

In vitro investigation of a new dynamic cervical implant: comparison to spinal fusion and total disc replacement

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Abstract

Purpose and methods For the treatment of degenerative disc diseases of the cervical spine, anterior cervical discectomy and fusion (ACDF) still represents the standard procedure. However, long term clinical studies have shown a higher incidence of pathologies in the adjacent segments. As an alternative to spinal fusion, cervical total disc replacement (cTDR) or dynamically implants were increasingly used. This in vitro study analyzed the kinematics and intradiscal pressures in seven multi-segmental human cervical spine using hybrid multidirectional test method. The aim of our study was to compare the intact condition with a single-level dynamic stabilization with DCI[®], with cTDR (activC[®]) and with simulated ACDF (CeSPACE[®] cage and CASPAR plate).

Results No significant changes in the kinematics and pressures were observed in all segments after arthroplasty. The DCI[®] significantly decreased the motion of the treated segment in flexion/extension and lateral bending with some remaining residual mobility. Thereby the motion of the upper segment was increased significantly in flexion/extension. No significant changes of the intradiscal pressures were observed. With simulated fusion the motion of the indexed level was significantly decreased in flexion/extension and axial rotation with the greatest changes in the adjacent levels and the highest pressures.

Conclusion Based on our biomechanical study the DCI[®] can pose an alternative to fusion, which has a lesser effect on adjacent levels. This might reduce the risk of long-term degeneration in those levels. In particular, the facet joint arthritis and kyphotic deformity, as a contraindication to the arthroplasty, could be a clinical application of the dynamic implant.

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Introduction

Anterior cervical discectomy and fusion (ACDF) and cervical total disc replacement (cTDR) are two concurrent options in treatment of degenerative disc disease. Biomechanical studies have shown that arthrodesis of the cervical spine leads to an increase in the segmental range of motion (ROM) and the intradiscal pressure (IDP) in the levels proximal and distal to a simulated mono- or bisegmental fusion [1–3]. In contrast, when treated by arthroplasty, the kinematics in the target segment as well as in the

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neighboring segments reach near to physiologic state, indicating an almost physiologic restoration of the affected motion segments [1, 2, 4].

From a clinical point of view, patients with a history of cervical arthrodesis have a higher incidence of adjacent segment degeneration [5, 6]. Controlled clinical trials with a prospective and randomized study design have published the results after 4- to 5-year follow-up. They show at least comparable or even better findings after cTDR in contrast to ACDF with a lower reoperation rate after arthroplasty [7, 8].

Accepted contraindications for cTDR are osteoporotic bone and cervical instability [9]. Furthermore, segmental kyphosis and symptomatic facet joint arthrosis are reported as contraindications for arthroplasty, because first disc prosthesis are not able to restore a pathologic kyphotic sagittal profile and second the facet joints are expected to be overstressed mainly in extension due to preservation of normal ROM with cTDR [9].

Another treatment option, so called dynamical implants, has been proposed by several manufactures. The aim of these devices is to provide stability but at the same time reduce adjacent segment degeneration by providing some motion in the stabilized segment. One such device is the dynamic cervical implant (DCI[®], Paradigm Spine, Germany), which is a single-piece design of titanium alloy. The DCI[®] was developed to bridge the gap between fusion and disc arthroplasty by addressing the potential downsides of fusion and by offering the advantages of motion preservation.

The aim of our experimental study was to analyze the kinematics and intradiscal pressures in a multi-segmental human cervical spine model after single-level dynamic stabilization with DCI[®] in comparison to the intact condition and after simulated ACDF and cTDR. We hypothesized that the stabilizing capabilities of the dynamical cervical implant put the DCI[®] between fusion and prosthesis regarding motion in the treated segment and adjacent level effect on motion and pressure.

