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A Novel Design of an Expandable Cage used in Posterior Interbody Fusion for Lumbar Spine Surgery

Jing-Jing Fang[1], Yu-Ching Hsiao[2] and Ruey-Mo Lin[3]

1National Cheng Kung University, Taiwan, fangjj@mail.ncku.edu.tw
2National Cheng Kung University, Taiwan, louis@vr.me.ncku.edu.tw
3 Tainan Municipal An-Na Hospital, D71081@mail.tmanh.org.tw

Correspoding author: Jing-Jing Fang, fangjj@mail.ncku.edu.tw

Abstract. Spinal fusion surgery is applied to permanent joining two or more vertebrae to solve uncontrollable human low back pain when physical therapy is helpless. An interbody fusion cage is a prosthesis used in spine fusion procedures to maintain foraminal height and decompression. We have designed and constructed the prototype expandable cage to be used in posterior lumbar interbody fusion (PLIF) surgery. Protocol of implanting the expandable cage was investigated via in Vitro simulation to examine its feasibility and stability. Repeating stress analysis was applied to the mechanisms and then layouts correction before metal manufacture. According to the analysis, the maximum stress of the cage is less than the yielding stress of the material, briefly conclude that our design is stress allowance.

Keywords: expandable cage, spinal fusion surgery, in Vitro, stress analysis.
DOI: https://doi.org/10.14733/cadaps.2019.679-687

1 INTRODUCTION

Spinal fusion surgery isn't necessary for every patient with lower back pain. However, when such pain is unbearable and physical therapy is no longer helpful, spinal fusion surgery [9] was proven as a feasible option for treatment. Compare to normal spine (Figure 1(a)), degeneration of lumbar vertebrae, such as intervertebral disc herniation (Figure 1(b)), is a common disease in a modern aging society. To treat this, cage implantation in spinal fusion surgery (Figure 1(c)) is often utilized to replace human vertebral discs, which has been clinically proven as a safe and effective treatment option. In particular, for patients with vertebrae tumors or severe fractures, vertebrae body removal and replacement is necessary. Interbody fusion can permanently join two or more vertebrae so that there is no movement between them. An interbody fusion cage (spine cage) [12] is a prosthesis used in spine fusion procedures to replace vertebrae body and to maintain foraminal height and decompression. Due to anatomical and safety issues, cervical and lumbar fusions are usually performed by making an incision through the anterior and lateral/posterior regions, respectively. There are two types of technology available in cage design: statics or expansion devices. Heights of the static cage were given when they produced; therefore, it is necessary to prepare cages of many different sizes during the operation.

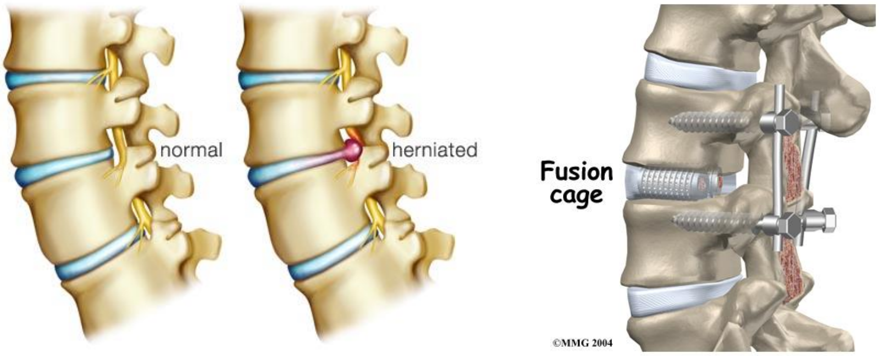

Figure 1: (a) Normal vertebral disc [10], (b) Herniated disc [10], (c) Fusion surgery and cage implantation [6].

Cutting-edge technology provides adjustable and restorable cages which can continuously expand and sustain neighboring vertebrae to an appropriate height during the placement process. There are two kinds of expandable cage for vertebrae body replacement and vertebral disc. Expandable cages are available in several mechanisms on the orthopedics market [1,11]. However, due to workspace limitations during surgery, commercial expandable cages for cervical body replacement are only available for anterior cervical discectomy and fusion (ACDF). The reasons for approaching from anterior but posterior is to avoid nerves and veins from distributing to the posterior region of the vertebrae, and also accommodate the limited space provided by the small size of the cage after removing the facet joints. But anterior approach need to pass through the organs in abdomen and the trajectory is long. Another technology called TLIF (transforaminal lumbar interbody fusion), involves placing only one bone graft spacer in the middle of the interbody space, without retraction of the spinal nerves. The wound of the transforaminal approach is bigger than the others. As with all spinal fusion surgery, a posterior lumbar interbody fusion (PLIF)[5] involves adding bone graft to an area of the spine to set up a biological response that causes the bone to grow between the two vertebral elements and thereby stop the motion of that segment. The wound is small and common use now but nerves retraction is needed during the cage insertion.

