An Herrn
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Sehr geehrter Herr Professor Wilke,

anbei finden Sie den Abschlussbericht zu unserem von der Deutschen Wirbelgesellschaft geförderten Forschungsprojekt:

Biomechanical stability of a percutaneous PMMA augmented pedicle screw ring osteosynthesis as a treatment of osteoporotic OF4 pincer fractures in a human cadaveric model.

Introduction

According to the OF classification of osteoporotic thoracolumbar spine fractures from the Spine Section of the German Society of Orthopaedics and Trauma (DGOU) it is recommended to treat OF4 and OF5 via long dorsal instrumentation with augmentation or ventral reconstruction [1-2]. The treatment of an OF4 subgroup the so-called pincer fractures compose a clinical challenge. Minimal invasive vertebral augmentation procedures secure no sufficient stability therefore the recommendation is to treat this kind of fractures with long dorsal instrumentation and ventral reconstruction. Such invasive treatments are associated with a high perioperative complication rate. The fact that these fractures affect commonly the elderly and patients with significant comorbidities adds to the complexity of the treatment decision and underlines the need for minimally-invasive methods. For this reason, we developed for the treatment of OF4 pincer fractures a minimally-invasive percutaneous procedure which addresses only the injured vertebra. This consists of augmented pedicle screws which adapt the two fracture fragments, which are connected with a rod to form a ring osteosynthesis. The rationale behind this procedure is to adapt the displaced fracture fragments through the pedicle screws and prevent any further displacement. The addition of the rod is to prevent a lateral displacement and provide rotational stability. Purpose of this study is to evaluate the biomechanical stability of this novel procedure in an osteoporotic human cadaveric model.

Materials and Methods

Specimens

For 12 human fresh frozen specimens (-20°) of the thoracolumbar (L3-5 or Th12-L2) region CT scans were conducted (General Electrics, Lightspeed VCT16, GE Medical Systems, Waukesha, WI, USA) and bone mineral density was individually specified. The mean bone mineral density was 66.7 ± 10.5 mg/ cm^3. Specimens with morphological abnormalities and preexisting fractures were excluded. Testing was conducted in room temperature for minimal effect on the biomechanical qualities. The specimen were prepared with the removal of fat and muscle leaving parts of the supporting apparatus like discs, facet joints and bone intact. For the testing the cranial and caudal part of each specimen were embedded in bone cement (Technovit 3040). For the radiographic measurement of the vertebral height a 10mm metallic sphere was inserted as calibration.

Setup

In order to simulate everyday spine loads a biaxial servo-hydraulic testing machine was used (858 Mini Bionix II, MTS, Eden Prairie, MN, USA) for multiple purposes like the fracture creation, the execution of the cyclic loading protocols and the application of standardized axial force. Every specimen was embedded at the caudal and cranial vertebra and anchored with flanges. At the cranial end a round compression plate with a use of a roll guaranteed an even distributed force application.