Materials and methods

Specimen preparation

The study was conducted on seven, five female and two male, multi-segmental human cervical spine specimens [C4–C7; median age 59.5 years (27–73 years), median weight 54.4 kg (38.5–104.3 kg), median bone mineral density 0.62 g/cm² (0.47–0.89 g/cm²)]. The specimens were radiologically screened before testing and an experienced surgeon (DD) evaluated the state of the disc to exclude specimens with degenerated intervertebral

discs. All extraneous soft tissue was dissected, leaving the ligamentous structures including the intervertebral discs intact. The proximal (C4) and distal (C7) ends of the vertebrae were embedded in casting resin (Rencast FC52/53, göss&pfaff, Germany). Optical markers for the tracking system (Polaris P4, NDI, Canada) were rigidly attached to the vertebral bodies (Fig. 1). To apply a compressive preload the follower load technique was used, with loading frames attached to C4, C5 and C6 [10]. The follower load was applied bilaterally at C4 by two steel cables, which passed freely through guides of the lower two loading frames. The path of the follower load was adjusted to the contour of the spinal column and to the rotation center of each motion segment in the sagittal plane. Pressure sensors (Type FMSPEZ10, MIPM GmbH, Germany) were placed in the nucleus pulposus of C4/5 and C6/7 under fluoroscopic control to measure intradiscal pressure.

Test setup

The specimens were loaded with the hybrid multidirectional test method [11]. Hereby, the specimens subjected to a constant follower load of 120 N were loaded in the intact state with pure moment loadings sequentially in flexion and extension (*x*-axis), lateral bending (*z*-axis), and axial rotation (*y*-axis). The resulting total range of motion (tROM), total neutral zone (tNZ) in all motion segments, as well as the IDP in C4/5 and C6/7 were measured. The testing device consisted of a sensor-guided robotic system (robot system: KR15/1, KUKA, Germany; sensor: KMS 60, IpeA GmbH, Germany, Fig. 1) and a servo-hydraulic system with force controlled actuators (Type 8417-6005, Burster, Germany) [12]. The robot is used as a manipulator and capable of applying unconstrained rotational moments about three axes according to the standard flexibility test protocol [13]. The rotational velocity of the robot was 0.2 deg/s for all tested directions. The cranial vertebra C4 was fixed to the sensor of the robotic system and the caudal vertebra was mounted on a rigid base. The kinematic and kinetic of the whole specimen were recorded by the robotic system. The intersegmental range of motion (iROM) and intersegmental neutral zone (iNZ) were measured by the optical tracking system. Local coordinate systems were defined with a digitizing probe for each vertebra according to the recommendation of Crawford et al. [14]. The kinematic data were collected together with the values for the low-pass filtered IDP using a custom-made program (LabView 2010, NI, USA). As the range of the pressure sensor is limited (measuring range up to 1 MPa), an offset was performed in situ in neutral position under follower load. Thus reported pressure values represent change in intradiscal pressure.

