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Experimental tests on new titanium alloy interbody cervical cages

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Abstract

Degenerative diseases of the spine, when not solvable with clinical treatments or with suitable stabilization systems, can be cured by means of the technique of arthrodesis through the interbody fusion of two or more vertebrae. The paper deals with the tests carried out on commercial and innovative cervical cages, used in the primary stabilization of the vertebrae, able to maintain the right distance and to assure the interbody fusion. Additive manufacturing (AM) is a powerful new tool offering the necessary competitiveness to the biomedical manufacturing companies, having the possibility to create materials with controlled porosity combined with solid parts, providing to the workpiece excellent capacity in the subsequent phases of osseointegration. Based on the knowledge developed either in the biomechanics of the spine or in the properties of biocompatibility and osseointegration of titanium alloys, MT Ortho has developed some models of cervical cage made from modern additive printing techniques with titanium alloy. Three different cervical cage made of different materials were subjected to static compression test: a commercial cervical intervertebral cage in PEEK and two cervical intervertebral cages in Ti alloy produced by the EBM process by MT Ortho. Tests on the innovative cage produced by EBM have shown encouraging results. From this first preliminary analysis its showed that the mechanical and functional failure of the innovative devices made in melted Ti alloy by EBM is achieved by load values greater than physiological ones of the cervical spine.

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Keywords: Cervical cages; Additive Manufacturing; EBM Ti alloy; Biomechanical tests.

1. Introduction

Degenerative diseases of the spine, particularly the cervical spine, when not solvable with clinical treatments or with suitable stabilization systems, can be cured by means of the technique of arthrodesis through the interbody fusion of two or more vertebrae. The resulting motility loss is however compensated by the effectiveness of stabilization, which ensures the very serious risks associated with spondylolisthesis and/or possible cord injury. Over the past decades numerous arthrodesis techniques have been developed, either through bone grafts or by insertion of external or interbody stabilization systems (Rolander 1966, White and Panjabi 1990). Among these, depending on the operative technique and the system morphology, many devices have been produced capable of stabilizing the vertebrae, spacing them properly and encourage the colonization of bone tissue in intersomatic zones to ensure interbody spinal fusion.

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In 1996, the FDA approved the cage for use in intervertebral disc space, providing a new technique that allows the spine to be fused with less morbidity than in the past. By the use of the cage, the structural support is obtained by the device while healing proceeds both within the cage that around the cage with bone graft or a bone substitute.

In particular, several devices of the type cage of different shape and material have been developed (Steffen et al. 2000). Based on the knowledge developed both in the biomechanics of the spine that in the properties of biocompatibility and osseointegration of titanium alloys, MT Ortho has developed some models of cervical cage made from modern additive printing techniques with titanium alloy (Arcam EBM System).

Additive manufacturing (AM) is a powerful new tool offering the necessary competitiveness to the biomedical manufacturing companies. According to ASTM F42 Committee, Additive Manufacturing is defined as "the process that allows the realization of artefacts from a 3D virtual model, realized by overlapping of layers fused between them (layer by layer)".

The great power of AM, from which comes the real advantage of technology, is taking root in the field of realization of medical products. In this field, we have the possibility to create materials with controlled porosity combined with solid parts, providing to the workpiece excellent capacity in the subsequent phases of osseointegration (bone ingrowth). All the pieces produced with this technology are characterized by a rough surface, which is an advantage in terms of primary fixation with the patient's bone (Yang et al. 2014, Tsai et al. 2016). Another feature is the high purity of the materials used, guaranteed by the manufacture in a controlled environment (vacuum with minimum presence of oxygen) which makes also the melting process even more stable (Mahale 2009, Petrović et al. 2012).

The manufacturing process consists of two fundamental steps: disposition of the powder and fusion. The provision of the powder is a process in which the material is lying down on the work surface in a very thin layer (between 0.03mm and 0.20mm). The selective fusion refers to the printing process of the slice using the action of a source of concentrated energy. The active energy can be a light source, a laser beam, an electron beam. It acts on the material layer and transforms the raw material (powder) in solid metal. The power of the energy source depends on the chosen technology: by stereolithography that uses about 100 mW to EBM technique (Electron Beam Melting) that uses more than 3000 W.

