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Dynamic Vertebral body Prosthesis: A new invention and its biomechanical study

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Abstract

A newly designed vertebral body prosthesis was introduced. The aim was to reestablish spinal stability and maintain proper spacing between the vertebrae located immediately above and below the removed vertebra. Details of the prosthesis were presented. The design had many objectives including easily installed, required uncompleted tools, securely maintained the integrity of the spinal column and promoted prompt in growth of new bone formation.

The biomechanical study was performed by employment of universal testing machine for comparative tests between the normal porcine vertebral spine and the vertebral prosthesis spine contract. The tests included compressive axial, torsional, flexion and extension loadings. The results showed that the spine construct had similar or/and more rigidity than the normal control and are statistically significant.

There are many surgical indications for vertebral body prosthesis replacement. It is suggestive of continuing further clinical applications for this new prosthesis to study the outcome prior to be widely accepted.

Introduction : Background of the invention

The main structural support of the human skeleton is the spinal column, a bony column that consists of a plurality of vertebrae which are interlinked by flexible joints, spaced apart by gelatinous intervertebral disks of fibrocartilage, and held together by ligaments. Each vertebra has a roughly cylindrical body, with wing-like projections, and a bony arch. The arches, which are positioned next to one another, create a tunnel-like space which houses the spinal cord. The anterior cylindrical bodies of the vertebrae, which are spaced apart by intervertebral disks, bear most of the compressive load of the spinal column (approximately 80 percent of the total load). (Nardin and Frankel, 1989).

When it occurs, severe back pain can be among the most relentless and debilitating afflictions occurring to individuals, often making a normal life substantially impossible for victims of such conditions. The most common causes of severe spinal ailments include primary and metastatic malignant tumors which are unresponsive to standard therapy, non-malignant tumorous vertebrae, spinal cord compression associated with paresis or paraplegia, and vertebral collapse or backbone instability. These conditions all affect the anterior cylindrical body of a vertebra, which, as mentioned above, is the primary load-carrying part of the vertebrae.

The primary objectives of surgical intervention are to preserve the neurological function of the spinal cord and to relieve the intense pain associated with such conditions. It will be appreciated particularly by those skilled in the art that any such surgical intervention will necessarily involve the resection of the spinal column and the removal of the anterior cylindrical body of the vertebra. The resulting loss of bony support destabilizes the vertebral column, and therefore requires that the excised support material be replaced either by a prosthetic implant or other filler material.

One approach has been to remove the tumorous material, and then fill the space of the resected anterior spine with methylmethacrylate or some other plastic material. (White, *et al.* 1978; Dunn, 1977; and Keggi, *et al.* 1976.) This approach has been less than successful, since it is difficult to achieve proper bonding with the bony material of the vertebrae. In addition, such materials often involve an exothermic chemical reaction for the polymerization of the plastic material, which can release a significant amount of heat into the adjacent tissue. In addition, these plastic materials do not exhibit sufficient mechanical strength and stability, even when they are reinforced with metal pins or struts.

Another approach which has been utilized is to use a hollow cylindrical mesh cage (McAfee, 1979; and Ray, 1999) which is filled with bone chips or marrow. The bone material may be both excised from the patient's own fibula or pelvis, or, alternately, allograft material, which typically has been harvested from a deceased donor. In the case of a metastatic tumor, bone cement may be used instead of bone chips or marrow. A spreader is used to separate the vertebrae between which the cylindrical mesh cage is to be inserted. With the distance between the vertebrae maintained by the spreader, the cylindrical mesh cage is inserted into place, with the ends of the cylindrical mesh cage (which may include teeth) bearing on the opposing endplates of the vertebrae. The spreader is then released, so that normal compressive forces of the spine acting on the anterior column may anchor the

cylindrical mesh cage in place. Bone cement may also be applied at the ends of the cylindrical mesh cage to facilitate the ends of the cylindrical mesh cage being maintained in place. Immediate stabilization of the spine following this procedure does not occur, since it generally takes between three and six months for bony fusion to take place. In addition, if the patient is to be treated by radiation and/or chemotherapy following the surgery, in many cases the radiation and/or chemotherapy will have an adverse affect on the bone graft, preventing it from surviving and fusing the two vertebrae together. In this case, additional surgery will generally be required to establish a satisfactory degree of spinal stability.

