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Development and Biomechanical Evaluation of a New Type of Cervical Intervertebral Fusion Cage by 3D Printing

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Abstract: **Cervical implants have being widely used in cervical surgery, and when it is produced with 3d printing technique, there are more advantages than that with the traditional way. This article is aiming to introduce a new type of cervical intervertebral fusion cage by 3D printing, regarding to its design concept, making process and how to evaluate it biomechanically. Using nano hydroxyapatite and polylactide as raw material, generate the cervical intervertebral fusion cage with 3D print. The maximum compressive load of nano hydroxyapatite/polylactide (n-HA/PLA) group and the traditional carbon fiber group used a mechanical detector. The compressive load of n-HA/PLA group is slightly lower than the carbon fiber group. But it is not statistical significant (P>0.05). With the good compression resistance performance, the new type of n-HA/PLA cervical intervertebral fusion cage can meet the biomechanics requirements of clinical implant.**

Keywords: 3D printing; Cervical; Intervertebral fusion cage; Biomechanics

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1. Introduction

By the developments of medical science and clinical techniques improves, spine surgerys subject range is expanding increasingly and much more new type of spinal implants have been commonly used in clinic. But instead of the injection molding technology-created spinal implants which have a fixed dimension. New types of spinal implants adopt the CAD and 3D printing technique and can be able to meet the individualized needs of the patients.

Development of absorbable material has created a new field for studies on spinal implant. Theoretically, ideal absorbable material can overcome many material shortcomings of spinal implant, such as large modulus of elasticity; proneness to subsidence; postoperative imaging artifacts, etc. Implanted absorbable material can initially provide sufficient mechanical strength. As the degradation process goes on, the strength decreases gradually, and the load gradually shifts to the vertebrae fusion, promoting fusion of new bone; meanwhile, the imaging after degradation shows no artifacts. For its excellent tissue compatibility and bone growth inducement, Hydroxyapatite (HA) has been widely used clinically. Due to its affinity for bone tissue, after being implanted into bone, hydroxyapatite can induce the undifferentiated mesenchymal cells to be differentiated into bone cells which would be directly attached to surface of hydroxyapatite. However, due to poor biomechanics and big brittleness, the pure hydroxyapatite is difficult to be individually applied to load-bearing parts. Combination of hydroxyapatite with biomedical resin (which is with good adhesion and strong toughness) has advantages as follows: the brittleness of pure hydroxyapatite will be reduced and the mechanical strength increased; good plasticity, etc. Currently, composites of hydroxyapatite with gelatin, PLPG and polylactic acid have been applied clinically. Polylactic acid has good workability, biomechanical strength and biodegradability; thus, to make it compounded with HA for manufacturing bio-medical materials of excellent performance has become the focus of scholars at home and abroad. Meanwhile, the alkaline hydroxyapatite can neutralize the acidic environment generated during degradation process of polylactic acid material, providing the interbody fusion a more suitable environment.

After 20 years of development, 3D printing (also known as rapid prototyping technology) has developed a variety of molding technology, including: Stereolithography (SL), laminated object manufacturing (LOM), selective laser sintering (SLS), fused deposition molding (FDM), shape deposition manufacturing (SDM) and the like. Currently, Zhang Fan et al have reported to use 3D printing technology in development of cervical interbody fusion cage. Also, referring to traditional manufacturing process, Ma Jinliang has reported to use the partially absorbable material to produce the cervical interbody fusion cage. Debusscher has applied the cervical interbody fusion cage (developed by using the hybrid of β-tricalcium phosphate with PLLA) to 20 patients, and got satisfactory efficacy, and the fusion rate was as high as 96%. The author believes that the main causes for implant prolapse and osteolysis were deviations and unqualified strength of cage design. The development method for cervical interbody fusion cage (i.e. to combine 3D printing technologies with composite materials of hydroxyapatite with polylactic acid) in this experiment has not yet been reported, so this method is innovative.