2. Description of the investigation

ASTM F2077-03 Standard (Test Methods for Intervertebral Body Fusion Devices) provides guidance on materials and methods to test statically and dynamically intervertebral fusion devices such as spinal implants designed to promote arthrodesis (ASTM).

The mechanical tests include the axial compression, the shear-compression and the torsion. The present paper reports only the results obtained for the compressive tests. According to the ASTM taken as a reference, to make the axial compression test, the actuator of the testing machine must be connected to the load axis by means of a universal joint. The push rod was then connected to the superior fixture by a minimal friction sphere joint (Figure 1a).

The experimental setup must then be assembled so that the vertical axis of the test device is coincident with the axis of the rod and collinear with the axis of the actuator and the load cell. The length between the center of the universal joint and the center of the ball joint must be at least 380 mm.

Following the specifications of ASTM F 2077 the experimental setup was designed using the SolidWorks 3D CAD software, then the components were realized in stainless steel in a mechanical workshop (Figures 1a and 1b).

The tested devices are cervical cages made of titanium alloy Ti6Al4V (ASTM F 2924) and produced by additive manufacturing technology EBM. The upper and lower surfaces of the cage, in contact with the vertebral plate, are constituted by a trabecular structure (Figure 1c), which increases the surface area of the cage by providing an optimal basis for bone growth (Lee et al. 1984, Imwinkelried 2007, Seaman et al. 2017, Zhao et al. 2018, McGilvray et al. 2018).

Three different cervical series of cages made of different materials were subjected to static compression test:

- Cervical intervertebral cage in PEEK, 14x11x4mm size (Figure 2a) (CC).
- Cervical intervertebral cage in Ti alloy, size 16x14x6mm, produced by the EBM process by MT Ortho (Figure 2b) (SC). The cage has a crosslinked structure and is hollow inside to allow the surgeon to insert the bone graft.
- Modified cervical intervertebral cage in titanium alloy, size 16x16x7mm, produced by the EBM process by MT Ortho (Figure 2c) (MC).

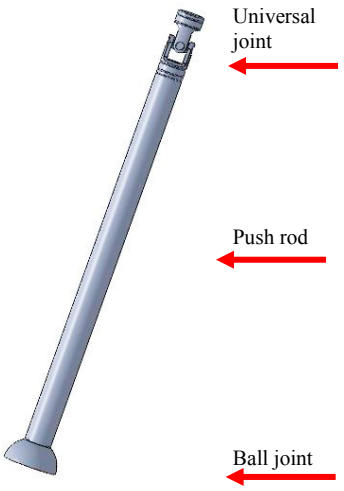

Figure 1a. CAD of the compressive setup.

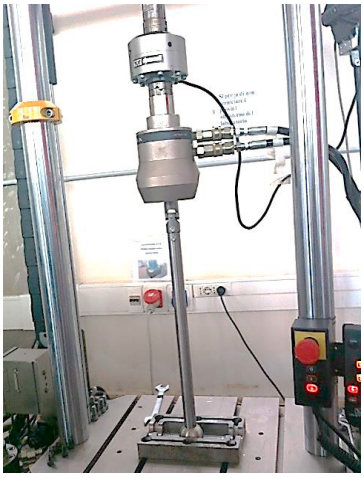

Figure 1b. Compressive setup.

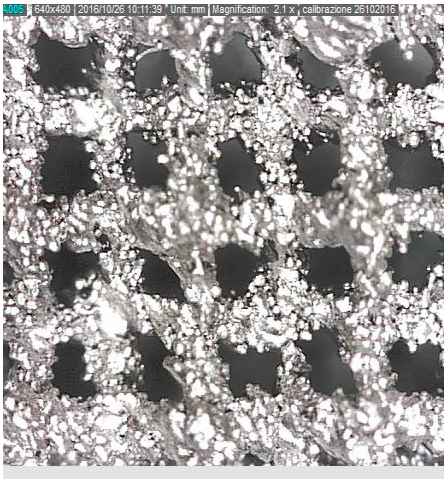

Figure 1c. Trabecular structure of Ti alloy cages.

