

## Assessment of adjacent-segment mobility after cervical disc replacement versus fusion: RCT with 1 year's results

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**Abstract** Disc prostheses have been designed to restore and maintain cervical segmental motion and reduce the accelerated degeneration of the adjacent level. There is no knowledge about the reaction of the neighbored asymptomatic segments after implantation of prostheses or fusion. The effects of these procedures to segmental movement of the uninvolved vertebrae have not been subjected to studies so far. The objective of this study was to compare the segmental motion following cervical disc replacement versus fusion and the correlation to the clinical outcome. Another aim was to compare the segmental motion of the asymptomatic segments above the treated ones and to compare both with Roentgen stereometric analysis (RSA) including the asymptomatic segments. 20 patients with one-level cervical radiculopathy scheduled for surgery were randomized to arthroplasty (10 patients, study group) or anterior cervical discectomy and fusion (10 patients, control group). Clinical results were evaluated using Visual Analogue Scale and Neck Disability Index. RSA was performed immediately postoperative, after 6 and 12 months. The adjacent segment showed a significantly

higher segmental motion in all three-dimensional axes in comparison to the segment treated with prostheses ( $P < 0.05$ ). In the fusion group the segmental motion of the adjacent segment was significantly higher in all three-dimensional axes ( $P < 0.05$ ) at each examination time. When the adjacent level of both groups is compared, the fusion group could show a higher segmental motion in all three-dimensional axes, but without significant difference ( $P > 0.05$ ) 1 year after surgery. Regarding the clinical results, there was no significant difference in pain relief between both groups ( $P > 0.05$ ). In conclusion, the adjacent segment could show a higher segmental motion, when compared with the segment either treated with prostheses or fusion. There was no significant difference in segmental motion adjacent to prosthesis or fusion. Clinical results did also show no significant difference in pain relief between both groups.

**Keywords** Spine · Arthroplasty · Adjacent disc disease · Motion · RSA

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### Introduction

Anterior cervical discectomy and fusion (ACDF) is up to now the most common procedure for symptomatic degenerative cervical disc disease [5, 17, 37]. Radiographic and clinical studies have shown that with time, the disc adjacent to the fused spinal segment occasionally degenerates or becomes unstable [1, 8, 17, 18, 24, 41, 47]. However, it is still debatable, whether cervical fusion creates an unfavourable biomechanical situation at adjacent levels causing accelerated disc degeneration or the actually observed degeneration of the adjacent segment is causally related to a natural development in a predisposed person.

There are many potentially important factors associated with the development of adjacent segment disease, starting with increased segmental motion, stress, load, and intradiscal pressure at levels adjacent to the fusion site [4, 6, 26, 33, 34, 43, 45, 46].

There is also a considerable number of authors who reported an increase in adjacent segment disease following anterior cervical fusion, indeed most of their studies were retrospective [10, 11, 14, 15, 28].

Hilibrand et al. [17] reported a large retrospective series in which patients underwent ACDF, and the authors concluded that symptomatic adjacent-segment disease occurred at a relatively constant incidence of 2.9% annually (in 18% of the single-level cases symptomatic cervical disc disease developed at the adjacent level). They predicted that in 25.6% of the patients who underwent anterior cervical fusion, new symptomatic disease would occur at an adjacent segment within 10 years of the operation.

Goffin et al. [11] showed that after at least a 60-month follow-up, they had a 6.11% reoperation rate due to symptomatic adjacent level degeneration.

Therefore, adjacent-segment disease has generated considerable interest, and a new implant, the disc prosthesis, is being developed in response to concerns about this disorder. Motion preservation procedures have become increasingly popular during the last years.

The primary goal for introducing cervical disc prostheses is to protect the patients from developing symptomatic adjacent disc disease by preserving motion.

Meanwhile there are many studies, which came to the results that disc replacement preserves segmental motion [2, 12, 13, 29, 30, 32]. However, the effect of motion preservation to the adjacent level is still unclear. Therefore, the aim of this current study was to determine the segmental motion following cervical disc replacement as well as the asymptomatic upper segment and compare both segmental motions with patients who received ACDF.

## Materials and methods

### Study design

This is a prospective randomized controlled study, approved by the local ethical committee of Saarland (Germany) Nr. 21/06.