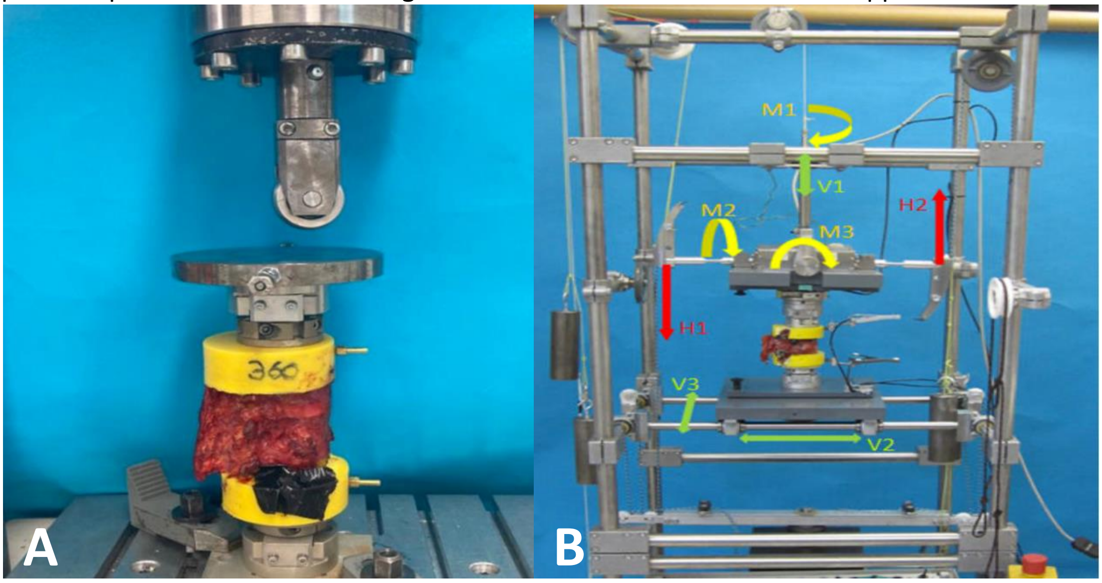

Figure 1: (A) The servo-hydraulic testing machine used. **(B)** Spine simulator with applied moments and motion axes.

The Spine Simulator was constructed according to the simulator of Wilke et al. [25] with six-degree-of-freedom and the testing was performed in flexion/extension, lateral bending right/left and rotation right/left. Data recording was performed using an ultrasound-based 3D motion analysis system (Winbiomechanics, Zebris, Isny, Deutschland). Throughout the cyclic testing the relative movement of each spine segment was measured and recorded in all three axes over time with the use of Winbiomechanics software.

Fracture creation

The middle vertebra of every specimen was fractured in a standardized manner. The medial endplates of the vertebra were marked with K-Wires and then a chisel was used to fracture the vertebral body with inclusion of the endplates bilaterally. After that the OF-4 pincer fracture was completed with the use of the testing machine according to the following scheme. 1. Preconditioning with cyclic loading with 20-100N at 1 Hz for 20 cycles. Axial displacement of 6mm with a velocity of 0,5mm/s. 3. Loading with constant displacement from stage 2 for 10s. 4. Decrease of the load for a displacement of 2mm from stage 3 at a velocity of 0,5mm/s. 5. Increase of the Load for relative displacement of 2mm from stage 4 with a velocity of 0,5mm/s. 7. Constant loading for 10s. Purpose of this stage was to reduce the height of the fractured vertebra approximately to 50% of its intact height. This was also confirmed with biplanar fluoroscopy.

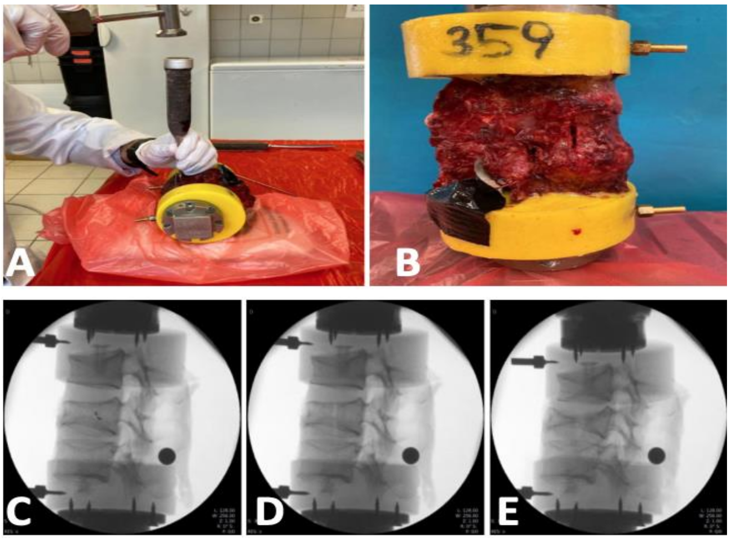

Figure 2: (A) Induction of pincer fracture using a hammer and chisel. **(B)** Fracture in the medial portion of the vertebra. Radiographic presentation **(C)** of marked medial vertebral portion with K-Wires **(D)** of the fractured vertebra **(E)** of fracture completion through applied force in the testing machine.

