bone mineral density, intervertebral disc geometry, and presence or absence of osteophytes .(77) Haddadi et al compared bilateral laminotomy and laminectomy with a follow up of one year concluded that patient satisfaction, as well as back pain or leg pain, were significantly lower in the bilateral laminotomy group.(78)

Several alternative procedures to conventional laminectomy have been tried over the years and none could prove its superiority over laminectomy in terms of clinical outcomes. In a systematic review by Overdevest et al, they concluded by saying that the evidence provided so far by the various studies comparing laminectomy and other tissue preserving decompression procedures is of low quality.(19)The different types of tissue preserving surgeries which are described are unilateral laminotomy, bilateral laminotomy, bilateral laminotomy with posterior ligament complex resection, spinous process splitting laminectomy etc.

Previous biomechanical studies have also compared laminotomy and laminectomy in terms of postoperative structural stability. Tai et al in 2008 compared bilateral laminotomy and laminectomy in a porcine model. They found that under flexion motion, intervertebral displacement was statistically significant in the laminectomy group. He concluded by saying preserving posterior complex ligament integrity makes the segment more stable.(79) In 2002 Rao et al published his data in calf spine model comparing intradiscal pressure and range of motion between bilateral laminotomy and laminectomy. His findings were that laminectomy causes more destabilization of a spinal segment than a bilateral laminotomy.(80) Ho et al in a porcine model compared flexion and extension motions in unilateral laminotomy, bilateral laminotomy, and laminectomy. He found that instability is significant in laminectomy group.(81)

Our study was done in the medical physics laboratory of Vellore Institute of Technology over a period of nine months and 6 calf spines under the age of one year was used. This biomechanical study provides a quantitative measure of the mechanical stability in terms of the range of motion and intradiscal pressure. We have compared four procedures – unilateral laminotomy, bilateral laminotomy, bilateral laminotomy with posterior ligament complex resection and conventional laminectomy. These were compared with the values of the intact specimen. All six degrees of motion were studied and compared. Intradiscal pressure was significantly raised after laminectomy in all testing directions-right lateral bending (18%), left lateral bending (18%), flexion (13%), extension (23%),clockwise rotation (22%) and anticlockwise rotation (22%). In the bilateral laminotomy with ligament resection group, extension (9%) and clockwise rotations (11%) were found to be significantly elevated. Bilateral laminotomy group had only right lateral bending (8%)which was significant. In terms of the range of motion, all the values in the ligament resection group and the laminectomy group had significant values confirming instability of the spinal segment. These values suggest that removal of the posterior ligament complex adds to the Surgery Induced Spinal Instability (SISI). Conventional laminectomy causes both increased intradiscal pressure and range of motion leading to destabilization of the spinal segment. Ours is the only study which compares all the 4 procedures in terms of 6 degrees of range of motion and intradiscal pressure. All experimental variables of spinal biomechanical testing like providing a pure moment to the testing specimen, type of loading, magnitude of loading and rate of load applied were followed in this study.(82)

The main limitation of the study is the anatomical difference between the calf lumbar spine and human lumbar spine. All 4 procedures being done in the same specimen and putting it to test through all 6 degrees of motion could have affected the biomechanical properties of the specimen. The human cadaveric studies should be done to confirm the findings in the future. Furthermore, as degeneration was not present in any of the calves, we should cautiously apply these findings in real clinical practice.

CONCLUSION

Our study has rejected the null hypothesis and confirms that laminectomy can cause surgery induced spinal instability (SISI) as compared to laminotomy in terms of the range of motion and intradiscal pressure. Bilateral laminotomy with posterior ligament complex resection also causes instability which confirms the role of the posterior ligaments in stabilizing the spine. We also found that Unilateral and bilateral laminotomies are safer procedures for decompressing the spinal canal in terms of structural stability.

ANNEXURES

CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

May 10, 2017

Dr. Febin C Kunnath,
PG Registrar,
Department of Orthopaedics,
Christian Medical College,
Vellore – 632 004.

Sub: **Fluid Research Grant New Proposal:**
Biomechanical comparison of lumbar laminectomy versus laminotomy in a cadaveric calf spine model.
Dr. Febin C Kunnath, PG Registrar, Department of Orthopaedics, Dr. Kenny S David, Professor & Head Department of Orthopaedic surgery, Dr. N. Arunai Nambi Raj PhD, Professor of Physics , Vellore Institute of Technology

Ref: IRB Min. No. 10528 dated 01.02.2017

Dear Dr. Febin C Kunnath,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - ETHICS COMMITTEE
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

CC: Dr. Kenny S David, Professor Department of Orthopaedics, CMC, Vellore

1 of 4

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

May 10, 2017

Dr. Febin C Kunnath,
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Department of Orthopaedics,
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Sub: **Fluid Research Grant New Proposal:**
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Ref: IRB Min. No. 10528 dated 01.02.2017

Dear Dr. Febin C Kunnath,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Biomechanical comparison of lumbar laminectomy versus laminotomy in a cadaveric calf spine model" on February 01st 2017.

The Committee reviewed the following documents:

1. IRB Application format
2. Cvs of Drs. Kenny S David and Arunai Nambi Raj
3. No. of documents 1 – 2.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on February 01st 2017 in the Jacob Chandy Hall, Paul Brand Building, Christian Medical College, Vellore 632002.

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Ratna Prabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Dr. Rajesh Kannangai	MD, PhD.	Professor, Clinical Virology, CMC, Vellore	Internal, Clinician
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Visalakshi. J	MPH, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist &Epidemiologist
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse

Data sheet:

	A	B	C	D	E
1	Intact	Uni-Lam	Bi-Lam	Lig-Res	Laminec
2	0.080	0.080	0.090	0.090	0.160
3	0.090	0.130	0.130	0.130	0.250
4	0.061	0.065	0.130	0.120	0.190
5	0.09	0.080	0.11	0.120	0.137
6	0.11	0.160	0.21	0.200	0.290
7	0.080	0.090	0.110	0.060	0.140
8	0.040	0.017	0.050	0.050	0.140
9	0.040	0.160	0.080	0.110	0.230
10	0.180	0.190	0.100	0.120	0.180
11	0.080	0.140	0.070	0.090	0.170
12	0.050	0.050	0.070	0.040	0.160
13	0.130	0.170	0.090	0.210	0.240
14	0.030	0.030	0.070	0.080	0.090
15	0.090	0.080	0.080	0.110	0.160
16	0.140	0.145	0.110	0.120	0.190
17	0.08	0.090	0.11	0.110	0.140
18	0.09	0.080	0.09	0.100	0.120

	A	B	C	D	E
1	Intact	Uni-Lam	Bi-Lam	Lig-Res	Laminec
2	5.27	8.33	3.22	6.64	13.31
3	61.81	70.13	66.80	62.15	78.87
4	10.02	10.08	13.09	15.08	22.98
5	2.17	4.32	4.42	5.60	7.35
6	2.61	4.14	3.25	7.77	9.64
7	10.02	11.08	13.09	16.08	24.98
8	4.17	2.96	3.51	6.24	17.15
9	5.61	6.13	6.88	7.66	9.80
10	5.86	5.27	7.11	9.80	12.79
11	20.79	21.54	24.12	24.13	28.07
12	1.48	3.94	2.78	3.64	7.79
13	4.86	5.27	7.11	9.80	15.79
14	85.07	86.89	91.29	100.28	107.44
15	85.97	86.48	85.57	90.88	96.91
16	76.84	72.00	76.28	78.26	90.28
17	63.60	62.54	63.17	69.14	73.56
18	70.14	73.06	73.16	81.90	86.93

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