Twenty patients [13 men and 7 women, mean age 43 years, standard deviation (SD) 9 years] suffering from symptomatic degenerative soft disc disease with single-level radiculopathy, not responding to a trial of conservative treatment were treated between January 2006 and August 2007. All patients have had confirmatory imaging

studies and were informed of the purpose of the study and given written informed consent at least 24 h before surgery. Randomization evolved by drawing cards in sealed envelopes. Ten patients received ACDF in single level with ABC titanium plate fixation (control group) and 10 patients received single-level disc replacement with ProDisc C prostheses (study group). Surgery was performed by one of the authors (A. N.). A standard left-sided anterior approach was performed; and the lateral parts of the annulus were preserved. However, the symptomatic disc and the posterior longitudinal ligament were removed. Either prosthesis or a titanium plate and a cage filled with Tribone were inserted according to the manufacturers' recommendation. Finally, 7–9 tantalum markers of 0.8-mm diameter (RSA Biomedical, Box 7972, S-907 19 Umea, Stockholm, Sweden) were placed into the vertebrae adjacent to the treated segment, as well as 4–5 into the adjacent asymptomatic upper segment (Fig. 1) [21].

Clinical symptoms such as cervical and brachial pain were investigated preoperatively and 1 week, as well as 6 and 12 months postoperatively. Visual analogue scale (VAS) was used for grading brachial pain. The Neck Disability Index (NDI) was used to assess cervical neck pain.

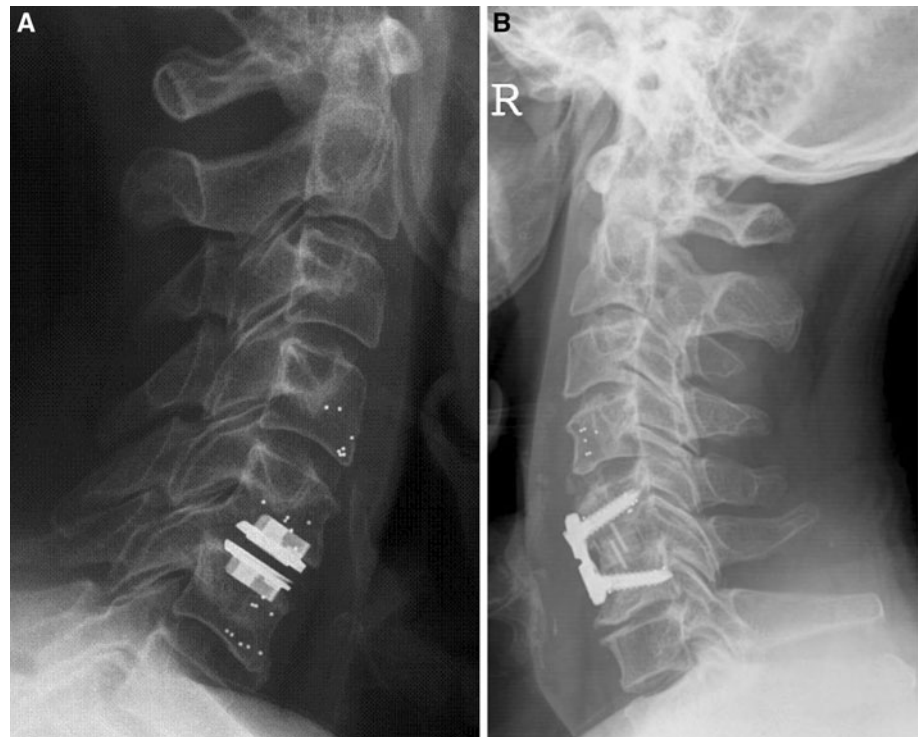
### Implants used in the study

The cage used here is named Solis (Stryker Howmedica GmbH, Gewerbeallee 18, 45478 Mülheim, Germany). It is made from polyetheretherketone (PEEK), comes in two different diameters (12 and 14 mm), and in different heights (4, 5, 6, 7, 8, and 9 mm). The cage has a large central perforation to allow bony ingrowths. Titanium anchoring spikes and bone-hugging serrations should enhance a secure fit.

The titanium alloy plate is the ABC (advanced biomechanical concept) plate (Aesculap AG, AM Aesculap-Platz, Tuttlingen, Germany) for anterior osteosynthesis of the cervical spine. It is a dynamic, titanium plate that can be bent to match the patient's individual lordosis. The screw for monocortical fixation is a titanium, self-tapping, conical screw of 10, 12, 14, 16, and 18 mm length with an outer diameter of 4.0 mm. The single level plate is offered with a length of 20, 22, 24, 26, 28, 30, and 32 mm.

