Biomechanical Evaluation of Lumbar Intervertebral Discs Using Novel Intervertebral Artificial Disc: A Finite Element Analysis Study

Ashutosh Khanna, Pushpdant Jain

Abstract Advances in computing and manufacturing have paved the way for patient-specific prostheses with clinical requirements in trauma, injury or degenerations. In this study, a novel simulation-driven approach is applied to design an artificial intervertebral disc (IVD) for lumbar spine. with the aim of providing long-lasting motion preservation; with its unique hexagonal lattice core for stiffness demands as well as potential for biocompatibility. Using Materialize MIMIC 21.0, SolidWorks 2016 PE and ANSYS R19, a healthy human subject's DICOM datasets of lumbar spine were segmented and than re-engineered to form a advanced CAD model that mimics human bones, tissues and ligaments. A finite element study was conducted to compare biomechanical performance of this intact lumbar spine (IS), with two implanted models, one a FDA-approved SB Charite (SBC), the other a novel implant (AUX) replacement at IVD L4-5. Axial compressive forces, of 500 N, 800 N, 1000 N, and a moment of 10 Nm were used for computing flexibility and stability in these models. The results of range of motion (ROM),IVD stress, strains, and total deformation were recorded and evaluated. The methodology for the design resulted in the biomimetic design of the implant's Ti6Al4V endplates, similar to natural endplate thickness of around 0.6 to 1.2, with curvature customisable to 2.5 mm under various stress conditions. The regular hexagon core cellular geometry of the titanium alloy core of AUX establishes its importance in delivering desired responses of spine segments and stress distribution. The implant designed in this study demonstrates suitability of Ti6-AL-4V alloy in two endplates and auxetic core. The Finite Element model developed could be useful in clinical evaluations, implant customisation, pre-surgery evaluations and additive manufacturing alongside its customisation to accommodate large variations in human morphometrics due to injuries and degenerations.

Keywords Artificial intervertebral disc, Finite Element Analysis, Biomechanics, Auxetic metamaterials, Ti6Al4V.

I. INTRODUCTION

In a spinal injury, a large portion of the human organ is damaged, and the body also loses its capacity to regenerate. Lumbar total disc replacement (LTDR) involves replacing the damaged intervertebral disc with an artificial one. The surgical objective is to restore natural disc biomechanics and prevent further degeneration. However, post-LTDR problems do exist, such as device operation, compatibility, subsidence, adjacent segment disease. In one study related to post-LTDR follow-up of 200-plus patients, 11% had to undergo a second operation due to inaccurate segmental range of motion (ROM) causing lack of flexibility [1]. The second operations were between 6% and 1% at index-level and adjacent-level on patients with ActivL™ implants, but achieved the desired ROM similar to FDA-approved devices [2]. The third generation of SB Charité™ restores ROM, but there is restricted segmental motion near the surgical region . The upper endplate, made of NiCrMo alloy with an UHMWPE polyethylene core, was delivering the desired twist motion [3]. These metallic implants were unable to address the issues of device compatibility and osseointegration. In spite of the need for a second operation, LTDR surgery has demonstrated risk reduction for the subsequent progression of adjacent segment disease [4]. Implant placement, intraoperative change in lordosis, and magnitude of physiologic compressive preload all contribute to the performance of LTDR prosthesis [5]. From ODI or VAS tools, ROM or flexibility of the lumbar spine has been singled out as a primary parameter for design interventions in LTDR [6]. An artificial intervertebral disc (AID), with endplates and core, has reported lower adjacent segment degeneration and better flexibility on follow-ups. Patient healthcare records indicate that these spinal implants are safe and effective in improving Oswestry

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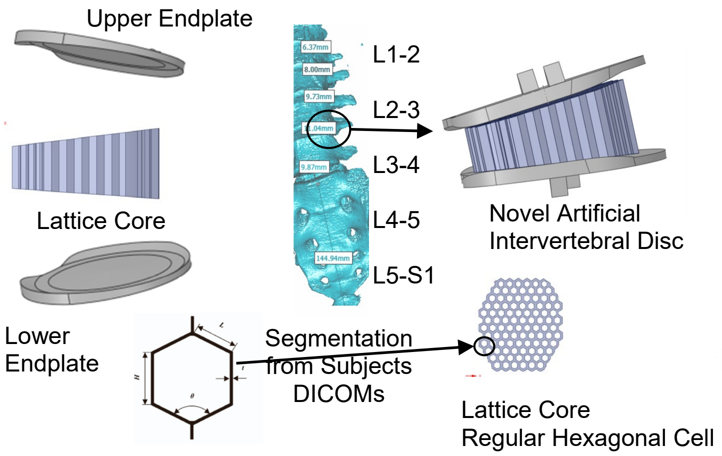
disability index [7]. Their biomechanical effectiveness, design features, materials, clinical efficacy, in vitro/in vivo experiments and use of computer methods and FE simulations all contribute to an effective lumbar prosthesis [8].

