Mechanical properties of artificial intervertebral discs prepared by additive manufacturing

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Abstract. This study uses the selective laser melting technology in additive manufacturing technology combined with high-frequency welding technology to prepare the artificial intervertebral disc. Static axial compression test, static compression shearing test, static torsion test and dynamic axial compression fatigue test were performed according to the ASTM F2346-05 standard specification. The static axial compression test results that the average compression stiffness of the artificial intervertebral disc is 543.81 N/mm. When the ultimate displacement is 1.854 mm, the ultimate force is 3053.10 N, and the static compression shear compression stiffness is 114.92 N/mm. When the ultimate displacement is 4.363 mm, the ultimate force is 339.95 N. The fatigue test results show that the height of the artificial intervertebral disc changes from 8.35 mm to 8.25 mm.

1. Introduction

In recent years, additive manufacturing technology has been widely used in aerospace, automotive industry and medical, food, construction, and apparel industries. For example: rocket engines, auxiliary prostheses, transparent corrective braces, 3D Knitting technology to produce customized shoes, etc. Therefore, the stability of the manufactured workpiece is relatively significant. Additive manufacturing technology differs depending on the lamination method and materials that laminated by melting or softening the material. It can be summarized as photopolymerization curing technology, material extrusion technology, material spray molding technology, binder spray molding technology, powder bed melting molding technology, directional energy deposition technology, and laminate manufacturing molding technology [1].

Additive manufacturing technology can be applied to human intervertebral space in medical treatment. Degenerative disc disease has become a common disease, with the advance of science and technology, artificial disc replacement surgery has become a popular choose for the patients. Artificial intervertebral discs are non-fusion techniques that maintain normal spinal activity, witch is gradually becoming the mainstream surgical treatment for degenerative disc disease. In the past, most of the artificial intervertebral discs were manufactured by traditional machining methods. Nowadays, due to the maturity of additive manufacturing technology, many geometric structures that are difficult to complete by conventional machining methods can be realized by additive manufacturing [2-3].

Cunningham [4] et al. Compared the propertys between artificial discs and interbody fusions, the results showed that the activity pattern performace of the artificial intervertebral disc is more simulated to the normal spine, which can effectively reduce the burden on the adjacent vertebrae. Kim [5] et al. observed the motions of each active segment by implanting the Charite III artificial intervertebral disc into the L4-5 knots of the lumbar vertebrae , 400 N preload force, 8 Nm moment and displacement were used in their study. Moumene [6] et al. implanted the Prodisc II into the L4-L5 lumbar model to study the difference of the stress of the facet joint and the polyethylene core in the non-constrained artificial intervertebral disc at different positions. The test parameter were preload 400 N, front curve 9 degrees, back curve 3 degrees, side curve 5 degrees and the torsion 2 degrees.The results of their study showed that the constrained type had higher vertebral facet joint force and polyethylene core stress.

In this study, the artificial intervertebral disc was prepared by selective laser melting of powder bed fusion molding technology combined with hot embossing. The static and dynamic mechanical properties test of the artificial intervertebral disc were carried out in accordance with the requirements of the ASTM F2346-05 [7] standard specification.

2. Experimental method

The artificial intervertebral disc used in this study is UFO Cervical Artificial Disc. As shown in Figure 1, for buffering bending and extension, the artificial intervertebral disc's inner cushion is made of silicone as the main elastic impedance device, the upper and lower fin covered with micro-needle shape structure are made of titanium metal. The micro-needle shape structure promotes better bone biocompatibility, and improves bone stability in the initial and long-term after implantation.

The UFO artificial intervertebral disc 3D STL image file was based on a 2D dimensional drawing that was obtained in cooperation with a medical device manufacturer. Titanium alloy metal fins of the artificial intervertebral disc used in this study were processed with Ti-6Al-4V powder as material, using laser melting technology. Artificial intervertebral discs were fabricated by Renishaw AM-250 printing system. During the process, laser focus spot diameter, laser power, layer thickness, dot distance, line distance, laser exposure time, are 70 μm, 200 W, 30 μm, 55 μm, 55 μm, 50 μs, respectively. After the metal workpiece is successfully printed, the surface is polished, as shown in Figure 2. Bonding is processed after the polished is finished, the rubber material in the bonding process can be adjusted according to the elastic demand. The bonding process is to inject the silicone material into the metal mold, then the artificial intervertebral disc used in this study can be obtained after the high-frequency welding process, performed on the metal mold.