The prosthesis used here was the ProDisc C, which consists of a modular design, two metal plates, and a polyethylene inlay that is safely secured into the lower end plate. The metal end plates have a keel design for enhanced primary stability and fixation, and the end plate coverage with a coating that consists of a titanium plasma spray allows bony ingrowth and long-term fixation. The polyethylene inlay determines the height of the prosthesis (Synthes Spine, Paoli, PA).

**Fig. 1** Lateral X-ray of a cervical spine showing the tantalum markers of the vertebral body C4, C5 and C6. **a** Incorporated tantalum markers after disc replacement. **b** The same with titanium plate fixation



#### Roentgen stereometric analysis (RSA)

Patients underwent RSA postoperatively, after 6 and 12 months. For more details about the Roentgen stereometric analysis and images, please refer to our article published in [29].

#### Statistic

*t*-Test for paired values was used to determine a statistical difference of residual intervertebral motion within the same group ( $P < 0.05$ ).

Mann–Whitney *U* test for unpaired values was used to determine a statistical difference of residual intervertebral motion between both groups in the three axes of motion ( $P < 0.05$ ).

#### Results

No perioperative or postoperative complications were observed and no patients of both groups required revision of the device.

#### Radiological analysis

##### *Study group (prosthesis)*

**ROM of treated segment** Between 1 week and 6 months postoperatively, segmental motion decreased significantly

in extension, axial rotation and bending ( $P = 0.02$ ,  $P = 0.03$  and  $P = 0.01$ ). However, 1 year postoperative, no further decrease in segmental motion in extension, axial rotation and bending ( $P > 0.05$  for all three axes) was seen. Data for each axis are contained in Table 1 and Figs. 2, 3, 4.

**ROM of adjacent segment** Segmental motion at adjacent cranial levels (Table 2; Figs. 2, 3, 4) did not exhibit a significant change between 1 week and 6 months after surgery in extension, axial rotation and bending ( $P = 0.3$ ,  $P = 0.07$  and  $P = 0.5$ ). One year after surgery, there was also no significant change in segmental motion in all three directions, when compared to the 6-month results ( $P = 0.2$ ,  $P = 0.6$  and  $P = 0.4$ ).

The segmental motion of the adjacent segment was significantly higher in extension ( $P = 0.001$ ), axial rotation ( $P = 0.002$ ) and bending ( $P < 0.0001$ ) after 1 week in comparison to the index level. The segmental motion 6 months and 1 year after surgery was also significantly higher when compared to the values measured for the segment treated with prosthesis ( $P < 0.05$ ) (Figs. 2, 3, 4).

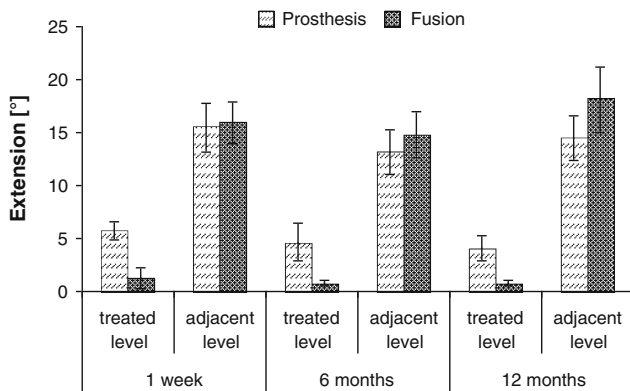
##### *Control group (ACDF)*

**ROM of treated segment** Six months postoperative, there was a statistically significant decrease in segmental motion in extension, axial rotation and bending ( $P = 0.04$ ,  $P = 0.03$  and  $P = 0.03$ ), when compared to the values obtained after 1 week. However, 1 year postoperative, no significant

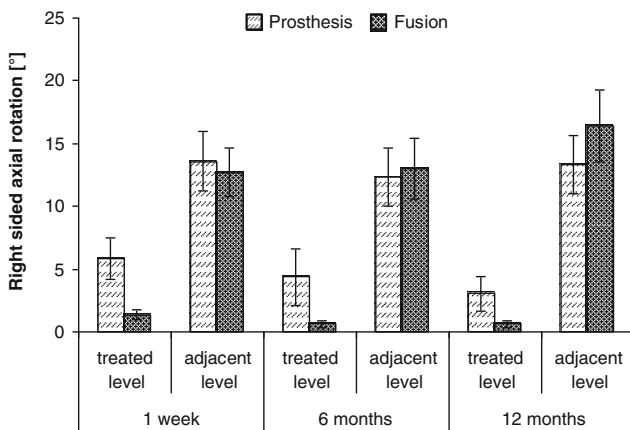
**Table 1** Rotations in degree (°) 1 week, 6 and 12 months after surgery for the treated segment

