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A Biomechanical Comparison of a Cement-Augmented Odontoid Screw with a Posterior-Instrumented Fusion in Geriatric Patients with an Odontoid Fracture Type IIb --Manuscript Draft--

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Abstract:	<p>Purpose: Possible surgical therapies for odontoid fracture type IIb include odontoid screw osteosynthesis (OG) with preservation of mobility or dorsal C1/2 fusion with restriction of cervical rotation. In order to reduce material loosening in odontoid screw osteosynthesis in patients with low bone density, augmentation at the base of the axis using bone cement has been established as a suitable alternative. In this study, we compared cement-augmented OG and C1/2-fusion according to Harms (HG).</p> <p>Methods: Body donor preparations were randomized in 2 groups (OG vs.HG). The range of motion (ROM) was determined. Subsequently, a cyclic loading test was performed. The decrease in height and the double amplitude height were determined as absolute values as an indication of screw loosening. Afterwards the ROM was determined again and loosening of the screws was measured in a computed tomography.</p> <p>Results: Two groups of 8 specimens with a median age of 80 years and a reduced bone density were examined for their biomechanical properties. Before and after exposure, the OG preparations were significantly more mobile. At the time of loading, the OG had similar loading properties to HG decrease in height of the specimen and the double amplitude height. Computed tomography revealed similar outcomes with regard to the screw loosening rate (p=0.586).</p>	

Conclusion:

In patients with an odontoid fracture type IIb and reduced bone density, cement-augmented odontoid screw yielded similar properties in the loading tests compared to the HG. It may, therefore, be considered as a primary alternative to preserve cervical mobility in these patients.

**A Biomechanical Comparison of a Cement-Augmented Odontoid Screw with a
Posterior-Instrumented Fusion in Geriatric Patients with an Odontoid Fracture Type
IIb**

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Declarations

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Conflicts of interest/Competing interests

The authors declare that they have no conflict of interest.

Availability of data and material

Not applicable

Code availability

Not applicable

Ethical approval

The study was approved by the local ethic committee.

Authors' contributions

All authors contributed to the study conception and design. Data collection and analysis were performed by Falko Schwarz, Christian Liebsch, Nikolaus Berger-Roscher, Yasser Sakr and Albrecht Waschke. The first draft of the manuscript was written by Falko Schwarz and reviewed by all authors. All authors read and approved the final manuscript.

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Purpose:

Possible surgical therapies for odontoid fracture type IIb include odontoid screw osteosynthesis (OG) with preservation of mobility or dorsal C1/2 fusion with restriction of cervical rotation. In order to reduce material loosening in odontoid screw osteosynthesis in patients with low bone density, augmentation at the base of the axis using bone cement has been established as a suitable alternative. In this study, we compared cement-augmented OG and C1/2-fusion according to Harms (HG).

Methods:

Body donor preparations were randomized in 2 groups (OG vs.HG). The range of motion (ROM) was determined. Subsequently, a cyclic loading test was performed. The decrease in height and the double amplitude height were determined as absolute values as an indication of screw loosening. Afterwards the ROM was determined again and loosening of the screws was measured in a computed tomography.

Results:

Two groups of 8 specimens with a median age of 80 years and a reduced bone density were examined for their biomechanical properties. Before and after exposure, the OG preparations were significantly more mobile. At the time of loading, the OG had similar loading properties to HG decrease in height of the specimen and the double amplitude height. Computed tomography revealed similar outcomes with regard to the screw loosening rate ($p=0.586$).

Conclusion:

In patients with an odontoid fracture type IIb and reduced bone density, cement-augmented odontoid screw yielded similar properties in the loading tests compared to the HG. It may, therefore, be considered as a primary alternative to preserve cervical mobility in these patients.

Keywords: Odontoid screw, cement-augmented, odontoid fracture, biomechanical, elderly

1. Introduction

The surgical approach to odontoid fractures type IIb in the elderly is challenging. Anchoring the osteosynthesis material may be needed due to the reduced bone mineralization[1]. The optimal approach to achieve this target remains unclear[2]. The least invasive surgical method is an odontoid screw, which represents the treatment of choice in many clinics, but in the long term this procedure is associated with a high risk of pseudarthrosis, material dislocation and subsequent neck pain[3]. Another established surgical procedure in these patients is the C1/2 fusion according to Harms or Magerl which are associated with higher fusion rates[4, 5]. However, both methods are more invasive and are associated with higher morbidity. A major disadvantage C1/2 fusion is the resulting stiffening of the 1st and 2nd cervical vertebrae and the associated restriction of rotation of the head[6].

