ARTIFICIAL DISC REPLACEMENT - DEVELOPMENT

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Abstract: The Laboratory of Biomechanics, CTU in Prague is engaged in development of spinal replacement, among others on the basis of silicone. The design of the new type of spinal replacement assumes the restoration of the physiological properties in spine segment especially its normal mobility. The use of silicone as the main part of the artificial disc comes from the material properties that are similar to the intervertebral disc and from the biocompatibility of this material. For the evaluation of the artificial disc based on silicone has been generated non-linear finite element model of artificial disc replacement in the software package ABAQUS.

Introduction

Low back pain is one of the most common problems in our society. Almost every person will have at least one episode of low back pain at some time in his or her life. The pain can vary from severe and long term to mild and short lived. It may be related to damage or aging of the disc, muscular problems, arthritis of the spine, problems with tendons or ligaments in and around the spine or malpositioning of vertebrae, sometimes may be caused by excessive stress to the back, such as lifting something heavy.

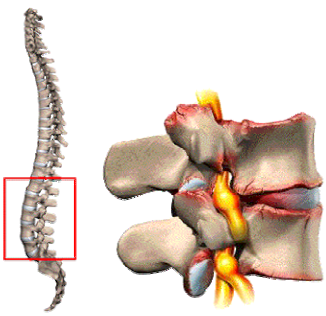

Figure 1: Low back – lumbar spine, degenerative disc disease

Treatments for back pain are multiple and varied. In most cases, simple therapies such as mild pain medications and rest are effective in relieving the immediate pain. Occasionally stronger medications such as muscle relaxants and narcotics are used for a short period. Other conservative therapies can be corset, course of exercise and stretching, injections, drugs etc. When "conservative" therapies are unsuccesful, surgical procedures have become common. Most commonly performed operation for back pain has been spinal fusion (vertebrae are fused together with bone grafts and internal devices). Fusion surgery eliminates the movement between the fused vertebrae, which leads to increased load and stress on the adjacent vertebrae. Major disadvantage of this fusion is decrease of mobility in dependence on the increasing of adjacent vertebras and discs load. This causes next degenerative changes followed by another pain.

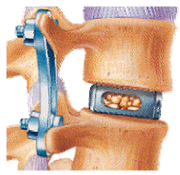

Figure 2: Spinal fusion

Artificial disc replacement is an alternative to spinal fusion, an artificial disc serves to replace the degenerated disc, restore the functional biomechanical properties of the motion segment, and protect neurovascular structures. The implanted device should re-establish normal kinematics to the functional spinal unit and promote an anterior/posterior column load-sharing environment. None of current available artificial intervertebral discs does respect all physiological properties of natural disc. The main disadvantage of current available artificial discs is low ability for damping and unlimited rotational movement by axial rotation. Therefore surgeons came with demand to develop a new type of artificial disc replacement, which would respect physiological properties of natural intervertebral disc. The development of a new artificial disc replacement runs in Laboratory of Biomechanics of Man, CTU in Prague.

Materials and Methods

The replacement should be given the same mechanical properties as the natural intervertebral disc to prevent different mechanical properties of the vertebral column. The intervertebral disc consists of a gelatinous nucleus pulposus, surrounded by a fibrous annulus fibrosus. This particular construction can withstand the high loads acting on the spine during everyday life, while giving the vertebral column its mobility.

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The requirements results from the natural disc properties are geometry, function (stiffness, range of motion, strength...) and the fixation to the adjacent vertebrae. To restore the mechanics of the spine, the artificial intervertebral disc should fully restore height and wedge angle of the healthy situation (Table 1). The shape of the artificial discs endplates should be complementary to the surface of the adjacent bones and has to be large enough to prevent migration, without the chance of coming into contact with surrounding vital tissues.