Rotations (deg)	1 week		6 months		12 months	
	Prosthesis	Fusion	Prosthesis	Fusion	Prosthesis	Fusion
Extension	4.75 (0.85)	1.3 (0.98)	3.64 (1.8)	0.82 (0.26)	2.08 (1.13)	0.81 (0.26)
Right-sided rotation	5.88 (1.65)	1.35 (0.36)	4.37 (2.27)	0.61 (0.3)	3.07 (1.38)	0.62 (0.3)
Right-sided bending	2.6 (0.95)	0.85 (0.62)	1.27 (0.65)	0.56 (0.28)	0.9 (0.5)	0.56 (0.28)

Mean value and standard deviation are given for each time



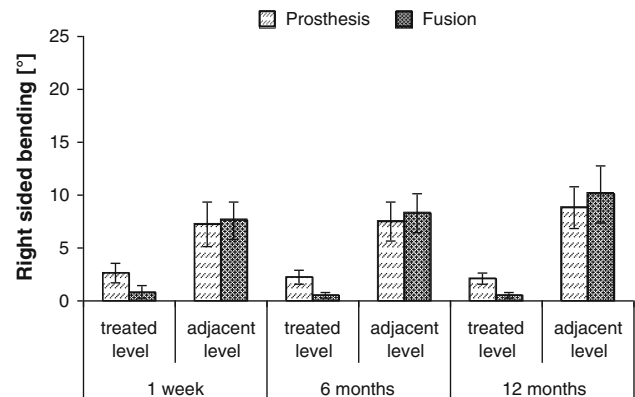
**Fig. 2** Graph illustrating segmental motion in extension (degree) (mean value and standard deviation) for each follow-up examination



**Fig. 3** Graph illustrating segmental motion in right-sided axial rotation (degree) (mean value and standard deviation) for each follow-up examination

difference could be noticed when compared with the 6 months value ( $P > 0.05$ ). Data for each axis are contained in Table 1 and Figs. 2, 3, 4.

**ROM of adjacent segment** Segmental motion at adjacent levels (Table 2) did not show a significant difference between 1 week and 6 months after surgery in extension, axial rotation and bending ( $P = 0.1$ ,  $P = 0.5$  and  $P = 0.7$ ). However, 1 year after surgery, there was a slight increasing segmental motion for all three directions, but



**Fig. 4** Graph illustrating segmental motion in right-sided lateral bending (degree) (mean value and standard deviation) for each follow-up examination

without a significant difference ( $P = 0.3$ ,  $P = 0.2$  and  $P = 0.3$ ) (Table 2; Figs. 2, 3, 4).

The segmental motion of the adjacent level was significantly higher in extension ( $P < 0.002$ ), axial rotation ( $P < 0.001$ ) and bending ( $P < 0.001$ ) after 1 week in comparison to fused cervical segment. The segmental motion 6 months and 1 year after surgery were also significantly higher compared to the values measured for the fused segment ( $P < 0.05$ ) (Figs. 2, 3, 4).

*Study group (prosthesis) versus control group (ACDF)*

**ROM of treated segment** Segmental motion was significantly higher in the prosthesis group in comparison to fusion for extension after 1 week ( $P = 0.001$ ), 6 months ( $P = 0.01$ ) and 1 year after surgery ( $P = 0.02$ ).

There was also a significant difference in axial rotation ( $P = 0.002$  after 1 week,  $P = 0.021$  after 6 months and  $P = 0.013$  after 1 year).

Segmental motion was not significantly different between both groups for bending ( $P = 0.3$  after 1 week,  $P = 0.1$  after 6 months and  $P = 0.06$  1 year after surgery) (Table 1; Figs. 2, 3, 4).

**ROM of adjacent segment** The segmental motion of the adjacent level shows a slightly higher segmental motion for

**Table 2** Rotations in degree (°) 1 week, 6 and 12 months after surgery for the adjacent segment

Rotations (deg)	1 week		6 months		12 months	
	Adjacent to prosthesis	Adjacent to fusion	Adjacent to prosthesis	Adjacent to fusion	Adjacent to prosthesis	Adjacent to fusion
Extension	15.5 (2.3)	15.95 (2)	13.2 (2.1)	14.8 (2.2)	14.5 (2.1)	18.1 (3.1)
Right-sided rotation	13.6 (2.4)	12.7 (1.9)	12.3 (2.3)	13 (2.4)	13.3 (2.3)	16.4 (2.9)
Right-sided bending	7.2 (2.1)	7.6 (1.8)	7.5 (1.9)	8.3 (1.8)	8.8 (2)	10.1 (2.7)

Mean value and standard deviation are given for each time

all three axes in the fusion group, but without significant difference for any direction (extension, axial rotation and bending) at any examination time ( $P > 0.05$ ) (Table 2; Figs. 2, 3, 4).