In addition to flexibility, recommendations for LTDR are based on specific patient conditions, availability of sophisticated surgical techniques, interpretation of previous healthcare data, device selection, subsidence, and an implant's durability [9]. In our study we have used accurate and predictive FE simulations to design implants that can return exact biomechanical effects on stabilisation and device functioning at vertebral levels corresponding to the injury or disease.

II. METHODS

Lumbar Spine Intact Modelling and Validation

For modeling complex structures like lumbar spine, the CAD model assembly via DICOM of a Lumbar segment (Fig. 1(a)) was redesigned to have 40 parts and initialised with a material model [10]. For computation efficiency, the hex-dominant meshing method for structural analysis (Fig. 1(b)) was applied. It also introduces robustness with hexahedral element shapes, and reduces mathematical calculation times on ANSYS 19.3 R2 APDL workbench.



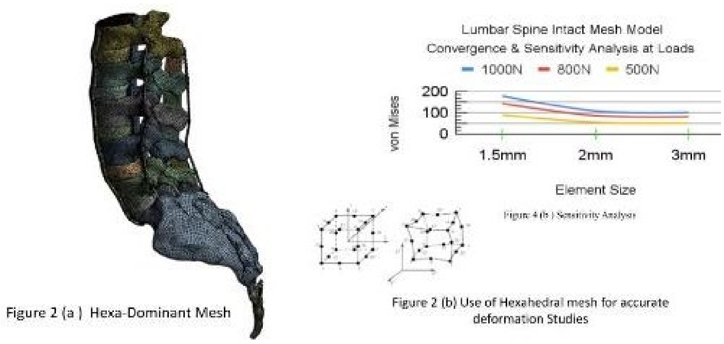


Fig1 Novel Artificial Intervertebral Disc Design

Fig. 2. Hexahedral FE model of intact lumbar spine

Mesh sensitivity analysis and mesh convergence ensured that the results of the analysis were not affected by changing the element size (Fig. 3) [11]. Simulations were recorded with von Mises stresses at three different loads for elements from 1 mm to 3mm. The mesh exhibits convergence when the difference in the von Mises stress values is less than 2% compared to the most refined mesh (Fig. 3) [12]. Force of 1000 N and mesh element size of 2 mm were confirmed for biomechanical analysis. Deformation probes in ANSYS were set to retrieve ROM data. The angle between the deformation probe plane before and after deformation is considered ROM of IVD level.

Finite Element Analysis

Upon validation of Intact lumbar spine model(ISM), this model geometry was ported as a parasolid file and opened in spaceclaim design tool of ANSYS 19.2, IVD at L4-5 was replace with SB Charite (SBC) representative geometric model parasolid file, and formed a new model, fig 3(b). In a similar manner a third model of novel IVD (AUX) with replacement at L4-5 was developed. Here a large number of simulations were carried out for proper stress response of implanted models, with proper placements to arrive stress behavior exhibited close to that of intact model at boundary conditions, 1000N and 10Nm moment. Sacrum was kept fixed with support and load where applied at IVD L1-2 upper surface.

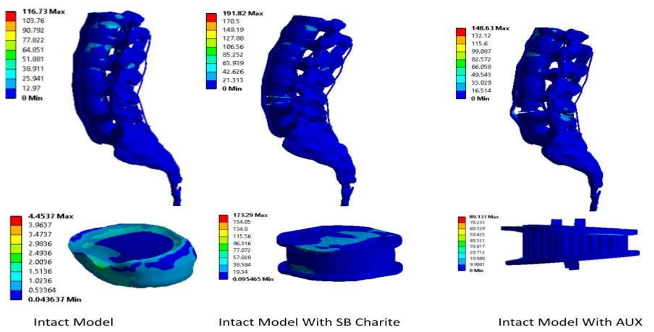


Fig. 3. Total von Mises stress on Three models

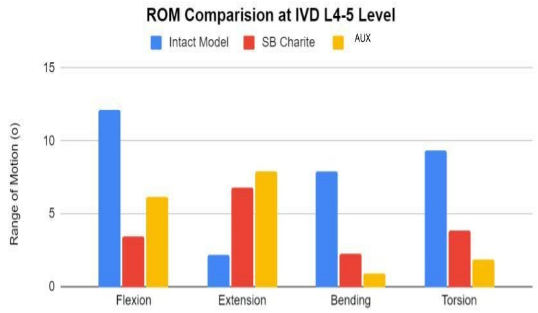


Fig. 4. ROM evaluations in implants at L4-5.

