

FEASIBILITY STUDY OF THE DESIGN OF ARTIFICIAL DISC
REPLACEMENT PROSTHESES

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This report submitted in partial fulfillment of the requirements for Degree of
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DECLARATION

“I hereby declare that the work in this report is my own except for summaries and quotations which have been duly acknowledged”

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ABSTRACT

Nowadays, there are lots of designs of artificial disc produce for the total disc replacement but the long term effect still under observation. Some of complications cause by the effect of artificial disc design especially on the polyethylene core. This study is to investigate the effect of the design artificial disc on compressive stress. This study involve of development of three dimensional modeling using computer-aided design software (CAD) to construct Prodisc-L artificial disc and a three-dimensional nonlinear finite element of vertebral body L4-L5. A simulation study is undertaken by Marc Mentat and Solidworks software to analyze the effect of the prostheses design. The result shows that the highest compressive stress occurred at polyethylene core which lead to polyethylene damage and may be relevant reason of the failure mode for lumbar artificial disc replacement. The analysis of the effect of implant design using FE analysis may help in identifying the weakness of the design and prevent the long-term failure of implant.

ABSTRAK

Pada masa kini terdapat banyak rekabentuk cakera tiruan yang telah dihasilkan tetapi kesan pemindahan cakera tiruan untuk jangka masa panjang masih dalam pemerhatian. Terdapat banyak komplikasi yang di sebabkan oleh impak dari rekabentuk cakera tiruan terutamanya ialah pada teras polietilena . Kajian ini adalah untuk mengkaji impak tekanan mampatan kepada rekabentuk cakera tiruan. Kajian ini melibatkan permodelan tiga dimensi menggunakan perisian rekabentuk berbantu untuk menghasilkan cakera tiruan Prodisc-L dan tiga dimensi tidak linear unsur tak terhingga tulang belakang L4-L5. Simulasi telah dilakukan menggunakan perisian Marc Mentat dan Solidworks. Hasil simulasi menunjukkan tekanan mampatan tertinggi telah berlaku di teras polietilena yang menyebabkan kerosakan polietilena dan menjadi penyebab kepada kegagalan penggantian cakera tiruan pada bahagian lumbar. Analisis menggunakan unsur tak terhingga membantu dalam mengenalpasti kelemahan rekabentuk dan menghalang kegagalan dalam jangka masa panjang implan.

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NOMENCLATURE

E	–Elastic Modulus
ε	–Strain
σ	–Stress
N	–Poisson’s ratio

ABBREVIATIONS

LBP	–Low back pain
DDD	–Degenerative disc disease
CAD	–Computer-aided design
3D	–Three-dimensional
MRI	–Magnetic resonance imaging
TDR	–Total disc replacement
CT	–Computed tomography
FE	–Finite element
ROM	–Range of motion

CHAPTER 1

INTRODUCTION

1.1 Overview

Low back pain (LBP) is a pain that occurs at lumbar region due to the flexibility and tends to received most stress compare to other region of spine. LBP is the leading cause of disability. A variety of pathologies can cause low back pain, one of which is degenerative disc disease (DDD). DDD can result in abnormal motion of the segment and biomechanical instability causing pain. Surgery is considered as other treatment options when conservative treatment fails (Van Den Eerenbeemt, 2010).

Fusion technique has been the traditional surgical treatment for low back pain but is often associated with unconvincing results, prolonged recovery time and future degeneration at adjacent level. The latest development in spine surgery has developed an alternative in the treatment of chronic low back pain from degenerative disc disease symptoms, the lumbar artificial disc replacement. But the disc is still under clinical trial, as the complication of the prosthesis still under studies. The possible short and long term unsatisfactory result from disc prostheses surgery is still ongoing by the researcher in term of longevity of the implant, the forces transmitted at the operated level and adjacent levels, and ultimately the clinical outcome for the patient.

In this study, the current prosthesis is analyses based on the design and the effect of compressive stress. This is to identify the feasibility of the current prostheses and the data could potentially be used to develop a new prosthesis for disc replacement.