In this study, we found that the expandable cage design for PLIF is still far from ideal, US patent 5665122[4] because unbalanced skew can easily occur during the process of height expansion. Small regions of the contact area between the vertebrae body and autologous bone as well as limited volume containing autologous bone with osteoinductive growth materials would reduce the effectiveness of bone fusion. Besselink [2] invented an assembled cage for anterior insertion operation that contains two expandable components and a reinforcing strip. These two components generate an intervertebral hollow in between the vertebrae. The reinforcing strip rolls up substantially planar inside the hollow to occupy the central region of the cage that improves the body’s stability in longitudinal direction. This is technically demanding and challenging for surgeons. Jackson [3] later proposed an expandable cage for posterior insertion by using three selective components of different sizes during operation. These components contain different radiuses of circular discs at anterior and external thread at posterior to match the internal thread of the cage. Surgeons may choose different expansion components or partially insert them into the cage to adjust the height during the expansion process. It need to prepare three components and trial the right one to expand.

In this study, we designed and constructed a prototype of an expandable cage along with tools needed to be used in a PLIF surgery. Due to workspace limitations imposed by the posterior approach, the width and height limitations of the cage before expanding is one of the crucial issues that needs to be addressed. Nevertheless, the ease of handling the cage and operational tools during the implant procedure is also taken into consideration.

We visited and discussed with several orthopedics' surgeons to collect clinical data for this study. We also observed surgeons performing a PLIF surgery at the operating room in the National Cheng Kung University (NCKU) hospital. Several discussions were carried out with the surgeons to meet unmet needs for an ideal PLIF cage. From this, we then concluded that four requirements are necessary for the design of an optimal PLIF cage. First, the cage should be applicable for a PLIF surgery, and the height of the cage should also be expandable after being placed in a proper position between two vertebrae. Additionally, the PLIF cage can be easily fixed with expandable and restorable height. Lastly, it provides sufficient workspace for filling in autologous bones with the posterior approach.

We developed a surgical simulation software to animate the process of lumbar cage implantation with C++ and Open Graphics Library, which examines the feasibility and stability of the proposed cage mechanism and its associated tools. Stress analysis was applied to the expandable cage model to examine permissible stress on a human body. We then fabricated a template of the proposed cage and its tools by using a 3D printer. The fabricated prototypes were conducted using an artificial lumbar model in in Vitro testing.

2 MATERIALS AND METHODS

First of all, we collected and measured the artificial sawbones [7] and used the average human lumbar size [8] as a reference to evaluate possible dimensions for cage apparatus. The average depth and width of endplate are 35 mm and 41 mm, respectively. The maximum height of interbody disc is 14mm. Size of the cage body and its associated tools for cage installation include screws, expanding devices, push in tools, and screw drivers were setup accordingly.

We investigated the shape of human disks and compared the disk height in both anterior and posterior regions, results of which show that the former was slightly larger. This resembles a trapezoid-like shape, which provides support for a human's posture when standing upright. Hence, the shape of the designed cage is trapezoid-like in both lateral and axial views. According to previous lumbar average measurements, we first set up the total length, anterior and posterior widths, as well as anterior expanded height of the cage. The design of the novel expandable cage is shown in Figure 2, which consists of five components, namely, upper cage (A), transmission screw (B), transmission helical gear (C), lower cage (D), and inner driver (E). An internal thread was embedded in the proximal of the upper cage (A'). An internal thread (A') and the screw on transmission screw (B) would be self-locking after the adjustment.

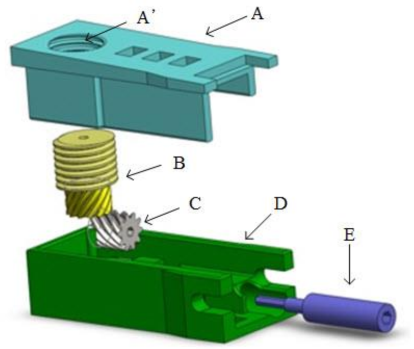

Figure 2: Cage in exploded view.