Figure 2a. Intervertebral cage in PEEK (CC).

Figure 2b. Intervertebral cage in Ti alloy produced by EBM (SC).

Figure 2c. Modified intervertebral cage in Ti alloy produced by EBM (MC).

The investigation is articulated in two subsequent ways. The first one performs the experimental tests following the standard indications, in order to verify if the intervertebral cages produced by MTOrtho in Ti alloy have strength comparable with those commercial produced in PEEK. Once verified that the new cages are able to resist in the same way than those of already well consolidated use in surgical practice, the second part of the study tends to correlate forces and displacements under loading, in order to verify the functionality of the cages in comparison with the physiological values. Because the push system can import many errors in the displacements along the measuring chain due to the clearances and to the displacements of the components among them, the cages were tested directly between the compression plates of the testing machine.

Following the ASTM Standard, because the cages don't have upper and lower flat and parallel surfaces, in order to avoid out of axis loading (causing not uniform distribution of the load), the biomedical device during the test was interposed between two of 316L steel blocks, obtained with the technology DMLS (Direct Metal Laser Sintering). The material of the blocks is characterized by a breaking load of about 600 MPa, then one order of magnitude higher than the apparent yield stress (load/area) of the device, then subject to negligible deformations in our measurements. These two connection blocks have been appropriately designed to accommodate the upper and lower surfaces of the prosthesis, ensuring a correct distribution of the efforts to the interface (Figure 3a).

3. Experimental tests on the intervertebral cages

In order to obtain the fore-displacement behavior of the Ti device and to compare it with that of the commercial one, in the first preliminary tests about the proper sizing of the device, the cervical cages have been subjected to a

static compression load according to the standard ASTM F 2077. Carefully following the indication, the cage CC and SC were subjected to the axial compression test. Five cages SC (SC1 to SC5) and one cage CC have been tested.

After the first experience, aimed to verify if the Ti alloy devices were able to resist to the cervical physiological loads as well as the commercial cages, a different procedure was carried out. In particular, we have been tested 10 devices in larger size (7mm x 16mm x 16mm), 7 of which in accordance with the ASTM standard reference and 3 by removing the upper push rod in order to assess correctly the actual deformation of the device, thus overcoming the clearances of the measuring chain. The size of the cage tested was the result of the worst case assessment. The size choice is a good compromise between a small footprint surface and the highest height of the device.

The cages were placed inside the experimental setup designed for the test (Figure 1a). The tests were performed using an Instron 8501 hydraulic testing machine with a frame able to support 100 kN and a 100 kN load cell. The experimental setup was then assembled so as to align the vertical axis of the test device with the push rod axis, with the axis of the actuator and the load cell. The distance between the center of the universal joint and the center of the ball joint, as required by the standard, was 380 mm.

Once performed these tests according to the ASTM standards, it was considered useful to carry out further testing compression eliminating the push rod. It has been observed, in fact, that the push rod and the universal joint connected at its upper end introduced errors in measuring the displacements of the cage during the test. Since the height variation of the cage is the criterion by which the functional failure of the prosthetic device is identified, other compression tests were conducted by removing the push rod, the universal joint and the ball joint, leaving only the interface blocks.

Compression was transmitted through a perfectly straight and horizontal plate; The horizontal plate used had the center corresponding to the centers of the steel blocks and with a surface area larger than that of the block (Figures 3).

Figure 3a. Cage between the interface blocks.

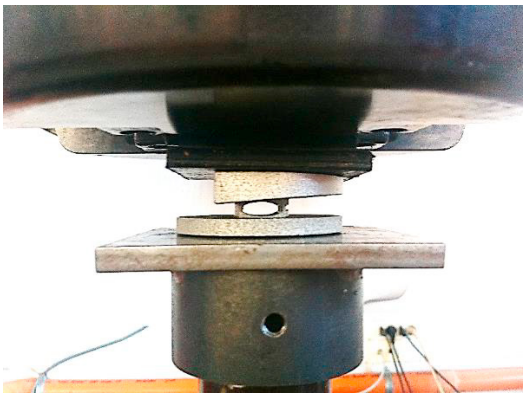

Figure 3b. New experimental setup.

