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THE EVOLUTION OF LUMBAR TOTAL DISC REPLACEMENT (LTDR): RESEARCH TRENDS OF DEVICE DESIGN, BIOMECHANICS, AND CLINICAL OUTCOMES

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ABSTRACT

Lumbar total disc replacement (LTDR) has emerged as a motion-preserving surgical for treating degenerative disc disease (DDD). This article reviews the evolution of LTDR technology with emphasis on advances in device design, biomechanical research, and clinical performance. The integration of finite element analysis (FEA) and biomechanics has enabled more precise optimization of implant design and material properties. Clinical potential evidence indicates that modern LTDRs can maintain spinal mobility with long-term performance and personalized models challenges. Future research in biomimetic materials, and additive manufacturing (AM), and FEA-based optimization is expected to drive the next generation of personalized, durable disc replacement technologies.

1. INTRODUCTION

Lower back pain (LBP) has increasingly become a worldwide major public health issue. The lifetime prevalence of lower back pain has been reported to be as high as 84%, with nearly a quarter of the population suffering from chronic lower back pain and 11–12% of the population disabled by lower back pain. Lower back and neck pain causes more disability than any other disease, thus leads to serious social and economic consequences. Lower back and neck pain are thought to be closely associated with degeneration of the intervertebral disc (IVD).

Current, clinical treatments for pain and disability due to degenerative disc disease (DDD) generally include the conservative method, surgical intervention, and the tissue engineering approach. Surgical intervention includes fusion and artificial total disc replacement (A-TDR). While fusion surgery has the characteristics of a simple procedure, preserves intervertebral height, and relieves pain, the range of motion (ROM) of the functional spinal unit (FSU) is lost and the degeneration of adjacent discs is potentially accelerated. Unlike fusion, A-TDR not only maintains segmental height but also preserves the segmental ROM and slows the degeneration of adjacent segments, thereby effectively resolving the shortcomings of fusion in some patients. The technique has commonly been used in clinical practice in recent years. The age of the ideal TDR candidate is considered to be 18–60 years, optimally below 50 years, with back pain severe enough to impact activities of daily living and work. L-TDR was mainly unitized to one- or two-level discogenic back pain in the absence of radiculopathy. Generally, TDR devices are implanted in the body to achieve therapeutic results since from 1980s–1990s. However, the lack of functional and mechanical properties restricts the clinical outcomes and commercial transformation. The latest advances in structures, materials, and processing technologies are accelerating the development of implants, paving the way for multi-function and high performance, especially with regard to personalized customization.

The present work reviews the evolution of lumbar total disc replacement (LTDR), highlighting major research trends in device design, biomechanical understanding, and clinical performance.

2. EVOLUTION OF DEVICE DESIGN:

Lumbar total disc replacement (L-TDR) devices offer good biomechanical properties and exhibits satisfactory patient clinical results. Since 1966 and Fernström's first TDR implantation, many designs and concepts have been proposed. In this section, the structural design, biomaterials, functionality, mechanical properties, and main advantages and challenges associated with L-TDR devices are summarized chronologically in detail:

2.1 Early Generation Devices (1990s–2000s):

The kinematics of early generation was ball-on-socket type (BOS). According to the materials used in this type, there is metal-on-metal type (MoM), ceramic-on-ceramic type (CoC), metal-on-polymer (MoP), and polymer-on-polymer (PoP) as shown in Figure1. The endplates include keels or teeth to provide initial fixation, and titanium or hydroxiapatite coatings for promoting long-term bone growth.

MoM-type devices (such as: Kineflex-L, Flexicore, Maverick-L….) have great fatigue resistance, and good biocompatibility with materials: titanium alloys (Ti6Al4V), cobalt-chromium-molybdenum (CoCrMo) alloys. It has also favorable stiffness, ductility, durability, pain relief, ROM restoration, and disc height

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preservation. But in clinical application they don't absorb shock, so there are also metal wear debris, artifacts, osteolysis, migration, subsidence, heterotopic ossification, and inability to replicate structural features.
Devices with CoC type (such as Min-T from zirconia) are preferable wear resistance, and disc height preservation, with challenges of Limited load-bearing ability and brittleness.
MoP-type devices (such as: ProDisc-L, Activ-L, CHARITÉ™, M6-L….) with polymeric cores (polyethylene (PE), Ultra-high-molecular-weight polyethylene (UHMWPE), polycarbonate urethane (PCU)……) and metallic endplates materials (Ti, CoCrMo alloys) have high strength, good viscoelasticity, durability, pain relief, ROM restoration, and disc height preservation. Among the challenges polymeric wear debris, heterotopic ossification, isotropy, and the connection between the polymer core and endplate still existing.
Devices with PoP type (such as ORBIT™-R), with many different polymeric materials used in this type (e.g. PE, PCU, Polyetheretherketone (PEEK) ……) have uniform stress distribution, avoiding the risk of mechanical failure and delamination, and good ROM, with challenges of polymeric wear debris, isotropy, and osteolysis.