1.2 Problem Statement

There are several complications occurred on the lumbar artificial disc replacement, especially on the polyethylene core which be the main source of pain after the surgery. The purpose of this study is to investigate the effects of the compressive stress to artificial disc replacement prostheses using computational method by develop 3D model of current prostheses using Solid-works CAD software and simulation of finite element model.

1.3 Objective

The objective of this study is to investigate the effect of the artificial disc replacement prostheses for degenerative disc disease patient.

1.4 Scope

The scopes of study are:

- i. To develop 3D model of current prostheses
- ii. To assemble the prostheses model into human vertebral-segment model.
- iii. To simulate and study the effects of compressive stress to the prostheses design.

CHAPTER 2

LITERATURE REVIEW

2.1 Structural Anatomy of Human Spine

The human spine is a complex structure that provides both mobility and stability, and also protects the spinal cords. The vertebral column consist of seven cervical vertebrae (C1-C7), twelve thoracic vertebrae (T1-T12), five lumbar vertebrae (L1-L5), the sacrum which consist of five fused segments (S1-S5), and the coccyx as shown in Figure 2.1.

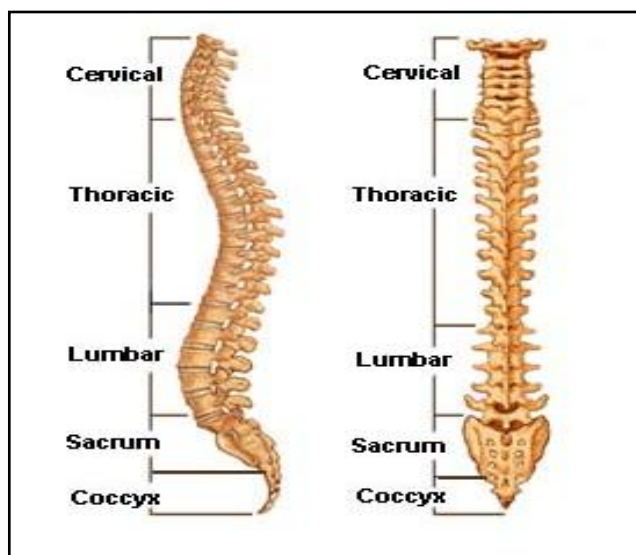


Figure 2.1 The lateral (side) and posterior (back) structure of spinal column.

Adapted from www.spineuniverse.com.

The different curvatures in each mature vertebral column help to form the posterior wall of the pelvis. The cervical spine from the first cervical through the second thoracic vertebra is convex forward, the thoracic curve from the second to the twelfth vertebra is convex backward, the lumbar curve from T12 to the lumbosacral junction is convex forward, and the sacrum and coccyx are concave forward (and convex backward).

Each region spine has its own function, the cervical spine support load from the weight of the head and allow for its rotation, and the thoracic region is only experience little movement. The lumbar region is the most flexible and tends to experience most motion compared to other region due to the pressure from the body weight.

2.2 Intervertebral Disc

The vertebra is connected by intervertebral disc between the vertebral bodies starting from the second cervical to the first sacral level. The intervertebral discs being thicker at levels where the vertebral bodies are taller as it vary in thickness at different spinal level. The intervertebral disc is composed of a tough layer of ligament, the annulus fibrosus which does receive some blood supply from adjacent vessel, and the nucleus pulposus. The structure acts a shock absorber to cushion the vertebrae during movements of the spine, provides flexibility and helps to transmit vertical, horizontal and torsional forces, which support the vertebra and the entire weight of the upper body (Urban and Robert, 2003).

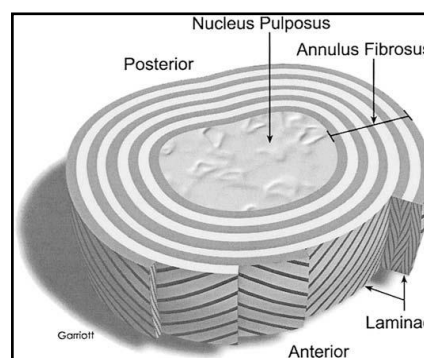


Figure 2.2 The intervertebral disc. Adapted from Devereaux, 2009.