In a cadaver study, Waschke et al. demonstrated a significant improvement in biomechanical stability with a novel surgical method by additionally augmenting the screw in the corpus using bone cement, thus minimizing the migration rate of the screw in osteoporotic bone[7].

The aim of our study was to compare the biomechanical stability after a cement-augmented odontoid screw to dorsal stabilization according to Harms in C1/2 in geriatric patients. We hypothesized that the biomechanical stability using the less invasive cement-augmented odontoid screw would be equivalent to that using C1/2 dorsal stabilization, justifying its use as primary approach to maintain cervical mobility in these patients.

2. Material and methods

A total of 16 body donor preparations of the 1st and 2nd cervical vertebrae were included. The preparations were cryopreserved for storage. Subsequently, a bone density measurement was carried out using quantitative computed tomography in the area of the base of the axis (Q-CT, CT LightSpeed™ VCT, GE Healthcare).

The dens axis was fractured with an oscillating saw, resulting in a type IIb fracture without destroying the transverse ligament. Randomization was then performed using computer-generated sequence in 2 groups of 8 specimens each. Each group was treated surgically, either with a cement-augmented odontoid screw or with a spondylodesis according to Harms.

Cement-augmented odontoid screw implantation

The perforated odontoid screw was inserted ventrally into the body of the fractured second cervical vertebra. A reamer was used to open the cortex centrally at the anterior lower edge. A Kirschner wire was inserted thereafter from the opened cortical bone through the fracture gap into the fractured dens tip. The screw was implanted bicortically over the Kirschner wire and thus the dens tip was fixed to the corpus. A yamshidine needle was used to apply high-viscosity polymethylmethacrylate cement (Confidence Spinal Cement System, DePuy Spine™, Leeds, England) to the body around the screw base, which fixes the lag screw proximally. After the cement has set for 5-10 minutes, the lag screw was tightened again to achieve additional strength and compression of the fragment onto the body (Fig. 1).

C1/2 spondylodesis according to Harms

A total of four screws, two each in the first and second cervical vertebrae, were implanted dorsally and fixed with two rods. The entry point for the screws in the first cervical vertebra

1 was located centrally in the inferior-posterior massa lateralis of the atlas. A polyaxial screw
2 was inserted bicortically. The entry point in the second cervical vertebra was the medial upper
3 quadrant of the pars interarticularis with a 20°-30° converging and cranially directed screw
4 position. These screws should also be placed bicortically. In many cases, a monocortical
5 position is possible in vivo. This depends on the anatomy of the transverse vertebral foramen.
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7 The screws in C1 and C2 are finally fixed with a titanium rod (Figure 2).
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18 ***Testing procedure***

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21 The range of motion (ROM) of all preparations was measured in 3 motions plains using a
22 spine tester that has been previously established[8]. With the help of three motors, pure
23 moments were applied: flexion/extension, lateral bending left/right and axial rotation
24 left/right. Loads were applied angle-controlled at a speed of 1°/s. The specimens were loaded
25 to a pure moment between +/- 1 Nm in the individual directions of movement, while three
26 loading cycles were performed per plane, of which the third cycle was evaluated in order to
27 minimize viscoelastic effects[9].
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38 After the flexibility tests all specimens were taken to another a material testing machine
39 (Instron 8871, Darmstadt, Germany). This servohydraulic dynamic testing machine was
40 equipped with a self-developed rotating device for continuous loading[10, 11]. In this fixture,
41 the specimen was rotated axially at a speed of 360°/min and at the same time eccentricly
42 loaded cyclically with a lever arm of 30 mm and a gradually increasing force (from 200 N to
43 1200 N in steps of 100 N) and a frequency of 2 Hz.
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53 As a result, repetitive movements starting with a flexion which merges to lateral bending left
54 and followed by extension to lateral bending right were applied, which corresponds to a head
55 movement in the sense of a circular movement. During loading, the decrease in height of the
56 specimen and the double amplitude height, which corresponds to the deflection of the lever
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1 arm pressing on the specimen, were determined as absolute values as an indication of screw
2 loosening. Following the cyclic loading tests, the ROM of all specimens was measured in the
3 spine tester and computed tomography of the specimens was performed to determine screw
4 loosening[12]. Loosening was defined when a loosening seam has occurred around a screw or
5 when a screw was dislodged.
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11 *Statistical analysis*