Another technique used to stabilize the spine following the removal of the anterior column of a vertebra is the use of a plurality of metal rods (Kaneda, *et al.* 1977; Kostuik, *et al.* 1988; and Onimus, *et al.* 1986.) which are attached by bolts or screws to the two vertebrae on either side of the removed vertebrae. This technique presents a variety of problems, particularly due to the presence of large localized forces in the areas in which the rods are attached to the vertebrae by the bolts or screws. In addition, some areas of the spine are difficult or impossible to stabilize with this technique due to the presence of sensitive tissue located adjacent to the areas in which the stabilizing rods would be used.

It is accordingly the primary objective of the present invention that it provides an improved vertebral body prosthesis which may be used following the removal of the anterior column of a vertebra to reestablish spinal stability and maintain proper spacing between the vertebrae located immediately above and below the removed vertebra. It is an objective of the vertebral body prosthesis of the present invention that it be of a design and physical configuration which may be easily installed in place intermediate the endplates of the two adjacent vertebrae via an anterior surgical approach. It is a related objective of the vertebral body prosthesis of the present invention that the implant procedure not require the use of complex tools to install and position the vertebral body prosthesis intermediate the two vertebrae.

It is a further objective of the vertebral body prosthesis of the present invention that it be implantable in a surgical procedure reducing both the trauma to the patient and the time for the surgeon to implant the device. It is also an objective of the vertebral body prosthesis of the present invention that, when installed, it will securely and present invention that, when installed, it will securely and permanently maintain the integrity and security of the spinal column. It is yet another objective of the vertebral body prosthesis of the present invention that it promotes prompt and permanent ingrowth of bone material intermediate

the vertebrae located immediately above and below the removed vertebra to facilitate permanent fusion of the spinal segment. Still further objectives of the vertebral body prosthesis of the present invention are that it be made of biocompatible material compatible with long term implant in the human body, and that it be either adjustable in length or available in different sizes and configurations to fit a wide variety of patients and different locations in the spine.

The vertebral body prosthesis of the present invention must be of a construction which is both durable and long lasting, and it must require no maintenance once it is implanted. In order to enhance the market appeal of the vertebral body prosthesis of the present invention, it should also be of a simple mechanical design and relatively inexpensive construction to thereby afford it the broadest possible market. Finally, it is also an objective that all of the aforesaid advantages and objectives of the vertebral body prosthesis of the present invention be achieved without incurring any substantial relative disadvantage.

The Invention: Dynamic vertebral prosthesis[1]

The dynamic vertebral prosthesis of variable height includes the vertebral support column and upper and lower mounting brackets. The vertebral support column is hollow to allow bone chips or marrow to be placed therein to facilitate bony ingrowth to fuse the two vertebral.

The vertebral support column has a plurality of blood holes located in the sides thereof to provide paths for fluid communication between the interior and the exterior of the vertebrae support column. The upper and lower mounting brackets each consist of a base member mounted atop a cylindrical support, with a curved mounting plate being mounted on one side of the base members of each of the upper and lower mounting brackets.

The upper and lower ends of the vertebrae support column are threaded on the outside thereof, one and being threaded with regular thread (right hand thread) and the other end being threaded with reverse thread (left hand thread). The upper and lower mounting brackets each have a threaded aperture extending through the base member and the cylindrical support. The thread in the aperture located in one of the mounting brackets is regular thread, and the thread in the aperture located in the other of the mounting brackets is reverse thread.