Fracture treatment – Instrumentation

After successful fracture induction, pedicles of the fractured vertebrae were prepared with awls and afterwards K-Wires were introduced in the pedicles. The correct placement of the K-wires was confirmed using biplanar fluoroscopy. Then canulated and fenestrated pedicle screws were inserted over the wires in the fractured vertebral body (VERTICALE polyaxial Screws SILONY Medical). After the fluoroscopic confirmation of the correct screw placement the pedicle screws were augmented with 1ml PMMA and the procedure is completed with the placement of a bended rod connecting the screws being secured with Innies.

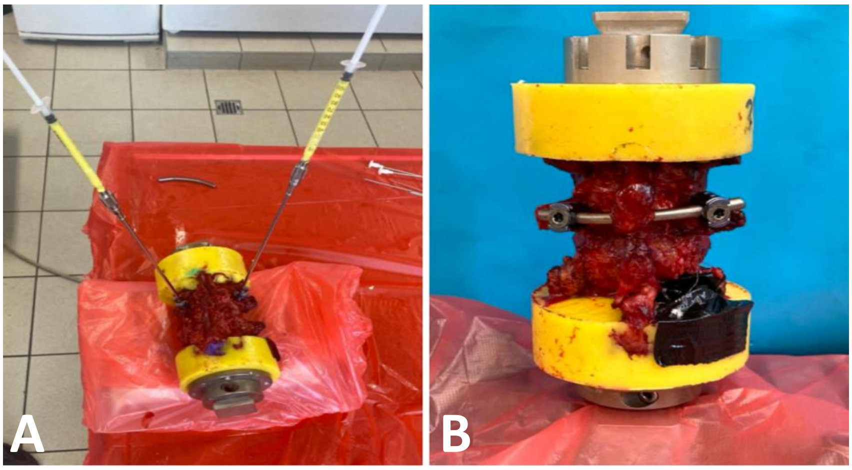

Figure 3: An example of a treated vertebra with the proposed method. **(A)** PPMA-Augmentation of the pedicle screws. **(B)** Ring-Osteosynthesis with a rod connecting the pedicle-screws through the interspinous ligament.

Flexibility testing

For the acquisition of the biomechanical properties in the native state each one of the specimens was placed in the spine simulator and loaded with ±3.75N in flexion, extension, lateral bending and rotation. Afterwards they were loaded with 500 N and the vertebral height was measured with the use of an x-ray. After fracture induction and surgical fixation measurements of the RoM and vertebral height were also documented for later analysis.

Cyclic loading

Cyclic loading consisted of three intervals of axial loading of the treated specimens in the testing machine with measurements of the Rom in the spine simulator and of the vertebral height taking place after each of them the RoM and the vertebral height were measured. Each interval consisted of 10 steps through which axial loading was applied with an initial force of 500 N increased in each step for 50N so that the applied force at the end of the first interval was 1000 N. Accordingly the applied force of the second interval was between 1000 and 1500 N and of the third between 1500 and 2000N. At the end pf cyclic loading a flexibility testing was performed in the spine simulator.

Data analysis

MATLAB was used to perform the data analysis. For each specimen measurements of the RoM and vertebral height were documented in native, fractured state, after fixation and during the course of cyclic loading and used to create matrices. The RoM was calculated for each of these six measurements in three motion axes (flexion/extension, lateral bending, rotation) and raw data were graphically represented. For better comparability these values were normalized to the native and fractured states and the absolute differences were calculated. The vertebral height was measured in the ventral, medial, and dorsal part of the vertebra and the values were used to build matrices. These values were also normalized to the native and fractured state and represented in charts. For this purpose, the median value as well as the quartiles were calculated to form the boxplots.

Results

From 12 specimens 8 were available for testing and analysis in the results. 4 of the specimens were excluded due to inadequate fracture creation.

