Biomechanical evaluation of titanium trabecular sphere in kyphoplasty procedure

A Krüger¹, N Francaviglia², S Di Bella³,⁴ and R Mineo³,⁴

¹ Unfallchirurgie, Handchirurgie, Diakonie Klinikum Jung-Stilling, Siegen, Germany
² Department of Neurosurgery, ARNAS Hospital Civico, Palermo, Italy
³ Mt Ortho srl, via Fossa Lupo sn, Aci Sant’Antonio (CT), Catania, Italy
⁴ University of Catania, DICAR – Department of Civil and Architecture, via Santa Sofia 64, 95125, Catania, CT, Italy

e-mail: rosalia.mineo@mtortho.com

Abstract. The treatment of osteoporotic vertebral compression fractures using transpedicular augmentation has grown significantly during the past two decades. Balloon Kyphoplasty allowed to restore vertebral height and to improve the deformity, but has several disadvantages related to the filler material used: the bio-cement. The aim of the current study is to investigate the mechanical behaviour of cadaveric fractured osteoporotic vertebral treated with a new filler material made by Spheres in Trabecular Titanium alloy (Ti6Al4V-ELI), under static loading conditions. The Strength of the VBs remain almost the same. So, the VBs maintain their physiological values after the kyphoplasty procedure with trabecular titanium sphere. The stiffness was instead significantly reduced in some VBs. This data can be affected to the limit of ex vivo study.

1. Introduction

Vertebral compression fractures (VCFs) are clinically recognized in 1.4 million individuals worldwide annually [1], often resulting in pain disability, vertebral deformity and considerable negative economic impact [2]. Painful vertebral fractures can have significant effects on quality of life and physical function. Chronic pain and decreased mobility can lead to a depressed mood and loss of independence. VCFs are usually treated with augmentation procedure of the vertebral body (VB) to restore anatomical geometry and to provide strength and support. Galibert et al [3] first described vertebroplasty in 1987 for vertebral body tumors in France in 1984 and in the United States in 1993. Initially born as cancer treatment of VB it was gradually redirected toward osteoporotic vertebral fractures.

Vertebral augmentation through vertebroplasty or kyphoplasty involves the percutaneous injection of bone cement into the fractured vertebral body. Both vertebroplasty and kyphoplasty have been shown to provide rapid pain relief with relatively complication rate especially in cases where conservative medical therapies have failed. Vertebroplasty (VP) doesn’t allow to restore the VB height and the reduction of the fracture and, thus, doesn’t eliminate spinal deformity caused by the fracture. Due to the high pression need to insert the filler material, extravasation of the filler material into the epidural space or paraspinal vasculature is a potential complication of this method.

Balloon Kyphoplasty (BCK) is a newer technique with several potential advantages, it involves the introduction of a working cannula into the VB followed by insertion of an inflatable bone tamp creating
a cavity to be filled with a void material, generally bio-cement. This inflatable bone tamp expands into the surrounding cancellous bone and is designed to elevate the vertebral endplate reducing the fracture and improving the deformity. It creates a cavity in which the filler material can be inserted at low pressure and thus reduce the potential for extravasation of the filler material from the VB [4-8].

The most common used cement is polymethylmethacrylate (PMMA). Unfortunately, PMMA has several potential disadvantages. PMMA is not bioabsorbable and remains permanently in the body. Its unreacted monomer is toxic, and its high polymerization temperature causes necrosis of adjacent tissue [9]. The high compressive strength and stiffness of PMMA causes a biomechanical mismatch between treated and untreated VBs which may increase the risk of adjacent level fracture [10]. Leakages of PMMA from the VB treated due to the fluid-state of the material, are a common clinical problem related to both procedures.

Additives are sometimes added to PMMA to improve properties like antibiotics or radiopaque agents. Research has shown that adding various types of antibiotics to PMMA, does not adversely affect its mechanical properties. Radiopaque substances, such as tantalum powder, tungsten, barium sulfate or zirconium dioxide have been added to PMMA to facilitate fluoroscopic visualization to monitor possible cement extravasation.