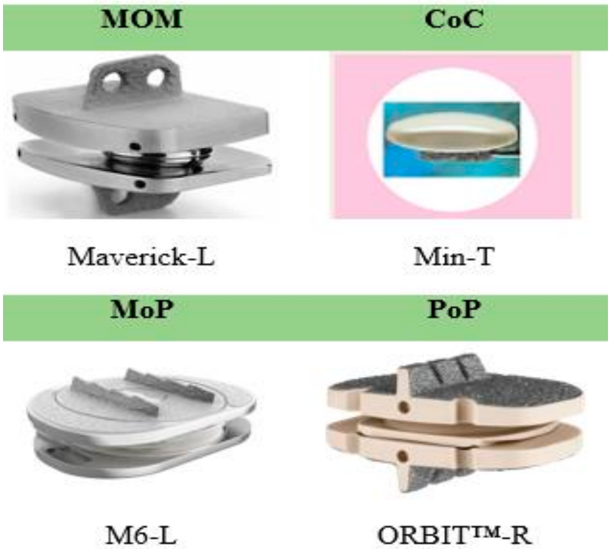


Figure 1. Major product classifications of L-TDR devices.

2.2 Second Generation / Viscoelastic Designs (2010s–Present):

The second generation of LTDR was 1-piece type. Because the healthy human intervertebral disk has a deformable elastic structure with 6 degrees of freedom, elastomeric one-piece intervertebral prostheses might be the most physiological implant for mimicking physiologic levels of shock absorption and flexural stiffness.

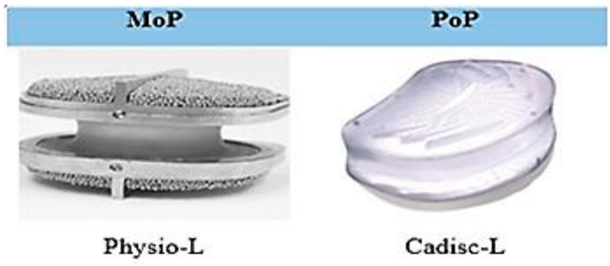


Figure 2. Major product classifications of 1 piece L-TDR devices.

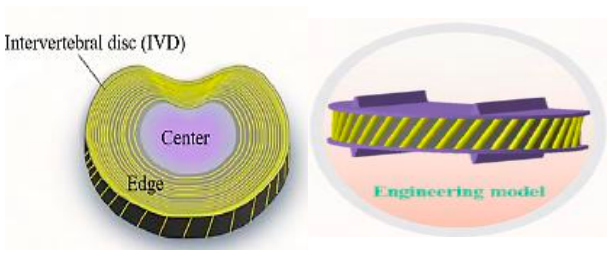
In these designs, there is no articulation between the components, and the materials could be metal-on-polymer (e.g. Freedom-L, Physio-L….), or polymer-on-polymer (e.g. Cadisc-L, 3DF-L…..) as shown in Figure 2. These models with polymeric cores and viscoelastic layers are closer replication of physiological motion and load distribution. In clinical application of the two generations of implants reveals that both designs have biomechanical advantages and limitations.

2.3 Emerging Trends:

To avoid the challenges resulting from clinical complications in the first and second generation of artificial discs, many ideas and possible modifications have been proposed in recent studies, both in designs and in the materials used. The possible trends can be classified as follows:

2.3.1 Bioinspired materials and hybrid structures:

Tissue engineering (TE) technology provides a promising alternative to restore physiological functionality of damaged intervertebral disc (IVD). Some studies engineered a biomimetic integrated scaffold, which was biomimetic annulus fibrosus and nucleus pulposus (AF-NP) composite with circumferentially oriented poly (ε-caprolactone) microfibers seeded with AF cells, with an alginate hydrogel encapsulating NP cells as a core.



(a) (b)

Figure 3. Schematic overview of natural disc and the BIVD-L structural design. (a) Structural characteristics of the natural IVD. (b) A bionic engineering model composed of distinct constructs that mimic the structure of natural IVD.