Table 1. Specimen Characteristics	
Age, years (mean, SD)	75.5 ± 8
Male Sex	10 (83.3%)
Fractured vertebra	
L1	3 (25%)
L3	2 (16.7%)
L4	7 (58.3%)
Bone Mineral Density, mg/cm^3 (mean, SD)	66.7 ± 10.5
Amount of PMMA , ml (mean, SD)	4.6 ± 0.8

Flexibility Testing

Flexion

For better comparability the absolute difference to the native state of each vertebra was calculated as shown in Figure 4. Through fracture creation there was an increase in the RoM with the median value of this increase being 9.32°. After fracture fixation the RoM was reduced in every specimen but without reaching the values of the native state with a Median difference between native state and instrumentation being 6.15°. During the three intervals of axial loading there was an increase in the RoM, which in four specimens was more than in fractured state. Compared to the native state the RoM at the end of cycling loading showed differences between 5.08° and 19.02° with a Median value of 8.84°.

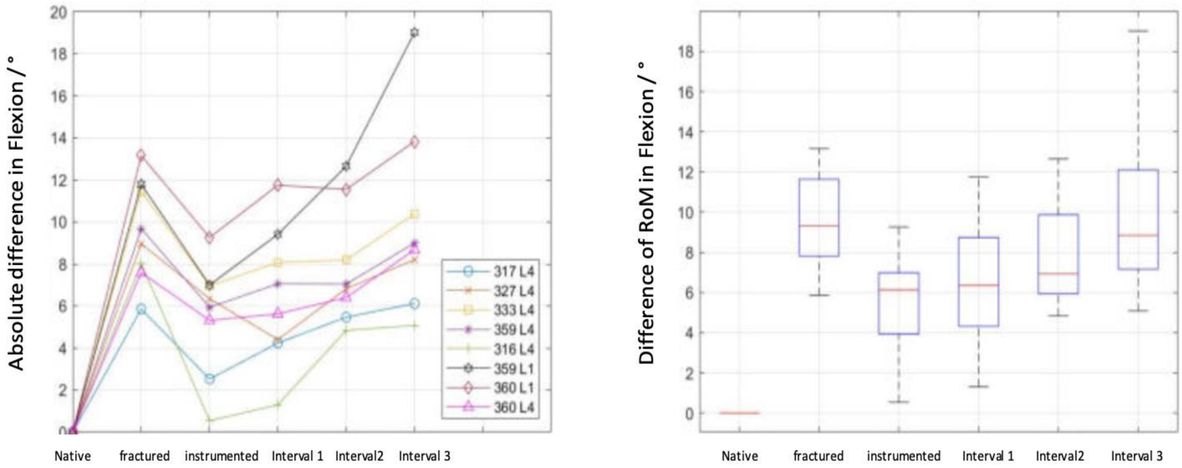

Figure 4: Absolute difference of RoM to the native state in flexion.

Lateral bending
Compared to flexion and rotation there was a greater increase of the RoM in the measurements of lateral bending after fracture creation with a median value of 15.42°. The instrumentation seems to reduce these values but could not reach the native state in none of the specimens. Our results show an increase throughout the cycling loading exceeding the values of the fractured state in four of the specimens (Figure 5).

