DESIGN OF LUMBAR IVD IMPLANT BASED ON 3D PRINTING METHOD USING BIOCOMPATIBLE POLYMERS

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ABSTRACT:

Spinal fusion surgery is a common procedure for treatment of degenerative disc disease, herniated discs, and spinal fractures. Intervertebral disc implants are commonly used to replace damaged or diseased discs and restore spinal stability. However, currently available implants have limitations such as limited range of motion, subsidence, and stress shielding. In this paper, we propose a new design for intervertebral disc implant that overcomes these limitations and improves clinical outcomes.

The proposed implant is designed to mimic the biomechanics of a healthy intervertebral disc, with a composite structure that allows for both flexibility and stability. The implant consists of an outer ring made of a durable polymer and an inner core made of a compressible material, allowing for shock absorption and load transfer. The implant provides a porous surface for bone ingrowth, promoting osseointegration and long-term stability.

Finite element analysis and was conducted to evaluate the performance of the proposed implant design. Results exhibited that the implant had superior load-bearing capacity and reduced stress concentration. In addition, the implant exhibited minimal subsidence and preserved range of motion, which may lead to improved patient outcomes and reduced revision rates.

In conclusion, the proposed intervertebral disc implant design has the potential to improve clinical outcomes and provide a more effective treatment option for patients administered for spinal fusion surgery. Further studies are needed to validate the efficiency and safety of the proposed implant in clinical settings.

Keywords: **Dynamic stabilization; Disc prosthesis; Motion preservation; Arthroplasty; Total disc replacement; Lumbar vertebrae.**

I. INTRODUCTION

One of the vital parts of the human anatomy is the vertebral column which provides a pivotal role of being the structure of support and mobility for the torso region of the body, and a protective layer for the spinal cord preventing it from any damage or fatigue. This vertebral column is basically not a single structure but an array of many vertebrae of different size and morphology which is varied based on the position in the vertebral column.

The vertebral column of human body is categorized into 5 divisions namely: The Cervical spine, The Thoracic spine, The Lumbar spine, The Sacrum spine and The Coccyx. The categorization is made possible by the anatomical structure of the vertebrae at each position. These vertebrae are nothing but bony structures, so to prevent any frictional abrasions between them Intervertebral Vertebral Disc (IVD) is present.

The intervertebral discs are found to be soft, cushion-like structures located in the middle of two vertebrae (bones) of the spinal column. They function to absorb shock, distribute pressure evenly, and allow for movement and flexibility in the spine. Each disc is composed of annulus fibrosus which is a tough outer layer, and a soft, jelly-like center which is defined as the nucleus pulposus. The annulus fibrosus contains layers of fibrous tissue that surround and protect the nucleus pulposus. The nucleus pulposus is found to be a gel-like substance that provides cushioning and support to the spine. Together, they form the intervertebral disc.

At times these IVD get damaged which is stated as Degenerative Disc Disease, this is a condition of the discs between vertebrae with loss of cushioning, fragmentation and herniation related to ageing. There may be no symptoms. When the spine becomes less flexible, bone spurs may wrap a nerve root and cause pain or weakness. Spinal disc degeneration affects anywhere between 12% and 35% of the population today, making it a fairly common problem. When severe enough, it can result the intervertebral disc itself bulging and herniating. It typically affects the lumbar region of the spine.

Multiple treatment methods are currently available to address this issue, with spinal fusion surgery and total disc replacement (TDR) being two of the most popular. Although the majority of patients experience pain relief from these treatments, there are still a number of drawbacks. For instance, TDR can result in hypermobility in between the vertebrae and provide little to no shock absorption of loads, and spinal fusion surgery drastically restricts the mobility of its patients by joining two vertebrae together, prohibiting any individual movement. Therefore in order to ease patients' discomfort and retain shock absorption, motion, and load cushioning that are equivalent to the criteria of the healthy intervertebral disc while yet staying biocompatible, a better therapeutic alternative is required.

II.ANATOMY OF LUMBAR AND IVD

1.LUMBAR SPINE

The lumbar portion of the spine connects the thoracic spine to the pelvis and extends to the sacrum. It holds five vertebrae (L1-L5) and five discs between the vertebrae. The lumbar spine's principal roles include carrying high loads, protecting the spinal cord when there is a movement and when the trunk bends or twists, and providing utmost stability while preserving the trunk's essential mobility around the hips and pelvis.