The intervertebral disc is responsible to withstand all the compressive loading subjected to vertebral body includes different types of load stresses, like dynamic loads, static loads, tensile stresses, torsional loads, shear stresses and combination of tensile, compressive and shear stresses (Jongeneelen, 2006). The water content of the disc decreased then causing spinal disc degeneration and increased lower back pain among older people (Keivan, 2010).

2.3 Spine-related disease and Low Back Pain

Spine-related disease, such as pain in the neck, mid back and low back is a most common problem in adult which lead to limitation of movement. There are many potential source of pain such as from the bone, joints, ligaments, muscles, nerves, and intervertebral disks. Also, due to posterior body condition and some other routine activity include certain occupations.

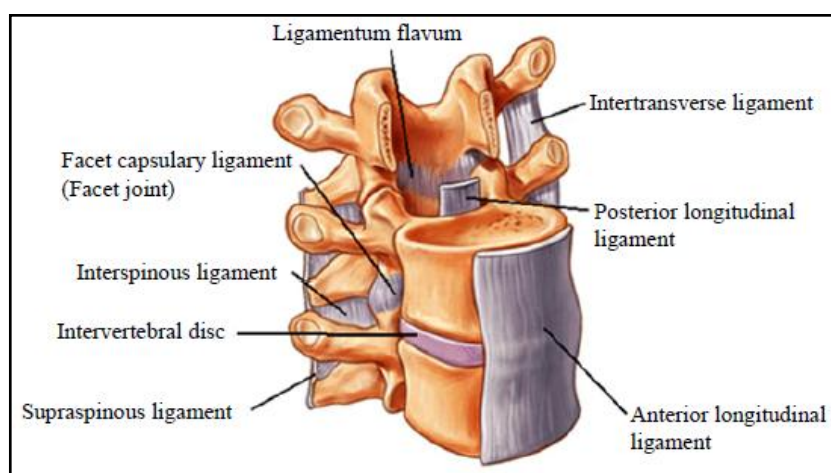


Figure 2.3 Lumbar region of spine. Adapted from www.spineuniverse.com.

The most common spine-related disease is low back pain (LBP) which occur at lumbar region as shown in Figure 2.3. The normal motion of lumbar segment includes independent translation and rotation in all three planes of motion, which are flexion-extension, lateral bending and axial rotation (Geisler, 2004). LBP is experience by two-thirds to three-fourths of people which is very common even in people without any of risk factor such as history of low back in adolescence, lower socioeconomic status, lower level education, poor physical conditioning, certain

physical activities usually experienced in work such as heavy lifting, bending and twisting, static work positions such as prolonged sitting or standing, exposure to whole body vibration, certain psychological and psychosocial work factors, depression, obesity, cigarette smoking, etc (Bartleson and Gordon Deen ,2009).

Variety of pathologies can cause LBP, one of which is degenerative disc disease (DDD) as shown in Figure 2.4. It has been hypothesised that through intervertebral disc dehydration, annular tears, and loss of disc height or collapse, DDD can result in abnormal motion of the segment and biomechanical instability causing pain (Van Deen Eerenbemt, 2010).



Figure 2.4 MRI of lumbar spine with degenerative disc disease (DDD) at L5-S1.

Adapted from www.spine-health.com.

2.4 Degenerative Disc Disease

Degenerative disc disease (DDD) is an important problem concerning low back pain which lead to secondary clinical problems including herniated disc, bulging disc as shown in Figure 2.5 that alters disc height and the mechanics of the rest of the spinal column, possibly adversely affecting the behavior of other spinal structures such as muscles and ligaments (Urban and Robert, 2003). The cause of

DDD can be both abnormal mechanical as abnormal chemical factors within the interveterbral disc which are reflected in the disc composition, structure and properties.