Alternative filler materials have been generated great interest, as synthetic bone substitute. The calcium phosphate cement and calcium sulfate were appreciated for their capacity of remodeling and integrating into the surrounding bone [11]. This material avoids any potential thermal effects of PMMA and expected to work as an optimum carrier for osteo-inductive proteins. However, has been reported that calcium sulfate is rapidly resorbed, it might not be able to support spinal alignment while it is remodeling. Other problems related to bio-cement materials include their low viscosity, handling characteristics different from those of PMMA, and high costs.

The purpose of this study was to investigate the mechanical behavior of fractured osteoporotic vertebral treated with a new filler material made by Spheres in Trabecular Titanium alloy (Ti6Al4V-ELI), under static loading conditions.

2. Materials and methods
To evaluate the mechanical behavior of fractured vertebral bodies treated with Trabecular Titanium (Ti6Al4V-ELI) spheres the activities summarized in flowchart were performed (figure 1).

**Figure 1.** Flowchart of experience procedure.
2.1. Specimen Selection

In order to analyze the characteristics of this new filler material it was necessary to create similar operative condition of the kyphoplasty procedure. Three fresh-frozen human cadaver spines, obtained from female human donors, were used for this study. A total of 15 vertebral bodies were selected from levels T7-L4 of each spine. (Table 1)

Table 1. Features of the three donors: donor number, level treated, age, race, sex, height, weight, BMI, cause of death.

| Donor Number | MD13031115 | MD16021141 | MD16091350 |
|--------------|------------|------------|------------|
| Donor        | Donor 1    | Donor 2    | Donor 3    |
| Level of spine vertebral body tested | T7, T9, T10, T11, T12 | T10, T11, T12, L1, L2, L3, L4 | T9, L2, L4 |
| Age          | 76         | 69         | 73         |
| Race         | C          | C          | C          |
| Sex          | F          | F          | F          |
| Height [cm]  | 162,56     | 162,56     | 157,48     |
| Weight [kg]  | 90,7       | 90,7       | 90,7       |
| BMI          | 34         | 34         | 37         |
| Cause of death | Arteriosclerotic Cardiovascular | Diabetes Complications | Metabolic Acidosis |

There were performed X-ray scan to evaluate the condition of the cadaveric spines, especially to identify any pathologies, as preexisting vertebral fractures or deformities.

The bone mineral density (BMD) was determined using the dual-energy x-ray absorptiometry technique (DXA, Hologic Discovery A System S/N 83278) and showed osteoporosis. The results of DXA scan were of -4.2 (donor 1), -3.2 (donor 2) and -5.1 (donor 3). Osteoporosis was defined according to the World Health Organization criteria: BMD (bone mineral density) of more than 2.5 standard deviation below the mean of a young healthy reference population of the same gender (T-score).

2.2. Titanium sphere (TS)

TS was made by EBM® (Electron Beam Melting) additive manufacturing technology in Ti6Al4V-ELI material. Arcam Q10 system (Ge Additive, Gothenburg, Sweden) was used to build the spheres. In the Arcam EBM® process fully dense metal components are built up, layer-by-layer of metal powder, melted by a powerful electron beam. Each layer is melted to the exact geometry defined by a CAD model. The additive manufacturing technology allow to build a trabecular structure, obtain as 3D repetition of unit cell. The unit cell used in the device production was dodecahedron unit cell (figure 2). The porous and the bulk sections of the implant are built in one process step, this ensures structural continuity between the solid and porous sections.

The device (TS) has a spherical shape (ø3.3mm) (figure 2) and its structure is a combination of a trabecular and a massive part: the central core provides a mechanical solid structure [12], the trabeculated component [13], placed peripherally and in continuity with the previous one, induce bone growth within it and also ensure that the spheres interact each other when they are in-situ without separating[14].
A cannulated instrument (figure 3) properly loaded with spheres was used to introduce the TSs inside the Vertebral body as the traditional cement insertion of the kyphoplasty procedure. A specific push-system connected to the cannulated instrument, push the TSs in controlled and manual way to ensure the properly distribution of the TSs.