III. RESULTS

The maximum stresses at IVD L4-5 in flexion for intact SB Charité™ and implant were 2.82 MPa, 129.88 MPa, and 179.97 MPa. During extension, the stress values for the intact model were 3.79 MPa, 165.14 MPa, and 364.13 MPa (Fig. 3). Data for Strain and Deformation are also depicted using images for various physiological loads for L4-5 at 1000 N load, 10 Nm moment.

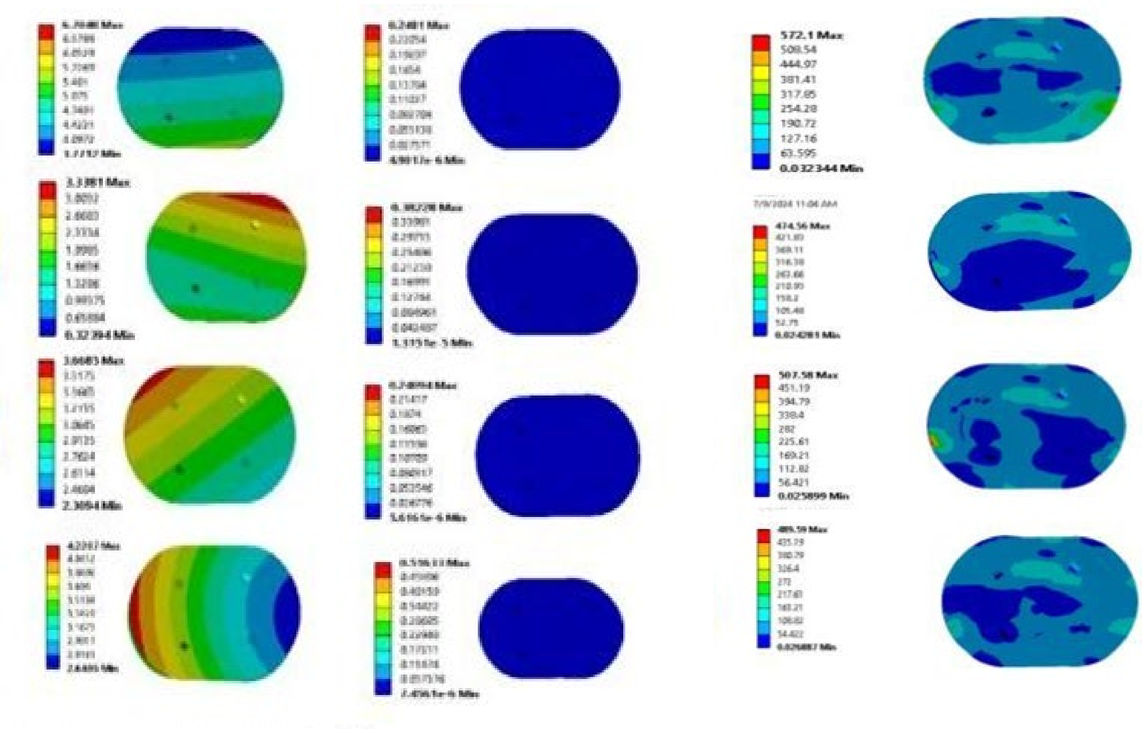


Fig.5(a) Total Deformation (mm) Fig.5(b) Total Stress (MPa) Fig.5(c) Total Strain

Fig. 5. Comparative Stress, Strain and Deformation at L4-5: L4-5 (at load = 1000 N moment = 10 Nm)

The comparative range of motion is calculated and presented in the bar chart in Fig. 5. In the present work, the equivalent stresses for a twist in the intact spine SB Charité™, and AUX are 116 MPa, 191.88 MPa, 148.63 MPa, respectively, as depicted in Fig. 5. However, at the L4-5 segmental level undergoing implantation the maximum stresses observed were 4.45 MPa, 171.63 MPa and 85.63 MPa. The AUX design exhibited a better stress response than the SB Charite implant . In the AUX model, the annulus fibrosus (AF) is mimicked by tubular hexagon lattice structures, offering high fracture toughness and corrosion resistance. [18].

