
Design of an Artificial Intervertebral Disc Exhibiting a Negative Poisson's Ratio

Erik O. Martz¹, Roderic S. Lakes², Vijay K. Goel³ and Joon B. Park⁴

¹Disc Dynamics, Inc. 9600 West 76th Street, Suite T, Eden Prairie, MN 55344, USA

²Department of Engineering Physics, Engineering Mechanics Program; Biomedical Engineering Department, Materials Science Program and Rheology Research Center, University of Wisconsin-Madison, 147 Engineering Research Building, 1500 Engineering Drive, Madison, WI 53706-1609, USA

³Department of Bioengineering, 5051C Nitschke Hall, University of Toledo, Toledo, OH 43606, USA

⁴Department of Biomedical Engineering, University of Iowa, Iowa City, IA 52242, USA

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ABSTRACT

An artificial intervertebral disc exhibiting an anisotropic negative Poisson's ratio has been designed and characterized in the laboratory. This disc prosthesis incorporates negative Poisson's ratio to prevent bulge which might impinge on nerves, as well as the duplication of compressive axial stiffness of the natural lumbar intervertebral disc. The disc is also compliant in bending and torsion.

1. INTRODUCTION

When an injured or diseased spinal disc is compressed, depending upon its condition, this compression may force material from the nucleus of the disc to press against the annulus, or periphery of the disc. If the annulus has been weakened by injury or disease, then it is possible for compression to induce bulging of the disc to a greater extent than usual. This in turn will apply unwanted pressure to various nerves surrounding the disc, which can result in low back pain. Chronic disabling back pain caused by degenerative disc disorders has often been treated surgically by spinal fusion during the past twenty years. Spinal fusion is costly and requires long recuperation, and it can cause other problems including the degeneration of discs above and below the diseased one.

Low back pain, its causes, and its treatments have been studied for decades, and as of yet, it is still difficult to gather a general consensus on even some of

²Corresponding author. Email: lakes@engr.wisc.edu

the so-called simpler issues. Low back pain described as dull, deep, aching, or pressure-like in quality, and centered in a fairly limited area in the lumbosacral region is referred to as somatic low back pain⁽¹⁾. This may be provoked through nociceptor (pain sensation) activity from one of the tissues or skeletal structures in this region, such as the facet joints, capsular ligaments, the dura mater, outer annulus of the intervertebral disc, as well as the vertebral periosteum⁽²⁾. However, there is a growing recognition that the source of low back pain may not be entirely mechanical or chemical in nature, but rather psychosocial⁽³⁾. Industrial studies have revealed that those workers who felt that their job was emotionally stressful, anxiety provoking, or depressing, showed an increased likelihood to experience low back pain⁽⁴⁾. Other factors that have been associated with an increased incidence of low back pain are: smoking, educational level, social problems, and drug and alcohol abuse.

Treatment of low back pain is as varied as the speculation as to its definitive causes, however, it is clear that the overall cost is enormous. Ninety five percent of people who suffer an episode of low back pain respond to conservative treatment (i.e. rest and muscle exercises) and return to work within three months⁽⁵⁾. The remaining 5% of the above patients incur 85% of the cost of treatment of low back pain. When conservative therapy does not succeed in treating so-called degenerative disc diseases, surgery may be turned to, be it discectomy or fusion. Fusion surgery presents many complications including loss of motion and degeneration of adjacent discs. Fusion was at one time the preferred treatment for disabling arthritis of the hip and knee, but joint replacements are now done to restore motion. Moreover, it is not known whether disc bulge is causally related to low back pain. An artificial intervertebral disc has the potential for advantage over fusion in that motion could be restored to the spinal disc elements. Possible candidates for disc replacement could include those patients suffering from severe sciatica, degenerative spondylolisthesis, and disc disruption syndrome.