The load was applied with a speed of 5 mm/min, to have a control of the same and to be able to record several points of the curve, until reaching the functional or mechanical failure of the intervertebral device. For each of the three last MC devices the test was stopped once the desired actuator displacement recorded: the cage 8 to a shift of 0.5 mm, the cage 9 to a shift of 0.8 mm and, finally, the cage 10 to a displacement of 1mm. The three samples were inspected at the end of the test to assess whether the recorded deformation could influence the functional failure of the device.

4. Analysis of results

Figures 4 and 5 show the results obtained by the compression tests for the SC and CC series. In addition, Table 1 shows the values of loads in which it was observed the functional or structural failure of the cage.

The load-displacement curve in the case of the cage SC increases until it reaches a maximum, in which it has the structural failure of the cage, around 3 mm with the load values between about 16 kN and 18 kN and then decreases rapidly. In the case of the cage in PEEK instead, the curve increases with a certain slope up to 14 kN where it has the architecture failure of the intervertebral prosthesis, but then the load continues to grow with different slope until it reaches the displacement of 5 mm, stop condition of the test.

The different behavior can be attributed to the different structure of the cage tested, the SC cage is hollow, while that in PEEK is full then, in the second case, following the functional failure of the device it has the compression of the massive structure of the cage. Figures 5a,b,c show the cages after the compression test.

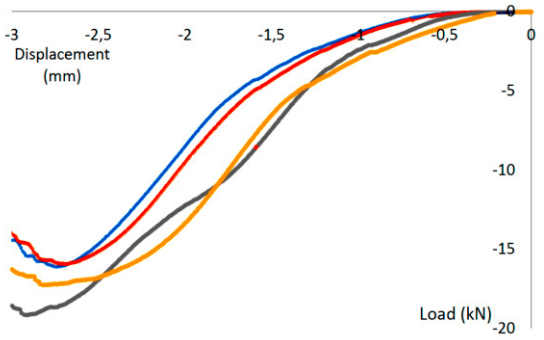

Figure 4a. Load-displacement curves for the SC cages.

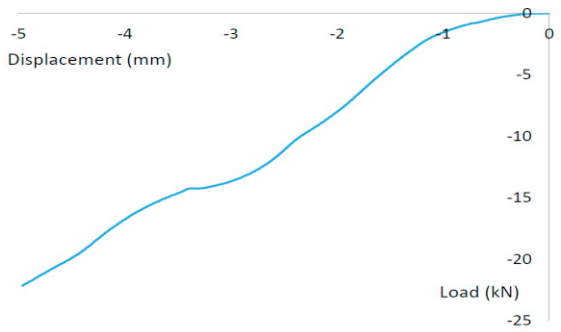

Figure 4b. Load-displacement curves for the CC cage.

Fig. 5a. Cage SC after the compression test.

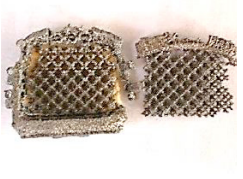

Fig. 5b. Cage SC after the compression test.

Fig. 5c. Cage CC after the compression test.

Fig. 5d. Cage 7 after the compression test.

Fig. 5e. Cage 10 after the functional test.

Table 1. Functional failure loads at the compression tests.

Cage	SC1	SC2	SC3	SC4	SC5	CC
Load (kN)	18,44	19,18	15,94	17,3	16,11	14,3

Once the curves demonstrate that the compression load supported by the cages is always much greater than the physiological one and compatible with the commercial ones, the second purpose of the study was carried out. . In fact, it has been shown that the average compressive strength of the C4-C5 segment is just about 1 kN (Moroney et al. 1988) and the corresponding physiological displacement is about 1 mm.

Aim of the further study, then, as previously outlined, was to verify the functional behavior of the cages in Ti alloy.