This engineered biomimetic AF-NP composites have potential application for IVD replacement. And further researches are needed to test the outcome of TE-IVD organization and integration.

Because current A-TDR devices lack the unique structure and material characteristics of natural intervertebral discs (IVDs), they fail to replicate the multidirectional stiffness and characterize anisotropic behavior (figure 3-a).

For this purpose, a bioinspired intervertebral disc (BIVD-L) (figure 3-b) has been developed from advanced polymer biomaterials (functional gradient materials (FGMs)) with various Shore hardness values and fabricated using a commercial multimaterial 3D printer to reproduce the multidirectional stiffness needed for the most common physiological kinematic behaviors. This approach may provide new inspirations for the design and fabrication of A-TDR devices for both engineering and functional applications.

2.3.2 Additive manufacturing (AM) (3D printing) for patient-specific geometry:

Manufacturing strategies are also critical to the implanted devices. Additive manufacturing (AM), especially multi-material additive manufacturing (MM-AM), can control the formation of complex structures and achieve the combination of multiple materials in multiple length scales. Recently, because it offers rapid prototyping and personalized manufacturing, it has also been applied to the field of biomedical engineering. In addition, as a new branch of AM technology, bioprinting technology provides reconstruction and regeneration capabilities. For example, the engineering model in (figure 3-b) had been manufactured by the Polyjet multimaterial 3D printer shown in Figure 4.

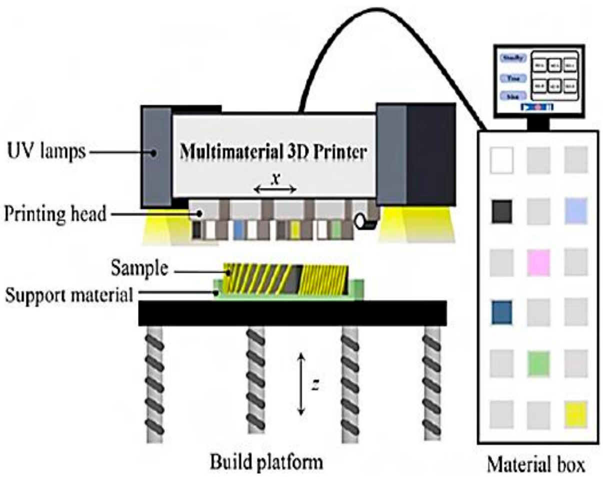


Figure 4. Illustration of the fabrication of an engineering model by the Polyjet multimaterial 3D printer.

The required geometry to be printed can be obtained from shape parameters from CT images, or from CAD models reconstructed from the magnetic resonance imaging (MRI) results as in the study [1] , where a monolithic total disc replacement (MTDR) was made of two types of thermoplastic polyurethane (TPU 87A and TPU 95A) and fabricated using a 3D printing approach: fused filament fabrication as shown in figure5.

In addition, a novel artificial intervertebral disc implant with modified "Bucklicrystal" structure was designed and 3D printed using thermoplastic polyurethane in the study [2].

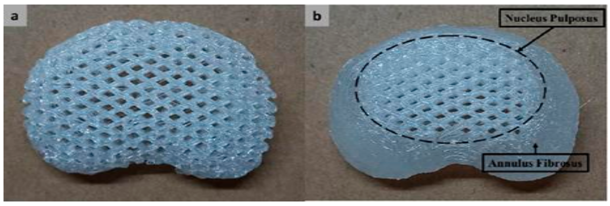


Figure 5. Representative products of two lattice configurations of MTDRs fabricated using a 3D printing approach for TPU 87A.

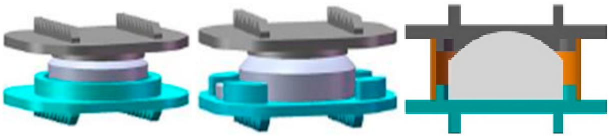
2.3.3 Incorporation of FEA-based optimization and biomechanical Research:

Recent advances in finite element analysis (FEA) have become integral to the design optimization and biomechanical evaluation of lumbar artificial disc devices. Early prostheses were primarily designed through experimental and mechanical prototyping, but modern development integrates computational modelling at every stage from conceptual geometry to predict the performance under complex spinal loading. FEA technique allows designers to simulate the biomechanical behavior of the implant, thereby reducing the need for extensive in vitro testing.