One of the earliest attempts at replacing the intervertebral disc with an articulating implant was done in Sweden. Fernström⁽⁶⁾ inserted stainless steel ball bearings into the spaces between vertebrae to reduce low back pain and sciatica. In evaluations four to seven years post-operative, 74% of his patients had moderate disc space narrowing, due to subsidence of the stainless steel balls into the vertebral body⁽⁷⁾. More recently total disc prostheses have been proposed, with the common theme of a "ball-and-socket" gliding interface for motion. The Waldemar Link™ SB Charite III artificial disc has gone through a number of clinical trials^(8,9). Problems included dislocation and subsidence. Disc prosthesis of the ball and socket type, however, may show adverse effects on the facet joints or adjacent segments due to abnormal

amount and/or patterns of motion produced by prostheses and lack of shock attenuation.

Bulge of a spinal disc is a manifestation of the Poisson effect in the disc materials. Poisson's ratio relates the strain in the lateral direction to the strain in the longitudinal direction. Most materials have a positive Poisson's ratio: they bulge when compressed and become thinner when stretched. Materials that exhibit a negative Poisson's ratio expand laterally when stretched in the longitudinal direction, and conversely, these materials contract laterally when compressed longitudinally. Poisson's ratio is relevant in spinal discs since bulge of the disc can impinge on the exiting nerves, causing pain. Based on energy arguments presented by Fung⁽¹⁰⁾, the theoretical range of Poisson's ratio ν that isotropic materials may possess is between $-1.0 \leq \nu \leq 0.5$. For anisotropic materials, values outside this range are possible. Honeycomb structures can exhibit either positive or negative Poisson's ratio^(11,12) depending on the cell geometry. Negative Poisson's ratio foams⁽¹³⁾ with inverted cell shapes have been developed and explored⁽¹⁴⁾. The structural deformation mechanism of negative Poisson's ratio materials was analyzed by introducing the concept of re-entrant cell structure and non-affine deformation⁽¹⁵⁾. There is no characteristic length scale in the theory of elasticity, therefore the positive or negative Poisson's ratio cannot depend on the presence of a coarse microstructure such as that present in the foams or in the honeycombs studied previously. As with foams of conventional structure, there is no predicted effect of cell size.

If one decides to do a disc replacement, it is considered desirable to restore as many properties as possible to "normal" values following disc arthroplasty. It is not yet known what properties are most important, but flexibility is presumably important. However, the present ball-and-socket type designs do not restore motions back to "normal", due to inherent lack of flexibility in the artificial disc itself, especially in the axial loading mode; also, there is no bulge. The elastomer discs, capable of restoring disc bulge and motion, so far have not proven clinically successful. Thus, there is a motive to explore alternative designs such as proposed in the paper. The proposed disc design, shown to be comparable in flexibility to the normal disc in the axial direction, will provide some flexibility in other modes as well. Our synthesis of the literature suggests that the most pressing design improvement is to mimic the normal deformation response of the segment following surgery in the axial direction. This paper addresses this issue.

The purpose of this study is to investigate the feasibility of an artificial intervertebral lumbar disc. This design incorporates a negative Poisson's ratio to eliminate problems of bulge. It also restores disc height and function and

provides compliance. In doing so, it is envisioned that this artificial disc should alleviate the suffering of people with low back pain who might otherwise be treated by spinal fusion.

2. MATERIALS AND METHODS

An artificial intervertebral disc with an inverted honeycomb structure was designed. The inverted honeycomb structure as shown in Figure 1 has a negative Poisson's ratio and produces an inward bulging effect when it is loaded. Key aspects of the design of this architecture are: shape of the disc, degree of inversion of the cell walls, loading conditions, wall thickness, and material type. The compressive stiffness of the implant design was to be within the range of the natural lumbar disc reported in the literature^(16,17,18): 850 N/mm to 2,500 N/mm. A partial restoration of the flexion and extension functions of a lumbar vertebral motion segment are also to be incorporated into this design.