The mounting bracket having the regular threaded aperture is mounted onto the end of the vertebrae support column having regular thread thereon, and the mounting bracket having the

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[1] United States Patient, year 1998.

reverse threaded aperture is mounted onto the end of the vertebrae support column having reverse thread thereon. The variable height vertebral body prosthesis is then installed with the base members of the upper and lower mounting blocks being located on the respective endplates of upper and lower vertebrae between which a vertebra has been removed. The mounting plates of the upper and lower mounting blocks may then be attached to the sides of the two vertebrae using screws extending through apertures located in the curved mounting plates.

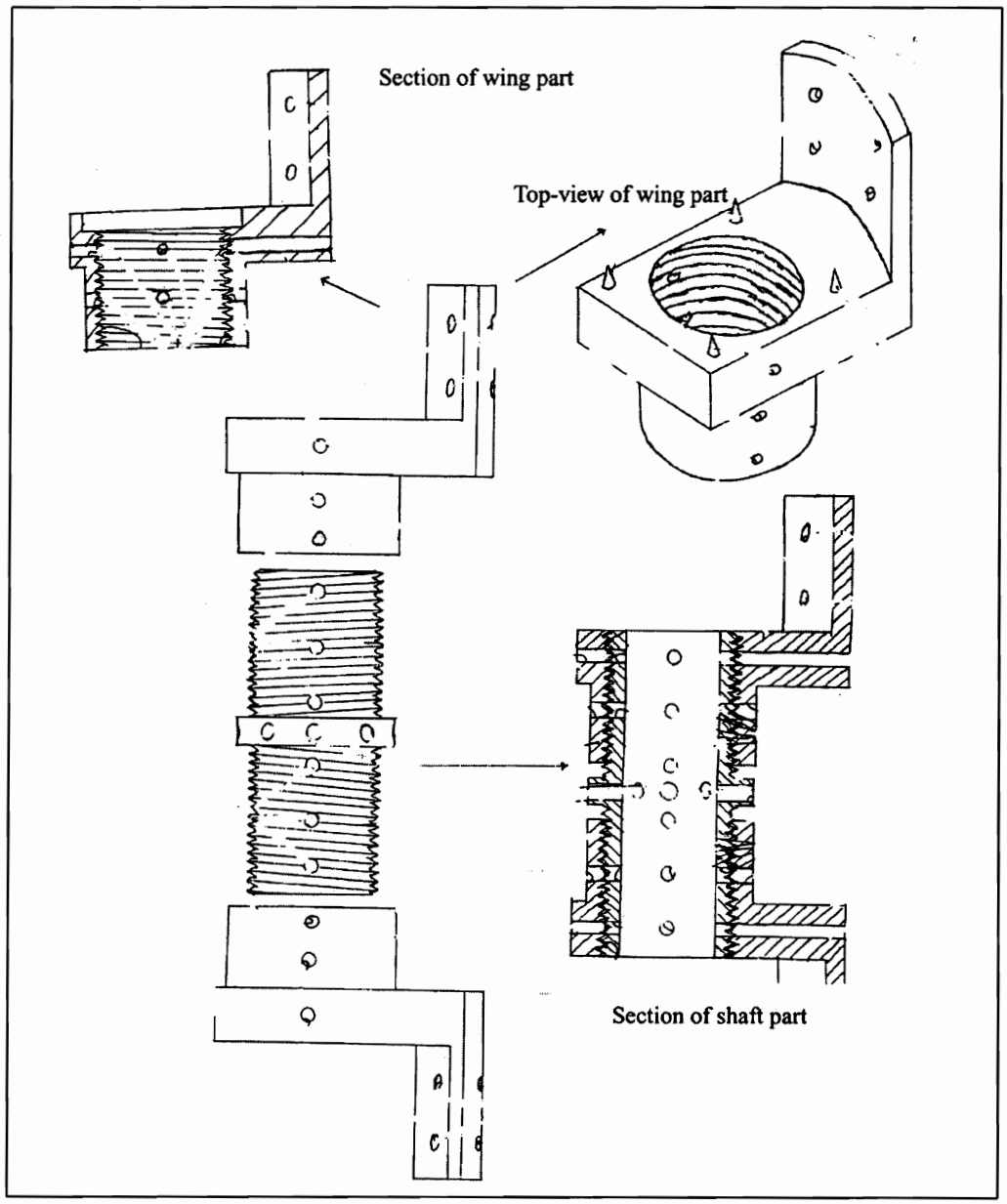

Diagram I. Showing details of Dynamic Vertebral prosthesis