A bayonet system ensures a solid and easily interchangeable connection between the cannula and the thrust system. Pushing the trigger gun, a metallic piston moves inside the cannula and press the TSs outside. The inner diameter of the cannula was designed to ensure the correct movement of the spheres inside it and to avoid the locking of them. Pre-cuts were made at the end of the cannula to guarantee the controlled insertion of the spheres one by one into the VB (figure 4).
2.3. Specimen preparation
The spines were denuded of soft tissue, disarticulated, and posterior elements and lamina were removed to facilitate the mechanical tests. Each vertebral body (VB) were wrapped in saline-soaked gauze, sealed in plastic bags, and stored at -20°C until the day before testing. All specimens were thawed at room temperature 20°C, 24 h before testing. Each VB was floated in its sealed plastic bag in a water bath maintained at 37°C for at least one hour before mechanical testing. Impressions of the end plates of each vertebra were made using Technovit 3040 (cold-curing resin for surface testing and impression; Heraeus Kulzer, Wehrheim, Germany). The anterior, central, posterior, lateral left and lateral right height were measured using CT scan images (figure 5) through mimics software (Materialise, Leuven-Belgium) as CT-image manipulator.

![Figure 5. Height measurements using the six-point method. The height of the posterior (A) and anterior (C) wall of the vertebral body as well as the central height (B) were measured at three time points.](image)

2.4. 1° Fracture procedure
Vertebral compression fractures were created by material testing machine (Universal testing machine, Instron 5566, Darmstadt, Germany), each VB were seated between its respective impressions and then they were placed between platens of Instron testing machine (figure 7). Compression was applied vertically at a rate of 5mm/min to create an anterior wedge-fracture. The load was applied to the superior plate along the central axis of the VB until failure occurred. To create wedge compression of the anterior wall of the vertebral body, the main vector of the axial force was centred on the sagittal midline at the end of the anterior fourth of the vertebral body. The failure load was defined as the inflection point on the load-versus-deformation curve and stiffness was defined as the slope of the load-versus-deformation curve between 500 and 1500 N (figure 6).
Figure 6. Initial and post-treatment VB strength and stiffness.

Load and displacement data were recorded at 10 Hz. Measurements of each VB height after crushing were taken as before (figure 5). Computed tomographic scans were acquired using a Siemens Somaton Definition scanner.

Figure 7. 1° fracture procedure using a testing machine (Universal testing machine, Instron 5566). The load was transferred by a pivot-mounted pressure plate on the superior vertebral end plate.
2.5. Balloon Kyphoplasty procedure
Before the balloon kyphoplasty test, two guidewires were placed through both pedicles using Jamshidi needles. The fracture were reduced using an inflatable bone tamp (Kyphon, Sunnyvale, CA) advanced by two working cannulas. The balloons were inflated simultaneously, creating two cavities and squeezing the surrounding trabeculae to the periphery until the maximum volume of the balloons was reached or until the first signs of endplate fracture occurred. The resulting cavities were then completely filled with TS (figure 8). The volume of TS injected into each pedicle was 2-4 cm³ that corresponding to a 150-200 TS. CT scan images acquisition were performed to evaluate the anterior, central, posterior, lateral left and lateral right height of each VB and to assess the proper distribution of the TS inside each VB.

All procedures were performed by the same surgeon using an image intensifier. The placement of the K-wires was monitored by fluoroscopy in three planes (antero-posterior, lateral, and craniocaudal).

2.6. 2° Fracture procedure
After kyphoplasty procedure, mechanical test of each VB was again performed according to initial crush protocol. After, measurement and graphs were obtained as described previously for each VB. Post-treatment strength and stiffness were calculated as shown on figure 6.

3. Results
Compression fractures were established in all vertebral bodies, according to the Orthopedic Trauma Association classification they were all A-type fractures [15].

They were evaluated, according to the protocol, 15 VBs obtained from three donors from thoracolumbar levels. For each VBs were recorded anterior, central and posterior height (figure 9 and table 2). These values were obtained at the end of every phases (at the beginning, after fracture, after kyphoplastic procedure, after post treatment fracture) and were estimated on CT images as the figure 5 shows.