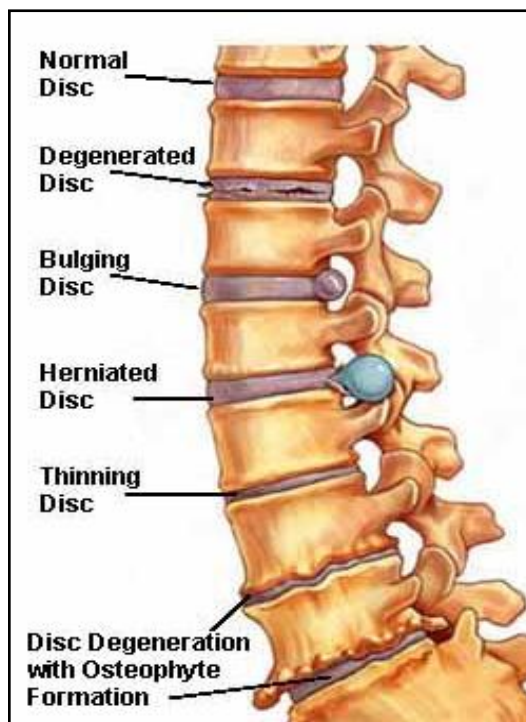


Figure 2.5 Example of degenerative disc disease. Adapted from www.spineuniverse.com.

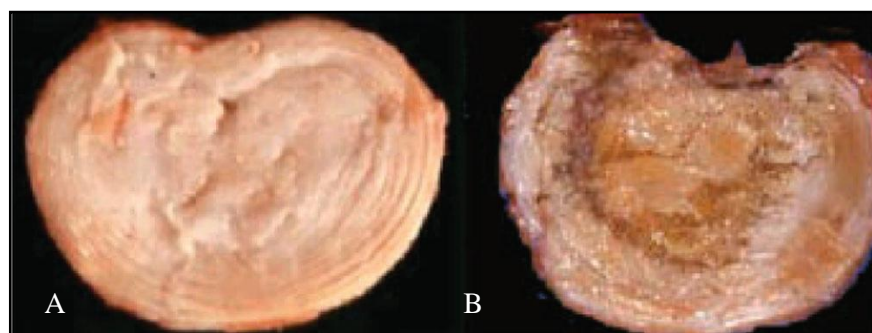


Figure 2.6 A. The normal intervertebral disc B. Degenerate lumbar intervertebral disc. Adapted from Urban and Robert, 2003.

DDD occurs as a part of aging, also caused by environmental and genetic factors and ultimate mechanical factors. The most significant biochemical change to occur in disc degeneration is loss of proteoglycans as shown in Figure 2.7. The loss of proteoglycans is a major effect on the disc's load-bearing behavior. The degenerated disc

no longer behaves hydrostatically under load and inappropriate stress peaks may occur which can lead to cleft and tear formation (Jongeneelen, 2006).