Wedges may also be used between the base members of the upper and lower mounting brackets and the vertebrae to better fit the mounting bracket to the surface of the endplate of the vertebrae. These wedges may be either fixed in position relative to the mounting brackets, or they may be moveable with respect thereto *(Diagram II)*.

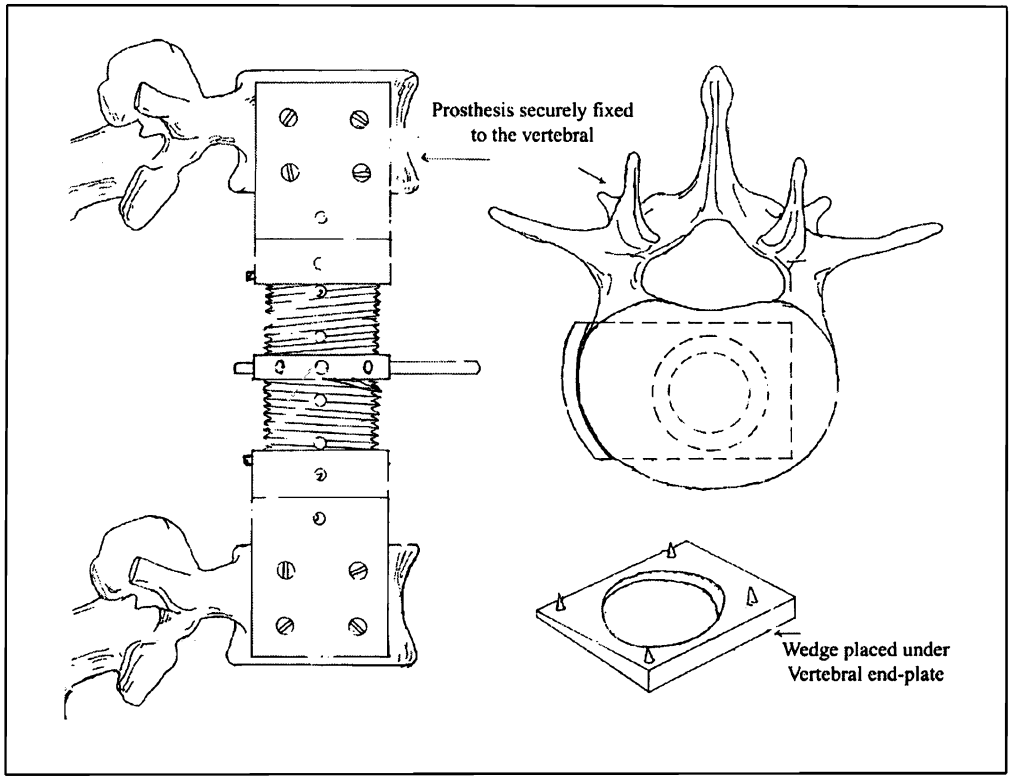

Diagram II. Showing excised vertebra replaced by prosthesis

It may therefore be seen that the present invention teaches an improved vertebral body prosthesis which may be used following the removal of the anterior column of a vertebra to reestablish spinal stability and maintain proper spacing between the vertebrae located immediately above and below the removed vertebra. The vertebral body prosthesis of the present invention is of a design and physical configuration which may be easily installed in place intermediate the endplates of the two adjacent vertebrae via anterior surgical approach. The implant procedure for the vertebral body prosthesis of the present invention also does not require the use of complex tools to install and position the vertebral body prosthesis intermediate the two vertebrae.