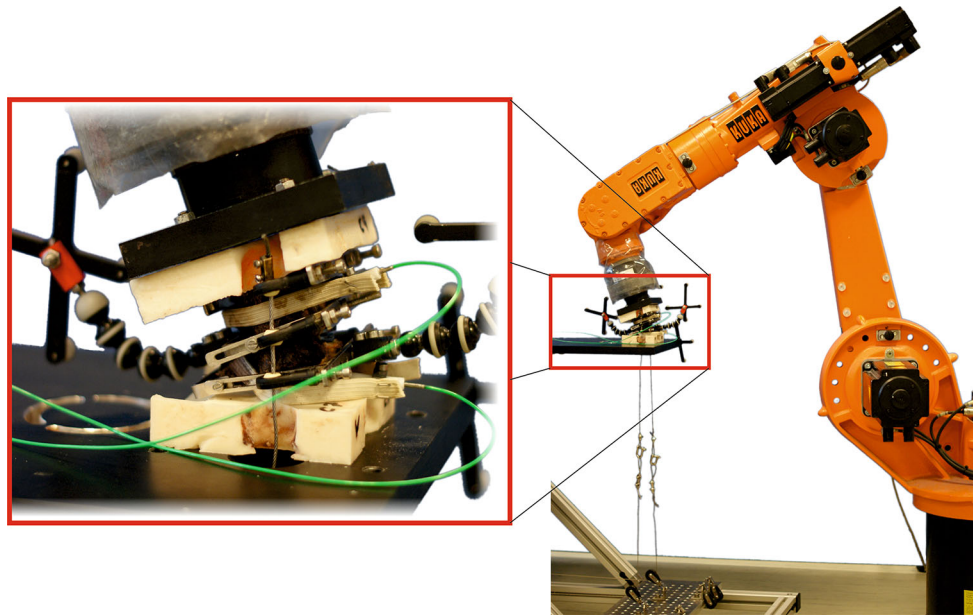


Fig. 1 Test setup: Six-axis robot KR-15 (*right*) applying pure moment on the specimen (*left*). Wires connected to hydraulic cylinders apply a follower load of 120 N, reflective markers aid in

measuring motion and green wires are connected to pressure sensors in the adjacent level intervertebral discs

Reconstructive conditions and test protocol

The specimens were first tested in an intact state with ± 2.0 Nm of pure moment loading about the respective testing axis. After (1) a complete discectomy at C5/6, the specimen was subsequently tested with (2) dynamical cervical implant DI (DCI[®] Paradigm Spine, Germany), (3) arthroplasty cTDR (activC[®] artificial disc, Aesculap AG, Germany) and (4) fusion ACDF (cervical cage CeSPACE[®] and an anterior CASPAR plate stabilization, both Aesculap AG, Germany). Thereby the posterior longitudinal ligament was kept intact to preserve the stability. All surgeries were performed by an experienced spine surgeon (DD) and according to manufacturer's instructions. The three treated conditions had ap and lateral radiographs to check their correct position in the intervertebral space (Fig. 2). In the treated states, the specimens were tested until the tROM of the treated spinal construct was equal to the total range of motion of the intact state. Thus the applied moments were different depending on the treatment. The percentage changes of the iROM were calculated using the hybrid test method to evaluate the effects on the adjacent and indexed levels when comparing the treated to the intact state ($iROM_{change} = (iROM_{treated} - iROM_{intact})/iROM_{intact}$) [11].

Data and statistical analysis

According to the recommended standard protocol three test cycles were carried out for each condition and the third

cycle was used for the analysis [13]. The Wilcoxon matched-pairs signed rank test was performed using SPSS (SPSS Statistics 20, IBM, USA) to determine the significant changes of the three treated conditions (cTDR, dynamic cervical implant, fusion) to the intact state. A significance level of $\alpha = 0.05$ was applied. Due to the limited sample size no Bonferroni correction was used.

Results

All the seven tested specimens could be fully tested in all conditions.

Flexion/extension

Mean tROM in all tested conditions was $38.7 \pm 9.4^\circ$ (Fig. 3), whereby the largest contribution of movement was observed in the most cranial segment C4/5.

The implantation of the DI leads to a significant 25 % increase of required moment ($p = 0.016$) to achieve intact tROM in flexion, while iROM of C4/5 was significantly increased ($p = 0.016$) and of C5/6 was significantly decreased ($p = 0.016$). The tNZ and iNZ of the indexed level C5/6 were not significantly affected and IDP increased only slightly. With implantation of the cTDR, no significant changes in iROM, tNZ, iNZ, required moment and IDP occur. The application of the ACDF resulted in a significant 66 % increase in required moment ($p = 0.016$) and a