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Taking hydroxyapatite (with good osteoinductive effect) and polylactic acid (with good biocompatibility and adjustable degradation) as raw materials, this study aims at developing the composites (with excellent mechanical strength and biodegradability) which would be took as molding material for 3D printing. Exterior design of the new-type interbody fusion cage is similar to the control group's carbon-fiber interbody fusion cage. The new-type cage can be developed by using the FDM technology of 3D printing technology. Assumes that mechanical strength of new-type cervical interbody fusion cage meets requirements of clinical applications, the contrast verification should be done by using the mechanical detector for the purpose of testing.

2. Experimental procedure

2.1. Sample preparation

2.1.1. Experimental material

Pure HA (Provided by Nanjing Emperor Nanometer material co., LTD) is white powder, and the specific parameters is: average diameter ≤40nm; Element content: $Ca_{10}(PO_4)_6(OH)_2$ ≥99.5%; heavy metal ≤8ppm; arsenic≤1ppm; weight loss on drying 0.59%; weight Loss on ignition 2.59%; whiteness 96; PH 7.4; Hydrochloric acid insoluble 0.02%. PLA (provided by Shenzhen Esun New Material Co., Ltd) is Semi-transparent spherical particles, the specific parameters: average diameter 3mm; chemical formula (C3H4O2)n; purity >95%; density: 1.2 kg/L; melting point 180 ℃.

2.1.2. Instrument and equipment

The equipment of Mixing experiment is internal mixer, the model number is X(S)M-1.7L (Provided by Qingdao University of Science and Technology), Main Technical specifications: capacity:1.7L; rotor speed: 0~250rpm; main motor: model Z4-180-21, nominal voltage 400V, rated power 40.5KW, rated speed 1350 rpm, rated current 114A; the ram piston pressure: 0.1-1MPa.

The equipment of 3D printing experiment is FDM 3D printer (provided by Beijing University of Chemical Technology) Main Technical specifications: printing speed: 1~10mm/s; Print Temperatur: 0-250℃; sprayer diameter: 0.2mm.

Pulverizer, provided by Qingdao University of Science and Technology; spinning machine, provided by Beijing University of Chemical Technology; Mechanical detector, provided by Qingdao University of Science and Technology.

2.2. Experimental program

HA/PLA composite material with good mixing effect was provided by internal mixer; HA/PLA spinning required for 3D printing was prepared by using grinder and spinning machine; then the STL files after three-dimensional design were applied to FDM 3D printers for preparation of new-type cage, so as to study that whether there were differences in mechanical properties between new-type cage and current clinical interbody fusion cage. At same compression rate, the compression load tests were implemented, so as to analyze that whether the mechanical properties of new-type interbody fusion cage can meet the clinical application.

2.3. Experimental process

2.3.1. The design of cage

Appearance design of new-type cage referred to CT imaging data of 10 patients with C5/6 disc herniation and cervical spondylosis. By analyzing disc space height and endplate angle of symptomatic vertebrae, combined with carbon-fiber interbody fusion cage of the control group, the new-type cervical cage has been designed. Its shape is similar to an isosceles trapezoid; with quasi-circular hole in the middle; high forwards and low afterwards; with rounded corners. Specifications: length of 12mm, width of 14.5mm, back-end height of 4.34mm; angle between upper endplate and lower endplate is 7°, the hole inside is 8.37mm at width and 7mm at length. See Figure 1.

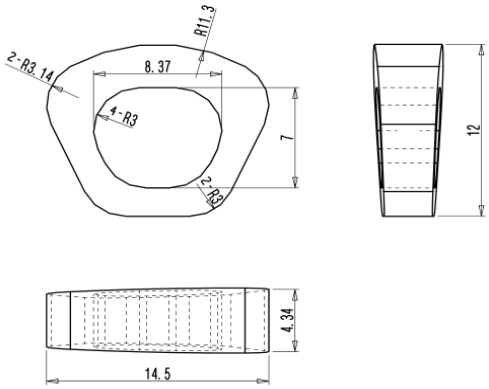

Figure 1. The size of the new type of cage.

2.3.2. The preparation of HA/PLA composite materials

Accurately weighed the PLA and HA, mixed uniformly According to the proportion of 4:1 in the internal mixer, the Main Technical specifications: filling coefficient: 0.6; the ram piston pressure: 0.1-1MPa. Print Temperature: 180℃; rotor speed: 0~250rpm; Mixing time: 30 minute.