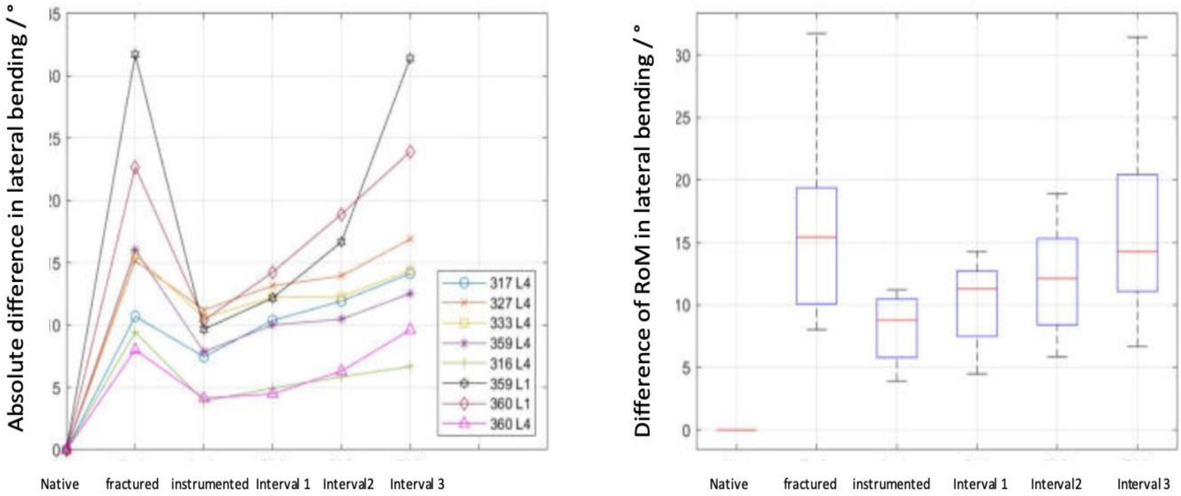

Figure 5: Absolute difference of RoM to the native state in lateral bending.

Rotation
Similar to flexion and lateral bending creating a fracture led to an increased RoM in Rotation with a maximum of 17.73° in specimen 359 L1 (that why this specimen is marked as a red cross outside the boxplots and does not affect the quartiles). The minimum of change was 2.23° with the median value being at 4.81°. Fracture treatment with the proposed method could reduce the RoM without reaching the values of the native state. The median value of the difference between native and instrumented state was 2.35°. After the first loading interval this median value increases to 2.82° and after the second to 3.02°. Following the same pattern, the difference between native state and instrumentation increases 0.50° after the third interval with specimen 359L1 still deviating outside the boxplot (Figure 6).

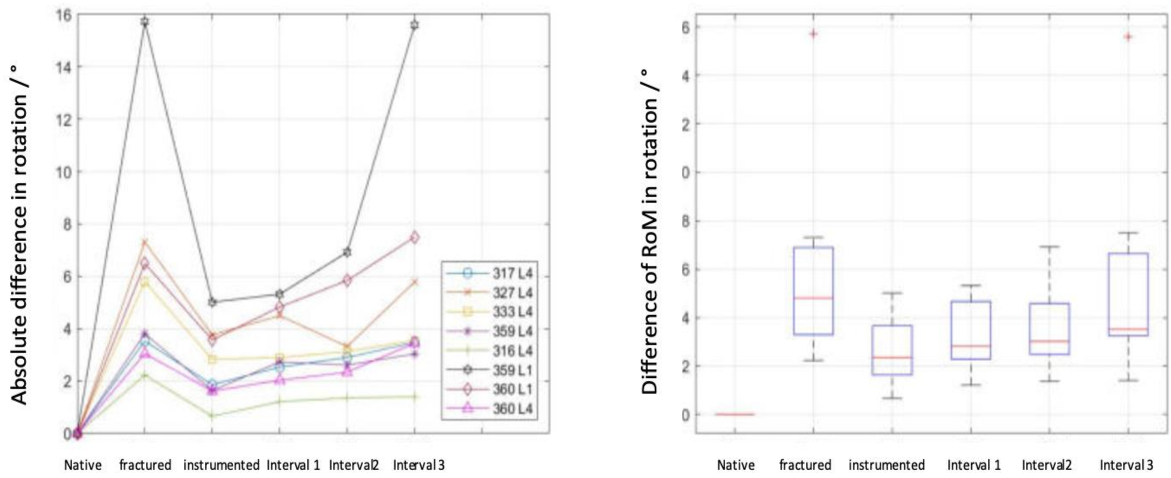

Figure 6: Absolute difference of RoM to the native state in rotation

Vertebral height

The vertebral height was measured in three parts of the vertebra marked as ventral, medial and dorsal beginning at the native state and afterwards in the fractured state, instrumented state and through the course of the cycling loading after each interval. The absolute differences to the native state were used to demonstrate our results. As expected in this type of pincer fracture the height loss was more intense at the medial portion of the vertebra with minimal change at the ventral and dorsal parts (Figures 7-9). In a similar way the ring osteosynthesis led to an increase of the vertebral height in every part of the vertebra with the largest increase being at the medial part. After cycling loading the height loss was evenly distributed in every part of each specimen. It is important to note that after the cycling loading none of the specimens reached the minimum height values documented at the fractured state.