Expandable mechanisms are usually threaded cylindrical or square-shaped devices. Upper cage and lower cage are the part that withstands vertebrae end-plate-to-end-plate directly. Between them, there are several holes which allow autologous bone insertion and future vertebrae fusion. Expandable mechanisms are at the forefront of technology in the field of cage expansion, with cages that expand in place for optimal end-plate-to-end-plate fit and correction of lordosis. Transmission screws and transmission helical gears are power transmission components to undertake power from the auxiliary tools. Transmission screws are composed of two parts: screw and helical gear. The screw on transmission screw has an external thread that matches the internal thread on the upper cage; while the helical gear on transmission screw and transmission helical gear operates on nonparallel and nonintersecting shafts, called crossed helical gear. Table 1 shows the design parameters of the helical gear. For the helical gear design, we set the number of teeth for the module to 0.25 and 10, respectively. Module is a pitch diameter in millimeters divided by the number of teeth; whereas pitch point is the cutting point between the two pitch circles. The line of action indicates the line connecting the pitch point and contact point. Pressure angle is the included angle between the line of action and the tangent line of the pitch circle. Face width represents the width of tooth, which is the thickness of helical gear. Inner driver is used to transmit power from the outer driver to the transmission helical gear.

Operation mechanism of the expandable cage is rotated in the transmission screw to drive the internal thread to push up the upper cage in order to achieve anterior expansion. A detailed construction of the power transmission is shown in Figure 3. To increase the height of the cage, we rotated the outer driver to transmit power to the inner driver and the transmission helical gear. Then the crossed helical gear transforms the rotation from X-axis to Y-axis. Finally, the helical gear transmits power to the transmission screw for raising the upper cage.

Parameter	Value
Module	0.25
The number of teeth	10
Pressure angle	20 degree
Face width	3mm
Helix direction	Right hand
Helix angle	45 degree

Table 1: Components parameters.

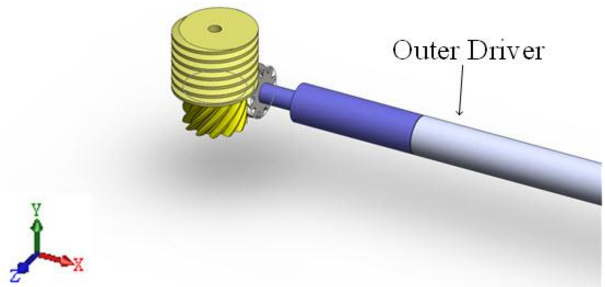

Figure 3: Power transmission.

We set the upper limit of the raising height of the anterior cage to 4mm (Figure 4). After the cage was expanded to a suitable height, surgeons can fill patient’s autologous bone into the inner space of the cage. Then, the upper and lower baffles were placed in posterior regions to close the space, which prevents autologous bone transudation. The upper and lower baffles had zigzags between them provide stably locking at posterior side. A placement tool, as shown in Figure 5, was used to stably push the cage parts into a proper position between the upper and lower vertebrae from the posterior region. An empty channel allows the outer driver to pass to contact the inner driver (Figure 6).

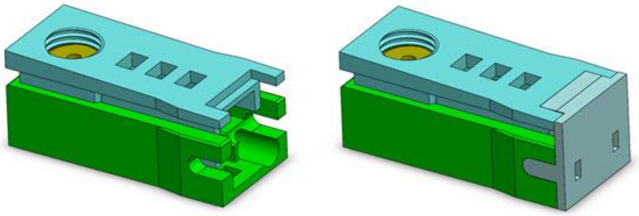

Figure 4: (a) Cage expansion, (b) Baffles placement.

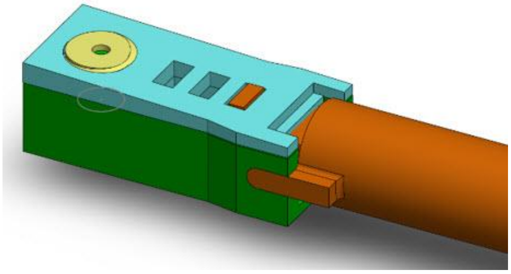

Figure 5: Cage and placement tool.