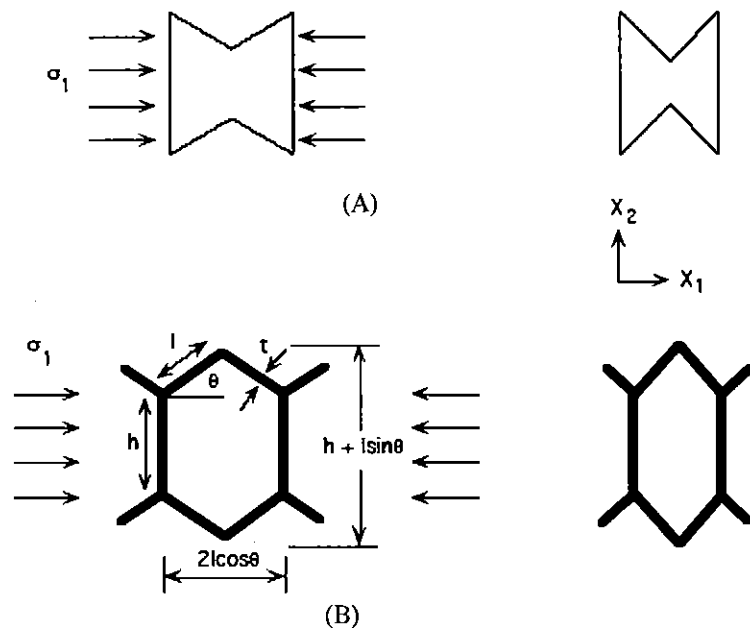


Figure 1. (A) shows an inverted honeycomb that exhibits a negative Poisson's ratio when loaded in the X1 direction, (B) shows a regular honeycomb structure with standard dimensions

An initial inverted honeycomb design was developed, and from this it was further modified to make its manufacturing simpler. The initial design made use of analysis of thin wall honeycomb cells for which analytical solutions are available. The desired wall thickness was calculated based in a target value for axial compliance; the honeycomb wall angle was chosen to achieve a negative Poisson's ratio. Such analysis does not capture the wall shape or thickness used in the manufactured honeycomb, in which the honeycomb structure was achieved by the drilling of transverse holes. Therefore analysis by the finite element method (FEM) was conducted. Finite element analysis was used to refine the design and was done using HP-UX workstations and the finite element program ANSYS 5.0 (Swanson Analysis Systems Inc., Houston, PA). The material properties given to the model were those of the high density polyethylene (HDPE) used in the experiments. If a polymeric disc were to be implanted, it would be UHMPE, ultra high molecular weight polyethylene, which is biocompatible, and somewhat stiffer than HDPE. It was assumed that the polymer was isotropic, with Young's moduli independent of direction: $E_x = E_y = 773 \text{ MPa}^{(19)}$, and the Poisson's ratio was taken to be 0.3. A linear analysis of the model was performed, and plane stress as well as plane strain models were investigated. Bending stiffness was assumed to be independent of the depth of the implant. The model was tested for convergence and was found to converge as the number of elements in the model was increased. The mesh of this design was iterated until a favorable combination of compressive stiffness and bending stiffness was obtained.

Since this implant, in its final form, is intended to replace the nucleus, as well as the inner layers of the annulus of the L_4 - L_5 disc, dimensions of these endplates were used. Compromising between the dimensions quoted by Berry *et al.*⁽²⁰⁾ and Panjabi *et al.*⁽²¹⁾, a major diameter of 48 mm and a minor diameter of 33 mm were chosen to model the L_4 - L_5 disc as an ellipse. Next, a rectangle was created within the confines of this ellipse, and its dimensions were varied until the largest area was obtained so that a given force will result in a minimized pressure. This rectangle represented the dimensions of the next design iteration of the artificial disc, with length equivalent to a major diameter of 33 mm, and a width equivalent to a minor diameter of the disc of 24 mm. The height of the disc was chosen to approximate that of a typical disc.

Excess disc bulge is the result of weakened or damaged annulus. If one replaces most or all of the annulus, an artificial disc with a negative Poisson's ratio need not be isotropic to be effective; moreover, the spinal nerves are near the disc only over part of its periphery. The Poisson's ratio is therefore designed to be negative in only one direction. Negative Poisson's ratio in both transverse directions could be incorporated if deemed necessary. After several iterations, the

geometry was determined, and the implants were manufactured by strategically drilling a series of holes into a piece of HDPE, to obtain an inverted honeycomb structure of the type shown in Figure 2; no holes were made through the end plates. Also shown in Figure 2 is the position of an implant as it might be used between two vertebrae. These HDPE specimens were then tested to verify the compressive stiffness and the Poisson's ratio that were predicted through the finite element analysis. Three of the implant samples were tested four times on an MTS machine (Model No. 812.21, MTS System Corp., Minneapolis, MN) to determine their axial compressive stiffness. Displacement control was used, and the rate was 10 mm/min. The three specimens were tested four times each with the first three runs tested in the elastic region. The final run tested the implant until the load/displacement curve was very much in the non-linear realm, observed when the slope representing the elastic region began to decrease. The effect of the stiffness of the MTS column was determined, and found to be negligible.