The lumbar spine contains nerves which are much more similar to those of the spine in cervical , in that each nerve that comes out of the different levels of vertebrae have very unique functions, which if disturbed or damaged can hinder an individual's daily life and possibly leave them get paralyzed below the waist down .These nerves control mainly the anterior of the lower extremities, and include: L1 nerve that controls partial lower back, partial lower abdominal, and partial hip flexor muscles; L2 nerve that controls muscles that extend or flex the hip joint (hip flexors, outer gluteus/gluteus medial), and groin regions; L3 nerve that controls major quadriceps muscles to extend the lower limb leg and straighten the knee; L4 nerve that controls the ankle muscles that cause dorsi-flexion of the foot (drawing the toes upwards), great toe, and outer quadriceps muscle; L5 nerve that control outer muscles of the lower extremity (iliotibial tract, tibialis anterior), and major foot muscles .

The L1, L2, L3, and L4 nerves share sensations for the anterior and inner surfaces of the lower extremity; L4 and L5 nerves share sensations for the foot; L4 creates sensations in the medial side of great toe;

2.INTERVERTEBRAL DISC

Intervertebral discs, which are named after the two vertebrae they positioned between (e.g., C6-C7, T7-T8, and L4-L5, also known as L4/L5) for every set of vertebra all through out the vertebral column. About 20 to 30 percent of the spine is contributed by these discs, which perform a number of vital tasks like cushioning loads, absorbing shock from impacts, distributing weight, allowing individual vertebrae to move, and allowing nutrients along with other fluid to reach the spinal cord and spine.

The thickness of each disc varies across the spine along with a varied change in the cross-sectional areas of the discs. According to research, the cervical and the lumbar spines have substantially thicker discs than the thoracic spine, probably as an adaptation to the ROM (Range Of Motion) expected from these regions, including flexion-extension and torsion.

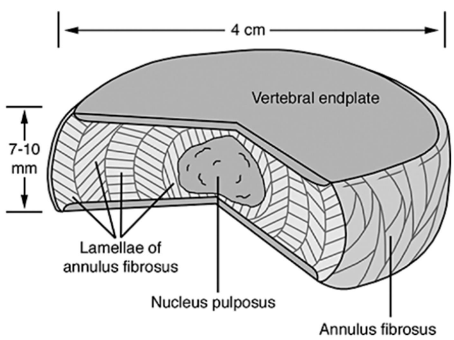


Figure 1: A Cutout Portion of IVD

3. LUMBAR DISC

There are five intervertebral discs in the lumbar spine, numbered L1/L2 through L5/S1. Out of all the spinal segments, the lumbar discs have the largest cross-sectional area, with L2/L3 - L5/S1 being nearly equal. This is necessary because these discs must withstand the most strain without becoming overly stressed and failing. The mean cross-sectional areas of the lumbar discs are as follows; L1/L2 having an area of 1400 mm2; L2/L3 having an area of 1640 mm2; L3/L4 having an area of 1690 mm2; L4/L5 having an area of 1660 mm2; L5/S1 having an area of 1680 mm2

The three major components of each intervertebral disc, which has a complex structure, are the nucleus pulposus, the cartilage vertebral endplates, and the annulus fibrosus. These components give certain necessary properties to the intervertebral discs' structural integrity and properties as a whole

4. ANNULUS FIBROSUS

The inner and outer annulus fibrosus are considered to be the two main portions of the annulus fibrosus, which is made up of concentric rings, or lamellae, enclosing the nucleus pulposus. Proteoglycans (11-20% inner and 5-8% outer dry weight), water, and fibrocartilage, and other factors involved in extracellular-matrix, however with increasing radial distance from the nucleus, the concentration of some of these components change, mainly collagen and proteoglycans. These tissues and cells contribute to the annulus fibrosus' more rigid structure, which is necessary for it to perform its essential functions in the intervertebral discs. The nucleus pulposus is housed in the annulus fibrosus, which also protects the spine by maintaining its pressure and prevents it from impinging on the disc by virtue of its inhomogeneous, anisotropic, and nonlinear mechanical characteristics. The structure of numerous lamella and alternate collagen fiber angles enables these key functions.

5. NUCLEUS PULPOSUS

The annulus fibrosus surrounds the nucleus pulposus, which prevents it from leaking into the spinal canal, and it is located in the centre of the disc. In order to perform its essential functions in the intervertebral disc of compressive load dispersion, compressive shock absorption, and maintaining the interior of the disc swelled for appropriate internal pressure, the nucleus, an incompressible structure, is composed of around 80–90% water.