Table 1: Range and average values for lateral and sagittal diameter, disc height and wedge angle of lumbar intervertebral discs (T12/L1 –L5/S1)

	Range	Average
Lateral diameter (mm)	35 - 63	50
Sagittal diameter (mm)	27 - 45	35
Height (mm)	6 - 14	10
Wedge angle (degrees)	6 - 14	10

The stiffness of intervertebral disc is important for the shock absorbing ability of the vertebral column. In general, low stiffness in either direction results in spinal instability. Low stiffness in compression increases the range of motion and results in overloading of the facet joints, whereas high compression stiffness of the artificial disc decreases its shock absorbing capacity (Table 2).

Table 2: Average stiffness and stiffness ranges of a lumbar motion segment

Force/Moment	Stiffness
Tension	770N/mm
Compression	2000 (700-2500) N/mm
Anterior shear	121N/mm
Posterior shear	170N/mm
Lateral shear	145N/mm
Flexion	1.36 (0.8-2.5) Nm/deg
Extension	2.08 Nm/deg
Lateral bending	1.75Nm/deg
Axial rotation	5.00 (2.0-9.6) Nm/deg

The range of motion and its range in degrees for lumbar intervertebral discs are shown in the Table 3. There is a risk of ligament overloading and instability of the spinal column, when the range of motion of the total intervertebral disc exceeds the range of motion of the physiological disc.

Table 3: Range of motion and its range in degrees for lumbar intervertebral discs

Motion	L1-L2	L2-L3	L3-L4
Axial rot	2(1-3)	2 (1-3)	2 (1-3)
Lat. ben.	6(3-8)	6(3-10)	8(4-12)
Flex.+Ext.	12(5-16)	14 (8-18)	15 (6-17)
Flexion	8 (5)	10 (2)	12 (1)
Extension	5 (2)	3 (2)	1 (1)

Motion	L4-L5	L5-S1
Axial rot	2 (1-3)	1 (1-3)
Lat. ben.	6(3-9)	2(2-6)
Flex.+Ext.	16 (9-21)	17(1024)
Flexion	13 (4)	9 (6)
Extension	2 (1)	5 (4)

Migration of the replacement into the vertebrae is one of the risks of an intervertebral disc replacement. The intervertebral disc replacement has to be fixated firmly to the vertebra immediately after implantation. To achieve this, pins are placed on top of the endplates. Penetration of these fixation elements into the vertebral body should ensure a firm fixation. Dislocation of a disc may result in serious damage to vital systems such as the spinal cord and large veins and arteries. Long term fixation will probably be improved by stimulation of bone ingrowth, using specific coatings. Similar techniques are widely used in other orthopedic implants.

The new artificial disc was designed in accordance with these requirements. All the materials used in this new replacement are fully biocompatible and can be use for long-term implantation. The new artificial disc replacement comprises two rigid endplates made of PEEK (polyetheretherketone) with openings and the elastic silicone core inserted between these endplates. The openings serve to improve the retaining of the core while movement. The designed replacement eliminates the main disadvantages of existing artificial discs (LINK SB Charité, Pro Disc) that are not resilient and cannot damp the shock stresses. This may lead to further degeneration of the surrounding tissues and the discs at adjacent levels that are overloaded. The new implant damps the shock stress and loading due to properties of silicone core and has required limited range of motion with rotational and bending stiffness. The artificial disc replacement designed geometry is shown in Figure 3.