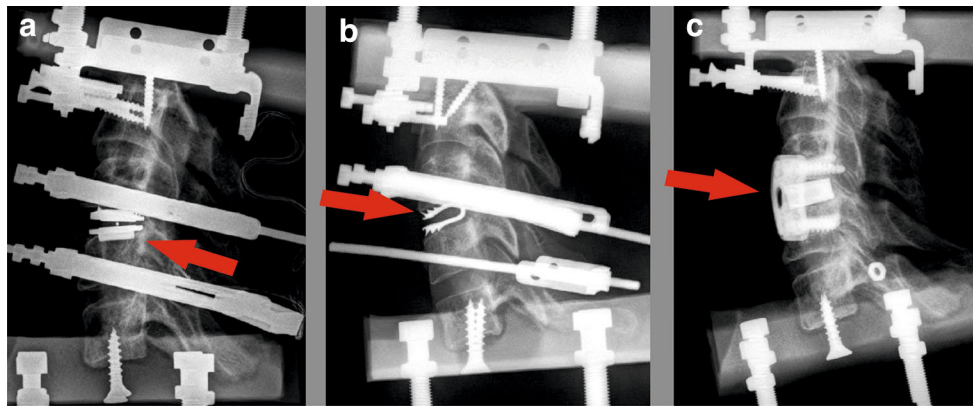


Fig. 2 Lateral radiographs of the treated spine specimen. **a** activ[®] C total disc replacement. **b** DCI[®] device. **c** CeSPACE[®] and Caspar plate fusion. The red markers indicate the respective implant

significant increase of iROM in C4/5 ($p = 0.016$) and C6/7 ($p = 0.031$) and a decrease in C5/6 ($p = 0.016$). IDP in C6/7 also increases significantly ($p = 0.047$) (Tables 1, 2, 3).

Lateral bending

Mean tROM in all tested conditions was $12.5 \pm 6.7^\circ$ (Fig. 3).

The implantation of the DI leads to a significant 20 % increase of required moment ($p = 0.031$) to achieve intact ROM on the right side, while iROM of C5/6 is significantly decreased ($p = 0.031$). The tNZ and iNZ are not significantly affected and IDP increases slightly. With implantation of the cTDR, no significant changes in iROM, tNZ, iNZ, required moment and IDP occur. The application of the ACDF resulted in no significant changes in iROM, tNZ, iNZ, required moment and IDP (Tables 1, 2, 3).

Axial rotation

Mean tROM in all tested conditions was $12.2 \pm 6.2^\circ$ (Fig. 3).

With implantation of the DI or cTDR prosthesis, no significant changes in iROM, tNZ, iNZ, required moment and IDP occur. The application of the ACDF resulted in a significant decrease of iROM in C5/6 ($p = 0.047$) and a significant increase in C6/7 ($p = 0.016$). The tNZ, iNZ, required moment and IDP did not change significantly (Tables 1, 2, 3).

Discussion

The aim of the presented in vitro study was to determine and to compare the effects of different stabilization treatments on the biomechanics of the affected and adjacent

spinal motion segments. The tests were conducted on human multi-segmental specimens using the hybrid test method [11] to analyze the biomechanical behavior of a cTDR, dynamical cervical implant and spinal fusion on the adjacent motion segments. As it is a motion preserving technology, we found that the artificial disc (cTDR) had no significant effect on the kinematics and intradiscal pressures in all motion directions tested. The dynamical implant (DI) stabilized the treated segment in flexion/extension and lateral bending. The iROM in treated segment C5/6 was significantly reduced by the DI while allowing residual mobility. The spinal fusion (ACDF) showed the greatest effects on the tested kinematics and intradiscal pressures in the upper and lower adjacent levels.

Anterior cervical discectomy and fusion is currently the standard procedure for the treatment of most degenerative disc disease in the cervical spine. However, clinical long-term studies have shown evidence of an increased incidence of pathologies in the motion segments adjacent the fused segment [5, 6]. Our testing protocol showed that the reduced iROM in the ACDF treated C5/6 was compensated by increased motion in the adjacent levels. In our study, the cranial segment (C4/5) compensated motion in flexion/extension and lateral bending slightly more than the caudal segment C6/7. Due to the postoperative state in the in vitro setup some residual motion is still remaining in the treated segment. This is a common limitation of in vitro studies in which the stabilizing bony ingrowth could not be simulated. Next to the greatest changes in the kinematics of the adjacent levels, the highest values for the intradiscal pressures were observed after spinal fusion for all treated conditions except for IDP in C6/7 in lateral bending and axial rotation. The stiffness of the whole specimens increased after ACDF in all three tested directions, as reflected by the increase in the applied