Ventral

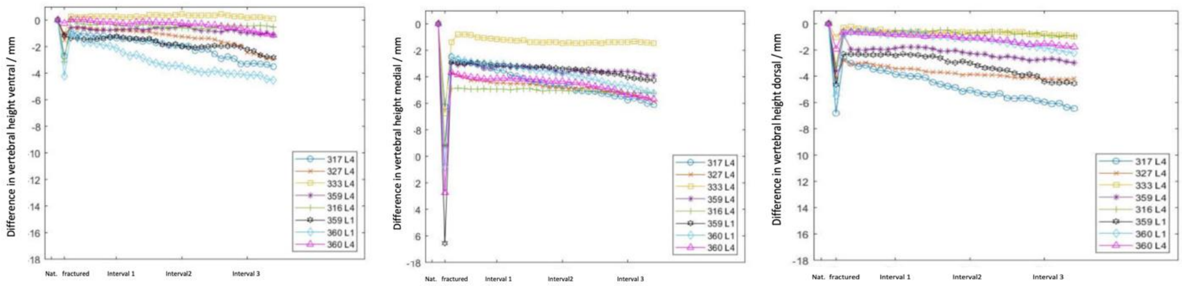

Figure 7: Absolute difference of vertebral height to the native state (ventral; medial and dorsal).

At the ventral part of the vertebral there was a height loss in every specimen after fracture creation. With treatment the ventral vertebral height increases in each specimen and throughout the cycling loading decreases evenly with four out of eight specimens having an absolute difference of less than 2mm to the initial state and four of them having more than 4mm (Figure 7).

At the medial portion only one specimen didn't lose more than 2mm of height after the three intervals with the rest showing a decrease of up to 6mm but all of them staying over the fractured state (Figure 7). The dorsal values show the widest spread with the difference to the initial varying between 1mm and 6mm after axial loading staying on the same pattern (Figure 7).

The statistical analysis via boxplots shows only minimal reaction to the axial loading in the ventral and dorsal parts after instrumentation. The data of the medial part reveal that a specimen reacts notably little to the axial loading (lies outside the boxplots) in comparison to the others. Fracture creation led to a decrease of vertebral height with the median values of the absolute difference to native state being in ventral, dorsal and medial part 1.3mm, 3.9mm and 9.2mm respectively. Through the instrumentation comes to an increase with the absolute differences lying at 0.6mm, 0.8mm and 2.9mm respectively. At the end of the axial loading show these values again an increase at 2mm, 2.6mm and 5.2mm compared to the initial state (Figure 8).

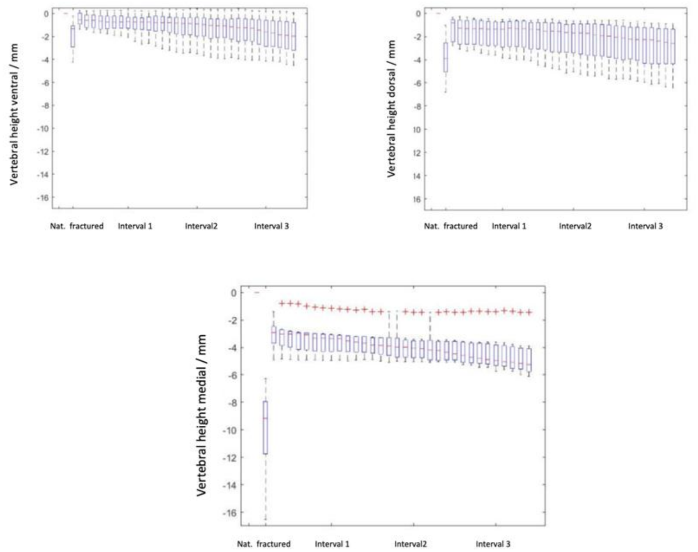

Figure 8: Boxplots presenting the data analysis of the absolute difference to the native state in **(A)** ventral **(B)** dorsal and **(C)** medial part of the vertebra.

Discussion

2018 the Spine Section of the German Society for Orthopaedics and Trauma (DGOU) released the OF classification which describes 5 morphological types of thoracolumbar osteoporotic fractures (OF1-OF5) [14]. The parallel published Osteoporotic Fracture (OF) Classification-based Scoring System was proposed as a decision making tool to decide whether such a fracture should be treated conservatively or surgically.