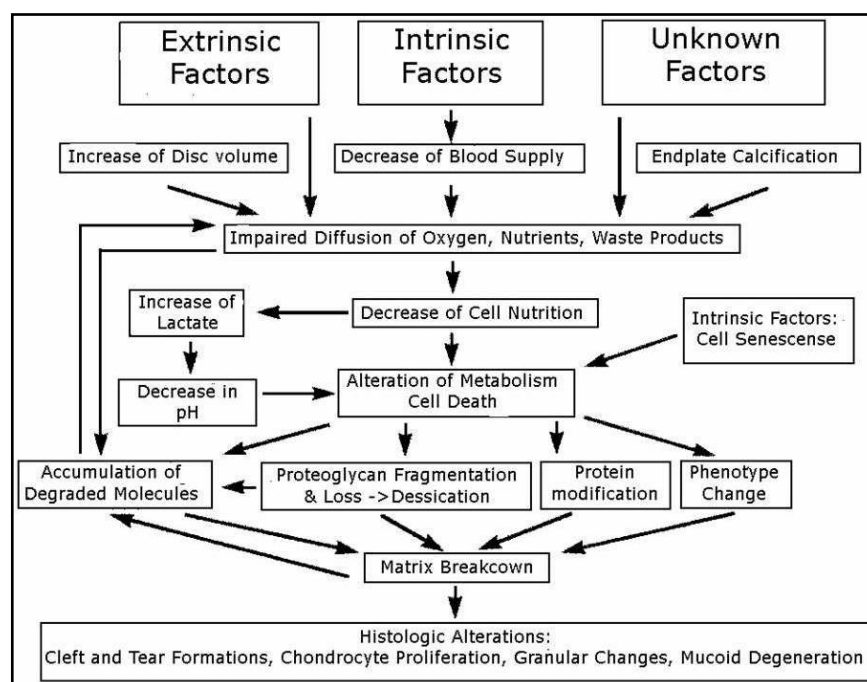


Figure 2.7 Schematic presentation of the possible pathomechanisms involved in the age-related changes. Adapted from Jongeneelen, 2006.

2.5 Facet Joint Degeneration

Facet joint is a complicated biomechanical structure in the spine that provides a low-friction interface to facilitate motion during normal conditions in a healthy spine (Jaumard, 2011). They also play an important role in load transmission through the vertebrae, where the normal facets carry 3% to 25% of the load applied at the vertebra and potentially as high as 47% if the facet joint is arthritic. Because of their high level of mobility and the large forces influencing the facet joints, especially in the lumbar area, the joints can develop significant degenerative changes.

The facet joint degeneration (arthrosis) has been recognized as a source of LBP by the previous studies. The occurrence of degeneration of facet joints and disc at neighboring levels caused by the migration and subsidence of the prosthesis, thus resulting in the reduction and misalignment of the facet joint space (Figure 2.8). The fixation of the prosthesis to the bone of the vertebral body is very important. The

long-term fixation is desired to prevent migration or subsidence of the prostheses (Ooij, 2003).

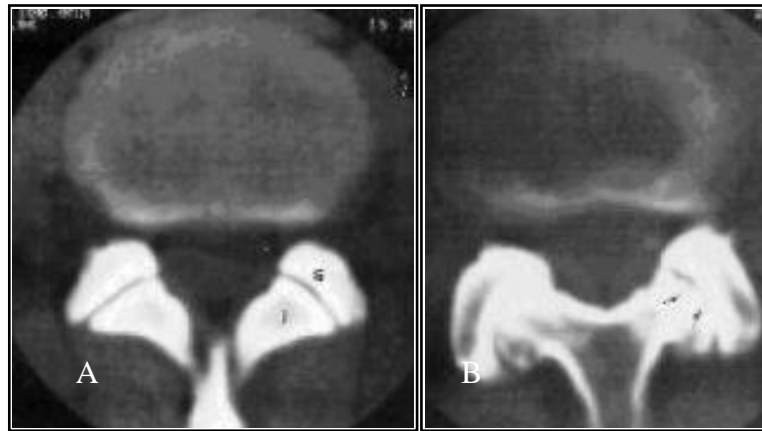


Figure 2.8 A. Normal facet B. Notice reduction of the joint space.

Adapted from www.nsmec.com.

2.6 Conventional Treatment of Low Back Pain

The best approach treatment for patient who has acute or chronic back pain includes of (Savigny, 2009);

- i. Education; including advice from practitioners regarding exercise and cause of back pain, formal education session and written education material
- ii. Exercise; including group and individual supervised exercise
- iii. Manual therapies; including manipulation, massage, mobilization
- iv. Other non-pharmacological interventions; including interferential, laser, lumbar supports, transcutaneous electrical nerve stimulation, traction, ultrasound
- v. Invasive procedures; including acupuncture, electro-acupuncture, nerve blocks, neuroreflexotherapy, percutaneous electrical nerve stimulation (PENS), injection of therapeutic substance into the spine,
- vi. Surgical referral and
- vii. Medications