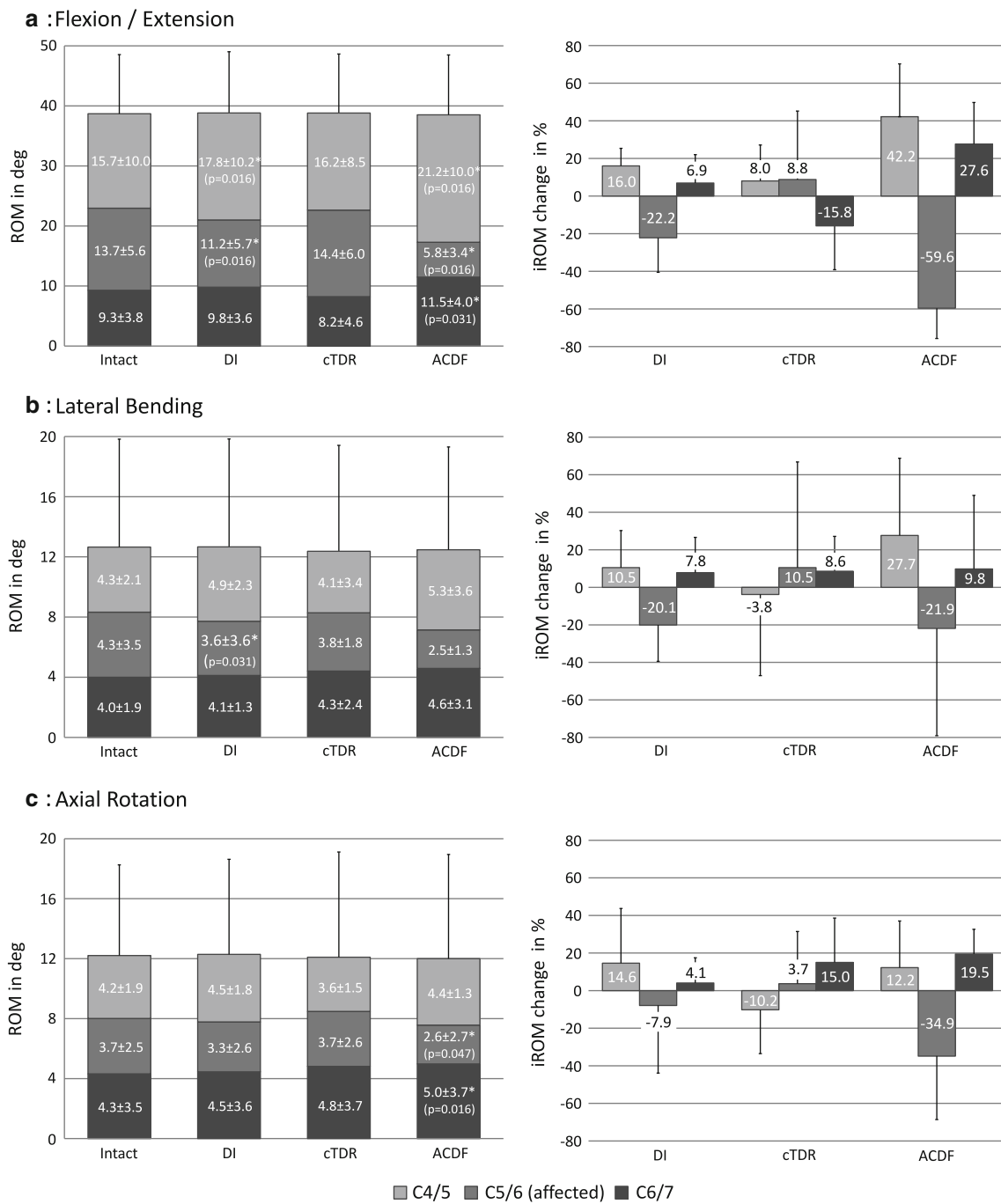


Fig. 3 ROM (left) and percentage change of iROM (right) in different directions in four testing conditions with applied follower load of 120 N. Results from upper level C4/5 are colored in light grey, the affected level C5/6 in medium grey and lower level C6/7 in dark grey

moment required to reach the tROM of the intact state (up to 66 % in flexion). This is due to the fact that motion segment stiffness increases non-linearly with increasing flexion angle. As the adjacent segments are forced to compensate for the motion lost in the treated segment, the required moment to reach physiologic tROM is increased. Nonetheless, although iROM of the

adjacent levels increases, it is still within physiological range reported in the literature [15].