Surgical treatment varies from minimal invasive cement augmentation of the fractured vertebra to long-segment cement-augmented posterior instrumentation with ventral reconstruction depending on the type of fracture. OF-4 morphologic type consists of three subtypes and it is considered as an unstable fracture (OF-Score > 6) needing surgical treatment. OF-4 pincer type fractures involve both endplates and can lead to severe deformity of the vertebral body if not treated [1]. According to the DGOU recommendations treatment of choice is a long-segment dorsal fixation with ventral reconstruction[2]. Taking in consideration this vulnerable group of patients with comorbidities and lower functional status this kind of invasive surgeries could impose a risk increasing the complication rate with a clear need of minimal invasive treatment methods. For this reason, many authors propose a short segment instrumentation in order to keep the operating time shorter, minimize blood loss, shorten in-hospital stay and preserve motion of the adjacent segments [3-5].

The lack of a current consensus for the treatment of osteoporotic OF-4 pincer fractures and the need new minimal invasive methods to treat older patients led to the idea of this novel method of a percutaneous PMMA-augmented pedicle screw ring-osteosynthesis. This type of fractures is characterized through the involvement of both endplates and the adjacent intervertebral discs with progressive disconnection of the anterior and middle spine columns which leads to pseudarthrosis

and kyphotic deformity if not treated. The proposed method consists of two percutaneously inserted augmented pedicle screws which are connected to each other through a rod to form a ring. The rationale behind this idea is that the pedicle-screws readapt the displaced fracture fragments preventing further dislocation and pseudarthrosis with the rod preventing coronal displacement. Purpose of this study was to examine the primary- and secondary biomechanical stability of this novel procedure in a human osteoporotic cadaveric model. Several studies in the literature describe the use of transpedicular implants as a treatment of vertebral fractures. La Barbera et al. showed in a comparative Finite Element Analysis that a Stent-Screw assisted internal fixation (SAIF) of osteoporotic fractures is biomechanically advantageous over vertebral augmentation methods [6]. Kettler et al. proved in-vitro that the use of the transpedicular implant (BeadEx) can be a sufficient alternative to vertebral augmentation [7]. Auerswald et al. used bisegmental human specimens to create and treat traumatic AO A2 fractures with transpedicular lag-screw osteosynthesis, showing encouraging results in their biomechanical model [8].
In this study the creation of a pincer fracture in-vitro was successful and reproducible in a standardized process (Figure 2).
Our results show an increase in the RoM after fracture creation in all three motion axes with this effect being greater in lateral bending. Through treatment a decrease was noted in every specimen but without reaching the values of native state (Figures 4-6). Throughout the cycling loading the RoM continued to increase and in 4 specimens exceeded the fractured state. Interpreting these results its clear that through fracture creation there is an involvement of both adjacent discs leading to increasing RoM that cannot be reversed through fracture fixation. Concerning the vertebral height, we noted a decrease in every part of all specimens with the medial region of the vertebra being more affected as expected in this type of fracture (Figure 7). A restoration of vertebral height was achieved after treatment with the ring osteosynthesis. The median height loss in the vertebral body center was 52% and was reduced to 17% after instrumentation. An increase of height loss to 26% was shown during the axial loading but was significantly lower to the initial 52% of the fractured vertebra. The proposed method showed only minimal reaction to the cycling loading avoiding further displacement of the fracture fragments, fracture progression and coronal displacement through the course of testing. None of the treated specimens subsided under the values of the fractured state at the end of the testing. It is to note that there was no implant failure.
Limitations of this study include its in-vitro nature, the small number of specimens and the absence of a control group.

Conclusion

The data of this study show sufficient primary and secondary stability and suggest that a minimal invasive percutaneous ring osteosynthesis could be a viable alternative treatment for osteoporotic OF4 pincer fractures, especially in older patient with significant comorbidities where a long-segment dorsal instrumentation with ventral reconstruction could be too risky with increased perioperative morbidity. This study has some limitations, therefore the need of further in-vitro but also clinical investigation is warranted.

References

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