12 Data were analyzed using IBM® SPSS® Statistics software, version 22 for Windows. The
13 Shapiro–Wilk test was used to verify the normality assumption of continuous variables.
14 Difference testing between groups was performed using Mann–Whitney test, Chi-square test,
15 or Fisher’s exact test, as appropriate. Changes in ROM, amplitude height, and specimen
16 height were assessed using Wilcoxon Test.
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31 Data are presented as medians and interquartile ranges (IQ), or counts and percentages (*n*, %).
32 All statistics were two-tailed and a *p*-value <0.05 was considered significant.
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40 **3. Results**

41 *Characteristics of the study preparations*

42 The median age of the body donors was 80 (IQ: 73.5-85) years at the time of death. In total,
43 specimens were taken from 10 women and 6 men. The median bone density value was 87.2
44 (IQ: 71.2-104.5) mg/cc dipotassium hydrogen phosphate (K₂HPO₄). In the Harms group the
45 median bone density was 89.5 (IQ: 66-115.9) mg/cc K₂HPO₄. The median age in this group
46 was 82 (IQ: 74-84) years with preparations from 5 female and 3 male donors (Table 1). In the
47 OG group the median age was 78 (72-88) years with a bone mineral density of 87.4 (IQ: 66.4-
48 110.1) mg/cc K₂HPO₄. As in the other group, the preparations were donated by 5 women and
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3 men (Table 1). Both groups were statistically comparable with respect to bone density ($p = 0.96$).

Results of the biomechanical tests

- ROM before and after the loading tests

ROM was markedly lower in the Harms than the odontoid screw group before and after loading (Figure 1). In flexion/extension, an increase in ROM after loading tests was observed in all specimens (flexion/extension before loading – OG vs. HG: 21.7° vs. 4.8° , $p = 0.003$; flexion/extension after loading – OG vs. HG: 31.6° vs. 7.8° , $p = 0.002$), mainly in the odontoid screw specimens (Flexion: 9.3° vs. 18.5° , $p = 0.012$, Extension: 10.6° vs. 13.3° , $p = 0.028$).

In lateral bending, significantly lower ROMs were measured for all specimens compared to flexion/extension. Likewise, ROM was lower during lateral bending in the Harms than the odontoid screw group before and after loading (Figure 1). A significant increase in ROM after loading tests was observed in all specimens (lateral bending before loading – OG vs. HG: 5.3° vs. 0.9° , $p = 0.003$; lateral bending after loading – OG vs. HG: 12.4° vs. 1.8° , $p = 0.009$).

In axial rotation, the clearest difference between odontoid screw preparations and Harms preparations was found with regard to their mobility. Higher range of motion was observed for odontoid screw preparations before and after loading state compared to Harms preparations (axial rotation before loading – OG vs. HG: 43.8° vs. 1.3° , $p < 0.001$; axial rotation after loading – OG vs. HG: 66.7° vs. 1.7° , $p = 0.001$).

- Change in specimen height and amplitude height during repetitive loading

During loading in the material testing machine, the constant pressure caused a decrease of the specimen height. The decrease in height of the odontoid screw group and the Harms group

1 was approximately in the same range (Table 2). A significant difference between the two
2 surgical methods was found in the low force range. This difference was evened out at higher
3 force values (Table 2).
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7 A similar behavior of odontoid screw preparations and Harms preparations was observed
8 during loading concerning amplitude height measurements, however, no significant
9 differences were found between the two groups (Table 3).
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18 *Computed tomography after loading tests*

19 Computed tomography revealed similar outcomes with regard to the screw loosening rate
20 between the odontoid screw and Harms groups (62.5 vs. 87.5 %, $p=0.586$).
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29 **4. Discussion**