Verification of the Poisson's ratio was performed by compressing the implant sample in increments of 0.254 mm, up to 1.524 mm. The corresponding

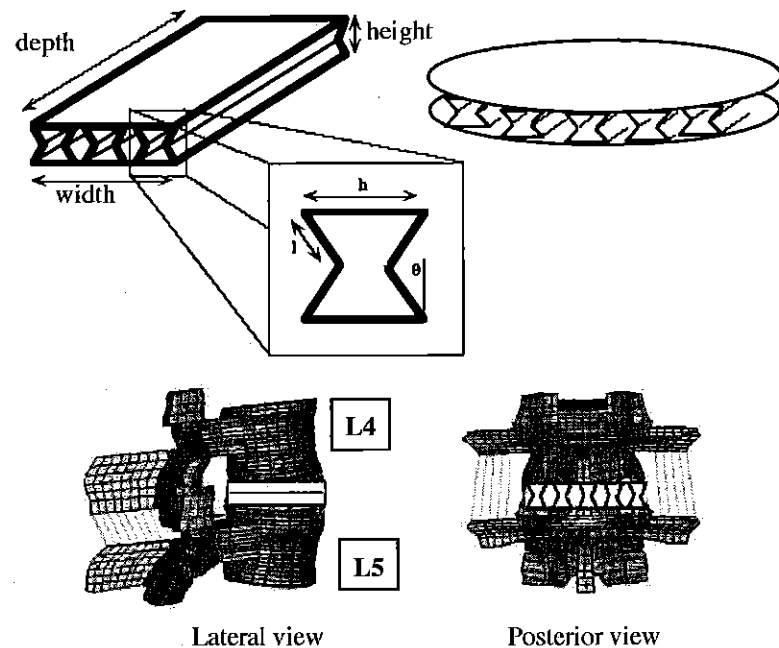


Figure 2. Structure of the proposed artificial intervertebral disc. Top left, rectangular model for testing; top right, elliptic version for implant. Bottom: a lumbar motion segment with an artificial disc in place; left, lateral view; right, posterior view

lateral displacement of one of the outer walls was measured at each of these six displacements. This point corresponds to node #1 shown in Figure 3. The inward bulging of this outer wall was measured using a Gaertner traveling microscope (Gaertner Scientific Co., Chicago, IL).

3. RESULTS

The final mesh for the finite element model is shown in Figure 3. The FEM analysis yielded the following results: in axial compression, the stiffness of the implant design was 1,930 N/mm, when a uniform vertical displacement of -0.254 mm was applied to the top row of elements. A bending stiffness of 1.56 Nm/deg, with an estimated 2.25 degrees of flexion was also obtained.