6. VERTEBRAL ENDPLATES

The vertebral endplates are made of hyaline cartilage containing proteoglycans for swelling qualities, and they are located on the top and bottom of each intervertebral disc. Their main duty is to mechanically connect the vertebral nucleus and annulus to the dense, more durable cortical bone shell and prevent the nucleus from protruding into the trabecular bone's soft, spongy/cancellous middle. The strongest part of the intervertebral disc, the vertebral endplates, usually snaps after the vertebral body has already fractured.

Additionally, the vertebral endplates play the unusual job of serving as the primary conduit for blood and nutritional flow into and out of the disc.. The mobile app initially displays the prescription to the pharmacist so that he or she may confirm that the meds are available before moving on to the next stage.

III. IVD ABNORMALITIES

1.DISC HERNIATION

Disc herniation, also known as a slipped disc or herniated disc, is a common IVD abnormality. It happens when a tear or other weakness in the out most layer of the intervertebral disc allows the soft interior material to emerge. Although it can happen anywhere in the spine, disc herniation frequently affects the neck and lower back (lumbar spine). Depending on where and how severe the herniation is, the symptoms of a disc herniation may vary.

2. DISC DEGENERATION

Disc degeneration is another common IVD abnormality, which can result in chronic pain in back bone and reduced mobility. It occurs when the intervertebral discs lose their ability of absorbing shock and provide support due to natural wear and tear over time. While disc degeneration is a normal segment of the aging process, certain factors can accelerate the degeneration, such as genetics, repetitive stress, poor posture, and injury. Preventive measures, such as maintaining good posture, engaging in regular exercise, and avoiding repetitive stress, can help reduce the risk of developing disc degeneration. A healthcare professional, such as a spine specialist or orthopedic surgeon, can provide guidance on appropriate treatment and preventive measures tailored to an individual's specific condition.

3.DISC BULGING

Disc bulging, also stated as a bulging disc or protruding disc, is a condition that occurs when the intervertebral disc extends beyond its normal boundaries. It is considered a common IVD abnormality and often occurs as a precursor to disc herniation or as part of the natural aging process.
In disc bulging, the outer most layer of the intervertebral disc weakens or sustains damage, causing it to bulge outward which exhibit effects like localised pain, radicular pain. However, unlike a herniated disc where the inner material ruptures through the outer layer, in disc bulging, the outer layer remains intact

4. DISC PROTRUSION

Disc protrusion is a type of intervertebral disc (IVD) abnormality in which a portion of the disc protrudes or bulges outside its normal boundary. It is often considered a mild form of disc herniation and can cause similar symptoms. In disc protrusion, the outermost layer of the disc may bulge outwards, but the inner material remains intact. This condition can occur anywhere in the spine but is most common in the lumbar (lower back) and cervical (neck) regions. Surgical intervention is typically not required for disc protrusion unless it progresses to a more severe condition or if conservative treatments fail to provide relief.

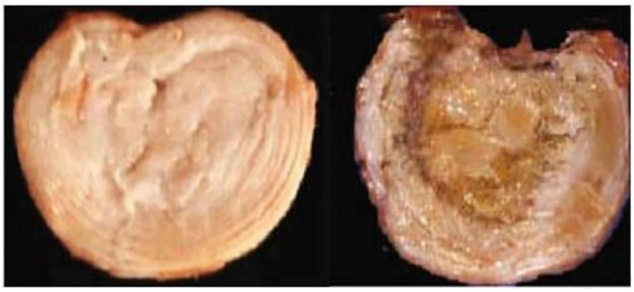


Figure 2: A comparison between a healthy and unhealthy disc

IV. EXISTING MODELS

Total disc replacement's original ideas first surfaced more than 30 years ago. Due to the intervertebral disc's intricate anatomical and functional makeup, an effective and trustworthy artificial disc is expected to both replicate motion and support loads. Total disc replacement (TDR), as opposed to spinal fusion, has produced outcomes that are comparable to or better than those of lumbar fusion. In lumbar TDR (0%-16.7%) and cervical TDR (0%-4.0%), a 5-year meta-analysis found that TDR had a reasonably low rate of problems

1.CHARITÉ

Unlike Charité I and II, which used stainless steel, Charité III and InMotion used CoCrMo with titanium calcium phosphate coating. The device had a highly mobile polyethylene core (Ultra High Molecular Weight Polyethlene [UHMWPe]) with convex surfaces that articulate with concave shaped metallic endplates. The Charité I implant's diminutive size contributed to its high subsidence frequency. This issue was addressed by the Charité II by adding thin lateral wings to increase the surface area. Sadly, these wings experienced early cracks.