2.3.3. The preparation of spinning

The resulting mixture was pulverized into particles by grinder (crushed for several times in order to ensure the grinding quality); then there would be particles of HA/PLA mixture, with a diameter of less than 1.75mm, uniform in size. The resulting particles were placed in a spinning machine for heating and the temperature was set to 180℃ (±5℃). By one single extrusion, the mixture spinning (with a diameter of 1.75mm) applicable to 3D printing was squeezed out.

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2.3.4. The preparation of the new cage

The three-dimensional model after design process was converted into STL files required for 3D printing; then the STL files were imported into FDM 3D printer of this experiment, followed by settings of processing parameters and placement position; taking the prepared HA/PLA mixture spinning as raw material, the new-type cage was done by one-time molding. Molding speed: 1mm/s; nozzle temperature: 180℃ (±5℃); test time: 40min. Four pieces of new-type cervical cage were prepared continuously. See Figure 2.

Figure 2. The new type of cage.

2.2. Mechanical analysis of cage

2.2.1. Compressive test

The test was divided into two groups-the group of new-type cage and the group of carbon-fiber cage, with four pieces of samples for each group. Carbon-fiber group used the carbon-fiber cervical interbody fusion cage (provided by Johnson & Johnson) which is commonly used in clinic at present.

The samples were placed in jig (with a slope of 7°) of the compression testing machine, at the levels of the upper endplate and the testing machine's upper plate; clamp's top and bottom were connected to both ends of compression testing machine; the specimen aimed at the center and was kept horizontal; upon precise fixation of the fixture, the compression load test was started, with uniform loading from scratch, and the moving speed was 1.5mm/min; the load displacement curve should be carefully observed during compression-sudden drop of the load curve means collapse damage of sample, at this point the maximum compression load should be recorded.

Table 1 The limit load of each group.

group	carbon-fiber	new-type
Limit load (N)	2,909.20±45.97	2,855.08±43.18

2.2.2. Statistically analysis

The results were statistically analyzed using the SPSS 18.0 program. Data was analyzed into arithmetic means and standard deviations, and t-tests were used for statistical analyses. Results were considered statistically significant if the P value was less than 0.05.

3. Results

Limit load of carbon-fiber group was (2909.20±45.97)N; limit load of new-type group was (2855.08±43.18)N, 98.14% of that of the carbon-fiber group. When the sample reached limit load, the new-type group collapsed first; places nearby the upper/lower endplates turned white, but the upper/lower endplates showed no fracture. The carbon-fiber group collapsed later, and the upper/lower endplates showed no fracture as well. Comparing two groups of implants, the compressive resistance of new-type group was slightly lower than that of carbon-fiber group; however, the difference was not statistically significant (P>0.05). See table 1 and Figure 3.

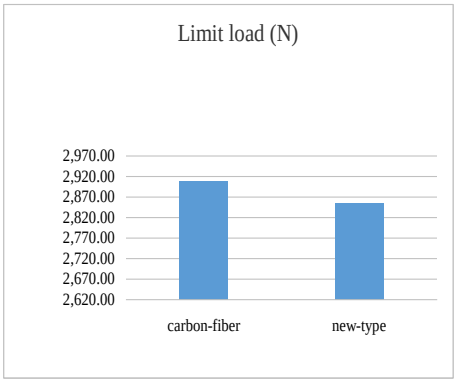

Figure 3. The differents of limit load about 2 group.

4. Discussion

Rapid prototyping technology, which is known as 3D printing technology, has already maturely developed in many aspects in the field of medicine including the fused deposition modeling, laser sintering technology etc., the main structure and working principles are stated as follows. The laser sintering technology is to use high temperature laser sintering the powder material (mainly metal and ceramic powder) and produce the three-dimension object. The operation procedures are: first spread a layer of powder material on the workbench, use laser on a pre-set path to increase the temperature of powder material until it reaches the glass transition temperature but below the fusion temperature, and when the powder start getting bonding to each other, spread another layer and keep on laser sintering until you get the final product. The level of precision of the final product is determined by the laser diameter and the size of the powder particles. This technology is

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widely used in manufacturing high melting point products.