According to the ASTM F2346-05 [7] specification, the axial compression, compression shear and torsion test fixtures are needed to perform static axial compression, static compression shear, static torsion test and dynamic axial compression test of artificial intervertebral disc. The number of static test samples per artificial intervertebral disc is six, and the number of dynamic test samples is one.

The strength of the fixture for static axial compression and static compression shear fixtures needed to be tested first, the compression stiffness(K_f) was obtained by setting the strength to 1000 N, rate of 200 N/min. Artificial disc destruction test was performed by applying a 100 N preload and the speed at 5 mm/min until the prosthesis was destroyed. Subsequently, The strength of the torsion fixture needed to be tested first, the torsion stiffness(K_f) was obtained by setting the strength to 3.5 N*m, rate of 10 o/min. Artificial disc destruction test was performed by applying a 100 N preload and the speed at 10 °/min until the prosthesis was destroyed.

Fig. 1 UFO Artificial intervertebral disc

The axial compression fatigue test fixture of the artificial intervertebral disc is shown in Figure 3. A strength 100 N preload is given. The ultimate load can be obtained from the static axial compression failure test, taking 50% of its ultimate load as the maximum load for dynamic fatigue testing. Frequency is 8 Hz. The number of cyclic dynamic fatigue is 10,000,000 cycles. The height and appearance of the artificial intervertebral disc needed to be observed every 2 million cycles during the dynamic fatigue tests.

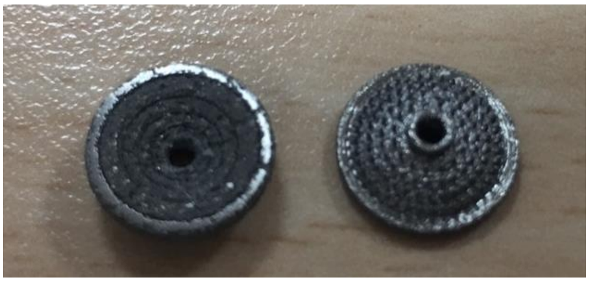

Fig. 2 Titanium alloy metal fins

Fig. 3 Dynamic axial compression fatigue test fixture

3. Results and discussion

3.1 Static axial compression tests

Figure 4 shows the strength of the axial compression fixture, the average fixture stiffness (K_f) is 16484.94 N/mm. Figure 5 shows the axial compression strength of the artificial intervertebral disc, the average system stiffness (K_s) of the artificial intervertebral disc is 543.81 N/mm. When the ultimate displacement is 1.854 mm, the ultimate force is 3053.10 N.

Calculate and report the device axial and torsional stiffness as follows:

$$K_d=K_s/(1-(k_s/k_f)) \quad (1)$$

K_d: device stiffness (N/mm or N·mm/deg)

K_s: system stiffness of device and fixtures in the linear region of the load displacement curve (N/mm or N·mm/deg)

K_f: fixture stiffness (N/mm or N·mm/deg)

Substituting the degree formula, the actual compression stiffness (K_d) of the artificial intervertebral disc will be 483.00 N/mm.