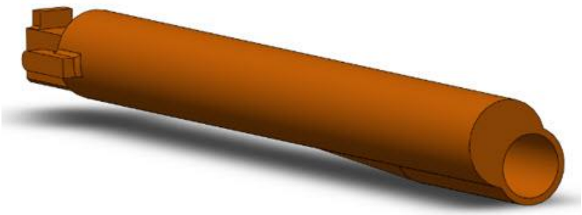

Figure 6: Placement tool.

3 ANIMATION AND IN VITRO REHEARSAL

We developed an animation software using Visual C++ and OpenGL. Figure 7 illustrates the assembly procedure of every part of the proposed cage. Via computer simulation, surgeons can fully understand how to assemble each part of the cage at its associated positions. Furthermore, it allows surgeons to preview the protocol of how the cage is implanted in adjacent vertebrae.

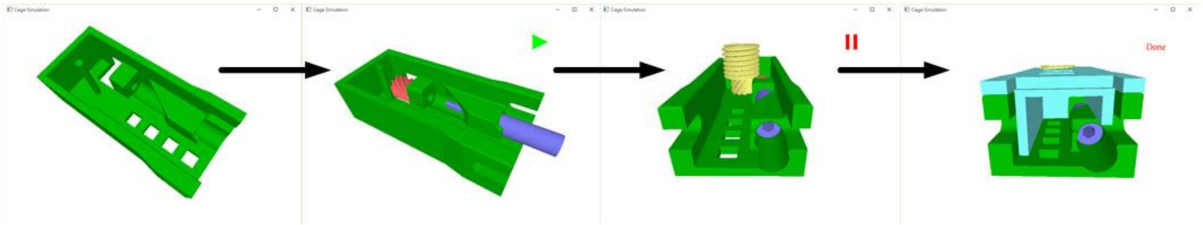

Figure 7: Assembly animation.

Spine model was sent for scanning by computer tomography first. Image model of the spine was then reconstructed by our developed software. In this simulation case, the disk within L2 (lumbar #2) and L3, the inferior articular process, part of the spinal process and transverse process of L2, and the superior articular process of L3 were removed before cage implant following the PLIF procedure. Status of the outer driver rotation and the associated height of cage expansion are shown at the upper left corner in Figure 8. That depicts a) entering position, b) proper position, and c) height expansion of the left cage with placement tools, respectively. Cage and placement tools were then fabricated using a high-density 3D printer for prototype construction, as shown in Figure 9. The material of the prototype is resins. Figure 10 shows a step-by-step in Vitro process and expandable cage in place. Finally, the baffles were placed after the autologous bone was filled up.

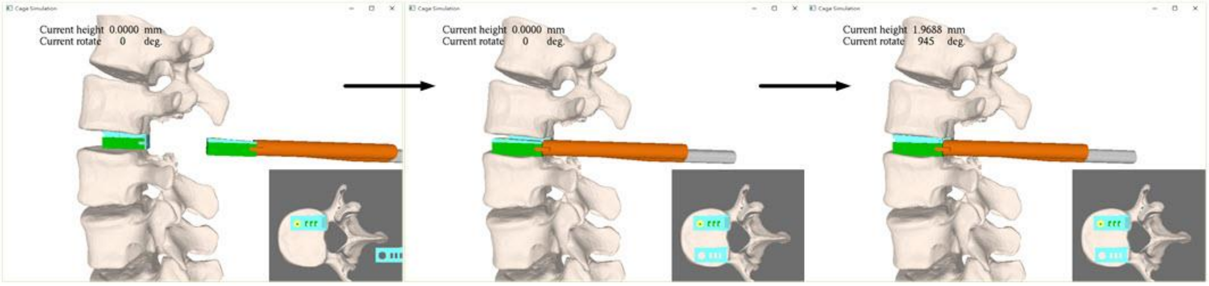

Figure 8: Implant simulation.

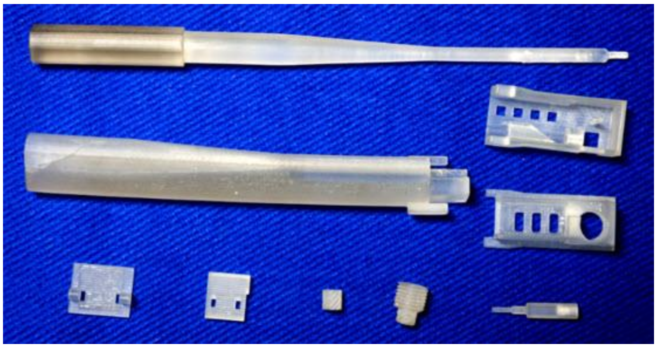

Figure 9: List of prototype parts and tools.