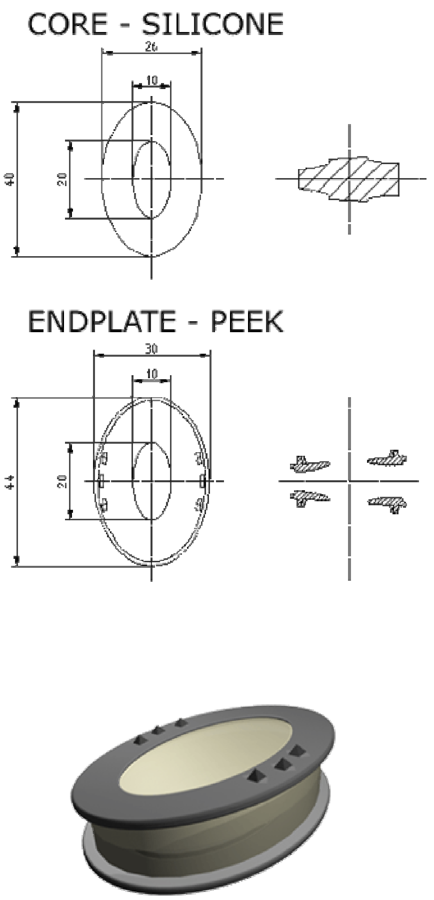

Figure 3: Designed artificial disc replacement.

The geometry of the designed artificial disc was used in non-linear finite element model of artificial disc in the software package ABAQUS. For the analysis two types of silicone were chosen – MED4550 and MED4575, considering the functional requirements (stiffness, range of motion, strength ...). The necessary condition for relevant simulation of silicone materials is the determination of their material properties that are not readily available.

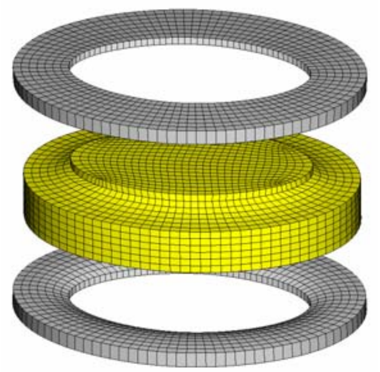

Figure 4: FEM model of artificial disc replacement.

It was necessary to perform the experimental measurement of the silicone material characteristics. On basis of the measured characteristics it was possible to determine the material parameters for several description of the material that are implemented in the environment of Finite Element Method solver.

Experimental measurements of the silicone characteristics were affected in accordance with standard specifications ČSN ISO 37 - Rubber from cured or thermoplastic resins. Determination of tensile properties. and ISO 7743:2004 - Rubber, vulcanized or thermoplastic. Determination pinch compression stress-strain properties. In computer programme ABAQUS elastomeric (rubber) materials are modeled using the hyperelastic material model. Hyperelastic materials are described in terms of a "strain energy potential," U(ε) , which defines the strain energy stored in the material per unit of reference volume (volume in the initial configuration) as a function of the strain at that point in the material. There are several forms of strain energy potentials available in ABAQUS to model approximately incompressible isotropic elastomers. The evaluation of fitting the measured experimental data from uniaxial tension and compressive tests to particular models was effected. Form Arruda-Boyce of strain energy potential was chosen (also known as the eight-chain model) that best fit to experimental data.

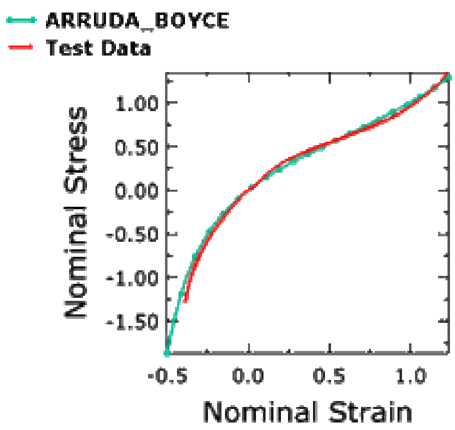

Figure 5: Comparison experimental data and computed data - model hyperelastic form Arruda- Boyce.

Results

Both artificial disc replacements models (with silicone MED 4550 and with silicone MED 4575) were analysed in compression and flexion. Models were loaded with an axial force of 3 kN and flexural moment 10 Nm. The size and shape of the replacement was chosen for L4/L5. The results were compared with the findings for the intact systems from literature. Figure 6 illustrates a deformed configuration of the artificial disc in compression.