30 In our study we found that the biomechanical stability was similar between a cement-
31 augmented odontoid screw and dorsal stabilization according to Harms in C1/2 in geriatric
32 patients.
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38 According to the literature, the odontoid fracture is one of the most common cervical fractures
39 in elderly patients and one of the most isolated fractures of the spine in geriatric patients[13-
40 15]. Neurological deficits are rare due to the relatively wide spinal canal in this area of the
41 spine[16]. Type II fractures according to Anderson&d'Alonzo account for as much as 95% of
42 the elderly population[17]. Operative or conservative therapies are associated with high
43 mortality[14]. Recent studies showed that surgical therapy can lead to a reduction in mortality
44 rates[18]. In addition, it has been shown that surgical therapy increases functional outcome
45 compared to conservative therapy. For this reason, many authors recommend that the surgical
46 procedure should always be considered in case of an odontoid fracture in elderly patients[19].
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60 Overall the optimal treatment of the fracture in elderly patients is unclear[20].
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1 Surgical options for the treatment of an odontoid fracture type IIb are on the one hand the
2 ventrally implanted odontoid screw and on the other hand a dorsal fusion, e.g. according to
3 Magerl or Harms. Fusion rates in the dorsal stabilization from C1 to C2 are almost 100% with
4 the major disadvantage that the movement, especially the rotation in the joint, is diminished.
5 This results in a significant restriction of the mobility of the cervical spine. The potential
6 advantages of a lag screw osteosynthesis are the relatively low invasiveness and the
7 preservation of the rotation of the C1/2 joint, however, these may be outweighed by the
8 possible high degree of screw loosening in patients with a low bone mineral density[21]. One
9 possibility to reduce the loosening rate is an additional augmentation of the lag screw with
10 cement. We have already been able to demonstrate this in a biomechanical study and in the
11 clinical practice[7, 22, 23]. In our study, we compared both surgical methods with the
12 background that if the examination results are approximately equivalent, lag screw
13 osteosynthesis is recommended for type IIb fractures. This surgical method does not restrict
14 the mobility of the cervical spine.

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In the course of our studies, we have applied a steadily increasing cyclical load to the specimens and imitated a circular motion similar to that which occurs during rotational movements of the head.

Before loading of the specimens, we measured flexion/extension, lateral bending and rotation using a spine tester. In this study we were able to confirm that specimens with lag screw osteosynthesis do not result in any significant limitation of movement compared to physiological preparations. Specimens that were fused by a dorsal C1/2 spondylodesis tended towards zero with their degree of movement in all directions.

1 After loading of all specimens in a cyclic loading test, similar results were found in both
2 groups operated on. A difference of 15% in favor of the Harms group, which was statistically
3 not significant, could only be detected in the postinterventional computed tomography.
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7 Regarding to the literature and our results the dorsal C1/2 fusion is the most stable. The
8 cement-augmented odontoid screw osteosynthesis, however, shows similar test values in
9 some phases and has the great advantage that there is no limitation of movement as occurs
10 with the dorsal fusion.
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17 **Study limitations**

18 A limitation of the study is that it was not possible to determine the exact time of screw
19 loosening. One possibility would have been to remove the specimen from the cyclic load
20 simulator after each loading cycle and to examine the bone structure around the screw in a
21 micro-CT. This would have made it possible to determine the exact degree of loosening after
22 each cycle. Furthermore, this was not practical because of time constrains and due to the large
23 height of the embedded specimen and the small size of the micro-CT, it was not possible to
24 examine the specimen after each cycle without damaging it further.
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44 **Conclusion**

45 A summary of the findings obtained shows that dorsal fusion according to Harms is the more
46 stable construction for the treatment of odontoid type IIb fractures. However, the cement-
47 augmented odontoid screw may show similar values in the load tests with additional
48 preservation of cervical mobility. Accordingly, the cement-augmented lag screw
49 osteosynthesis may be considered in patients with reduced bone density and a type IIb
50 fracture.
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3 In future studies, it would be advisable to examine the data obtained in vivo. In two
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5 prospective, randomized groups (cement-augmented lag screw vs. dorsal fusion) of geriatric
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7 patients with reduced bone mineral density and a type IIb fracture, quality of life, fusion rates,
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9 mortality/morbidity rates should be compared.
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11 12 13 **References**

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Figure legends:

Figure 1: Radiographic images of a surgically treated odontoid fracture with a cement-augmented odontoid screw; sagittal (left) and coronary view (right).

Figure 2: Sagittal radiographic images of a surgically treated odontoid fracture with a spondylodesis according to Harms.

Figure 3: Bar charts representing the median range of motion (ROM) of odontoid screw group (OG) and Harms group (HG) before and after loading in extension/flexion (panel 1), lateral bending (panel 2), and axial rotation (panel 3).