### Clinical outcomes

#### Study group

The NDI for neck pain decreased significantly from a mean value and SD of 0.49 (0.13) preoperatively to 0.1 (0.08) 1 year postoperative ( $P = 0.03$ ). The VAS for arm pain improved significantly from preoperative mean value of 8.4 (1.1) to 1.2 (1.1) 1 year postoperatively ( $P = 0.01$ ) (Fig. 5).

#### Control group

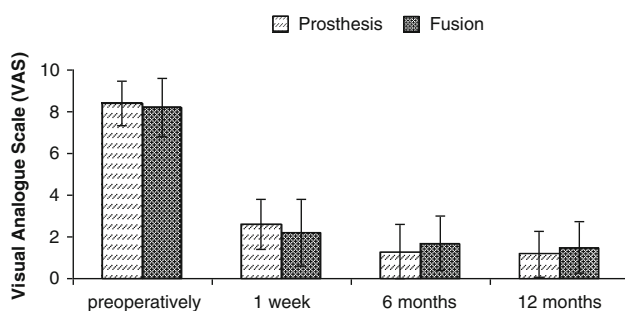
Mean values and SD for cervical pain measured using NDI decreased significantly from 0.47 (0.15) preoperatively to 0.16 (0.1) after 1 year ( $P = 0.01$ ). Mean values and SD for arm pain using VAS decreased significantly from 8.2 (1.4) preoperatively to 1.5 (1.25) 1 year postoperative ( $P = 0.014$ ) (Figs. 5, 6).

There was no significant difference between both groups in pain relief for neck and arm pain for each examination period ( $P > 0.05$ ).

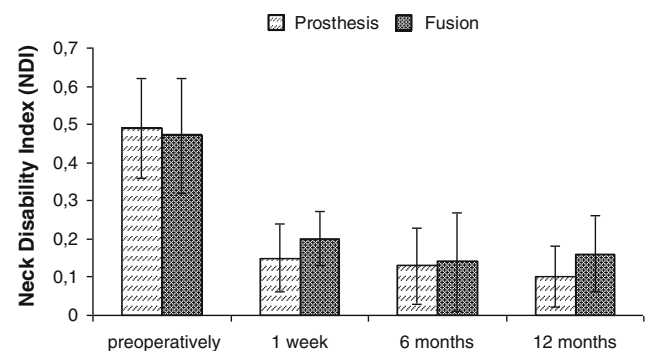
### Discussion

The development of adjacent level disease engaged all spine surgeons. It is supposed that the presence of a fusion could increase load and segmental range of motion at adjacent levels and cause localized trauma with subsequent accelerated disc degeneration [25, 26, 42]. Whether a cervical fusion results in accelerated adjacent disc degeneration with clinical manifestation of radiculopathy and/or myelopathy or these are related to a natural development in a predisposed person is currently under debate [7, 9, 22, 23, 25, 26, 42, 43].

In this study, at a mean follow-up of 12 months, there was no change in the average segmental motion immediately cranial to the disc prosthesis, whereas there was an increase in average segmental motion immediately cranial to the fusion but without a significant difference ( $P > 0.05$ ).



**Fig. 5** Visual Analogue Scale (VAS) for arm pain. Mean value and SD are given for each time. Both groups could show the same pattern of pain relief in arm to all examination times without statistically significant difference ( $P > 0.05$ )



**Fig. 6** Neck Disability Index (NDI) for neck pain. Mean value and SD are given for each time. Both groups could show the same pattern of pain relief in neck to all examination times without statistically significant difference ( $P > 0.05$ )



By assessing segmental motion in cervical spine, the chosen method becomes of critical importance. The evidence of the study increases clearly with the accuracy of the chosen measuring method. There are several methods to assess segmental motion. A few of these high accuracy methods are technically complex and time-consuming like RSA. Furthermore, it should be considered that we have a small patient number, so the results may change if more data from more patients are available. However, the precision of RSA is high, which makes it suitable for comparisons of small study samples and small changes. Nevertheless, our data give insight into the motion of the index and adjacent spine segment under physiological loads.