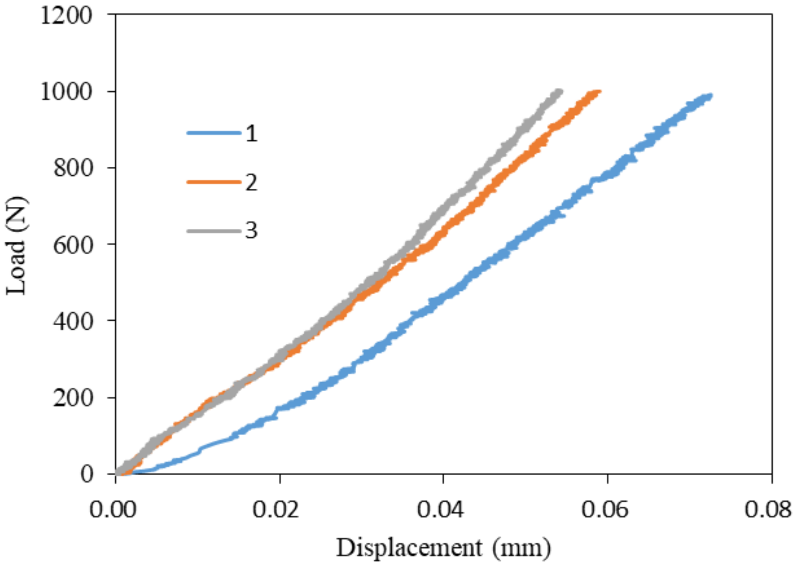

Fig. 4 The strength of the axial compression fixture

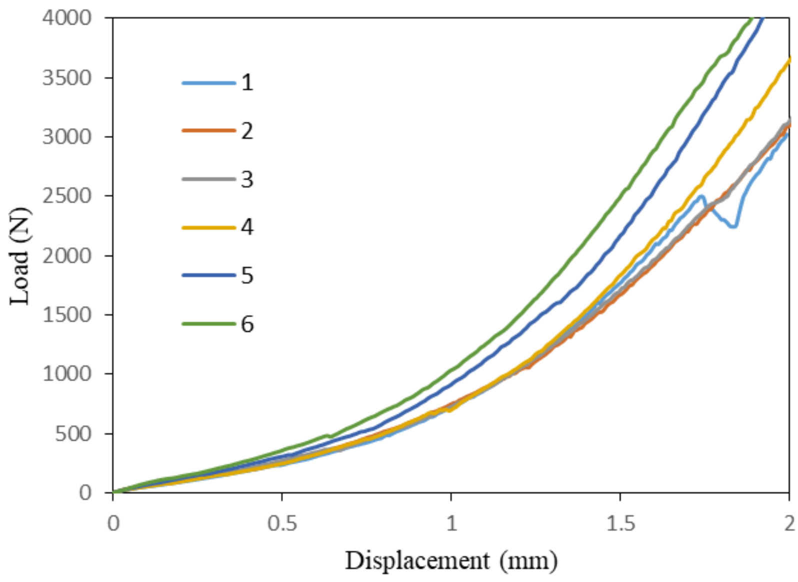

Fig. 5 The axial compression strength of the artificial intervertebral disc

3.2 Static axial compression shear tests

Figure 6 shows the strength of the axial compression shear fixture, the average fixture stiffness (K_f) is 9065.00 N/mm. Figure 7 shows the axial compression shear strength of the artificial intervertebral disc, the average system stiffness (K_s) of the artificial intervertebral disc is 114.92 N/mm. When the ultimate displacement is 4.363 mm, the ultimate force is 339.95 N. Substituting the degree formula, the actual compression shear stiffness (K_d) of the artificial intervertebral disc will be 116.57 N/mm.