The values of height loss are expressed as a percentage of the initial height (figure 9 and table 2). There was no significative different between the two groups.
Figure 9. Anterior, central and posterior vertebral heights after first and second fracture from the initial height.

Table 2. Overview of the results (the initial height equals 100%).

|                  | 1° fracture before treatment | after sphere treatment | 2° fracture after treatment |
|------------------|------------------------------|------------------------|-----------------------------|
|                  | Mean  | SD   | Mean  | SD   | Mean  | SD   |
| fractured anterior Height (%) | 88,8  | 7,2  | 99,3  | 7,9  | 88,8  | 7,8  |
| fractured central Height (%)   | 92,3  | 7,9  | 98,1  | 8,6  | 88,4  | 6,1  |
| fractured posterior Height (%) | 100,0 | 5,8  | 103,8 | 5,9  | 101,3 | 6,6  |
| fractured lateral left Height (%) | 96,8  | 6,3  | 100,4 | 9,8  | 95,0  | 10,1 |
| fractured lateral right Height (%) | 95,1  | 9,3  | 100,0 | 12,6 | 92,3  | 11,0 |
| fractured central coronar Height (%) | 101,1 | 8,0  | 102,6 | 9,4  | 97,3  | 6,9  |

Strength e stiffness pre and post treatment, volume of filler material, volume of the VB were also evaluated (table 3 and table 4) for each level. The VB’s volumes were estimated on the CT images, approximating the vertebral body to a cylinder. The diameter was evaluated on the axial slice and the height on the sagittal slice, both measured in the middle of the vertebral body (figure 10).

The average force needed to create the fracture to the healthy vertebral body was 2599,01 N. The mean initial stiffness was 2278,19 N/mm.
Figure 10. VB volume calculation, the diameter was evaluated on the axial slice and the height on the sagittal slice.

The volume measurement of the TS was obtained using the 3-matic software (Materialize, Leuven-Belgium) from the three-dimensional reconstruction of the post-treatment CT images. Reconstructions of the vertebral bodies and TS, were obtained by the thresholding function of the mimics software (Materialise, Leuven-Belgium) which use the different grey scale of the DICOM images (CT scan) to identify and mark the bone tissue and the titanium spheres (segmentation).

Table 3. Overview of the Volume values and filling percentage of each vertebral bodies.

| Patient | Level | d [mm] | h [mm] | Volume VB [mm³] | Volume VB_Lsst_frt [mm³] | Volume VB_post_treat [mm³] | Volume Spheres [mm³] | filling [%] |
|---------|-------|--------|--------|----------------|------------------------|---------------------------|----------------------|------------|
| MD13031115 | T7    | 25.77  | 18.57  | 9885.7        | 10451.0                | 10357.7                   | 2003.1               | 19.2       |
|         | T9    | 27.87  | 19.9   | 12139.9       | 11222.7                | 11569.8                   | 1792.0               | 16.0       |
|         | T10   | 31.08  | 25.2   | 17601.1       | 12422.1                | 13937.3                   | 1749.2               | 12.0       |
|         | T11   | 32.15  | 25     | 20295.1       | 16804.7                | 17618.1                   | 1858.6               | 11.1       |
|         | T12   | 34.33  | 24.4   | 22385.4       | 19160.7                | 21705.1                   | 2102.5               | 11.0       |
| MD16021141 | T10   | 33.45  | 20.45  | 17971.1       | 15726.2                | 18546.9                   | 1671.2               | 10.6       |
|         | T11   | 35.38  | 22.82  | 23720.9       | 19139.0                | 20189.0                   | 2212.7               | 11.6       |
|         | T12   | 35.54  | 24.83  | 24632.1       | 21743.7                | 24364.1                   | 2154.4               | 9.9        |
| MD16091350 | L1    | 35.65  | 26.92  | 26871.0       | 24371.2                | 24710.7                   | 1880.5               | 7.7        |
|         | L2    | 38.58  | 27.58  | 32408.4       | 19594.6                | 29106.5                   | 1995.8               | 10.2       |
|         | L3    | 39.07  | 27.87  | 33412.9       | 30257.1                | 29039.5                   | 2035.5               | 6.7        |
|         | L4    | 40.71  | 26.2   | 34103.1       | 29162.1                | 27065.9                   | 2727.5               | 9.4        |
|         | T9    | 25.86  | 18.48  | 12088.8       | 9487.4                 | 11875.3                   | 2901.8               | 30.6       |
|         | L2    | 34.59  | 25.95  | 23539.6       | 18596.4                | 22059.5                   | 3410.3               | 18.3       |
|         | L4    | 39.93  | 24.73  | 30968.0       | 24914.3                | 26338.6                   | 3428.6               | 11.8       |
Table 4. Strength and stiffness values pre and post treatment for each vertebral body.