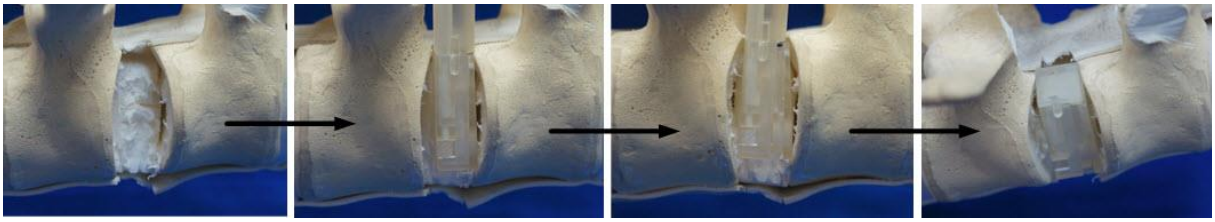

Figure 10: *in Vitro* process

4 STRESS ANALYSIS

The expandable cages were designed for lumbar vertebrae to be implanted side by side between the upper and lower endplates within two vertebral elements. Suppose the weight of an adult male is 80kg, lumbar is about locate in the middle of human body. A pair of cage is placed side by side between upper and lower endplates of two vertebras, therefore, we applied 20kg as a load for analysis. A simple statistic stress analysis was simulated by SolidWorks, Dassault Systèmes Ltd. Ti-6Al-4V was used as the cage material, and its material properties from SolidWorks database are shown in Table 2. In general, Ti-6Al-4V is usually used for implants which consist features of low density and excellent corrosion resistance. A yield strength is the value of stress at which the material significantly begins to deform plastically. It approximates the elastic limit, which is the highest stress the material can deform elastically and still return to its original shape prior to being loaded. Therefore, yield strength was used in the component design as a criterion of structure failure. Ultimate tensile strength is the maximum stress that material can withstand before failure. Modulus of elasticity, also known as Young's modulus, is a constant ratio between stress and strain when Hooke's law is applied.

Property	Value
Yield strength	$8.273*10^{8}$ N/m^2
Ultimate tensile strength	$1.050*10^{9}$ N/m^2
Modulus of elasticity	$1.048*10^{11}$ N/m^2

Table 2: Ti-6Al-4V Material properties.

In this study, we applied a 20-kg normal force to the upper cage and the top of the upper and the lower baffles, as shown in Figure 11(a). On the other hand, the lower cage and the bottom of the lower baffle are fixed, as shown in Figure 11(b). Outcome of the stress analysis shows that the maximum stress was located at the top of the transmission screw, as illustrated in Figure 12. The von Mises stress 5.57*108 N/m^2 is lower than the yield strength. Therefore, yield would not occur on such design. The von Mises yield criterion is one of the yield detection methods of material. The von Mises yield criterion can be expressed by von Mises stress. When von Mises stress is close to the criterion of yield strength, materials begin to yield. Chamfer (Figure 13(a)) was applied to the top of the transmission screw to avoid stress concentration. The value of maximum stress became 4.09*108 N/m^2, which occurred at the bottom of the helical gear after the top of the transmission screw was chamfered (Figure 13(b)). Rods and screws were used in lumbar fusion surgery to fix the upper and lower vertebrae after the cage was in place. We ignored load of rods in this stress evaluation, from which we found that the design of the expandable cage is stress allowance.

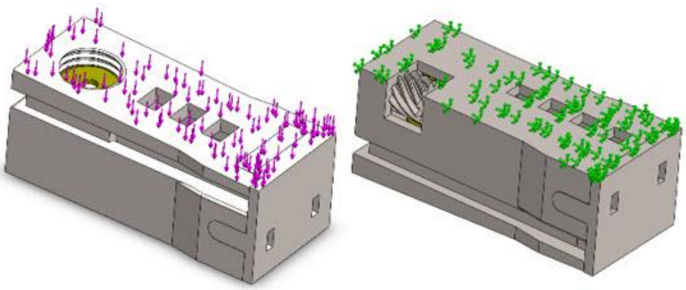

Figure 11: Loads: (a) Normal force, (b) Fixed.