In any case, however, after observing the fracture lines in the cages, the authors suggest to the company the reinforcement of the lateral walls. Following these remarks, a new cage was produced (Figure 2c).

Figure 6a shows the load-deformation curves obtained on the 7 specimens subjected to an axial load of static compression according to ASTM F 2077 standard**.** The tests were conducted under loading control until the complete failure of the device. Figure 5d shows the cage 7 after the compression test, highlighting the significant plastic deformations of the entire structure, and a noticeable fracture at the back of the device.

Figure 6b, instead, shows load-displacement curves obtained for other three cages (8-9-10), directly mounted between the compression plates, in order to avoid the clearances of the measuring chain. In the case of functional compression, the tests were carried out under displacement control, until reaching the displacements of 0.5, 0.75 and 1.0 mm respectively. The corresponding loads are higher than the physiological ones at the same displacement, testifying the functional resistance of the devices. Figure 5e shows the image of the cage 10 after being subjected to compression functional test, where is noticeable a slight flattening of the curvature of the upper surface but no damage on both the massive and the trabecular part has been detected.

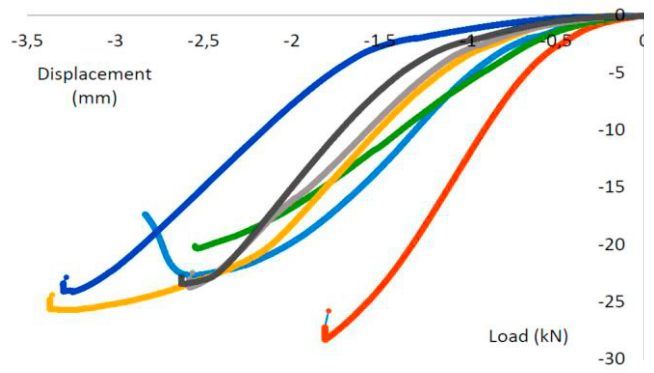

Figure 6a. Curves load-displacement for the 7 MC cages tested following ASTM Standard.

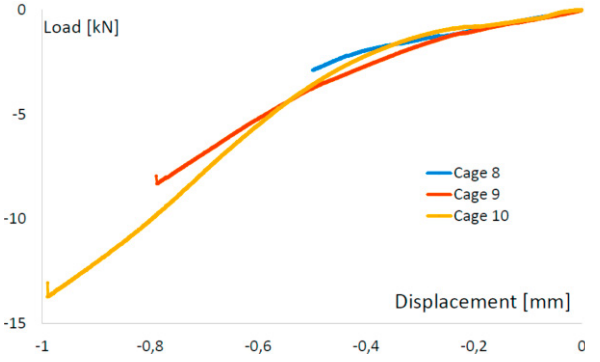

Figure 6b. Curves load-displacement for the 3 MC cages tested directly between the compression plates.

Conclusions

The work was conducted in collaboration between the company MT Ortho s.r.l. and the group of Biomechanical Engineering at the University of Catania. The aim of this collaboration was to perform a preliminary analysis of cages made of titanium alloy produced with EBM technology to evaluate the possibility of future commercialization. To this end, the basis of the first series of tests was to make a comparison between the experimental components and other currently implanted, to verify that the mechanical characteristics of the prosthesis produced by using the new EBM technology were comparable to those of the components currently on the market.

Tests have shown encouraging results. From this first preliminary analysis, it showed that the mechanical and functional failure of the device is achieved by load values greater than physiological ones related to the cervical spine. The static compression tests showed a higher resistance of the Ti alloy cage. Moreover, being hollow and porous, Ti cages allow the surgeon the possibility to insert inside a bone graft, increasing the success rate of spinal fusion.

In order to assure greater safety conditions relatively to the functional failure of the device, the structure of the cage was reinforced, so as to ensure that the curvature of this surface, specifically designed for maintain or restore the cervical lordosis, remains intact for even higher load values. The tests performed on this type of cages confirmed that the structure is able to support the loads in functional conditions with a high safety factor.

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