| Patient | Level | Initial Strength | Post-Treatment Strength | Initial Stiffness | Post-Treatment Stiffness |
|---------|-------|------------------|-------------------------|------------------|-------------------------|
|         |       | [N]              | [N]                     | [N/mm]           | [N/mm]                  |
| T7      |       | 2737.63          | 2586.26                 | 2351.03          | 638.45                  |
| T9      |       | 2109.15          | 2897.5                  | 2606.12          | 1385.36                 |
| T10     | MD13031115 | 2868.4          | 3622.34                 | 2161.11          | 691.16                  |
| T11     |       | 721.59           | 2134                    | -                | 927.59                  |
| T12     |       | 2198.09          | 2723.55                 | 2086.4           | 765.9                   |
| T10     |       | 3280.6           | 2971.74                 | 2895.44          | 752.23                  |
| T11     |       | 3406.23          | 2783.23                 | 4072.52          | 909.23                  |
| T12     |       | 3006.96          | 1478.25                 | 3697.96          | 273.07                  |
| T9      | MD16021141 | 2800.43          | 1753.14                 | 2841.23          | 451.19                  |
| T2      | L1    | 2944.05          | 2187.27                 | 2106.52          | 545.12                  |
| T3      | L2    | 2365.08          | 2820.62                 | 3243.67          | 782.66                  |
| T4      | L4    | 2876.52          | 2549.48                 | 1320.11          | 586.17                  |
| T9      | L2    | 1804.94          | 1694.72                 | 332.53           | 342.91                  |
| T4      | L4    | 1722.5           | 1111.27                 | 225.82           | 220.67                  |

There were no significant differences in median strength, the initial value was of 2737.63 N (SD: 999.48 N) and the post-treatment value was of 2549.48 N (SD: 675.14 N), with a percent reduction of approximately 10%. Instead, the no-treated VBs were stiffer than the post-treatment VBs. It has been recorded a decrease in stiffness of 70%. However, the reduction of the anterior height from initial condition to the 2nd fractur was of 13.7%.

4. Conclusions
The purpose of this study was to introduce an alternative system in the treatment of vertebral compression fracture, consisting in the use of Spheres in Trabecular Titanium alloy (Ti6Al4V-ELI) as filler for the Balloon Kyphoplasty (BCK) technique instead of bio-cement. The titanium spheres can be introduced inside the cavity created by the balloon with the standard kyphoplastic surgical technique and the cluster created by the compaction of the spheres ensure the vertebral strength and stability while the healing of the fracture occurred, stimulate by the osteoinductive material. This new technique allows to overcome some limits of the common kyphoplastic filler material as PMMA or other acrylic bone cement. It is introduced at room temperature, in solid phase (no risk of leakage can occur) and it is an osteoinductive material.

Moreover, the strength of the VBs remain almost the same. So, the VBs maintain their physiological values after the kyphoplastic procedure with trabecular titanium sphere as filler material. On the other hand, stiffness is reduced in some specimens. The reduction of stiffness can be associated to the limits of an ex-vivo study that doesn’t take into account the forces exerted by the soft tissues surrounding the vertebral body such as muscles, tendons and ligaments, but also the consolidation of the fracture that occurs over time, stimulated by the trabecular structure of the spheres. The VBs were tested immediately after the fracture and kyphoplasty procedure, the mechanical properties of the VBs should be evaluated, in vivo condition, after the consolidation of the fracture and the healing of the VBs. However, the reduction of the anterior, central, and posterior height compared to the initial alues was negligible.
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