The arthroplasty had the smallest effect on the intersegmental range of motion of the treated segment in all tested directions. In lateral bending the iROM even decreased, which is in accordance to a similar study by Patwardhan et al. [16]. Although investigating a slightly different prosthesis

Table 1 Mean moments (and standard deviation) required for reaching tROM of the intact case in each direction in Nm

| Direction | Intact | DI | cTDR | ACDF |
|-----------------------|-----------------|------------------|-----------------|-----------------|
| Flexion | 1.95 (SD 0.18) | 2.45 (SD 0.67)* | 1.93 (SD 0.76) | 3.24 (SD 0.53)* |
| Extension | −1.91 (SD 0.22) | −2.06 (SD 0.69) | −1.86 (SD 0.88) | −1.98 (SD 0.47) |
| Lateral bending left | 1.99 (SD 0.07) | 2.22 (SD 0.47) | 1.87 (SD 0.65) | 2.24 (SD 0.74) |
| Lateral bending right | −1.92 (SD 0.13) | −2.30 (SD 0.27)* | −2.23 (SD 0.77) | −2.50 (SD 0.97) |
| Axial rotation left | 1.96 (SD 0.04) | 2.04 (SD 0.31) | 2.08 (SD 0.51) | 2.28 (SD 0.69) |
| Axial rotation right | −1.96 (SD 0.09) | −2.05 (SD 0.28) | −1.87 (SD 0.39) | −2.13 (SD 0.47) |

In the intact case the moment limits were set to ± 2.0 Nm

Asterisks denote values significantly different from intact configuration (alpha = 0.05)

Table 2 Mean intersegmental neutral zone of the indexed level C5/6 and total neutral zone of the whole specimen C4–C7 (and standard deviation) for the intact and the three treated conditions in degree

| Direction | Level | Intact | DI | cTDR | ACDF |
|-------------------|-------|----------------|----------------|----------------|----------------|
| Flexion/extension | C5/6 | 0.78 (SD 0.45) | 0.66 (SD 0.71) | 1.38 (SD 1.69) | 1.02 (SD 1.69) |
| | C4–C7 | 4.15 (SD 3.14) | 4.43 (SD 4.42) | 4.92 (SD 4.57) | 5.35 (SD 3.94) |
| Lateral bending | C5/6 | 2.14 (SD 2.51) | 1.76 (SD 2.93) | 2.02 (SD 1.73) | 0.61 (SD 0.74) |
| | C4–C7 | 4.61 (SD 3.69) | 4.84 (SD 4.58) | 4.70 (SD 3.46) | 4.36 (SD 3.06) |
| Axial rotation | C5/6 | 0.58 (SD 0.58) | 0.48 (SD 0.41) | 0.51 (SD 0.37) | 0.40 (SD 0.40) |
| | C4–C7 | 3.22 (SD 3.01) | 3.24 (SD 1.95) | 3.57 (SD 3.28) | 3.12 (SD 2.04) |

In the intact case the moment limits were set to ± 2.0 Nm

Table 3 Maximum IDP (and standard deviation) in each direction for the upper (C4/5) and lower (C6/7) cervical disc in MPa

| Direction | Cervical disk | Intact | DI | cTDR | ACDF |
|-------------------|---------------|----------------|----------------|----------------|-----------------|
| Flexion/extension | C4/5 | 0.46 (SD 0.11) | 0.49 (SD 0.15) | 0.51 (SD 0.14) | 0.59 (SD 0.22) |
| | C6/7 | 0.47 (SD 0.24) | 0.50 (SD 0.20) | 0.38 (SD 0.13) | 0.64 (SD 0.28)* |
| Lateral bending | C4/5 | 0.28 (SD 0.09) | 0.33 (SD 0.14) | 0.36 (SD 0.16) | 0.36 (SD 0.15) |
| | C6/7 | 0.28 (SD 0.23) | 0.23 (SD 0.08) | 0.19 (SD 0.10) | 0.26 (SD 0.09) |
| Axial rotation | C4/5 | 0.15 (SD 0.08) | 0.16 (SD 0.08) | 0.21 (SD 0.11) | 0.24 (SD 0.16) |
| | C6/7 | 0.19 (SD 0.12) | 0.15 (SD 0.09) | 0.22 (SD 0.14) | 0.18 (SD 0.13) |