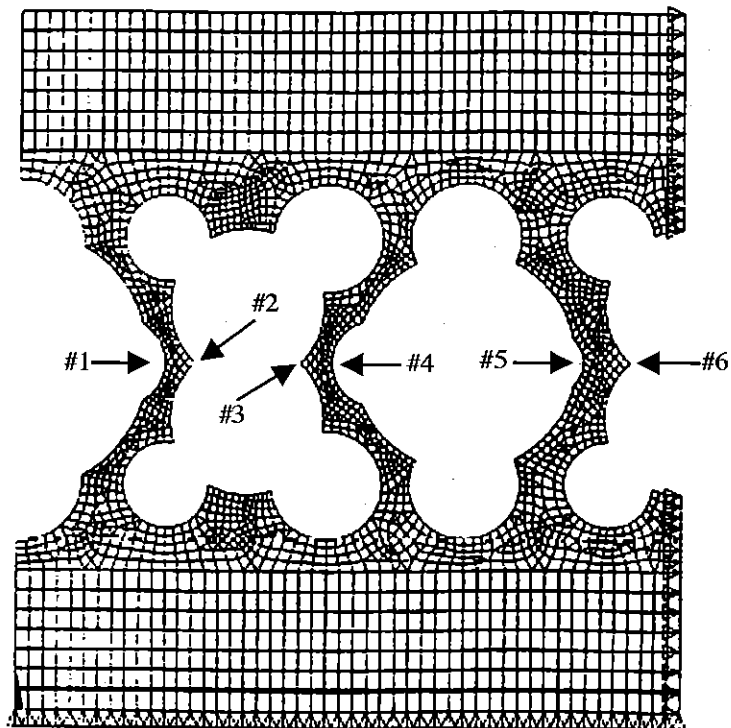


Figure 3. Mesh of the finite element model with the six nodes of interest used for convergence analysis. Only half of the implant was modeled due to its symmetry, which is shown above through the constraints (as indicated by the triangles) along the right side of the model

Axial compressive stiffness was taken as the slope of the load-displacement curve along the linear region of the curve. Table 1 summarizes the results of the mechanical tests. These averages match up well with the FEM prediction for stiffness. Since the computed values are about 10% to 15% higher than what these actual samples should be, this would translate into a predicted axial compressive stiffness of 1,640 N/mm to 1,730 N/mm. The difference between experiment and model is attributed to a seating effect in the experiment in which slack in the contact between specimen and platens is taken up. The model assumes idealised compression between perfectly parallel platens. Also, polymers of identical nominal composition can vary in properties *via* dependence on molecular weight, strain rate, and temperature. Average stiffness (1,560 N/mm) of all the full-sized samples, deviated from the predicted values by 5% to 10%. In viewing the results of the compressive stiffness tests, they were in reasonable agreement with the values of the finite element model. The likely cause of the small difference between stiffness values as well as the variation in stiffnesses is the slight imperfections that can occur during machining of the full sized specimens. For example, the holes in the implant specimens were drilled from both ends of the sample. This can lead to the possibility that when the samples were turned over to be drilled from the other end, the holes did not realign perfectly. Moreover, the polymer is viscoelastic, so a rate sensitivity can contribute to differences in observed moduli.

Both experiment and FEM showed negative Poisson's ratio but there were differences in the values, as shown in Figure 4. Linear FEM gave Poisson's ratio independent of strain, at variance with observation but nonlinear FEM produced results in reasonable agreement with the experimental Poisson

Table 1. Summary of experimental axial compressive stiffness results for full-sized samples

Sample	Trial Numbers (values are axial compressive stiffnesses, given in N/mm)				Avg. Axial Compressive Stiffness (std. dev.) (N/mm)	Non-Linear Load (N)
	1 (N/mm)	2 (N/mm)	3 (N/mm)	4 (N/mm)		
#1	1598	1504	-	-	1551 (± 66)	414
#2	1222	1363	1645	1504	1434 (± 182)	437
#3	1504	1551	1880	1857	1698 (± 198)	447

Note: the "-" indicates that the elastic region was exceeded during testing

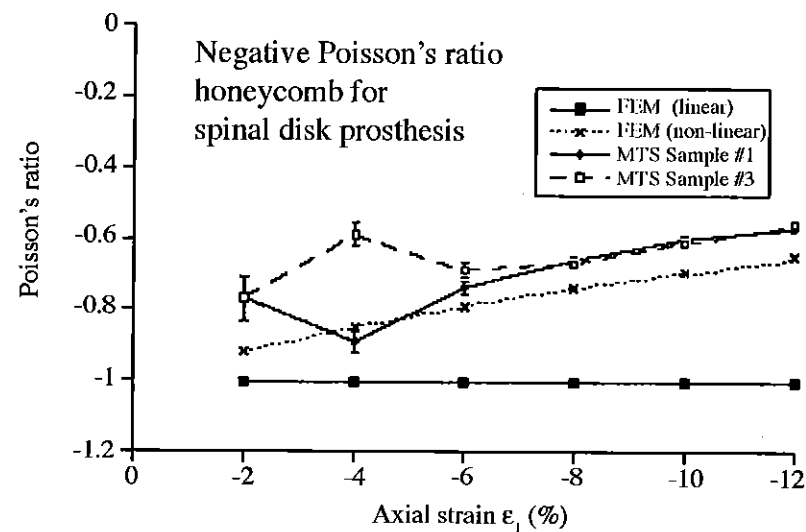


Figure 4. The variation of Poisson's ratio as a function of axial strain calculated from displacement is presented for both the MTS tested samples and the FEM model of the implant