Tab. 1: Characteristics of the donors and bone mineral density (BMD) of the related preparations

Donor	Sex	Age	BMD in mg/cc K ₂ HPO ₄
Harms group			
1	M	73	92.7
2	W	82	93.7
3	W	68	132.1
4	W	82	86.2
5	M	85	62.8
6	M	92	123.3
7	W	78	65.2
8	W	82	68.5
Odontoid screw group			
9	W	85	58.1
10	W	72	116.1
11	W	76	87.6
12	M	80	138.3
13	W	90	92.1
14	W	74	87.1
15	M	70	62.8
16	M	91	77.1

Tab. 2: Specimen height in both groups as a function of compressive force

Specimen height, mm, median, (IQ)	Compressive force in Newton										
	200	300	400	500	600	700	800	900	1000	1100	1200
Odontoid screw group	34 (31-35)	33 (31-34)	33 (30-33)	32 (30-33)	31 (29-32)	30 (28-32)	29 (28-32)	29 (27-31)	28 (26-30)	27 (26-29)	27 (26-28)
Harms group in mm	31 (27-32)	30 (26-31)	30 (26-31)	29 (25-30)	29 (25-30)	28 (25-29)	28 (24-28)	27 (24-28)	27 (23-27)	26 (23-27)	26 (22-27)
p-value	.003	.007	.021	.065	.065	.161	.161	.105	.105	.161	.234

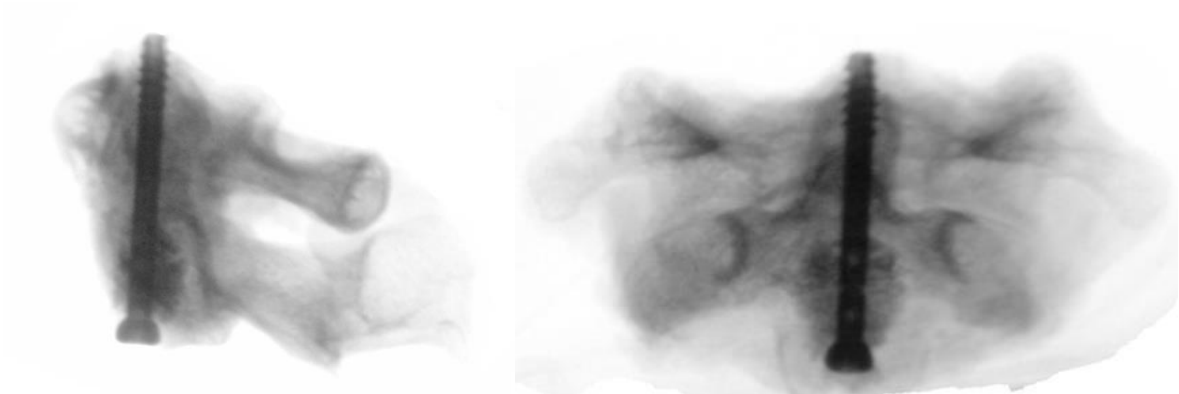
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Tab. 3: Amplitude height in both groups as a function of the compressive force

	Compressive force in N										
	200	300	400	500	600	700	800	900	1000	1100	1200
Amplitude height, mm, median (IQ)											
Odontoid screw group	4.2 (3.1-5.4)	4.4 (3.5-4)	4.4 (3.3-5.4)	4.5 (4.1-5.3)	4.5 (3.8-5.4)	4.8 (3.6-5.6)	4.8 (3.8-5.5)	4.7 (3.9-5.7)	4.5 (3.8-5.4)	4.7 (3.5-5.4)	4.9 (4.1-5.7)
Harms group in mm	3 (2.7-4.1)	3.5 (3.2-4.1)	3.9 (3.2-4.1)	4.3 (3.7-5.3)	4.4 (4.5-8)	4.7 (4.3-5.3)	4.7 (4.3-5.8)	5 (4.6,6)	5.2 (3.9-7.3)	5.4 (4.7.7)	5.5 (4.3-7.9)
p-value	.505	.574	.645	.879	.799	1.000	.798	.798	.645	.382	.505

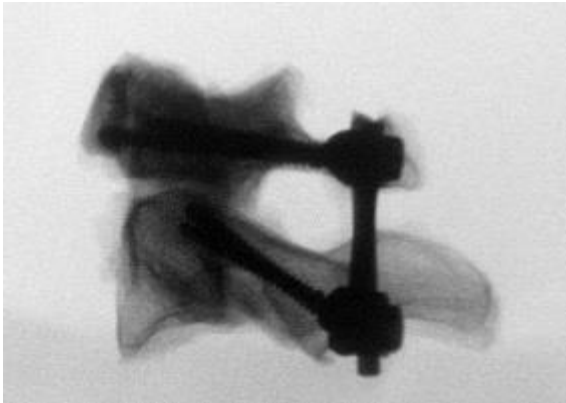
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Figure 1:



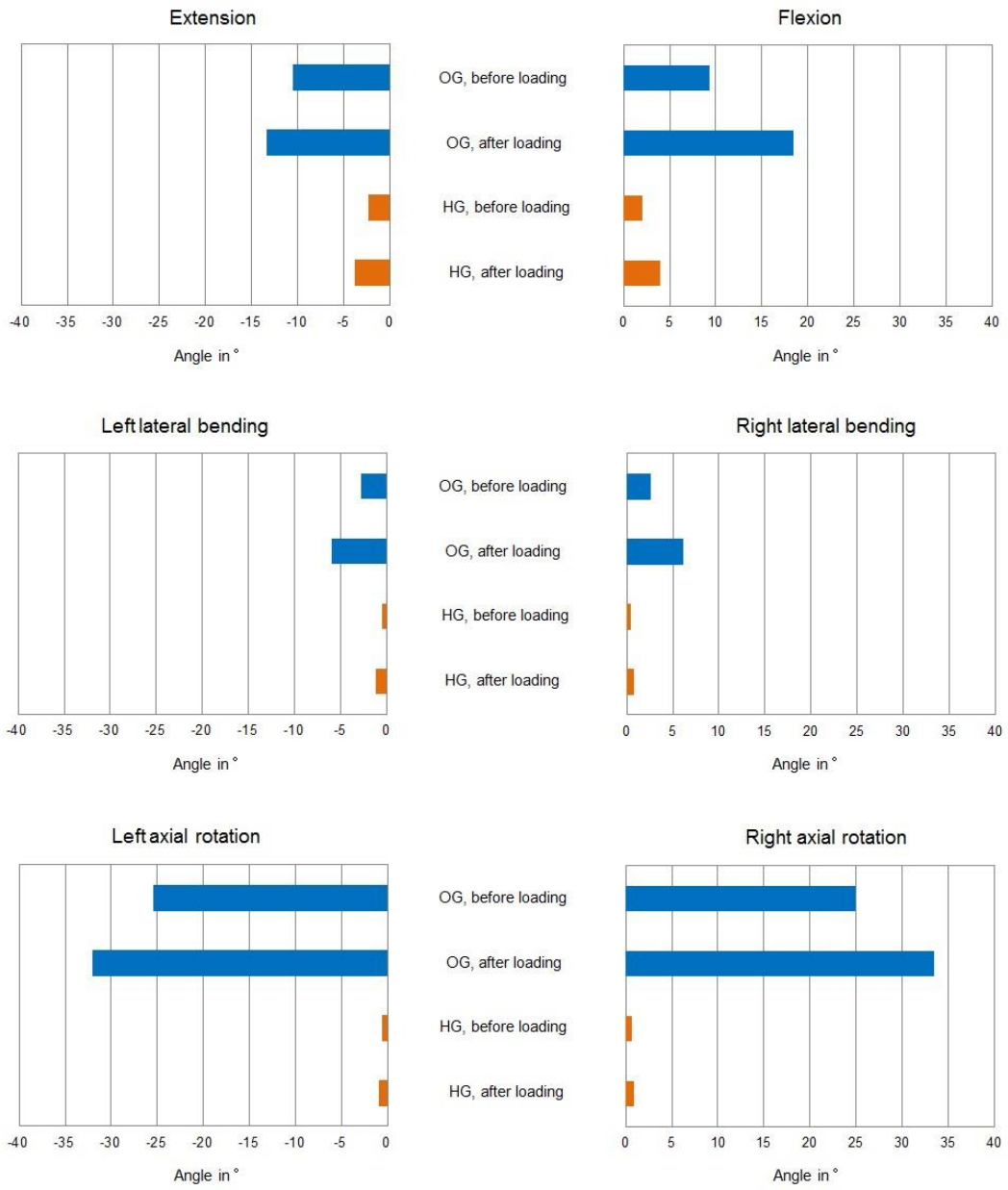
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Figure 2



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2 **Figure 3**
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Category of disclosure	Description of Interest/Arrangement

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Posterior-Instrumented Fusion in Geriatric Patients with an odontoid

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