2.PRODISC

The ProDisc II was created following the ProDisc I's original release. The upper metallic endplate and the upper surface of the polyethylene core act as a single movement interface in the contemporary ProDisc implant, in contrast to the Charité. The polyethylene core (bearing surface) is fixed to the lower endplate but not to the upper endplate, making it possible to classify it as a semiconstrained device. A single sagittal keel and two little spikes, as opposed to the Charité III's six tiny teeth, are used to improve endplate fixation.

3.MAVERICK

The Maverick has a posterior centre of rotation to match that of the disc segment intended to unload the facet joint, two metallic CoCrMo endplates that directly create a ball-and-socket system with the goal of minimising wear, and hydroxyapatite (HA) coating on the bone-implant interface to maximise early fixation with bony ingrowth. The prosthesis has been used in clinical settings since 2002 after receiving its CE mark in 2001.

4.FLEXICORE

A two-piece, restricted metallic ball and socket joint, the FlexiCore disc has no room for endplate translation. Enrollment in the clinical IDE is finished. preliminary data for three years are being portrayed as positive, however complete study results are still necessary to verify these.

5.KINEFLEX

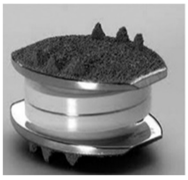
With its three-piece metal-on-metal construction and two CoCrMo endplates and one semi-constrained, fully articulating CoCrMo core, the Kineflex aims to provide of freedom movement (FOM) with translational stop. Outside of the United States, it has been utilised since 2002. With a comparison to the Charité TDR, an FDA IDE study started in 2005 and ended in 2006, with follow-up on the more than 500 patients lasting up to three years at this point.

6.MOBIDISC

The Mobidisc is a three-part design made up of two metallic endplates, a modular keel, and a polyethylene core. These geometries allow for regulated motion in all axes for an on-constraint prosthesis. In 2003, the device was made available. At the moment, it is unavailable in the USA.

7.XL TDR

Similar to Extreme Lateral Interbody Fusion (XLIF) cages, other implants, such the XL TDR, have a metallic design and are placed from the patient's side. An FDA trial began in 2009, and its primary completion date is anticipated to be in 2012.



(a)

(b)

(c)

(d)

(e)

(f)

(g)

Figure 3: (a) Charité (b) ProDisc (c) Maverick (d) FlexiCore (e) Kineflex (f) Mobidisc (g) XL TDR

V. METHODOLOGY

A CT scan of a human spine was used to isolate all the intervertebral discs between vertebrae T12 and L5, and measurements were gathered from all the 5 intervertebral discs. From the data gathered a disc was planned to be designed having a measurement which was the average of all the five discs. The finalised measurement was to have a height of 9 mm , anterior to posterior end had a distance of 32 mm and the widest length was 62 mm.

The overall implant design was highly inspired on the geometry of the intervertebral disc itself unlike other prevailing commercial implants which depended more on to the convex and concave surfaces. But we also used the idea of making two bodies attached to different but adjacent vertebrae but still bringing in the natural aspects of a intervertebral disc. So our proposed design has two bodies confining a superior endplate and inferior endplate

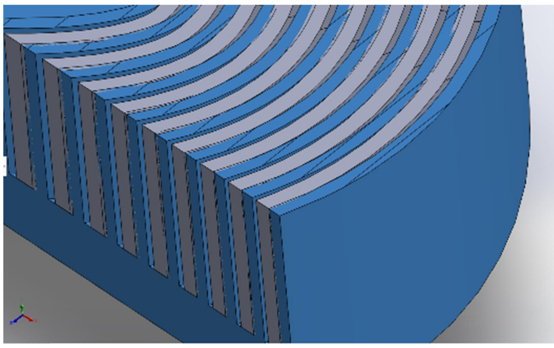


Figure 4 : An intersected view of the inside of implant

An average intervertebral disc was found to have 20-25 lamellae of annulus fibrosus, with this information our design was expected to have a number of 20 lamella at least and the number of lamella was divided into 2 and was shared between each endplate designs such a way that no two adjacent lamella were on the same endplate but the alternative ones were and all were designed such that each of the lamella were concentric to each other.