effect. In the implant specimens, the variation of Poisson's ratio with axial strain follows the same trend as that obtained from a geometric nonlinear FEM analysis. In the experimental curves, after an initial bump (which may be due to imperfections in manufacturing), the slope of the curves tracks the predicted geometric nonlinear curve well. This behaviour is attributed to an initial seating effect in the test machine, in which some movement was required for the specimen to achieve full contact with the loading platens. The result of the non-linear FEM model is similar to the nonlinear behaviour based on the analytical formulations of Gibson and Ashby⁽²²⁾ for an ideal honeycomb with thin uniform walls. Due to geometric nonlinearity, the rib angles change with strain, thus resulting in a change in the Poisson's ratio.

4. DISCUSSION

A proof of concept for an artificial intervertebral disc exhibiting a negative Poisson's ratio has been designed, produced, and characterized *in vitro*. The height, width, and depth comparable to dimensions of the height, minor, and major diameters of the L₄-L₅ intervertebral disc. The primary advantage of such a disc is that upon compression in the longitudinal direction, the disc will

not bulge outwards in the plane perpendicular to the compressive force. With no outward bulging, the nerves in the vicinity of the disc will not be impinged upon. If in fact such impingement is the cause of the pain, the lack of bulge will reduce pain. The fact that free nerve endings have been identified within the outer layers of the annulus indicates a nociceptive (pain sensation) function, which therefore makes diseased or injured lumbar discs candidate sources for low back pain⁽²³⁾. The disc also provides a designed axial flexibility. Axial compressive stiffness for this implant is comparable to that of the isolated lumbar disc (1,560 N/mm vs. 850 to 2,500 N/mm). Finite element analysis predicted a compressive stiffness of 1,930 N/mm and a bending stiffness of 1.56 Nm/deg. Unlike other implants, the present design contains no metal on metal, or metal on polymer articulating surfaces, eliminating wear and potentially reducing foreign body reaction to wear debris. Flexible materials can, however, shed particles if there is fatigue damage. The final implant design presented represents what is intended as a first iteration in the design of a lumbar artificial intervertebral disc exhibiting a characteristic negative Poisson's ratio.

Further study of compliant discs is recommended as follows. The material should be ultra high molecular weight polyethylene (UHMWPE), the preferred polyethylene for implantation. Since its modulus is higher than that of HDPE, more porosity would be required to achieve the desired structural stiffness. This could be achieved *via* additional holes in a direction perpendicular to that used in the present work. The disc should be oval shaped to match the anatomy of the natural disc. Suggested experimental testing *in vitro* includes fatigue, fracture, and creep tests. The finite element model should be refined to include three dimensional deformation. Spinal discs also experience bending in different directions as well as torsion. Each degree of freedom in the natural disc has its corresponding structural stiffness. The axial stiffness alone has been matched in the present design, therefore a refined design would match the other stiffness components as well. As for use of the implant, insertion into the disc space is to be laterally, and the implant will occupy the regions previously taken up by the nucleus and inner portions of the annulus. The outer regions of the annulus will be left intact. Implants may be attached through porous coated CoCr endplates such that the implant may lock into the endplates in a manner similar to how polyethylene blocks lock into the tibial trays of knee implants. Initial fixation may be achieved by adding spikes or other protrusions from the endplates. Finally, use of a spinal disc implant should be contemplated only if conservative, non-invasive methods have repeatedly failed to achieve satisfactory pain relief.

5. CONCLUSIONS

An artificial disc exhibiting an anisotropic negative Poisson's ratio has been designed, and characterized in the laboratory with the aim of achieving bulge free deformation and reasonable compliance. The compressive stiffness of the natural lumbar intervertebral disc has been duplicated, and partial restoration of flexion and extension has been predicted based on a finite element model.

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