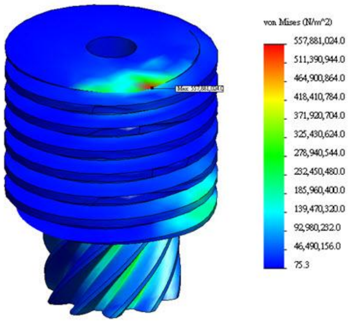

Figure 12: Outcomes of stress analysis.

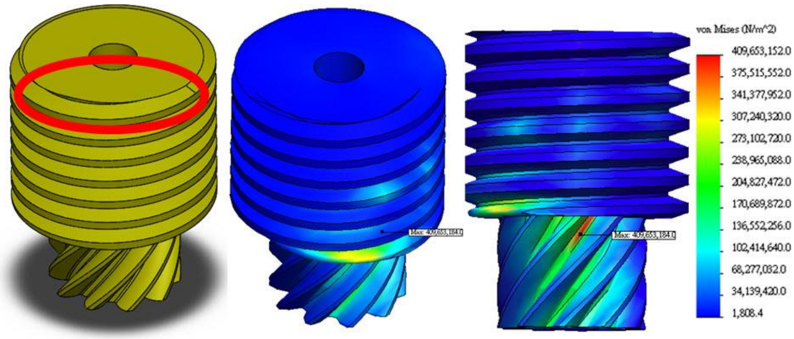

Figure 13: (a) Chamfer, (b) maximum stress after chamfer.

5 DISCUSSIONS AND CONCLUSIONS

The designed expandable cage is suitable for most patients and can be easily expanded with placement tools. Its trapezoid-like shape also corresponds with the curve of a human spine. Upper and lower baffles at the posterior of the cage can prevent the autologous bone from transudation and provide posterior strength support. The upper plate and the lower plate of the cage are the parts that directly and closely come in contact with the vertebral endplate. When such contact area takes up a large region, it helps in providing easy fusion in recovery. In addition, the more the internal volume of the cage, the more the autologous bone can be accommodated inside the cage.

Operation mechanism including a transmission screw and an internal thread in the upper cage were applied to perform anterior expansion to avoid potential risks of skewing during the process of height expansion and provide anterior strength support. The outer driver is the key member for power transmission from the operator to the cage. The height of the cage can be simply increased to a desired value according to simulation results by rotating the outer driver. In contrast to previous design [3], the proposed cage is simple for surgeons in that they can hold the placement tools to insert the cage into a proper position and rotate the outer driver to raise it.

In this research, we developed a prototype of a novel expandable cage to be used in posterior lumbar fusion surgery. Our novelty of the expandable cage is that the composite mechanism of the helical gear pair and the thread is unique which is capable to provide power transmission and self-locking simultaneously. In addition, cage with expandable function and trapezoid-like shape is unique compared to commercial products, which allow more suitable to mimic the curve of human spine. Artificial lumbar spine was used in *in Vitro* experiments to pre-investigate the clinical feasibility of cage implant protocol. Height of the cage can be fixed after expansion and restoration using placement apparatus. Simple stress analysis depicts potential failure parts, which allows us to reevaluate and modify the cage. From the stress analysis, the maximum stress was measured at 4.09*108 N/m2, which was less than the yielding stress $8.273*10^8$ N/m^2 of the material. This briefly concludes that the proposed cage design is stress allowance.

In this preliminary study, we used resins to fabricate prototype of expandable cage for rehearsal the whole procedure of operation. However, due to the size of the cage, the fabricated prototypes are small. For example, the diameter of the outer driver is less than 2mm, and the apparatus were easily broken in in Vitro simulation. The simulation cannot reveal the status of stress distributions, which indicates that failure is unpredictable. We will refabricate the design by Ti-6Al-4V, PEEK (Polyetheretherketone) or stainless materials with additive manufacturing to strengthen the stress of design for further testing. Rods and screws will be added in and in cooperated with the expandable cage for advanced biomechanical analysis to predict the force variation and stress distribution before we produce the metal prototype.

ACKNOWLEDGMENTS

We gratefully acknowledge the financial support from the Ministry of Science and Technology, Taiwan, R.O.C. under the grant number MOST-103-2815-C-006-022-E

Jing-Jing Fang, http://orcid.org/0000-0001-6494-1852
Yu-Ching Hsiao, http://orcid.org/0000-0001-6727-9235
Ruey-Mo Lin, http://orcid.org/0000-0003-4225-5020

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