There was a 0.5mm spacing between each of the lamella to facilitate the small range of displacement which could be observed under loading conditions which could disturb the true scale of the shape. The utmost specialty of the intervertebral disc was the 120degree orientation the muscle of each lamella from the other which facilitated in the cushioning effect and reduced torque. We also tried to induce the 120-degree changed orientation of lamella.

SolidWorks 2023 was used to produce the overall design of both the superior and inferior endplates and the annulus fibrosus lamellae. To determine the overall cross-sectional area, the outer circumference of the top view of the disc's SolidWorks 2023 design was set under evaluation. To calculate the core's area same feature from the SolidWorks 2023 was employed. After completion of the parts of the Intervertebral disc implant a keel on both the bodies was added at the centre of gravity. It was provided with sharp edges as to ease the procedure during surgery and also to increase the osseointegration. Each keel had two hole placed symmetrical to each other so as to get fixtured to the vertebrae of wish.

3D PRINTING AND MATERIAL CHOICE

The recent development in the additive manufacturing technology has brought us to achieving near to 100 percent of the originally designed model. However, limitations with preoperative modeling exist ranging from lack of surgically useful information such as joint instability and a sense of real-time information as provided with imaging combined with a significant learning curve for the software and hardware required to create the models. The capacity of surgeons to construct implants uniquely for each patient using 3D printing is arguably the most interesting application of the technology. However, there is more research being done on 3D printing biodegradable scaffolds that replicate the suppleness of the intervertebral disc using a degradable polymer.

The material of choice for our 3d design was cut short and focused to polylactic acid (PLA), polyurethane, poly lactic-co-glycolic acid (PLGA), and polyether ether ketone. Out of which PEEK abbreviated as Polyether ether ketone was decided to be the choice of material has it had the best of the mechanical properties for any biocompatible material of standard values could be

IV. RESULTS

To understand the loading conditions of the design the two bodies are first made into an assembly in Solidworks 2023 and were perfectly made to fix with each other under fully defined condition. Now the behavior of the model under applied stresses is digitally simulated by finite element analysis. To simulate a vertebra providing support along the base of the disc, model was fixed to avoid axial movement during simulation using Altair inspire 2022. To imitate the load on a spinal disc experienced under normal walking condition, an axial 1000 N load was applied. This load was applied as a vertical downward 1000 N force on the center core component and along the outer ring of the superior endplates. The applied loads had to be made simpler for the programme to run the analysis because of the model's vast number of components.

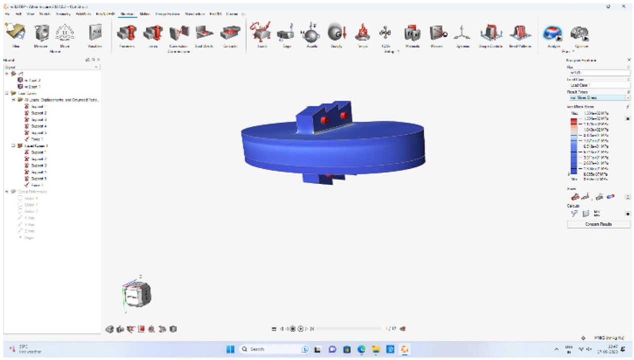


Figure 5: Output of von Mises stress simulation

Under the above stated load condition the von Mises stress was studied

V. CONCLUSION

The simulated study showed that the design was found to be functional at normal static conditions with minimal amount of work, with higher range of safety factor and limited stress load at anyone one defined point.

According to finite element analysis, when supported by the keel at the endplates the load has its impact the the joining point of the keel to the surface of the superior endplate, however the load is found to be distributed across the area of the design and bares very minimum stress. The mechanical properties of the PEEK play a major role in this.
The finest qualities of both materials—rigidity to sustain loads and flexibility to resist fracture—are preserved by the alternating structure of the two materials with differing attributes.

Using understanding of biomechanics, the human spine, this research set out to 3D print a pattern found in nature and adapt it to a medical implant prototype. The proof of concept was confirmed, as in many other biomimicry situations, yet the artificial design did not perform as well as the design found in nature. The greatest difference between the elastic modulus of any intervertebral disc to available biocompatible materials makes it difficult to full fill the utmost mimicking. Advanced future studies in the preparation of newer polymer materials may help in achieving it.

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