The vertebral body prosthesis of the present invention is implantable in a surgical procedure featuring both reduced implant trauma to the patient and reduced time required for the surgeon to implant the device. When the vertebral body prosthesis of the present invention is installed in place intermediate the vertebrae located immediately above and below the removed vertebra, it will securely and permanently maintain the integrity and security of the spinal column. The vertebral body prosthesis of the present invention promotes prompt and permanent ingrowth of bone material intermediate the vertebrae located immediately above and below the removed vertebra to facilitate permanent fusion of the spinal segment. The vertebral body prosthesis of the present invention is made of biocompatible material compatible with long term implant in the human body, and it may be either adjustable in length or made in different sizes and configurations to fit a variety of patients and different locations in the spine.

The vertebral body prosthesis of the present invention is of a construction which is both durable and long lasting, and it requires no maintenance once it is implanted. The vertebral body prosthesis of the present invention is also of a simple mechanical design and relatively inexpensive construction to enhance its market appeal and thereby afford it the broadest possible market. Finally, all of the aforesaid advantages and objectives of the vertebral body prosthesis of the present invention are achieved without incurring any substantial relative disadvantage.

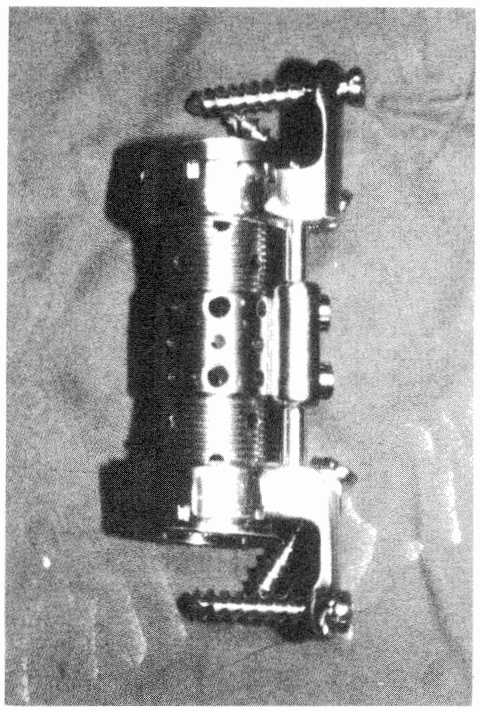

Figure 1 Picture of actual dynamic vertebral Prosthesis

The biomechanical study: Comparison between the dynamic vertebral prosthesis construct and normal vertebral spine

Materials and methods:

Specimen preparation

Sixteen fresh frozen mature porcine cervical spines were obtained for this study. The region spanning from C2 through C6 for each spine was isolated and stored at –60°C before testing. The specimens were thawed at room temperature and dissected all non ligamentous soft tissue, leaving the osseous and ligamentous structures intact. The C_2-C_6 vertebral specimen was fixed in plastic resin at its superior and inferior ends in vertical direction. Four gigs were used to fix the specimen for stabilization to the chamber prior to testing.

The intact porcine spine was used as control. After the intact spines had been tested, the dynamic vertebral prosthesis was implanted in these specimens by performing two level corpectomy, adjacent disc removal and four screws were securely fixed to the upper and lower vertebrae creating a rigid construct.

During testing, care was taken to keep the specimens moist by using physiologic saline.

Biomechanical testing[2]

The specimens were tested employing an universal testing machine (UTS, Instron)[3]. The intact normal spine was first tested nondestructively. Then the construct specimen was immediately tested to observe the differences from the control as the same load and direction of forces were used. The compressive axial, torsion, flexion and extension loadings were performed in this study.

During the specimens were tested, the load and deformation curves were recorded automatically by the UTS.