Some recent researches employed FEA to evaluate a novel artificial intervertebral disc. For example, in the study [3], they evaluated the effect of a novel artificial intervertebral disc geometry on stress, deformation and strain on lumbar segments to restore movement of the spine. The proposed geometry include endplates of titanium alloy (Ti6Al4V), polycarbonate urethane (PCU) core, and 3 titanium rings to replicate natural spinal biomechanics, including variable center of rotation (COR) and load distribution. The TIC's (Titanium Conix) design may reduce risks of implant loosening, wear, and adjacent segment degeneration, so the need for patient-specific customization using FEA simulations before clinical trials is advocated.

Al though, FEA is used also for the biomechanical analysis and assessing structural modification of current lumbar disc prostheses as in the study [4], where the structure of the Mobidisc-L was modified (Figure 6), resulting in the development of two new intervertebral disc prostheses with CoCrMo endplates: Movcore (a metal ring to restrict the center of rotation of the ball and socket), and Mcopro (includes an artificial annulus structure of UHMWPE, 4 ~50 MPa).

The Mcopro prosthesis is advantageous for patients with facet joint concerns due to its ability to reduce operative-level mobility and facet stress and long-term clinical studies are needed to validate its efficacy.

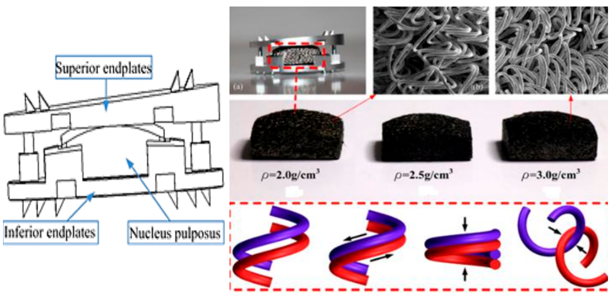


Mobidisc Movcore Mcopro

Figure 6. Mobidisc, Movcore, and Mcopro artificial discs.

As well as, the new elastomeric discs which reproduce better normal disc kinematics can be evaluated by FEA as in study [5] where the biomechanical performance of a new TDR (ADDISC) design: CoCr28Mo6 alloy endplates, intermediate piece: 2 PCU inlay instead of 1 piece in normal (ADDISC) had been evaluated for design, validation, and dynamic loading. For the clinical potential, the new disc mimics healthy disc biomechanics while addressing long-term issues of existing TDRs (e.g., wear, facet joint damage) making it a promising candidate for lumbar disc replacement.

Additionally, it's important to mention here the significant role of material properties in lumbar artificial disc functions, research studies try to integrate the design modification, selected materials, in vitro testing, and the FEA technique in both current and proposed models to reach the best promising candidate for long-term lumbar disc replacement. The study [6] aimed to explore the potential application of Entangled Porous Titanium Alloy Metal Rubber (EPTA-MR) as a nucleus pulposus material in artificial lumbar disc prostheses (Figure 7). It evaluated the biomechanical properties, fatigue life, and damping capabilities of EPTA-MR to determine its suitability for spinal non-fusion technology. For clinical potential, EPTA-MR combines high elasticity, wear resistance, and biocompatibility, addressing limitations of current polymer/metal prostheses (e.g., wear-induced failure).



(a) (b)

Figure 7. a) Structural design of non-fusion prosthesis (b) EPTA-MR products and microstructure

Current research also employs patient-specific FE models reconstructed from CT/MRI data which help in predicting individual postoperative outcomes. In parallel, coupled experimental–computational frameworks are increasingly applied. The synergy between FEA-based optimization and biomechanical experimentation represents a pivotal trend in LTDR evolution, enabling more reliable and personalized prosthetic design with enhanced functional outcomes.

3. SUMMARY

Lumbar total disc replacement (LTDR) has progressed from ball-on-socket to elastomeric motion-preserving implants. Modern devices use hybrid materials to mimic natural disc function and clinical potential is promising though challenges such as wear, long-term stability and performance. Finite element analysis (FEA) and biomechanical studies guide design optimization and performance evaluation of lumbar total disc replacement (LTDR). Future LTDR innovations will focus on biomimetic materials, additive manufacturing, and personalized implant design.

4. KÖSZÖNETNYILVÁNÍTÁS

A bemutatott kutató munka a TÁMOP-4.2.1.B-10/2/KONV-2010-0001 jelű projekt részeként az Európai Unió támogatásával, az Európai Szociális Alap társfinanszírozásával valósul meg

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