Functional X-ray with flexion and extension films is used quite frequently in clinical practice, because it is readily available.

Unfortunately, this measuring method has been shown to have poor reliability and their quantitative accuracy is limited [16, 31, 40, 44]. The video fluoroscopy is an improved technique to this relative inaccurate method. Several authors have advocated the advantages of the use of video fluoroscopy in the evaluation of intervertebral motion [3, 19, 27, 35].

The video fluoroscopy-based measurement allows continuities in intervertebral motion assessment. However, one of the major disadvantages of this method is the failure to account for the possibility that patients may have a different total range of motion at different time points.

RSA has already proven to be a highly accurate method to detect segmental motion between involved vertebrae [20, 38, 39] and allow for a three-dimensional motion analysis. This insertion of 4–6 radio-opaque titanium markers at the time of surgery in each vertebra is required to determine the geometric characteristics of the vertebral anatomy. Although the RSA method is ideal for a small patient group, it is possible that some relevant statistical differences may remain hidden. As an approximate power calculation, we analysed the corresponding power of Student's test for two independent normally distributed samples which typically also reflects the power of the Mann–Whitney *U* test for important distributions. Using a two-sided test with  $\alpha = 5\%$ , differences of mean values of segmental motion in a specific direction between the groups larger than 0.95 times the standard deviation can be detected with a power above 90%.

As in our previously published studies, cervical spine segmental motion of the segment either treated with ProDisc C or ACDF decreases over time, but with significantly higher loss of segmental motion in the fusion group in comparison to the preoperative values [29].

Our current results demonstrated that patients with prostheses had a significantly greater segmental motion at

the operative level in comparison to the ACDF group at each follow-up evaluation. When we looked to the adjacent level, we found a slightly increased segmental motion after ACDF 1 year after surgery, without a significant difference, when compared with prostheses.

In a recent study, Robertson et al. [36] prospectively compared the incidence of adjacent level radiographic disease and symptomatic disease in patients 24 months after undergoing either cervical arthroplasty with the Bryan Cervical Disc or cervical arthrodesis with a cervical cage. They reported a significantly higher incidence of X-ray changes indicative of degenerative disc disease at adjacent levels in patients with arthrodesis. The incidence of clinical symptomatic of the adjacent level disease was reported with a higher rate in patients with arthrodesis [36].

Reitman et al. [35] did not find a statistically significant change in ROM at the cephalad level adjacent to ACDF. They noticed that there were no X-ray changes indicative of degenerative disc disease at adjacent levels. Reitman et al. [35] suggested that degenerative disc disease may develop with or without alteration in cervical motion. If it is true, adjacent level disease may be the result of degeneration progression as results of altered cervical kinematics post fusion. Yet, our finding 1 year after surgery did not support the contention that altered kinematics and spondylosis are dependent entities. Therefore, kinematic changes, X-ray evidence of spondylosis, and clinical presentation may be different manifestations of the same underlying disease process with variable “expression” in a given individual.

Wigfield et al. [45, 46] prospectively compared the ROM between nonrandomized patients with ACDF and patients with prostheses. The fusion group demonstrated a higher segmental motion at the adjacent level in comparison to prostheses [45]. However, the increased ROM in patients with ACDF was distributed at spinal levels with no X-ray evidence of degenerative disc disease and not at discs with radiographic degenerative changes [45]. Although the published evidence supports a 34.6% rate of radiographic adjacent segment disease after arthrodesis versus 17.5% after arthroplasty at the 24-month follow-up evaluation [36], we did not find any significant differences in kinematics between the prostheses and ACDF groups in our relatively short follow-up period and relatively small patient number. In addition, our study did not address morphological changes to the adjacent level, which is very interesting. Therefore, we are currently investigating our earlier study, which has been started in 2004 to measure kinematics of the treated level, to evaluate morphological changes.

Both operative procedures lead to significant reduction of arm and neck pain without statistical difference between both groups. Several authors have published comparable

clinical results [2, 12, 13, 36]. However, it is too early to judge whether preserving segmental motion could reduce the incidence of adjacent level degeneration and improve clinical results.

## Conclusion

The results of this study demonstrate that there is no significant difference of the segmental motion of the adjacent level, either treated with prostheses or fusion, 1 year after surgery. Long-term results will be needed to determine further segmental changes in motion. Clinical results did also show no significant difference in pain relief between both groups.

**Conflict of interest** The authors do not have any financial interest in any of the implants used in the current study.

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