For the axial compression, loading was applied at a constant speed of 0.05 mm/sec.

For the torque test, the extremes of the specimens were held by a torsion jig and torsional loads were applied through a pulley with a maximal load of 250 N. The strain rate was kept at 0.05 mm/sec.

The flexion and extension test consisted of 250 N. compressive load at a constant speed of 0.05 mm/sec.

[2-3]The Metalliurgy and Materials Sciences Research Institute, Chulalongkorn University

Statistical Analysis

Data from the biomechanical testing of the anterior construct and normal spine were analyzed statistically by pair student's T test and $p < 0.05$ was accepted as statistically significant.

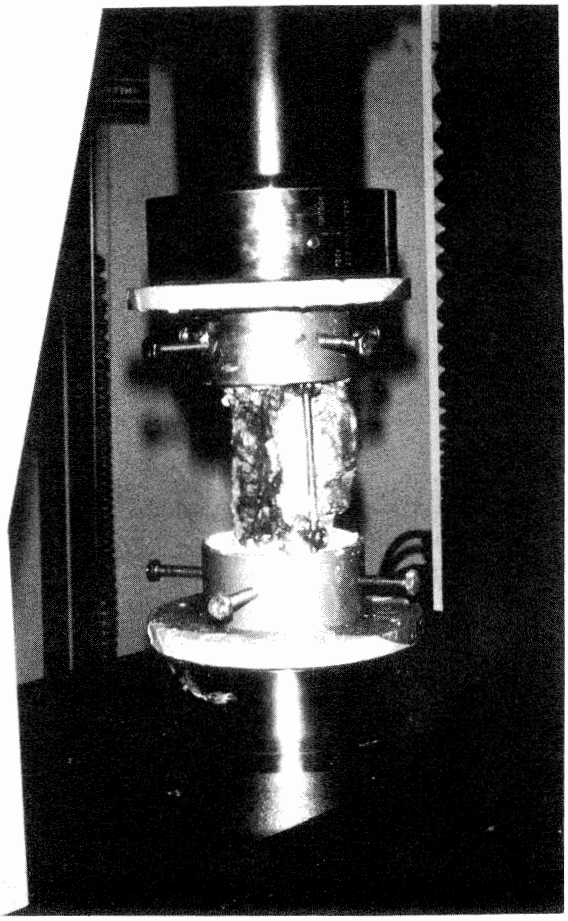

Figure 2 The construct under compressive load in Instron machine

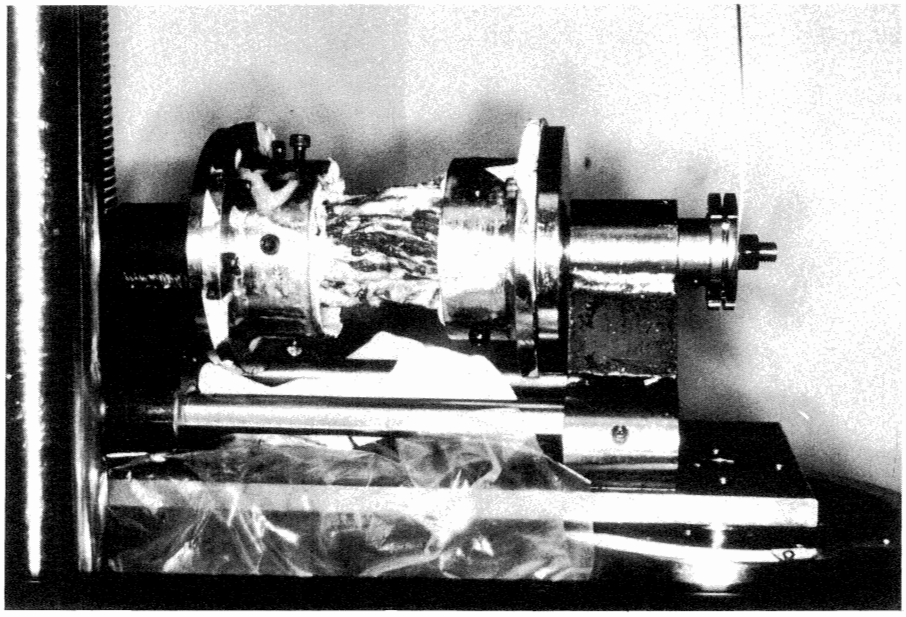

Figure 3 The construct under torsional load in Instron machine

Results

The rigidity of the specimen is defined as the amount of force reguired to produce change in deformation. In this study, the formulas of rigidities had a linear relation ship with the slopes which calculated from the load deformation curves.

Axial compression load test (N-m)

Specimens	Normal	New construct
1	282.75	362.98
2	264.66	380.14
3	308.00	416.14
4	289.92	387.02
Average	286.33	386.57
SD.	17.933974	22.154161

Compressive flexion test (N-m)

Specimens	Normal	New construct
1	52.82	90.54
2	60.12	121.10
3	66.54	95.15
4	66.36	128.46
Average	61.46	108.81
SD.	6.487464	18.775472

Compressive extension test (N-m)

Specimens	Normal	New construct
1	49.29	85.01
2	52.82	96.88
3	60.12	101.69
4	66.54	155.73
Average	57.19	109.82
SD.	7.692296	31.394291

Compressive torsional test (N-m/degree)

Specimens	Normal	New construct
1	18.14	18.93
2	29.54	24.69
3	33.58	27.77
4	19.50	21.29
Average	25.19	23.17
SD.	7.558509	3.872225

The axial compression test

Compared with the control, the construct specimen produced a statistically significant increase of the rigidity up to 35% of intact spine ($p<0.05$)

The torsion test

With the torsional load, the normal spine had more rigidity than the construct but this difference was not statistically significant ($p>0.05$). This implied that the construct had the rigidity similar to the normal spine.

The flexion test

The construct had more rigidity than normal spine with an increase of up to 77% of the intact. This was statistically significant ($p<0.05$).

The extension test