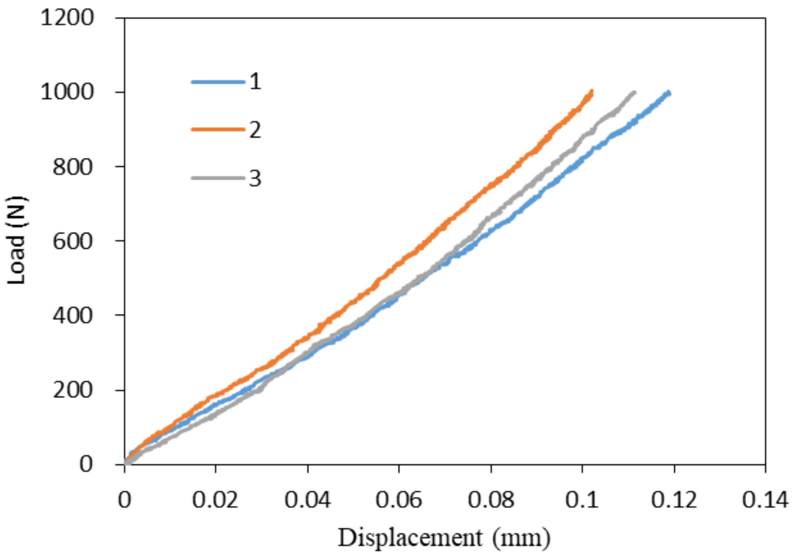

Fig. 6 The strength of the axial compression shear fixture

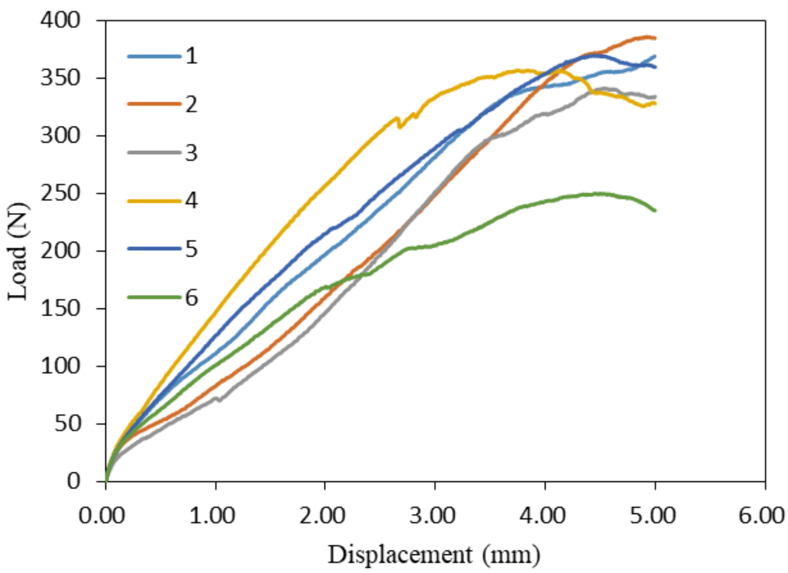

Fig. 7 Axial compression shear strength of the artificial intervertebral disc

3.3 Static torsion tests

Figure 8 shows the strength of the torsion fixture, the average fixture stiffness (K_f) is 1.39590 N*m/^{o}. Figure 9 shows the torsion strength of the artificial intervertebral disc, the average system stiffness (K_s) of the artificial intervertebral disc is 0.0282 N*m/^{o}. When the ultimate moment is 100.0^o, the ultimate force is 1.8966 N*m. Substituting the degree formula, the actual torsion stiffness (K_d) of the artificial intervertebral disc will be 0.0288 N*m/^{o}.