The working principle of fused deposition modeling is to put the polymer on top of the extruder machine, use the spray head to squeeze out the polymer. The spray head is moved on a pathway by pre-set programs on the workbench, once it finishes a layer structure the workbench needed to drop a layer's height and the spray head keeps on working until we get a 3D object. The present study is using this technology and it is mostly used in lower melting point materials such as the resins. Many scholars have reported such a problem before - the application of absorbable material to cervical implant can cause osteolysis and implant prolapse needed to be renovated. The author believes that the main reasons were the lack of mechanical strength and that the cage design failed to meet specific requirements of patient's disc space. In this study, the cage was developed by 3D printing technology; referred completely to particular patient's cervical-spine imaging data, the cervical cage design could meet with patient's intervertebral height, and angle and shape of the upper/lower endplates, which could be perfectly implanted into patient's cervical intervertebral space.

With excellent biocompatibility and biological activity of bone conduction, Hydroxyapatite is very suitable as the raw material for orthopedic implants; however, being brittle, it cannot be used individually for manufacturing implants for load-bearing parts. HA/PLA composites have same tissue compatibility and biological activity of ordinary HA. What's more, the addition of PLA improves the toughness and mechanical strength, thus meeting the plasticity requirement for 3D printing. Meanwhile, since traditional carbon-fiber cage is of non-absorbable materials, it's not conducive to bone fusion of cervical spine during fusion process. The n-HA/PLA cage is partially absorbable. In the fusion process, slow degradation of PLA materials generates CO_2 and H_2O, forming an acidic environment which is not conducive to intervertebral bone fusion. However, the HA is alkaline, with calcium and phosphorus as its main components; after mixing with PLA, HA can improve the acidic environment caused by PLA hydrolysis, promoting the cervical spine fusion. Main features of living bone tissue are as follows: constant coordinate activities between osteoclasts and osteoblasts promote the metabolism; channel network formed by blood vessels, bone canalicules and other tissues can ensure exchange and transportation of nutrients and metabolites; the loose porous structure of absorbent material during degradation can greatly contribute to growth of bone tissue, accelerating the fusion of vertebral body. The implant will be coupled with metabolism of bone tissue under such a way of implants degradation & formation of new bone tissue, and finally be replaced by autologous bone tissue, completing the process of vertebral fusion.

This study shows that Limit load of carbon-fiber group was (2909.20±45.97)N; limit load of new-type group was (2,855.08±43.18)N, 98.14% of that of the carbon-fiber group. The compressive resistance of new-type group was slightly lower than that of carbon-fiber group; however, the difference was not statistically significant ($P>0.05$). It means that the new type of cage is safe in Biomechanical aspects.

Meanwhile, there are some deficiencies in the experiment, which are stated as follows: There are some inherent vice that during the imaging data acquisition, three-dimensional reconstruction and 3D printing production process, there might be some unavoidable errors. By using the methods such as pre-operation thin layer CT scanning, repeated measurements, produce with high accuracy 3D printer, increase sample size, and carefully expose bone structure etc., may to some extent reduce the error. With the restriction of FDM technology and the experimental facilities, the appearance of the new cage may be relatively rough, and with a visible texture. This might be improved by upgrading the 3D printer with smaller diameter spray head.

Based on the above analysis, the result obtained after mechanical testing proofs that the new-type cervical cage developed in this study can meet the clinical requirement of mechanical strength. Therefore, cervical intervertebral implant developed by 3D printing technology has an incomparable advantage to other manufacturing processes. With the development of tissue engineering and material science, the higher requirements were proposed on the preparation of spinal implants. Recently, traditional manufacture process keeps renewing and developing, and with the introduction of new technology such as the 3D printing which combined with the medical imaging technology, digital simulation technique, material science and so on, there will be a broad prospect for development. Although the 3D printing technology at the present stage is not mature enough, the material and equipment itself has many limitations and may not fulfill the needs of clinical practice, with the rapid development and innovation however, will bring more choices to the clinical practice of orthopaedic implants in the near future.