The construct significantly increase the rigidity up to 92% of the intact normal spine ($p<0.05$).

Discussion and Conclusion

It may be therefore be appreciated from the above detailed description of the embodiment of the present invention that it teaches an improved vertebral body prosthesis which may be used following the removal of the anterior column of a vertebra to reestablish spinal stability and maintain proper spacing between the vertebrae located immediately above and below the removed vertebra. The vertebral body prosthesis is of a design and physical configuration which may be easily installed in place intermediate the endplates of the two adjacent vertebrae. The implant procedure for the vertebral body prosthesis does not require the use of complex tools to install and position the prosthesis intermediate the two vertebrae. Once it is installed it will securely and permanently maintain the integrity and security of the spinal column. The prosthesis is made of biocompatible material (titanium alloys),[4] compatible with long term implant in the human body, and it may be either adjustable in length or made in different sizes and configuration to fit a wide variety of patients and different locations in the spine.

As already mentioned, the construct was rigidly fixed to the adjacent vertebrae. Under intensive in vitro loading tests which included compressive, flexion, extension and torsional loads, the constructed vertebrae with this prosthesis still maintained its configuration. Comparing to the normal spine specimens under these various physiological loads, the newly construct had shown to have comparable stiffness. No breakage or loosening of any part of the construct was observed.

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[4]Micron Precision eng. INC. CA 91311, USA.

Data from the biomechanical testings were accepted as statistically significant.

Further clinical studies need to be performed to demonstrate whether this new vertebral prosthesis would work safely in the patients comparable as it had shown in vitro test. Many clinical cases are indicated for uses of this invention, such as a vertebral tumor or metastasis, vertebral tuberculosis, vertebral fracture and spinal kypnotic deformity. Until then this new dynamic vertebral prosthesis would be universally acceptable as a new alternative for the surgical treatment of the ailing spines.

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