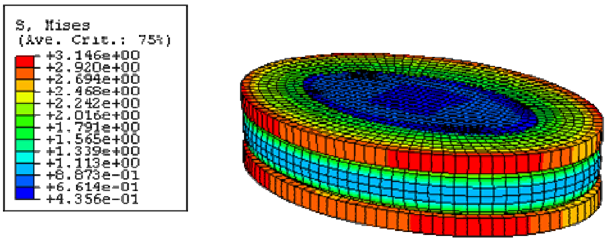

Figure 6: Deformed configuration of the artificial disc in compression (force= 3000 N, silicone MED 4575).

The results of load-displacement behaviour in compression both models (with silicone MED 4550 and with silicone MED 4575) and the corresponding experimental data obtained from literature are illustrated by load-displacement curves in Figure 7.

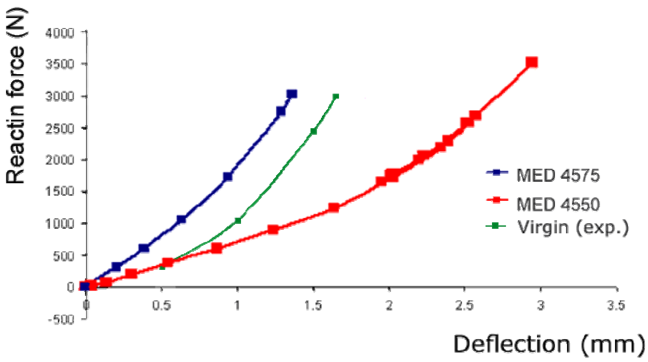

Figure 7: Reaction force versus deflection (comparison of two models silicone MED 4550, silicone 4575 and data from literature).

Figure 8 illustrates a deformed configuration of the artificial disc in flexion. The results of behavior in flexion and the corresponding experimental data obtained from literature are illustrated in Figure 9. There is also the curve how behave the segment without facets and ligament, that is most suitable for the comparison with the data obtained from the analysis.

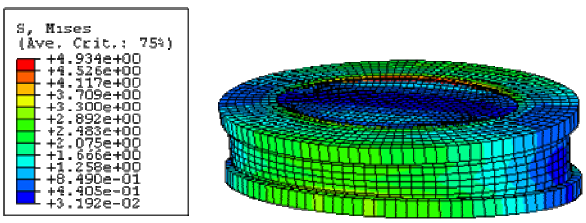

Figure 8: Deformed configuration of the artificial disc in flexion (moment= 10 Nm, silicone MED 4575).

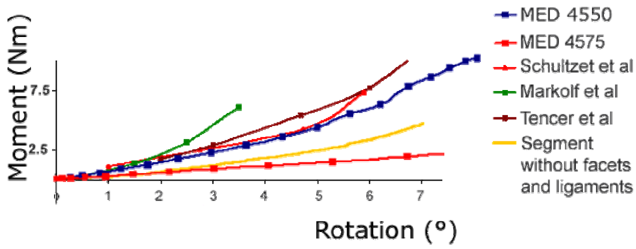

Figure 9: Flexural moment versus rotational angle deflection (comparison of two models silicone MED 4550, silicone 4575 and data from literature).

Discussion

This work proposed the use of silicone as the main part for the artificial disc replacement. The analysis of both artificial disc models with silicones gives very good results in comparison with experimental data obtained from literature. The stiffness, strength and the range of motion is near this data. The concept of the silicone artificial disc replacement seems to be sufficient. The advantage of this concept is the retaining the main function - shock-absorbing ability of the natural disc - that currently used artificial discs misses. Further advantage is that all the materials used in this new replacement are fully biocompatible and can be use for long-term implantation.

The development of the new artificial disc replacement is still not at the end. Finding an optimal model variant depends on many of another mathematical analysis and experimental measurements. After this, clinical tests yet remain so the development is still consulted with experts in spinal surgery.

Acknowledgement

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