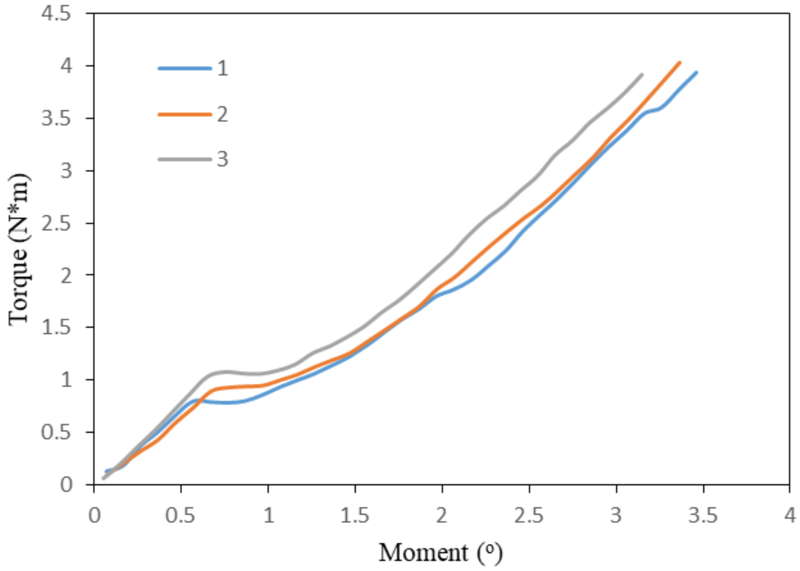

Fig. 8 The strength of the torsion fixture

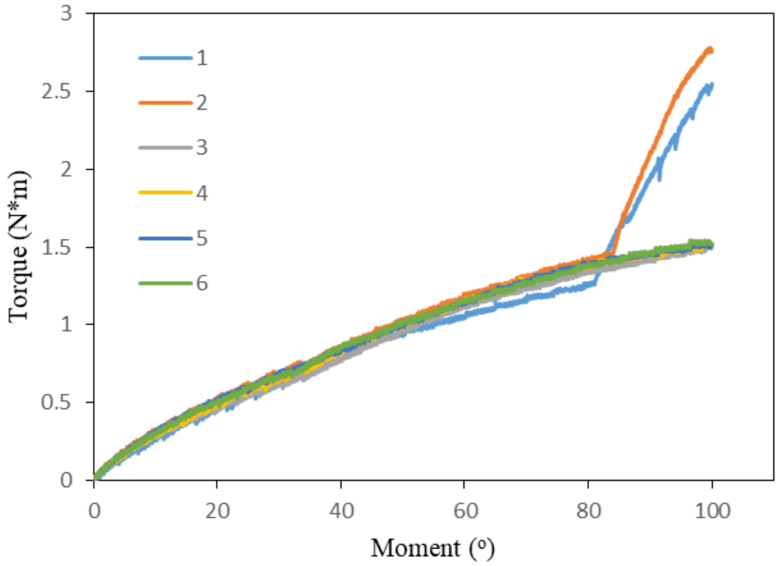

Fig. 9 Torsion strength of the artificial intervertebral disc

3.4 Dynamic axial compression fatigue tests

When performing the dynamic axial compression fatigue test of the artificial intervertebral disc, the artificial intervertebral disc was placed between the upper and lower polyacetal test fixture and given a preload of 100 N. After the static axial compression failure test, the ultimate load is obtained as 3053.10 N. According to the ASTM F2346-05 standard specification, taking 50 % of its ultimate load as the maximum load for dynamic fatigue testing. Therefore, 10,000,000 cycles of dynamic fatigue test were performed with the test parameters of amplitude -1500 N ~ -150 N and frequency 8 Hz. According to ASTM F2346-05 standard specification, the height and appearance of the artificial intervertebral disc is needed to be observed and documented every 2 million cycles.

After the artificial intervertebral disc was tested with 2,000,000 fatigue test in the first stage, the height of the artificial intervertebral disc changed from 8.35 mm to 8.25 mm, and the silicone around the artificial intervertebral disc was worn, as shown in Figure 10.

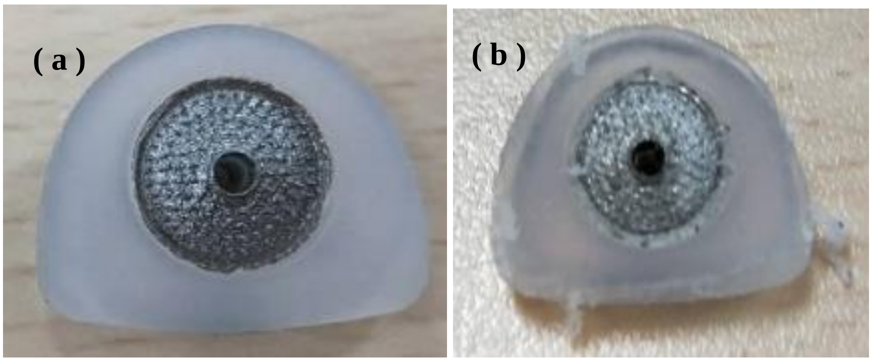

Fig. 10 The artificial intervertebral disc (a) before testing, (b) after testing

Summary

In this study, the titanium metal fins of the artificial intervertebral disc were successfully fabricated by the laminated manufacturing technique, and the UFO artificial intervertebral disc was also successfully bonded using a bonding process to combine it with the silicone. In order to obtain the mechanical properties of this artificial intervertebral disc, static axial compression, static axial compression shearing, static torsion testing and dynamic axial compression fatigue testing are performed in accordance with ASTM F2346. Dynamic axial compression fatigue test results show that the silicone around the artificial disc has wear, which is presumed to be related to the adjustment ratio of the silicone material. Since the test results are less than the 10,000,000 cycles set by the regulations, the artificial intervertebral discs need to be overcome the problem of silicone wear before applied to clinical operations.

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References

[1] J. Y. Jeng：3D printing additive manufacturing technology and Application. (Chuan Hwa Book Co., LTD, Taiwan 2017).

[2] J. O. F. Cavazos, E. F. Villalba, J. A. D. Elizondo, O. M. Romero, C. A. Rodríguez, and H. R. Siller, " Design Concepts of Polycarbonate-Based Intervertebral Lumbar Cages: Finite Element Analysis and Compression Testing ", Applied Bionics and Biomechanics, Vol. 2016 (2016), p. 7149182.

[3] N. de Beer and A. van der Merwe, " Patient-specific intervertebral disc implants using rapid manufacturing technology ", Rapid Prototyping Journal, Vol. 19 (2013), p. 126.

[4] B. W. Cunningham, J. D. Gordon, A. E. Dmitriev, N. Hu, and P. C. McAfee, " Biomechanical evaluation of total disc replacement arthroplasty: an in vitro human cadaveric model ", The Spine Journal, Vol. 2 (2002), p. 104.

[5] S. H. Kim, U. K. Chang, J. C. Chang, K. S. Chun, T. J. Lim, and D. H. Kim, " The Changes in range of motion after a lumbar spinal arthroplasty with Charite in the human cadaveric spine under physiologic compressive follower preload: a comparative study between load control protocol and hybrid protocol ", J Korean Neurosurg Soc., Vol. 46 (2009), p. 144.

[6] R. Bertagnoli, and S. Kumar, "Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indication" , Eur Spine J , Vol. 11 (2002), p. S131.

[7] ASTM F2346-05," Standard Test Methods for Static and Dynamic characterization of Spinal Artificial Discs ".