IV. DISCUSSION

There is substantial loss of bones and tissue through injuries and degeneration and the natural defense mechanisms are unable to repair damaged tissue with regeneration. There can either be a production of new and physiological tissue or a replacement. Regeneration or repair of tissues is time-dependent. However, designing a replacement component with regeneration abilities is a potential prosthesis. In the growth of living cells and during these transition phases stresses and loads are bound to occur. Studies [19-22] proposed Ti6Al4V alloy lattices for intervertebral cages and revealed that they can be tuned to match bone stiffness. The diamond and gyroid lattices with 750-micrometer pores were tested experimentally and simulated for spinal biomechanics. The cage prototype showed similar behaviour in stiffness and compression, showing elastic moduli of 3–22 GPa and yield stresses of 48–186 MPa. Simulations overestimated experimental findings by 25%, and noted that usual bulk material failure theories do not apply to lattice structures. In our study, the AUX design exhibited lower stress in the L4-5 region than the FDA-approved SBC and regular lattice hexagon (HNC) designs. Despite Ti6Al4V's material constraints, the lattice designs provided adequate flexibility, with deformations similar to previous studies [23-24]. We also found endplate curvature thickness of 1.2 mm ± 0.8 mm under 148 MPa stress for AUX, also comparable to the findings of [24]. Ansaripour et al*.* [25] also concluded that Ti6Al4V is a superior material for endplates. The AUX implant have the potential to be sophisticated motion-preserving technology. Their porosity, stiffness, and grain size can be tailored to achieve the consistent performance that is crucial for correcting spinal injuries or diseases [26-27].

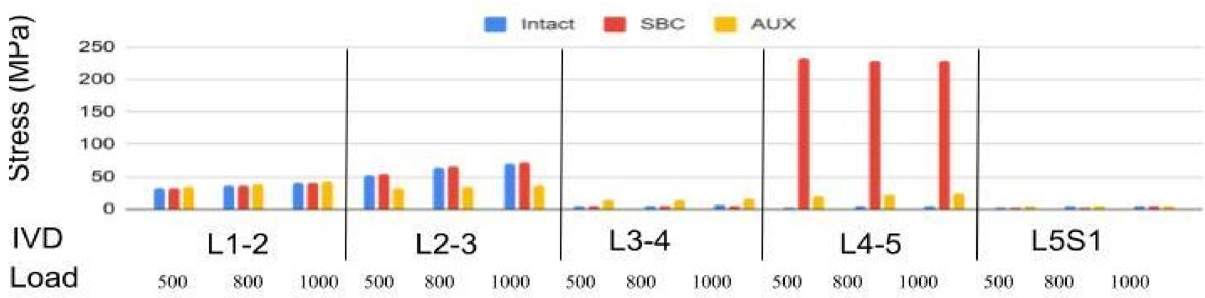


Fig. 6. Comparative Stress Response of IVDs in Lateral Bending .

The rationale for design of novel endplates is to distribute contact at the upper region, avoiding stress concentrations and subsidence [28]. Yue et al*.* [3] confirmed that metallic implants meet strength requirements, with maximum stress values at the L4-5 endplate ranging from 120 MPa to 440 MPa during physiological motions, well below the Ti6Al4V yield strength of 970 MPa and fatigue strength of 450 MPa in their FE analysis. Lvov et al. [29], in their non-destructive test on a spinal cage device, after 3,500 cycles under a 14 kN load with residual deformations ≤ 1% (0.21 ± 0.10 mm displacements), the prototype remained fully functional. The titanium alloy-based honeycomb had Young's modulus of 1.19 ± 0.03 GPa, similar to that of trabecular bone and vertebrae. Murchio et al. [30] found that surface modification of endplates improves implant stiffness and strain response.

V. CONCLUSION

Novel artificial intervertebral disc of auxetic metamaterials retains the ROM value during physiological motions. Its simulation-driven design of Ti6-AL-4V endplate and annulus, mimicking re-entrant hexagonal structures, exhibited the least ROM among the implanted models. Stress was distributed by the lattice. Faceted joint stresses distrin=bution were similar to the intact model. Ti6-Al-4V porosity, stiffness and grains can be customised for necessary stiffness for conditions like spinal injuries or diseases using powder bed-based laser metal additive manufacturing, which could enhance and optimise directional stiffness and Poisson's ratio of the lattice structures and strain on the optimised implant. So after experimental validation, followed by clinical trials, the titanium AUX implant may be considered for a degenerated disc. The in vitro study can be performed through proper experimentations before any clinical trials of the proposed implant. The clinical significance of our developed FE models is that they can be used quickly and conclusively for many applications, including investigating lower back pain, spinal deformities, injury biomechanics, implant design, design of protective systems, and degenerative disc disease.

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