References

[1] N. Xiang, C.H. Fang , Y.F. Fan, Int. J. Clin. Exp. Med., 8(2015) 18873-18878.
[2] S. Wüst, R. Müller, S. Hofmann, J. Funct. Biomater, 2(2011) 119-154.
[3] M.D. Junco, J. Endourol., 29(2015) 58-62.
[4] H.Y. He, J.Y. Zhang, X. Mi, Int. J. Clin. Exp. Med., 8(2015) 11777-11785.
[5] C.J. Zeng, J.D. Xiao, Z.L. Wu, Int. J. Clin. Exp. Med., 8(2015) 13039-13044.
[6] A.V. Do, B. Khorsand, S.M. Geary, Adv. Healthc. Mater., 4(2015) 1742-1762.
[7] J.W. Choi, N. Kim, Arch. Plast. Surg., 42(2015) 267-77.
[8] J.A. Inzana, D. Olvera, S.M. Fuller, Biomaterials, 35(2014) 4026-34.

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[9] G.B. Kim, S. Lee, H. Kim, D.H. Yang, Y.H. Kim, Y.S. Kyung, C.S. Kim, S.H. Choi, B.J. Kim, H. Ha, S.U. Kwon, N. Kim, Korean J. Radiol., 17(2016) 182-197.
[10] R.I. Haque, E. Ogam, C. Loussert, P. Benaben, X. Boddaert, Sensors (Basel), 15(2015) 26018-26038.
[11] M.J. Lee, S.K. Sohn, K.T. Kim, C.H. Kim, H.B. Ahn, M.S. Rho, M.H. Jeong, S.K. Sun, Clin. Orthop. Surg., 2(2010) 90-97.
[12] S. Erakovic, A. Jankovic, G. Tsui, C.Y. Tang, V. Miskovic-Stankovic, T. Stevanovic, Int. J. Mol. Sci., 15(2014) 12294-12322.
[13] O. Im, J. Li, M. Wang, M. Keidar, Int. J. Nanomedicine, 7(2012) 2087-2099.
[14] N.H. Kang, S.J. Kim, S.H. Song, S.M. Choi, S.Y. Choi, Y.J. Kim, J. Craniofac. Surg., 24(2013) 1042-1045.
[15] A. Bigham-Sadegh, I. Karimi, M. Shadkhast, M.H. Mahdavi, J. Orthop. Traumatol., 16(2015)141-149.
[16] A.M. Parizi, A. Oryan, Z. Shafiei-Sarvestani, A. Bigham-Sadegh, J Orthop Traumatol, 14(2013) 259-268.
[17] Z.Liao, G.R. Fogel, T. Pu, H. Gu, W. Liu, Med. Sci. Monit., 21(2015) 3348-3355.
[18] Z. Klezl, C.A. Bagley, M.J. Bookland, J.P. Wolinsky, Z. Rezek, Z.L. Gokaslan, J. Eur. Spine, 16(2007) 306-310.
[19] S.J. Ferguson, J.M.A. Visser, A. Polikeit, J. Eur. Spine, 15(2006) 149-156.
[20] R. Cincu, F.D.A. Lorente, J. Gomez, J. Eiras, A. Agrawal, J. Asian Neurosurg, 9(2014) 213-217.
[21] K.J. Song, S.J. Yoon, K. B. Lee, J. Eur. Spine, 21(2012) 2492-2497.
[22] M. Shousha, A. Ezzati, H. Boehm, J. Eur. Spine., 21(2012) 2512-2519.
[23] X. Yang, L. Liu, Y. Song, Q. Kong, J. Zeng, C. Tu, J. Indian Orthop, 48(2014)152-7.
[24] X. Yang, Q. Chen, L. Liu, Y. Song, Q. Kong, J. Zeng, Y. Xue, C. Ren, Int. Orthop, 37(2013) 2421-2427.
[25] M. Yoo, W.H. Kim, S.J. Hyun, K.J. Kim, T.A. Jahng, H.J. Kim, J. Korean Spine, 11(2014)127-135.

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