

Design Evaluation and Development of Lumbar Cage

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ABSTRACT

Lumbar spinal fusion is advance method of surgery to permanently join or fuse two or more vertebrae in the human spine in order to eliminate the relative motion between them. It is currently considered as the most successful surgery in the patients with spinal deformity and degenerative spondylolisthesis. Its success critically depends on the geometric design of the interbody cages and the material properties of the material used. The main objective of this work is to design analyse and develop a 3D model of the intervertebrae disc for human lumbar spine based on anatomical reverse engineering techniques (ARE techniques) such as magnetic resonance imaging (MRI) scan. For this purpose, the sizes of L4-L5 which are the largest vertebrae of the human spine, were observed and modeled accordingly by using CREO with standard dimensions. The prototype was made with PLA plastic using an FDM 3D printer. The analytical tests were carried on ANSYS by applying various complex motions on the intervertebrae disc surface and the stress distributions were compared for the optimization of lumbar cage design. The compression force was applied on the prototype and observed till failure. Results obtained were compared for static position of the lumbar cage, of both analytical and physical outcomes.

KEYWORDS: lumbar cage, inter-body fusion, intervertebral disc

INTRODUCTION

Lumbar interbody fusion is an advanced surgery method to eliminate the relative motion between two or more vertebrae. This is seen commonly in the people within 40 to 60 years of age. Anterior lumbar interbody fusion (ALIF) is considered as one of the surgical methods for the relief of chronic back pain, radiculopathy and neurogenic claudication in the patients with degenerative lumbar spine disease, low-grade spondylolisthesis and pseudoarthrosis. In particular the designs of ALIF cages and the materials used have evolved dramatically, the common goal is to improve fusion rates and optimize clinical outcomes. Developments in cage designs include cylindrical bagby and kulisch, cylindrical ray, cylindrical mesh, lumbar tapered, poly-ethyl ether ketone cage and integral fixation cages. Biologic implants include bone dowels and femoral ring allografts. Methods for optimization of lumbar cages include cage dimensions, use of novel composite cage materials and integral fixation technologies. A fusion cage is used to aid fusion of an intervertebral joint. Till now, cages have been made of materials that remain in the body. Post-operative complications with these permanent fixtures might be overcome by using biodegradable/ bioabsorbable composites (BBC). There are some requirements for the BBC to be used as cage material which may include loadbearing ability. Since this composite material would degrade gradually to be replaced by the bone.

The technique of posterior lumbar intervertebral fusion (PLIF) was introduced independently by jaslow and cloward

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in the mid 1940s. The theoretical basis is that mechanical stability is provided by the intervertebral fusion, the original disc height is restored and the intervertebral foramina are distracted. Thus the development of lumbar cage intervertebral disc was done by using additive manufacturing techniques since this would reduce the wastage of material. The term additive manufacturing (AM) encompasses many technologies including subsets like 3-D printing, rapid prototyping (RP), direct digital manufacturing (DDM), layered manufacturing and additive fabrication Additive manufacturing, the industrial version of 3-D printing is already used to make some niche items in many industries. The terms 3-D printing and additive manufacturing have become interchange-able. The term additive manufacturing refers to the technology or additive process of depositing successive thin layers of material upon each other, producing a final three dimensional product. Each layer is approximately 0.001 to 0.1 inches in thickness. A wide variety of materials can be utilized, namely plastics, resins, rubbers, ceramics, glass, concretes, and metals. Rapid prototyping refers to the application of the technology. This was the first application for AM, which assisted in the increase of time-to-market and innovation. It can be referred to as the process of quickly creating a model/prototype of a part or finished good. This part or finished good will be further tested and scrutinized before mass production occurs. Most commercial 3-D printers have similar functionality. The printer uses a computer-aided design (CAD) to translate the design into a three-dimensional

object. The design is then sliced into several two-dimensional plans, which instruct the 3-D printer where to deposit the layers of material. In the past few years, many companies have embraced AM technologies and are beginning to enjoy real business benefits from the investment.

Fused Deposition Modelling (FDM)

This technology was originally developed and implemented by Scott Crump founded, in the 1980s. With the assistance of FDM, you can print not just operational prototypes, but also ready for use products such as plastic gears etc. All components printed with FDM can go in high performance and engineering-grade thermoplastic, which is quite beneficial. 3D printers which use FDM Technology construct objects layer by layer from the very bottom up by heating and extruding thermoplastic filament. In addition to thermoplastic, a printer may extrude support materials (Nylon is typically used as a support material). The printer heats thermoplastic until its melting point and extrudes it throughout nozzle on a printing bed, which you may know as a build platform or a desk, on a predetermined pattern determined by the 3D model and Slicer software.

LITERATURE REVIEW

Lee CK et al in their study had reviewed 62 consecutive patients with chronic disabling back pain who were treated with disc excision and posterior lumbar interbody fusion. And they had evaluated the efficacy of the surgical treatment of patients with chronic disabling low back pain resulting from internal disc derangements that does not respond to the non operative treatments. The clinical outcomes from the 62 patients were evaluated by postoperative follow-up questionnaire, and the fusion results were evaluated by X-ray studies of lumbosacral spine. They found that approximately 87 % out of 62 patients responded properly to the follow up evaluation. Eighty nine percent of patients had satisfactory results., 93% returned to work and a successful result was obtained in 94% of patients.

Watkins R et al had found that when thirty one consecutive patients underwent anterior interbody fusion of the lumbar spine using autogenous, autologous or mixed iliac crest graft, each patient's disc space height was measured pre-operatively, immediately post-operatively and an average of months post-operatively. The immediate post-operative radiograph demonstrated an average increase in disc space height of 89% or 9.5mm for each operated level. And the late radiograph evaluation from 7 to 54 months showed an average decrease of 1% or 0.1mm for each level. At late follow up, they found no correlation between the time from the operation and disc space height. They also found that one hundred percent of patients developed disc space height decreases during the post-operative period, with 46% of levels being narrower than their pre-operative height at the last follow-up. And they concluded that disc space distraction is temporary with anterior interbody fusion.

Brantigan et al, has designed a carbon-fiber-reinforced polymer implant has been designed to aid interbody lumbar fusion. The cage-like implant has ridges or teeth to resist pullout or retropulsion, struts to support weight bearing, and a hollow center for packing of autologous bone graft. Because carbon is radiolucent, bony healing can be imaged by standard radiographic techniques. The device has been

mechanically tested in cadaver spines and compared with posterior lumbar interbody fusion performed with donor bone. The carbon device required a pullout force of 353 N compared with 126N for donor bone. In compression testing, posterior lumbar interbody fusion performed with the carbon device bore a load of 5,288 N before failure of the vertebral bone. Posterior lumbar interbody fusion performed with donor bone failed at 4,628 N, and unmodified motion segments failed at 6,043 N. He concluded that the carbon fiber implant separates the mechanical and biologic functions of posterior lumbar interbody fusion.

Duranceau et al. elaborated the quantitative three-dimensional surface anatomy of human lumbar vertebrae based on a study of 60 vertebrae. In their study the two lower vertebrae (L4 and L5) appeared to be transitional toward the sacral region, whereas the upper two vertebrae (L1 and L2) were transitional toward the thoracic region. Means and standard errors of the means for linear, angular, and area dimensions of vertebral bodies, spinal canal, pedicle, pars interarticularis, spinous and transverse processes were obtained for all lumbar vertebrae. This information provides a better understanding of the spine, and allows for a more precise clinical diagnosis and surgical management of spinal problems. The information is also necessary for constructing accurate mathematical models of the human spine.

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