Asterisks denote values significantly different from intact configuration (alpha = 0.05)

design, they found a significant increase of adjacent level iROM in flexion–extension and axial rotation. We observed no hypermobility in any direction, which is in contrast to a study by Chang et al., who found an increased iROM in two different prosthesis designs (ProDisc-C and Prestige) [17]. This hypermobility may partly be caused by the loss of the anterior longitudinal ligament due to the surgical approach. In our case, this may be partly stabilized by the follower load. On the other hand, McAfee et al. found no significant differences in iROM of a motion preserving implant with intact or resected posterior longitudinal ligament [18]. In a clinical study, the same cervical disc prosthesis as used in our study did show a decrease in flexion/extension from 9.8° post-op to 6.4° after 2 years [19].

The DI implant had the most homogenous effects of all treatments in all directions. The affected segment was stabilized as indicated by a significant decrease of iROM in flexion–extension and lateral bending. The moments required to reach intact tROM in flexion and lateral

bending were between moments for the prosthesis and fusion. The IDP of the C4/5 segment, however, was the lowest of all treated conditions. It might be due to a load transfer to the facet joints with an anterior shift of the center of rotation, as shown computer simulation by Mo et al. [20]. Their study also revealed a constant IDP in C4/5 during different conditions. Clinically, Wang et al. found a slight increase in flexion–extension iROM of the DI from 12.2° post-op to 13.6° at 2 years follow-up [21]. Additionally, Matgé et al. found a satisfying motion preservation at 2 years follow-up with only −5.5 % change of iROM in the indexed level [22].

The intersegmental neutral zone, as a parameter for instability, showed a stabilizing effect for the DI and ACDF in the treated segment. Due to the immediate post-operative condition the authors expect the stabilizing effect of the ACDF to further increase in the clinical situation a few weeks post-operative because of the bony ingrowth. The cTDR does not show a stabilizing effect in the iNZ.

There are several limitations to this study that must be acknowledged. As common with biomechanical in vitro test, only the immediate post-operative condition is represented. Thus, the bony ingrowth of implants is not considered. Especially in the case of the DI in axial rotation a relative motion between implant and bone cannot be ruled out. In the case of fusion, the uncommon configuration of plate and cage had to be chosen to assure additional stiffness in all directions. The hybrid test method used is one of many published methods for in vitro multi-segment spine testing. Other accepted standards are the flexibility test method [23], the pure moment method or the multi-directional test method of Panjabi [11]. We used the hybrid method to investigate the effect on the indexed and adjacent levels, but this is discussed controversially [24, 25]. The authors decided to use the hybrid method as the most suited protocol to determine the adjacent level effects. As the bending stiffness of the multisegmental specimen is nonlinearly distributed along the cranio-caudal axis it is not predictable how the motion change of the affected level will be compensated by the upper and lower level. The utilized follower load used in all directions represents a static model of compressive axial forces, but the line of action of the follower load needs to be precisely adjusted as we have done to avoid additional bending moment artefacts that would confound the results [26]. Furthermore the applied loading rate of 0.2 deg/s was below recommended threshold of 0.5 deg/s to keep shear forces from robot control to a minimum [13].

In summary, our study is the first biomechanical in vitro study on the dynamical stabilization implant DI. In clinical cases where a cTDR is contraindicated because of kyphotic deformities or facet joint arthritis, the novel dynamical cervical implant can pose an alternative to fusion, which has a lesser effect on adjacent levels. This might reduce the risk of long-term degeneration in those levels. First clinical studies have been promising, but long-term observations need to confirm these findings [22, 27, 28].

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Compliance with ethical standards

Conflict of interest The corresponding author BW received honoraria for lectures during two workshops of the Paradigm Spine GmbH.

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